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October 22, 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: Implementation of Section 5—WAC is neither a cost nor an ‘expense’; ranking of “costly drugs” must be based on net cost to payer; DCBS must collect net price information for audit purposes.

Committee Members:

This letter addresses proposed rule language for Oregon 836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans, item (l), which currently reads:

(l) Information regarding prescription drug costs included as an appendix to the filing and labeled “Appendix III: Prescription Drug Costs.” This document must include, for drugs reimbursed by the insurer under policies or certificates issued in this state:

- (A) The 25 most frequently prescribed drugs;
- (B) The 25 most **costly** drugs. In determining this list, the insurer must consider total annual spending, **including the net impact of any rebates or other price concessions if applicable;**
- (C) The 25 drugs that have caused the greatest increase in total **plan spending** from one year to the next. In determining this list, the insurer must consider **the net impact on total plan spending of any rebates or other price concessions if applicable;**
- (D) The impact of the **costs** of prescription drugs on premium rates, on a per member, per month basis, **including the net impact of any rebates or other price concessions if applicable.**

The inclusion of a reference to price offsets in the regulation is a step in the right direction. This approach complies with both the language and spirit of the statute and of the Insurance Code, as well as the

generally accepted cost accounting rules for price offsets. The current language of the proposed regulation still needs work. Most of the terms used in this Section (costly, cost, plan spending) are undefined, and the regulation does not identify any process to guarantee the accuracy of the net pricing information relied upon by health insurance carriers.

The changes proposed by Prime Therapeutics, Providence and Moda should be rejected.

Prime Therapeutics, on behalf of PCMA, requested deletion of the reference to “the net impact of any rebates or other price concessions if applicable.”¹ PCMA argues that “language addressing net impact of any rebates or other price concessions . . . goes beyond what the legislature intended and the plain language of the authorizing statute (HB 4005). Therefore, it exceeds the authority granted to Department of Consumer and Business Services (DCBS) by the Oregon legislature in House Bill 4005.”

The statements included in Prime Therapeutics’ letter are inaccurate. The plain language of the statute is vague and undefined, and thus non-dispositive of the issue, i.e. whether the term “expense” means net cost within the scope of HB 4005 and the framework of the Insurance Code. Furthermore, the act does not require disclosure of the “expense.” It only requires disclosure of a ranking, and the ranking must also comply with the requirements of the Oregon Insurance Code, i.e. it can’t be misleading. Considering the magnitude of the manufacturer rebates negotiated by health insurers, any ranking based on anything but net prices would be misleading.²

Moda Health similarly requests that the reference to “net impact of any rebate or other price concessions” be removed as it is, according to Moda, not required in the statute and outside of the legislative authority given to the Department with HB 4005.³

¹ Prime Therapeutics letter dated October 17, 2018 (Re: September 24, 2018 Version of Preliminary Draft HB 4005 Rules). Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181017-comments-Prime-Therapeutics.pdf>.

² For example, manufacturer rebates have a substantial impact on Prime Therapeutics’ trends. Prime Therapeutics acknowledged in its 2017 Drug Cost Trend Report (Attachment D) that the unit cost of brand drugs (excluding specialty drugs) decreased by 8.9% in 2017 thanks to substantial negotiated price offsets and discounts. Manufacturer rebates negotiated by Prime increased by \$1.6 billion in 2017.

³ October 15, 2018 email from: Robert Judge, Director of Pharmacy Services, Moda Health. Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181015-comments-Moda.pdf>.

Moda Health further argues that some plans receive rebates directly from drug manufacturers on a national level, rather than state-by-state from their PBMs, and, according to Moda Health, insurers may not report to Oregon regulators the share of these rebates that is specifically related to the Oregon market. This statement is at best disturbing, as it would suggest that insurers account for rebates earned from drug transactions in Oregon as general revenues (for the parent company that holds the rebate contracts) while basing premiums and cost-sharing paid by Oregonians on gross claims expense. If true, this statement would suggest that some insurers are providing misleading financial information to DCBS, NAIC and possibly CMS (calculation of CMS Medical Loss Ratios is on a state-by-state basis), i.e. that some insurers are under-reporting manufacturer rebates earned for Oregon drug purchase transactions.⁴ The scheme reported by Moda Health would appear to breach Oregon Insurance Code, but also Section 2718 of the Public Health Service Act (PHS Act) and the implementing regulation, codified at 45 CFR Part 158, as well as, possibly, the False Claims Act (FCA), 31 U.S.C. §§ 3729 - 3733—a criminal statute. ***Moda Health's allegations should immediately be investigated by DCBS, Oregon Office of the Attorney General and the U.S. Department of Justice.***

Providence proposed,⁵ on the other hand, to replace “rebate and other concessions” with “direct and indirect remuneration” or DIR. DIR is over-inclusive as it may include manufacturer coupons offered to some patients. Providence’s request that “inpatient Rx drug costs “ (medical benefits) be included raises

⁴ This allegation confirms T1DF’s identification of apparent under-reporting of manufacturer rebates by Oregon insurers. In 2010, this under-reporting may have amounted to \$45.5 million for commercial individual, small group and large group employer plans. See Attachment C. Oregon requires rebate receivable disclosure via NAIC blanks filing. For example, NAIC’s 2018 Supplemental Health Care Exhibit Report (for 2017) documents \$9.35 billion of manufacturer rebate receivables for gross claims expense for prescription drugs amounting to \$58.3 billion—an aggregate rebate rate of 16%. For Oregon, health insurance carriers reported \$99.57 million for commercial individual, small group and large group employer plans for aggregate drug prescription expenditure of \$831.64 million—an aggregate rebate rate of 11.97%. Pharmaceutical rebate information is also available by State and by carrier at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>. IMS Health/IQVIA has kept the effective benchmark rebating rate virtually unchanged since 2015 at c28% or \$128.6 billion. See: IQVIA Institute (formerly IMS Institute), *Medicine Use and Spending in the U.S.* (April 2018). IQVIA is known in the industry to be more conservative than, e.g., Credit Suisse—28% is a low estimate. A comparison between this industry benchmark and NAIC data would suggest that Oregon health insurance carriers under-reported manufacturer rebates by \$133.29 million in 2017, up from about \$45.47 million in 2010. This assessment is consistent with Moda Health’s acknowledgement on October 15, 2018, that a substantial part of pharmaceutical rebates earned on Oregon drug purchasing transactions is accounted by the holding company, not the Oregon plan. See email from: Robert Judge, Director of Pharmacy Services, Moda Health. Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181015-comments-Moda.pdf>.

⁵ Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181016-comments-Providence.pdf>.

new issues as providers and hospitals mark up drug costs by up to 1,000%, with 1 in 5 hospitals marking up drug prices at least 700%.⁶

OSPIRG's letter⁷ exclusively focuses on HB 4005 manufacturers' disclosures. Similarly, Courtney Helstein, a lobbyist for the Laura and John Arnold Foundation's Action Now!, makes no reference to rebates and insurers' disclosure requirements.⁸

WAC is neither a cost nor an expense for cost-accounting purposes.

We first bring to the committee's attention a recent ruling that relates directly to cost accounting and thus to the implementation of Section 5 of HB 4005 now being considered by this committee: whether WAC can be deemed an 'expense' for the purpose of identifying and ranking the most costly drugs and whether 'expense' means net cost for cost accounting purposes.

WAC is neither a cost nor an expense for cost-accounting purposes, and 'expense' as used in HB 4005 must be interpreted as requiring ranking based on net cost to insurers. DCBS rulemaking must define 'net cost' and establish an auditable data collection process for prescription drug rebates and net cost information.

On August 8, 2018, the Court in *Pfizer v. Johnson & Johnson* (Case No. 2:17-cv-04180-JCJ – ECF No. 58 at 21-22) noted:⁹

“WAC is essentially a metric reflecting list price, whereas ASP is based on an annual average that does account for rebates and discounts off list price. J&J argues that because WAC does not

⁶ <https://www.healthcarefinancenews.com/news/about-1-5-hospitals-mark-drug-prices-least-700-percent-study-finds>.

⁷ Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181015-comments-OSPIRG.pdf>.

⁸ Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181015-comments-OCAP.pdf>.

⁹ See Attachment A – Memorandum of August 10, 2018, denying motion to dismiss in *Pfizer v. Johnson and Johnson* (Case No. 2:17-cv-04180-JCJ – ECF No. 58). Note that the broader issues at hand in this complaint involve medical benefit, not drugs sold to consumers at pharmacies under the prescription drug benefit. We cite the Court's opinion here solely as a determination that WAC is not 'cost,' and thus that WAC cannot be the basis for ranking drugs by cost or expense. In the context of this RAC, it follows that WAC cannot be the basis for presenting to the insurance-buying public that selected drugs 'cost' more than others. Doing so based on WAC would be intrinsically misleading and deceptive, in breach of ORS 746.110. (See Attachment B.)

reflect the net price after discounts and rebates, it provides no indication about the price competition between Remicade and Inflectra.” (p. 21)

The Court concluded:

“We agree with J&J that the WAC provides minimal support for the proposition that Inflectra costs less on a unit-for-unit basis than Remicade.” (p. 21–22)

HB 4005 does not mandate that insurers rank most costly drugs based on list prices or WAC; it requires the use of ‘expense’ as the basis for ranking. Neither HB 4005 nor the Insurance Code defines ‘expense.’ Depending on context, ‘expense’ can either be a net cost (cost accounting) or a cash outflow (financial reporting). If WAC is not a cost, then WAC is neither a ‘net cost’ nor a cash outflow for cost-accounting purposes.

‘Expense’ as used in HB 4005 must be interpreted as requiring that the ranking mandated by HB 4005 be based on net cost to insurers.

Investopedia defines ‘expense’ as “the economic costs a business incurs through its operations to earn revenue.”¹⁰ Google definition similarly defines ‘expense’ as “the cost required for something.”¹¹ Merriam-Webster’s definition is more general and broader (“something expended to secure a benefit or bring about a result.”)¹² Collins acknowledges the tension between the specific economic definition of ‘expense’ as a net cost and the financial accounting definition of ‘expense’ as an outflow of cash or other valuable assets.¹³ The generally accepted definition of ‘expense’ in a cost-accounting context is thus consistent with ‘net cost.’

Ranking drugs is not a financial disclosure process subject to NAIC’s Statutory Accounting Principles or FASB’s Generally Accepted Accounting Principles. **Ranking “the 25 most costly drugs” is a cost accounting function** in furtherance of HB 4005’s transparency purpose. Its outcome (a ranking) is to be communicated to the insurance-buying public. The ranking must therefore be implemented to satisfy the

¹⁰ <https://www.investopedia.com/terms/e/expense.asp#ixzz5TjzKq6h>

¹¹ <https://www.google.com/search?q=definition+of+expenses&oq=definition+of+expense&aqs=chrome.0.0j69i57j0l4.3194j1j7&sourceid=chrome&ie=UTF-8>.

¹² <https://www.merriam-webster.com/dictionary/expense>.

¹³ <https://www.collinsdictionary.com/us/dictionary/english/expense>.

broader transparency goals of HB 4005, while complying with the consumer protection requirements of the Insurance Code, including ORS 746.110. If there is an ambiguity, the term must be liberally interpreted in order to protect the insurance-buying public and to convey information that is neither false nor misleading. (See Attachment B for a discussion of the consumer protection requirements of the Oregon Insurance Code.)

The general public will understand ‘expense’ to mean ‘net cost’ to insurers. This is the way Oregon consumers shop for groceries, cars, prescription drugs and even, since 2015, recreational marijuana. We don’t rely on SAP financial reporting constructs; we intuitively use net cost accounting. We don’t rank and select our grocery purchases solely based on sticker prices, and then enter our rebate or coupon savings separately as general income in our OR-40 tax returns. We don’t offset the sticker price of groceries with coupons and rebates on a quarterly basis as part of a summary cash flow reconciliation. We scan store shelves, we clip and download coupons, and we then rank similar grocery items based on their net unit cost at the point of sale (net of volume discounts, promotions, and coupons) in order to snap up the best deals.

Oregonians expect our health insurers to shop for the best-priced prescription drugs in a similar manner. And we expect that when an insurer reports to the insurance-buying public a ranking of the “25 most costly drugs,” that ranking will be based on the best net prices the insurers could negotiate—net of all off-invoice rebates and other volume discounts offered by manufacturers. Since WAC is neither a net cost nor an expense, it can’t be the basis for ranking drugs. From a cost-accounting perspective, **only a ranking based on average ‘net costs’ to insurers would further the transparency purpose of HB 4005** while conforming with the insurance-buying public’s lay understanding of the basis for ranking, i.e. the overall net cost of drugs to insurers, after accounting for all off-invoice discounts, incentives, and manufacturer rebates.

If the intent of the Oregon legislature were instead to rank drugs based on their inflated sticker prices (without adjustment for off-invoice discounts and rebates), or a cost incurred by pharmacies instead of health insurers, they would have mandated use of the Oregon Average Actual Acquisition Cost (OAAAC) or health plans’ gross Pharmacy Claims Expense as basis for the ranking. The OAAAC is maintained by the Oregon government; OAAAC is the only publicly available index of pharmacy costs in Oregon. It is an index that reflects the prices paid by pharmacies to wholesalers or distributors. OAAAC is not similar to WAC, as it includes distribution costs and fees as well as volume discounts (although it may not capture off-invoice

volume discounts offered by wholesalers).¹⁴ Although the OAAAC does not account for off-invoice rebates, fees and discounts paid by manufacturers to PBMs and insurers, it is close to an actual ‘expense’ for one set of actors in the drug supply chain—pharmacies.¹⁵ But HB 4005’s “costly drugs” ranking is for the benefit of the insurance-buying public, not for the benefit of pharmacists or insurers—and it is designed to report on the cost of drugs to insurers.

OAAAC isn’t an expense incurred by insurers or by uninsured Oregonians. OAAAC doesn’t meet the requirement of HB 4005, because it is a proxy for a net cost incurred by pharmacies, not a net cost incurred by insurers or a net cost incurred by the insurance-buying public. If legislators had intended to use the average actual acquisition cost of prescription drugs paid by pharmacies as the basis for ranking drugs, they would have specified OAAAC instead of the lay term ‘expense.’

Similarly, the legislature could have used an existing term of art—‘Pharmacy Claims Expense’—to mandate the use of gross, unrebated pharmacy prices negotiated by PBMs/insurers (acquisition cost plus negotiated dispensing fee, without off-invoice price offset). ‘Pharmacy Claims Expense’ is a technical term that has a well-known and defined meaning in the insurance industry. But the public ranking of “25 most costly drugs” is not for the benefit of the insurance industry. It is for the benefit of the general public. Thus, instead of using an insurance term of art, the legislature used the unqualified lay term ‘expense.’

The decision as to whether “expense” should be reported as a net cost is thus left to DCBS. In the absence of a statutory definition, DCBS must consider the general accounting and statutory context — GAAP practices, the SAP reporting framework, the American Academy of Actuaries’ SOP, NAIC’s Cost Management Guide, but also and primarily the purpose of HB 4005 and the lay meaning of ‘expense.’ Contextual information must also be liberally interpreted to give full effect to the consumer protection mandate of the Insurance Code. The purpose of the insurance code is “the protection of the insurance-buying public.”¹⁶ DCBS must thus liberally interpret ‘expense’ to give full effect to HB 4005’s transparency goals and to the Insurance Code’s consumer-protection purpose.

¹⁴ OAAAC as proxy for pharmacies’ cost is particularly true for the brand drugs that are the primary target of HB 4005; off-invoice wholesaler discounts to pharmacies are primarily on generics. Brand drugs are distributed; pharmacies do not generally receive volume discounts from wholesalers.

¹⁵ OAAAC matters for uninsured Oregonians as it is the starting point for pharmacies’ calculation of their cash or U&C prices, but Section 5 of HB 4005 only applies to the Insurance Code.

¹⁶ ORS 731.008.

NAIC's Statutory Accounting Practices already require that pharmaceutical rebates and discounts (list price offsets) be reported as a reduction to claims expense at the summary of operations level—for financial reporting purposes. FASB's Generally Accepted Accounting Practices also require that drug purchase transactions be reported on a net basis when the price offset is set by ascertainable contractual obligations.¹⁷ The ranking of drugs mandated by HB 4005 must similarly be based on average net unit cost to insurers based on the same NCPDP and X12N EDI Standards that insurers have been using since 1998 to manage their rebate transactions with PBMs and drug manufacturers.

DCBS rulemaking must define 'net cost' and establish an auditable data collection process for prescription drug rebates and net price information consistent with NCPDP standards.

The proposed regulation relies on undefined terms (expense, rebate) and does not provide any mechanism for generating net prices or for DCBS to audit insurers' compliance. In order to implement HB 4005, DCBS must (1) define 'estimated net price' and 'price offsets' specifically, (2) establish a process and format for reporting those price offsets, (3) establish a process and format for deducting these price offsets from gross pharmacy claims expenses, and (4) define the reporting format on a per-unit basis (in compliance with NCPDP data standards). Finally, DCBS must specify a quality assurance and audit process that would allow DCBS to ensure that price offsets are being reported accurately. This quality assurance process would also guarantee that Oregon carriers are reporting accurate rebate information in their financial reporting to DCBS via NAIC's Blanks and to CMS for medical loss ratio calculation purposes.

If HB 4005's purpose were to rank drugs based on gross pharmacy claims expense or WAC, HB 4005 would not need to create a separate reporting process for payers. DCBS/OHA could use the existing OAAAC database or the All Payer All Claims database (APAC) jointly maintained by DCBS and OHA. But as discussed above (and as recognized by the U.S. District Court of the Eastern District of Pennsylvania), WAC is not a cost, and reporting based on list price or gross claims expense would be deceptive, in breach of

¹⁷ OR4AD may provide a detailed analysis of the history of NAIC's treatment of off invoice price offsets under separate copy. This letter is a cursory and lay review of accounting principles governing the cost accounting of price offsets. DCBS should have already performed this analysis and provided the Rulemaking Advisory Committee a detailed report on GAAP, SAP and governing principles of cost accounting as they relate to price offsets/ manufacturer rebates.

ORS 746.110, of the consumer protection purpose of the Insurance Code and of the price transparency goal of HB 4005.

APAC doesn't collect net pharmacy claims expense data and price offset data on a per-unit basis.¹⁸ It can't therefore be used for cost accounting and actuarial valuation purposes. Payers do not currently report to the state any net cost information on a per-drug basis, based on NCPDP standards. It is in fact unclear how DCBS currently fulfills its premium rate oversight mandate and how DCBS audits medical loss ratio assessments. DCBS can't guarantee the accuracy of Oregon carriers' NAIC reporting and ACA MLR calculation (and related premium refunds, if appropriate, to insurance-buying Oregonians).¹⁹

DCBS's and OHA's inability to audit insurance carriers' reporting of aggregate rebate data is not inconsequential. Although rebate information is already provided for purposes of calculating MLR under the ACA and under the NAIC reporting framework, we are not aware of any quality assurance audit program to guarantee accuracy and completeness of reported rebate information. A review of the data provided by NAIC for 2010 would suggest that health insurance carriers in Oregon under-report the amount of off-invoice price offsets they receive from drug manufacturers. Based on Medco's disclosed retention rate and industry rebating average based on IMS Health data (also known to underestimate manufacturer rebates), NAIC's Supplemental Health Care Exhibit Reports (2011) should have included an aggregated rebate amount of \$74.5 million for the State of Oregon—based on average rebating rate of 14.8% derived from IMS Health industry data. Oregon private insurers reported only \$29 million or 5.8% of the total drug spend. The \$45.5 million discrepancy can't be explained.

¹⁸ <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

¹⁹ We note here that Mr. O'Brien was responsible for OSPIRG's rate assessment reports for many years—during which he appears never to have publicly questioned the basis of carriers' medical loss ratio assessments. He was also one of the key lobbyists for Strategies 360's insurer 'Coalition' in support of drug pricing legislation including HB 4005, along with Mark Griffith and Rep. Andrea Salinas. Like Rep. Salinas (embedded in the legislative committee with oversight over HB 4005), Mr. O'Brien moved directly from a lobbying role to employment under the Brown Administration, in his case to an appointment to lead the HB 4005 rulemaking advisory committee. It is thus unsurprising that, under Mr. O'Brien's leadership, this RAC has failed to fulfill its rulemaking function as it relates to the implementation of an auditable reporting process.

Similarly, DCBS/OHA do have access to drug-specific net cost information via OPDP, independently from the HB 4005 reporting mandate.²⁰ Moda Health could, as OPDP third party administrator, provide net price information at the DCN level. DCBS/OHA have not, however, availed themselves to this contractual access and have not audited OPDP once in 11 years.

HB 4005's drug ranking, mandated under Section 5, thus provides DCBS and OHA an opportunity to close these audit and compliance loopholes. HB 4005 requires that health insurance carriers calculate net prices and rebate amounts contractually owed for the purpose of identifying the most expensive drugs on a net cost basis; that same information can be used for other compliance and quality assurance purposes, e.g. for verifying compliance with CMS MLR calculations, for auditing financial reporting to DCBS, and for performing actuarial valuations of premium rates on a net cost basis.

The implementation of a regime of net price and rebate disclosure under HB 4005 would also allow DCBS and OHA to benchmark the performance of OPDP's third party administrator and to take corrective action for non-performance, including terminating the TPA contract for default in regard to the OPDP discount card program and re-procuring the OPDP contract to a 'transparent' pass-through PBM.

In order fully to implement HB 4005's mandate for drug ranking based on net unit cost/price to plan, DCBS must

- (1) set up a reporting and data collection process (possibly as an upgrade to the existing reporting regime) for manufacturer rebates and net prices paid by payers (with all manufacturer rebates, discounts, and price offsets paid to payers taken into account), on a per-unit basis per NCPDP standards,
- (2) clarify the reporting standard, definitions²¹ and data model and

²⁰ HB 4005's disclosure mandate does not apply to standalone prescription drug programs such as the CVS Caremark-managed NACo discount card marketed by the Association of Oregon Counties and several counties in Oregon, including Benton, Jackson, Crook, Polk, Yamhill, Clatsop, Union and Clackamas counties. The NACo discount card program is a private service that does not pass any off-invoice rebates to its members but does pay a kickback to the counties that promote the program and to the state and national levels of the NACo organization. OR4AD has already brought this loophole to the attention of the HB 4005 Joint Interim Task Force on Fair Pricing of Prescription Drugs.

²¹ The definition of rebates and price offsets used to derive net unit cost should be consistent with the process used in the ACA's MLR calculation, albeit applied to individual drugs on a per-unit basis. For the purpose of ranking "most costly drugs," rebates and price offsets should not be treated in terms of rebates actually received (rebate receivables). Estimated net unit prices must instead be calculated based on current contractual obligations—ascertainable based on historical utilization data and projected use.

(3) specify an audit and data quality assurance program.

There is no viable alternative to a ranking based on net cost accounting. A ranking of “25 most costly drugs” based on gross Pharmacy Claims Expense or WAC would be deceptive and misleading, in breach of ORS 746.110. The only definition of ‘expense’ that would be consistent with SAP financial reporting framework and GAAP price offset guidance, would comply with the general transparency mandate of HB 4005, and would convey to the insurance-buying public information that isn’t intrinsically deceptive or misleading is thus ‘net cost.’

In order to fulfill the letter—and price transparency intent—of HB 4005, DCBS and OHA must therefore require net price and rebate disclosure. The enhanced database of net unit prices thus available would then allow DCBS to audit OPDP, benchmark OPDP’s discount card program performance and finally implement effective oversight over financial reporting and actuarial valuation of premium rate increases for Oregon’s insurance-buying public.

Regards,



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Director

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cc:

Joint Interim Task Force On Fair Pricing of Prescription Drugs

Attachments:

- A. Memorandum of August 10, 2018, denying motion to dismiss in *Pfizer v. Johnson and Johnson* (Case No. 2:17-cv-04180-JCJ – ECF No. 58)
- B. Public comment from OR4AD's Charles Fournier to the September 27 meeting of the Joint Interim Task Force On Fair Pricing of Prescription Drugs (Revised 9/30/2018)
- C. T1DF's analysis of NAIC and ACA MLR rebate reporting for 2010
- D. Prime Therapeutics 2017 Drug Cost Trend Report - Commercial Plans
- E. October 15, 2018, email from: Robert Judge, Director of Pharmacy Services, Moda Health. Available at: <https://dfr.oregon.gov/help/committees-workgroups/Documents/prescription-price-transparency/20181015-comments-Moda.pdf>

ATTACHMENT A

September 30, 2018

PUBLIC COMMENT FROM OR4AD'S CHARLES FOURNIER TO THE SEPTEMBER 27 MEETING OF THE JOINT INTERIM TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS (REVISED 9/30/2018)

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

Good afternoon. I am Charles Fournier with Oregonians for Affordable Drug Prices Now (OR4AD). My comment is going to be in the form of a question to Insurance Commissioner Andrew Stolfi:

Moda Health, HB 4005's coalition members and their lobbyists—Strategies 360, AARP, AHIP, Cambia, OSPIRG, Providence, Kaiser Permanente—have engaged in practices and communications that are misleading, unfair and injurious to the insurance-buying public as well as discriminatory toward people with type 1 and other insulin-dependent diabetes. Will Insurance Commissioner Andrew Stolfi enforce Oregon's insurance laws?

HB 4005 Supporters' Campaign of Misinformation

In this afternoon's Task Force meeting, both PhRMA representative Saumil Pandya and Sen. Linthicum reminded us of the critical role that insulin pricing played in the campaign to pass HB 4005, the legislation that created this Task Force.

Going back to the start of the HB 4005 process, the bill was passed based on testimony—including testimony from Sen. Linthicum—about the 'price' of insulin. The statements submitted as testimony in support of HB 4005 contained incomplete, inaccurate and thus misleading information about insulin pricing. These misrepresentations and the related injurious practices by payers have tainted the work of this Task Force; they must be expressly addressed.

People with type 1 diabetes must inject insulin to stay alive.¹ If you have T1D and can't afford your insulin, diabetic ketoacidosis (also known as diabetic coma or DKA) or HHS² will kill you in a matter of days or

¹ https://tonic.vice.com/en_us/article/ezwwze/the-high-price-of-insulin-is-literally-killing-people.

² People with T1D who cannot access sufficient insulin (e.g. if they are rationing because of cost) may also die of Hyperosmolar Hyperglycemic State (HHS) also known as Hyperglycemic Hypersomolar Nonketotic coma (HONK). DKA develops over hours to days; HHS develops over days to weeks: http://academicdepartments.musc.edu/medicine/Divisions/Endocrinology/DSC/2017Strategies/Lewis-DKA-HHSandHypoglycemia_2017_Final.pdf. The incidence of HHS is lower than the incidence of DKA: <http://spectrum.diabetesjournals.org/content/15/1/28>.



weeks.³ A recent review found that in Maryland alone, 107 people died from diabetic ketoacidosis over a six-year period.⁴ The cost of DKA to the healthcare system is significant: a 2012 study noted that DKA was then responsible for more than 119,000 hospital admissions per year, costing over 1.8 billion USD to treat⁵—a sum equivalent to the production cost of 50,000 kg of pure insulin crystals, enough insulin to fill 1.4 million 10 ml vials of Novolog.⁶

Parents of children who have died of DKA have been charged with second-degree reckless homicide.⁷ What about insurance company officials who knowingly reduce insulin access and therapeutic adherence by artificially inflating the prices plan members pay to 300%–400% of insurers' net cost? and what about state regulators who enable this injurious practice by failing to vigorously enforce insurance laws?

If you take analog insulin Novolog, for example, a single vial of 10 ml costs about \$2.61 to manufacture. That's the bill of quantity of its components—packaging, glass vial, water for injection, inactive ingredients and insulin. The 35 mg of rDNA insulin crystals inside that vial costs \$1.47 to manufacture. This insulin vial is sold in Canada under the Novorapid label for about \$25.⁸ The effective net price of a Novolog vial paid by U.S. payers in 2016 is believed to be about \$55.⁹ Moda Health represents to its OPDP discount card holders and ACA members (individual members) that the cost to the plan or the cost to OPDP for this same 10 ml vial is \$284.

For Novolog insulin, the manufacturer rebate received by payers is now over 75% of list price.

Neither Moda Health nor HB 4005's other supporters have publicly acknowledged the magnitude of the manufacturer rebates that payers receive and the role that payers' 'rebate pumping' has played in driving up the list prices of insulins and other rebated brand drugs. This omission renders any representation that

³ <https://www.ontrackdiabetes.com/type-1-diabetes/mother-22-year-old-who-died-diabetic-ketoacidosis-speaks-out>; <http://www.baltimoresun.com/health/bs-hs-diabetes-orlando-brown-20111006-story.html>; <https://insulination.com/living/dka-death-jail/>; http://articles.latimes.com/1992-01-13/local/me-46_1_patrick-henry-high-school; <https://www.texasmonthly.com/the-daily-post/a-diabetic-woman-died-in-the-irving-jail-because-the-staff-didnt-give-her-the-insulin-they-knew-she-needed/>; <https://www.snopes.com/fact-check/shane-patrick-boyle-died-after-starting-a-gofundme-campaign-for-insulin/>; <http://www.sandiegouniontribune.com/sdut-coroner-casey-johnsons-death-diabetes-related-2010feb04-story.html>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4736534/>; <https://www.mdedge.com/emed-journal/article/102576/imaging/case-report-bittersweet-death>; <https://insulination.com/living/in-memoriam-to-the-undiagnosed/>; <http://www.fox5atlanta.com/health/fox-medical-team/19-year-old-georgia-college-students-dies-of-diabetes-complication>.

⁴ https://journals.lww.com/amjforensicmedicine/Abstract/2012/09000/Diabetic_Ketoacidosis__A_Silent_Death.1.aspx.

⁵ <https://pdfs.semanticscholar.org/2ba2/a5ceb96a6065d7cabd7703f805e4979a1c2b.pdf>. Broad access to affordable drugs, including analog insulin, is a moral imperative that also makes good economic sense.

⁶ Novolog is the brand name for a biosimilar rDNA analog insulin manufactured by Novo Nordisk using yeast. The originator rDNA analog insulin is Humalog, manufactured by Eli Lilly using *E. coli*.

⁷ <https://www.diabetesselfmanagement.com/blog/one-more-death-too-many/>.

⁸ In Canada, Novolog is sold under the Novorapid brand. In the U.S., the first generation of rDNA insulin called 'human' insulin (an rDNA insulin manufactured by Novo Nordisk via similar bioengineering processes) also sells for \$25.00 per 10 ml vial over the counter at Walmart. See: <https://www.walmart.com/ip/Pharmacy-Relion-Humulin-Insulin/167672445>.

⁹ \$55 per 10 ml vial is a supra-competitive net price. Based on production costs and distribution constraints unique to the U.S. market, the net price of Novolog should be less than \$35. The effective net prices of analog insulins have begun to decrease by 1% to 2% annually as payers now demand rebate increases greater than list price inflation.



the ‘cost’ of insulin to the State or private payers is its \$284 list price or \$330 U&C price intrinsically deceptive and misleading.

False, misleading or deceptive statements regarding insurance benefit design are prohibited by the insurance code pursuant to ORS 746.110. This is, however, the lesser breach. Health insurers and their instrumentalities have also publicly acknowledged they are engaging in undefined trade practices that are unfair, discriminatory and injurious to people with T1D and the general insurance buying public.

Injurious and Discriminatory Trade Practices

Moda Health and the Oregon Health Authority have acknowledged in writing to this Task Force that they do not pass any manufacturer rebates, centrally negotiated by NPDC on behalf of WPDP and OPDP, to OPDP discount card members, while according to Gov. Brown,¹⁰ PEBB, OEBC and union plans receive from OPDP the full benefit of 100% rebate pass-through pricing. During the meetings of this Task Force, Moda Health has further acknowledged that, in Moda’s commercial plans, those patients who need insulin and other rebated brand drugs to stay alive are **financially but also medically injured** by Moda’s failure to base coinsurance and cost sharing payments on the low effective net prices actually paid by Moda Health.

Moda has testified that these manufacturer rebates are substantial (“a lot of dollars”).¹¹ Moda has further testified that they direct bill to manufacturers for rebates. Moda Health thus holds the rebate contracts and knows the effective net prices its plan members are entitled under these rebate contracts to receive for each point-of-sale transaction—but Moda, in breach of its fiduciary responsibilities, instead charges some of its health plan members and all individual OPDP discount card holders the full gross pharmacy claims expense (gross WAC/actual acquisition cost plus negotiated dispensing fee). Moda Health has further acknowledged to the Task Force that this rebate-capture scheme targets a small subset of pharmacy claims in its health plans—less than 2.8%.¹²

Moda testified they do not pass rebates through to their individual insured health plan members. And they do represent to individual health plan members that \$284 is the cost to plan. The rebate thus captured by Moda is an additional condition-specific premium imposed on vulnerable Oregonians with acute and chronic medical conditions; this scheme is discriminatory under both the ADA and the ACA. The **unfairness** of requiring a subset of insured people to pay amounts predictably well beyond insurers’ net cost is heightened because this practice also directly and foreseeably **injures those patients’ health** (people who cannot afford insulin are forced to ration it, and insulin rationing leads to greater morbidity—

¹⁰ Testimony before the Senate Committee on Health, Education, Labor and Pensions, Kate Brown, Governor of Oregon, March 8, 2018: <https://www.help.senate.gov/imo/media/doc/Brown11.pdf>.

¹¹ Robert Judge of Moda Health, exchange with Neeraj Sood, PhD, during the Joint Interim Task Force On Fair Pricing of Prescription Drugs, August 21, 2018, at 2:07 in audio recording: http://oregon.granicus.com/MediaPlayer.php?clip_id=25011.

¹² Robert Judge, August 21, 2018. Additional patient payments beyond drugs’ net cost, charged only to patients with medical conditions where standard of care treatment is via rebated brand drugs, must be recognized as condition-specific additional premium payments.



HHS, DKA and complications); Dr. Santa reminded us today of the harmful health impacts that inflated coinsurance causes.¹³

While only a very small subset of insured Oregonians are directly injured by inflated coinsurance and excess cost-sharing payments, all insured Oregonians are injured by insurers' misused of unrebated gross claims expense in rate setting.

OHA and DCBS do not require disclosure of net prices and do not maintain a database of net prices. The OHA-managed All-Payer All-Claims (APAC) database, supposedly created “to enhance transparency and accountability,” only includes gross claims expenses. NAIC Blanks mandated by DCBS directs insurers to report only gross pharmacy claims expenses.¹⁴ The Medical Loss Ratio (MLR) in Oregon is based on inflated gross pharmacy claims expenses, and so is the actuarial assessment of premium rate increases.¹⁵

While insurers keep the full amount of manufacturer rebates, they use gross claims expenses to engineer statutory losses and inflated MLR in support of their requests for premium rate increases. Failure to use net cost of prescription drugs like insulin as the basis for all insurer accounting thus also ***injures the insurance-buying public as a whole.***¹⁶

In summary, Moda Health has admitted it engages in rebate pumping, rebate capture—in breach of its fiduciary obligations—and misrepresentation of ‘plan costs,’ i.e. undefined trade practices that are deceptive, unfair, discriminatory and injurious to a small subset of individuals with chronic medical conditions treated with deep-discount rebated brand drugs, but also to the general insurance-buying

¹³ Inflated coinsurance payments are linked to decreased therapeutic adherence, rationing, and resulting increases in morbidity. In the case of insulin and diabetes, diminished access to insulin predictably causes organ failure, loss of limbs, loss of sight, and death from diabetic coma (diabetic ketoacidosis).

¹⁴ Manufacturer rebates are separately reported as an aggregated amount. Reconciliation between claims expense and price offsets happens at the financial summary level, thus leaving all reporting of ‘costs’ used for actuarial purposes on a gross basis.

¹⁵ The ACA mandates the use of a federally-defined Medical Loss Ratio for assessing the reasonableness of the premium charged for ACA plans (the 80-20 rule). Contrary to states’ MLR, the ACA’s MLR uses net claims expense. CMS did not, however, put in place a uniform accounting standard and auditable reporting process for manufacturer rebates and other price offsets. CMS instead relied on payers’ voluntary disclosure, NAIC’s forms and the data model of NAIC’s financial reporting infrastructure. In the late 1990s, NAIC rejected the FASB’s GAAP that addressed price discounts; NAIC has failed to update its cost-accounting guide since 1989.

¹⁶ It has been a truism throughout the payer-sponsored HB 4005 process that list prices—not net prices—drive insurance premium increases. This messaging would itself be deceitful if payers were not, in fact, using list prices for purposes of premium valuation. Premium increases are also routinely attributed to rising list prices in the general media and in consumer-facing payer-sponsored media. See, e.g. Linda A. Johnson and Nicky Forster, “AP investigation: Drug prices going up despite Trump promise,” September 24, 2018: This piece reports extensively on *list price* increases and concludes, “[R]ising drug prices generally put pressure on insurers to raise rates. Patients with high-deductible or no insurance often get stuck being charged the full list price.” <https://apnews.com/b28338b7c91c4174ad5fad682138520d/AP-review-Drug-prices-keep-going-up-despite-Trump-pressure> On the specific relationship of insulin *list prices* to premium increases, see comments from North Carolina BCBS’s Estay Greene, in a November 2016 blog post on insulin’s climbing *list price* (“Why Does Insulin Cost So Much After 95 Years?”: <http://blog.bcbsnc.com/2016/11/why-insulin-cost-so-high/>). According to Mr. Greene, “[C]limbing insulin prices affect everyone, even people who don’t use insulin. We all pay for expensive drugs through higher insurance premiums.” Net insulin prices to insurers in November 2016 were flat and beginning to decline; climbing list prices for insulin impacted North Carolina’s BCBS health plan members’ premiums only if BCBS was using list prices for premium valuation.



public, in breach of both OR 746.240 (undefined trade practices injurious to the public—prohibited) and ORS 746.110 (false, deceptive or misleading statements).

The purpose of the insurance code is “the protection of the insurance-buying public.”¹⁷ The Insurance Commissioner must liberally interpret and strictly enforce the insurance code to give full effect to its consumer-protection purpose. There is no longer any doubt that health insurers have injured and continue to injure the most vulnerable Oregonians.

Mr. Stolfi, as the insurance commissioner, what are you planning to do about this?

¹⁷ ORS 731.008.

ATTACHMENT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,	:	
	:	
Plaintiff,	:	CIVIL ACTION
	:	
v.	:	No. 17-cv-4180
	:	
JOHNSON & JOHNSON and JANSSEN	:	
BIOTECH, INC.,	:	
	:	
Defendants.	:	

MEMORANDUM

Joyner, J.

August 8, 2018

Before the Court are Defendants' Motion to Dismiss (Doc. No. 27) and Corrected Memorandum in Support thereof (Doc. No. 31), Plaintiff's Response in Opposition thereto (Doc. No. 42), Defendants' Reply in Support thereof (Doc. No. 48), and Plaintiff's Notice of Supplemental Authority (Doc. No. 54). We deny Defendants' Motion for the following reasons.

I. BACKGROUND

This case arises from an antitrust action brought by Pfizer, Inc. ("Pfizer") against Johnson & Johnson, along with its wholly owned subsidiary, Janssen Biotech, Inc. (collectively, "J&J"), for allegedly anticompetitive practices in the pharmaceutical market for infliximab products. The practices at issue are embodied by exclusive agreements and bundled rebates. Pfizer's principal claim is that J&J violated federal antitrust laws by engaging in

anticompetitive behavior to shield Remicade from competition posed by Pfizer's biosimilar, Inflectra.

Under consideration is J&J's Motion to Dismiss Pfizer's Complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6). This Motion is fully briefed and ripe for the Court's adjudication. The Court has considered the parties' submissions and decides this matter without oral argument. Fed. R. Civ. P. 78; Loc. R. Civ. P. 7.1(f).

I. ALLEGED FACTS¹

The subject medications in this litigation are J&J's Remicade and Pfizer's Inflectra. Both are branded forms of infliximab, which is a biologic drug used to treat a range of immune-mediated diseases. Compl. ¶35. Biologics are relatively new medications to the pharmaceutical market, and their unique qualities are relevant to our decision.

Biologic medications, such as infliximab, are complex mixtures derived from living systems. Id. ¶28. Biologics stand in contrast to more common drugs that are chemically synthesized and whose structure is known. Id. Therefore, the composition of biologics are not easily identified or characterized. Id. This makes

¹ Unless otherwise noted, the following facts are taken from Pfizer's Complaint. On consideration of a Rule 12(b)(6) motion to dismiss, the allegations in the plaintiff's complaint are generally taken as true and all reasonable inferences are drawn in favor of the claimant. See Phillips v. Cty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008).

biologic medications difficult to replicate and produce in generic form. Id.

The emergence of biologics prompted Congress to enact the Biologic Price Competition and Innovation Act ("BPCIA"). Id. ¶31. The BPCIA provides an abbreviated regulatory approval pathway for the introduction of drugs that are biosimilar to a biologic, similar to the abbreviated approval process for generic drugs under the Hatch-Waxman Act. Id. ¶33. To prove that an applicant drug is biosimilar to an originator product, the applicant must show that it is "highly similar to the [originator] notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the [proposed biosimilar] and the [originator] in terms of safety, purity, and potency." Id. (quoting 42 U.S.C. §262(i)(2)).

One important difference between biosimilars approved under the BPCIA and generic medications approved under the Hatch-Waxman Act is that biosimilars are not automatically substitutable with the originator biologic. Id. ¶34. While it appears there is a process in which a biosimilar can become automatically substitutable once achieves interchangeability status with the FDA, Pfizer claims that whether the biosimilar can be automatically substituted would ultimately depend on state law. Id. A key aspect to this distinction, according to Pfizer, is that "it enables biologic originator firms to leverage their monopolies over

existing patients to extract anticompetitive commitments from insurers and providers.” Id.

With this in mind, we turn to the competing products in this case. J&J introduced the first infliximab product under the brand name Remicade in the United States in 1999. Id. ¶38. The FDA has approved Remicade’s indications for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Chron’s disease, and plaque psoriasis. Id. ¶¶45, 83. Pfizer estimates that 475,000 patients in the United States receive at least one dose of Remicade annually. Id. ¶39. Because of its patents, J&J enjoyed a monopoly over the infliximab market in the United States until 2016. Id. ¶3.

Pfizer brought Inflectra to market in 2016 after it received FDA approval as the first biosimilar to Remicade. Id. ¶5. The FDA approved Inflectra for the same indications as Remicade, except for pediatric ulcerative colitis, which accounts for a minimal amount of Remicade’s sales. Id. ¶45.

Remicade and Inflectra are administered intravenously at an institutional setting, such as a clinic or hospital. Id. ¶49. They are “medical benefit” products, in contrast to “pharmacy benefit” products. Id. ¶¶49-50. As medical benefit products, Remicade and Inflectra are first purchased by the providers, who later seek reimbursement after administering it on patients. Id. Because the provider bears financial risk posed by the patient or

patient's insurer not reimbursing them for the cost of medical benefit products, providers have an interest in utilizing drugs that are widely covered by insurers. Id. ¶50.

Within weeks of Inflectra's launch in 2016, J&J began to deploy its "Biosimilar Readiness Plan." Id. ¶6. Pfizer claims that the "core features of the plan are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing." Id. Pfizer alleges that J&J's anticompetitive scheme targeted both insurers and providers and involved exclusive contracts for Remicade, multi-product bundled rebates, rebates based on the bundling of existing (incontestable) and new (contestable) infliximab patients, and creating a "rebate trap" that prevented Pfizer and other competitors from competing with Remicade. Pzf. Resp. at 6 (citing Compl. ¶¶ 8, 9, 11, 55-79, 98) (Doc. No. 42).

Exclusive Contracts. A key component of J&J's scheme was to secure contractual commitments from commercial insurance companies to exclude biosimilars from coverage under their plans, thereby making Remicade the exclusive infliximab available to patients covered under those plans. Id. ¶58. A portion of these agreements contained express terms that would exclude biosimilars from their

medical policies and drug formularies. Id. The remaining portion of these agreements contained a “fail first” provision, which would require a patient to first try and fail on Remicade before the insurance company would reimburse Inflectra or another biosimilar. Id. However, if a patient first fails on Remicade, it would “defy sound medical judgment” for a physician to switch to a therapeutic equivalent biosimilar, such as Inflectra, rather than try another therapy. Id. At least 70 percent of commercially insured patients in the United States fall under plans that have adopted these express or de facto agreements to exclude Inflectra and other biosimilars. Id. ¶59.

Bundled Rebates and Multi-Product Bundling. Pfizer also alleges that J&J has forced insurers into accepting exclusive contracts by introducing a rebate program that would provide savings off Remicade’s increasing list price for all existing Remicade patients. Id. ¶¶9, 66. The threat of not qualifying for the rebate would result in significant costs for insurance companies because it would apply to both new and existing Remicade patients. Id.

Pfizer posits that the force of J&J’s “all-or-nothing” rebate program is effective because it bundles the base of existing Remicade patients with new patients entering the infliximab market. Id. ¶¶9, 65. Pfizer asserts that the exiting Remicade patients represent inelastic demand, or incontestable patients, who are “highly unlikely” to switch to a biosimilar regardless of price.

Id. By premising rebates on this incontestable population, J&J is able to force insurance companies to exclude Inflectra from competing for new patients entering the infliximab market. Id. ¶¶9, 66. Pfizer refers to this as the “rebate trap.” Id. ¶66.

Beyond bundling contestable and incontestable patients, J&J has also bundled rebates across multiple products. Id. ¶¶9, 67. In essence, if an insurer refuses to grant exclusivity to Remicade, the insurer would be forced to pay a higher price on other J&J products in addition to Remicade. Id. Pfizer identifies Simponi, Simponi Aria, and Stelara as other J&J products included in its multi-product bundled rebate program. Id. Pfizer also claims it could offer no competing drugs to these products. Id.

Pfizer claims that Inflectra’s exclusion from coverage by most insurers results in an even greater foreclosure than just the patients covered by those insurers. Id. ¶¶10, 69, 70, 71. As an infusion product, infliximab is administered at a provider’s facility. The provider therefore purchases and stocks infliximab products. According to Pfizer, the risk that Inflectra will not be reimbursed by a significant portion of patients’ insurers causes physicians to only purchase, stock, and proscribe Remicade for nearly all of their infliximab patients. Id. ¶¶10, 69-71.

Pfizer claims that J&J’s multi-faceted approach to control the infliximab market has foreclosed it from competing. Pfizer alleges that it continues to offer “a significantly lower price for

Inflectra unit-for-unit.” Id. ¶66. Despite a lower unit cost, insurance companies continue to enter into exclusive agreements with J&J to cover Remicade for all infliximab patients to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra. Id. To overcome the “rebate trap,” Pfizer claims that it would have to follow J&J’s lead and price Inflectra below its own average variable cost. Id. ¶¶66, 77, 78. Pfizer states that it continues to negotiate with providers to make Inflectra the lower-priced infliximab option on a per-unit basis, even in the form of offering guarantees. Id. ¶77. Again, according to Pfizer, its efforts to compete on price have failed because of J&J’s efforts to foreclose it from the market. Id.

As a result of J&J’s exclusionary contracting scheme, and despite Pfizer’s efforts to compete, Remicade’s price continues to rise. Id. ¶¶8, 12, 47, 80-82, 100, 102; Pfizer’s Not. of Supp. Auth. (Doc. No. 74). Pfizer alleges that both Pfizer’s Wholesale Acquisition Price (“WAP”) and “Average Sales Price” (“ASP”), which is a net price accounting for rebates and other discounts, continues to rise despite insurers and providers now having a lower-cost alternative that, according to Pfizer, differs in no meaningful way. Id. ¶¶13, 42, 45-47, 104; Pfz. Not. of Supp. Auth. at 2. According to Pfizer, J&J’s ability to increase the price of Remicade quarter after quarter since Pfizer brought Inflectra to market “underscores

the plausibility of [Pfizer's] allegations" that J&J's scheme has unlawfully restrained--and continues to unlawfully restrain--biosimilar competition to Remicade. Pfz. Not. of Supp. Auth. at 2.

As a result of J&J's anticompetitive conduct, Pfizer claims that it has been foreclosed from competing for at least 70 percent of all commercially insured patients in the United States. Compl. ¶8. The spillover effect that J&J's scheme causes on providers' purchasing decisions has led 90 percent of provider account stocking no Inflectra at all. Id. ¶12. As of September 2017, J&J maintained an over 96 percent marketshare of infliximab unit sales in the United States. Id. ¶102.

Pfizer points out that it is not the only one harmed as a result of J&J's exclusionary conduct. Id. ¶104. Since the FDA approved Inflectra, J&J has increased the price of Remicade by nearly 10 percent, which in turn increases the cost to private insurance companies, government payers, and consumers. Id. ¶¶13, 104.

II. LEGAL STANDARD

Fed. R. Civ. P. 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Plaintiffs are not required to provide detailed factual allegations in their complaint, though they must do more than merely state legal conclusions and formulaic

recitations of the elements of the cause of action. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

A party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a motion to dismiss under Rule 12(b)(6), a district court must "accept as true the factual allegations in the complaint and all reasonable inferences that can be drawn therefrom." Krantz v. Prudential Invs. Fund Mgmt. LLC, 305 F.3d 140, 142 (3d Cir. 2002) (quoting Nami v. Fauver, 82 F.3d 63, 65 (3d Cir. 1996)). While a court generally cannot consider matters outside the pleadings, "a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation marks and alteration omitted).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citation omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than

a sheer possibility that a defendant has acted unlawfully.” *Id.* at 678 (quoting Twombly, 550 U.S. at 556). A plaintiff is entitled to all reasonable inferences from the facts alleged, but a plaintiff’s legal conclusions are not entitled to deference, and the Court is “not bound to accept as true a legal conclusion couched as a factual allegation.” Papasan v. Allain, 478 U.S. 265, 286 (1986).

The Court’s analysis, below, applies this governing standard to J&J’s Rule 12(b)(6) arguments for dismissal.

IV. DISCUSSION

Pfizer has asserted claims under Section 1 and Section 2 of the Sherman Act and Section 3 of the Clayton Act. Compl. ¶¶110, 117, 125, 136. The law applicable to each claim is effectively the same as it applies to J&J’s Motion to Dismiss. Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 402 n.11 (3d Cir. 2016). Specifically, to sufficiently plead an actionable antitrust violation, Pfizer must plead facts showing that J&J engaged in anticompetitive conduct and that Pfizer suffered antitrust injury as a result. Id.

J&J raises three lines of attack against J&J’s Complaint. First, J&J generally targets Pfizer’s alleged pleadings, arguing that Pfizer has failed to plead facts that constitute an antitrust injury. Second, J&J argues that Pfizer has failed to plead specific allegations establishing antitrust injury with respect to the particular conduct that is the subject of Pfizer’s Complaint.

Lastly, J&J argues that the facts that Pfizer did plead lack sufficient basis to support its antitrust injury. We address each below.

A. General Antitrust Injury

“Competition is at the heart of the antitrust laws.” Philadelphia Taxi Ass'n, Inc. v. Uber Techs., Inc., 886 F.3d 332, 338 (3d Cir. 2018) (internal quotation omitted). Antitrust laws are only aimed at curtailing anticompetitive conduct, “or a competition-reducing aspect or effect of the defendant’s behavior.” Id. In other words, the underlying principle of our antitrust laws is to protect competition, not competitors. Id.

The law therefore establishes antitrust injury as a common pleading requirement for antitrust plaintiffs. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 US 477, 489 (1977); see also W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 101 (3d Cir. 2010); Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 875-76 (3d Cir. 1995). An antitrust injury is an “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” Brunswick, 429 U.S. at 489.

Under this requirement, Pfizer “must allege harm to competition, not just harm to its own business” to adequately plead antitrust injury. In re EpePen (Epinephrine Injection, USP) Mktg., Sales Practices and Antitrust Litig., 2017 U.S. Dist. LEXIS 209710, at *64 (D. Kan. Dec. 21, 2017); see also Philadelphia Taxi Ass'n,

886 F.3d at 338. "This standard, on a motion to dismiss, requires an antitrust plaintiff to allege facts capable of supporting a finding or inference that the purported anticompetitive conduct produced increased prices, reduced output, or otherwise affected the quantity or quality of the product." In re EpePen, 2017 U.S. Dist. LEXIS 209710, at *64-65 (citing National Collegiate Athletic Ass'n v. Board of Regents, 468 U.S. 85, 113 (1984); Cohlma v. St. John Medical Center, 693 F.3d 1269, 1281 (10th Cir. 2012); Mathews v. Lancaster Gen. Hosp., 87 F.3d 624, 641 (3d Cir. 1996)).

While an antitrust plaintiff must present plausible allegations establishing antitrust injury, "the adequacy of a [plaintiff's] contentions regarding the effect on competition is typically resolved after discovery, either on summary judgment or after trial." Brader, 64 F.3d at 869. Accordingly, "the existence of the antitrust injury is not typically resolved through motions to dismiss." Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 417-18 (3d Cir. 1997) (citing Brader, 64 F.3d at 876). The distinction between these propositions is that a plaintiff must assert allegations making plausible the claim that it, and the competitive market, suffered as a result of defendant's anticompetitive conduct; however, on a motion to dismiss, we liberally analyze the adequacy of those allegations, and of course, we do not judge the validity of those claims.

For example, in Brader, the Third Circuit reversed the district court's dismissal of antitrust claims based on the antitrust injury pleading requirement. 64 F.3d at 875-76. The Third Circuit noted that the plaintiff did in fact plead that the defendant hospital "prevented him and others from engaging in the practice of general vascular trauma surgery in the relevant market, and prevented other hospitals in the relevant market from employing or granting medical staff privileges to the [p]laintiff for the purpose of competing with defendants." Id. at 876. These allegations alone were sufficient to state a claim for antitrust injury. Id.

Pfizer's Complaint sufficiently alleges that it has suffered an antitrust injury as the result of J&J's anticompetitive conduct. J&J's efforts to foreclose Pfizer from the market, as Pfizer has alleged, have led to increased prices for consumers and limited competitive options for end payors, providers, and patients. Pfizer provides detailed allegations regarding J&J's exclusionary terms with many of the nation's largest insurers, the incentive structure that forces end payors and providers into accepting those terms, Pfizer's efforts to compete, including its guarantees that Inflectra would cost less than Remicade, and showed how market participants on many levels are injured from J&J's ability to sell Remicade without having to compete with Inflectra and other biosimilars.

Along a similar line of attack, J&J also takes aim at Pfizer's alleged antitrust injury by arguing that Pfizer's inability to gain

market share is caused by reasons other than J&J's alleged anticompetitive conduct. For example, J&J argues that Inflectra's lack of competition is the result of providers' lack of comfort and awareness of biosimilars, Inflectra's lack of "interchangeability" status with Remicade, and Remicade's substantial rebates. J&J Corrected Mem. at 1, 14-15 (Doc. No. 31).

While these arguments may prove true after discovery, they are not grounds for dismissing Pfizer's Complaint. The existence of possible alternative causes of an antitrust injury is not a valid ground for dismissal. In re EpePen, 2017 U.S. Dist. LEXIS 209710, at *76 (D. Kan. Dec. 21, 2017). In other words, an antitrust plaintiff is not required to disprove all other possible alternative causes to survive a motion dismiss.

This reasoning is illustrated in In re EpePen, in which Sanofi asserted antitrust claims against Mylan on the basis that Mylan prevented Sanofi's pharmaceutical from competing. 2017 U.S. Dist. LEXIS 209710, at *19-21. On a motion to dismiss, Mylan argued that Sanofi's inability to compete was instead a result of its poor marketing decisions. Id. at *76. Mylan also argued Sanofi's lack of success was more likely attributable to Sanofi's product recall than Mylan's conduct. Id. at *77. Rejecting Mylan's arguments, the district court noted that "[t]hese arguments merely foreshadow factual disputes that the court cannot resolve on a motion to dismiss." Id. The court therefore "refuse[d] to dismiss Sanofi's

claims at the pleading stage based on Mylan's arguments that alternative reasons caused the alleged injuries." Id. at *76.

While J&J may ultimately be correct that Inflectra's lack of success is the result of something other than J&J's conduct, its argument is misplaced at this stage in the litigation. In considering the sufficiency of Pfizer's alleged antitrust injury, "dispositive weight should not be given to lists of possible alternatives, which virtually any defendant can generate." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶338 (4th Ed., 2018 Cum. Supp. 2010-2017). We therefore reject J&J's invitation to dismiss Pfizer's Complaint on the basis that Pfizer's own actions caused Inflectra's lack of success to date.

B. Conduct Specific Antitrust Injury

J&J next asks us to dismiss Pfizer's Complaint on the basis that Pfizer has failed to allege facts establishing antitrust injury resulting from J&J's particular conduct that is the subject to Pfizer's Complaint.

As noted above, Pfizer claims that J&J has engaged in a multifaceted scheme to prevent Inflectra and other biosimilars from competing with Remicade. Pzf. Resp. at 19. This scheme includes "secur[ing] contractual commitments from commercial insurance companies to exclude biosimilars from coverage under their plans." Compl. ¶58. Such commitments, as Pfizer alleges, cause Remicade to

be the exclusive infliximab available to new and current infliximab patients. Id. The alleged scheme also includes bundling, in the form of multi-product bundles and a theory based on bundling Remicade's existing and new patients. Id. ¶¶65-68.

Exclusive dealing arrangements arise when a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time. These agreements can be in the form of express or *de facto* terms--terms that naturally result in the buyer purchasing exclusively from the seller. ZF Meritor, LLC v. Easton Corp., 696 F.3d 254, 270 (3d Cir. 2012). In ZF Meritor, the Third Circuit noted there was sufficient evidence of a *de facto* exclusive dealing arrangement where no risk adverse purchaser would refuse the agreement out of caution for jeopardizing its relationship with the largest seller. Id. at 283.

On one hand, such agreements may benefit consumers because they can assure supply and price stability. On the other hand, such agreements can also deprive competitors access to a certain market. We therefore consider exclusive dealing arrangements under a rule of reason framework, in which we analyze "the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services." Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 403 (3d Cir. 2016).

Another form of potentially anticompetitive conduct is bundled

rebates. Bundled rebates pose antitrust concern when a defendant forecloses competition from its product in a competitive market by linking it to a product on which it faces no competition. LePage's Inc. v. 3M, 324 F.3d 141, 156 (3d Cir. 2003); SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1065 (3d Cir. 1978). In SmithKline, the Third Circuit affirmed as an antitrust violation the defendant's rebates based on the purchase of multiple products because the bundle, in effect, "insulated its product from true price competition." 575 F.2d at 1065. The same was true in LePages's, where the defendant "used its monopoly in transparent tape, backed by its considerable catalog of products, to squeeze" its competitor from the market. 324 F.3d at 157. Similar to exclusive dealing agreements, bundled rebate claims are analyzed under a rule of reason framework.

Focusing on Pfizer's alleged antitrust injury, J&J makes several arguments specific to each aspect of its alleged anticompetitive conduct.

First, J&J argues that Pfizer's alleged antitrust injury based on J&J's multi-product bundling should be dismissed because Pfizer failed to allege that it offered its own multi-product bundles. According to J&J, Pfizer was either required to plead facts establishing that it offered its own competing bundle or that it was incapable of doing so. J&J Resp. at 13.

J&J relies heavily on Eisai, where the Third Circuit stated it

previously “limited the reasoning in LePage's to cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across multiple different product lines.” 821 F.3d at 405. In Eisai, the Third Circuit reviewed the circuit’s prior decisions in bundling cases and noted that bundling can be anticompetitive when it “forecloses portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer.” Id.

Pfizer, of course, is not a single-product producer. It admits as much in its Complaint. Compl. ¶18. Moreover, Pfizer has not alleged any facts suggesting that J&J is hindering its ability to compete with J&J’s multi-product bundles by offering their own multi-product bundles. J&J’s multi-product bundles, on their own, therefore do not present antitrust concern.

Second, J&J cites Eisai for the proposition that bundling contestable and incontestable demand, for the same product, cannot constitute an antitrust violation. However, the Third Circuit did not completely shut the door on such a theory, as J&J argues. Id. at 406. Rather, it affirmed summary judgment with the factual support that “nothing in the record indicates that an equally efficient competitor was unable to compete.” Id.

Bundling Remicade's incontestable demand could create anticompetitive consequences by foreclosing competition for new infliximab patients--thereby posing antitrust concern that was lacking in Eisai. Taking Pfizer's allegations as true, new infliximab patients are contestable because they have not yet been anchored to a specific infliximab product. If incontestable demand is truly inelastic, then this could fall into a traditional bundling case where J&J has bundled its power over existing Remicade patients to break the competitive mechanism and deprive new infliximab patients (and their insurers) of the ability to make a meaningful choice between Remicade and its biosimilars. See Eisai, 821 F.3d at 404. We therefore refuse to dismiss Pfizer's bundling claim as it relates to contestable and incontestable demand.

C. Allegations Supporting Pfizer's Efforts to Compete

Lastly, J&J argues that Pfizer's alleged antitrust injury based on J&J's exclusive contracts should be dismissed because Pfizer failed to plead adequate facts establishing that it attempted to compete. J&J supports this argument by claiming Pfizer's allegations regarding the price of Inflectra and Remicade lack sufficient accuracy to make plausible Pfizer's efforts to compete.

J&J mainly takes issue with Pfizer's reliance on Average Sales Price ("ASP") and Wholesale Acquisition Cost ("WAC"). According to J&J, Pfizer cannot rely on ASP and WAC to support its efforts to

compete with J&J by offering lower prices because both metrics lack sufficient specificity. J&J Corrected Mem. at 17.

As noted above, WAC is essentially a metric reflecting list price, whereas ASP is based on an annual average that does account for rebates and discounts off list price. J&J argues that because WAC does not reflect the net price after discounts and rebates, it provides no indication about the price competition between Remicade and Inflectra. The problem with ASP, according to J&J, is that because Remicade's current ASP reflects a yearly net average, and because Inflectra has been on the market for less than a year at the time Pfizer filed its Complaint, Remicade's ASP reflects pricing data from months where Inflectra was not yet on the market. J&J Corrected Mem. at 3-4, 16-18.

At this stage, we find that Pfizer's allegations containing ASP data do support the plausibility of its claims. According to Pfizer, it has priced Inflectra lower than J&J's Remicade even accounting for incentives such as bundled discounts and rebates. Pfizer also alleges that Remicade's ASP continues to increase despite Inflectra's entrance to the market at a 24 percent lower per unit cost. Supp. Auth. at 2. These allegations lend plausibility to Pfizer's theory that J&J is engaging in anticompetitive behavior, which is foreclosing biosimilars from competing.

We agree with J&J that the WAC provides minimal support for the proposition that Inflectra costs less on a unit-for-unit basis than

Remicade. Nevertheless, Pfizer's allegations regarding Remicade's increasing WAC does support Pfizer's theory that J&J's bundled rebate force purchasers into excluding Remicade's biosimilars from the market. Increasing Remicade's WAC in turn increases the penalties for not excluding Inflectra and other biosimilars in the form of lost incentives. Accepting as true Pfizer's allegations that existing Remicade patients will not switch to a biosimilar despite price competition, the increasing penalties that payors may face for exiting patients may effectively force payors into accepting J&J's exclusionary terms for all patients.

J&J's arguments against Pfizer's support for its pricing allegations are misplaced--or rather, mistimed. Discovery will reveal whether Pfizer has offered more competitive pricing for Inflectra, as alleged in its Complaint. If Pfizer's claims about pricing prove true, then the pricing data may indicate that J&J's conduct has prevented Pfizer from competing in violation of the antitrust laws. Ultimately, the legality of J&J's conduct will depend on whether it foreclosed a substantial share of the market such that competition has been harmed. ZF Meritor, 696 F.3d at 283 (citing Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 326-28 (1961)).

V. CONCLUSION

For the foregoing reasons, J&J's Motion to Dismiss is denied. An appropriate Order will follow.

ATTACHMENT C

Source: NAIC 2010 Supplemental Health Care Exhibit Report, 2011

		Comprehensive Health Coverage			Mini-Med Plans			Expatriate Plans		Student Health Plans	TOTAL
		Individual	Small Group Employer	Large Group Employer	Individual	Small Group Employer	Large Group Employer	Small Group	Large Group		
COUNTRYWIDE	Supplemental Health Care Exhibit Aggregated Totals Countrywide Part 1										
Prescription drugs	2.2	\$ 2,268,138,908	\$ 9,906,843,518	\$ 24,148,949,177	no report	no report	no report	no report	no report	no report	\$ 36,323,931,603
Pharmaceutical rebates	2.3	\$ 212,481,808	\$ 961,854,065	\$ 1,787,565,615	no report	no report	no report	no report	no report	no report	\$ 2,961,901,488
Net		\$ 2,055,657,100	\$ 8,944,989,453	\$ 22,361,383,562							\$ 33,362,030,115
% Total drug spending received by Payers as rebate		9.4%	9.7%	7.4%							8.2%
OREGON											
Prescription drugs	2.2	\$ 42,880,268	\$ 108,666,994	\$ 352,936,119	no report	no report	no report	no report	no report	no report	\$ 504,483,381
Pharmaceutical rebates	2.3	\$ 3,259,846	\$ 7,177,869	\$ 18,581,741	no report	no report	no report	no report	no report	no report	\$ 29,019,456
Net		\$ 39,620,422	\$ 115,844,863	\$ 371,517,860							\$ 475,463,925
% Total drug spending received by Payers as rebate		7.6%	6.6%	5.3%							5.8%

url: https://www.naic.org/prod_serv/HCS-ZB_2010.pdf

Rebate information from:

<https://nu-retail.com/tag/rebate-retention-rate/>

<https://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html>

	IMS Health / IQVIA	Projected Data based on NAIC Total Prescription Spending, Medco and IMS Data		Medco	
	billion			Composite Rebate Retention Rate	12.5%
COUNTRYWIDE					
Prescription drugs	\$ 320			Rebate earned	\$ 5.8
Pharmaceutical rebates	\$ 54	Rebate pass-back to Payers based on Medco Retention Rate (billion) (87.5% of \$54 billion)	\$ 47.3	Retained	\$ 0.7
Net	\$ 266	Total Drug Spending ((MS)	\$ 320.0		
% Total drug spending received by Payers as rebate		Effective Pass-back (or Pass-Through) Rebate Rate to Payers as % of Total Drug Spending	14.8%		
OREGON					
Prescription drugs		% of NAIC Total	1.39%	Based on Medco retention rate, Payers received about \$47.3 billion (87.5% of \$54 billion) or a 14.8% of total drug spending in 2010. NAIC-reported drug spending for Oregon represent 1.39% of the total NAIC-reported drug spending. Applied to IMS rebate data (assuming NAIC data is representative of the overall share of Oregon among all public and private plans), then Oregon public and private plans/program collected about \$656 million in pharmaceutical rebates.	
Pharmaceutical rebates		Total Drug Spending for Oregon (billion) (1.39% of \$320 billion)	\$ 4.444		
Net		Total Rebate Pass-back to Payer in Oregon (billion) (14.8% of \$4.4 billion)	\$ 0.656		
% Total drug spending received by Payers as rebate		Expected NAIC rebate based on effective Pass-back Rate (14.8% of \$504 million drug spending reported to NAIC for Oregon)	\$ 74,490,124		
		Reported Rebate received by Payer for NAIC-reported drug spending	\$ 29,019,456		
		Under-reported Rebate Amount:	\$ 45,470,668		
url: https://www.naic.org					
Rebate information from https://nu-retail.com/ and https://www.drugchar.com/					https://www.prnewswire.com/news-releases/medco-delivers-record-fourth-quarter-and-full-year-2010-earnings-116644004.html

ATTACHMENT D

focus on trend

COMMERCIAL

Prime’s commercial clients experienced an overall decrease in prescription drug expenditures in 2017 despite ongoing price inflation in some of the most expensive drug categories. Drug trend of -0.2 percent was achieved through substantial negotiated savings and increased use of powerful tools such as Prime’s NetResults™ formulary and Walgreens-anchored networks.

“Results like our 2017 drug trend require thousands of dedicated employees working tirelessly on behalf of our clients and their members. Prime stands with our clients as a fierce ally, powerfully aligned with the Blues to jointly combat unsustainable drug pricing. Our success last year in managing drug spending demonstrates the value of using both medical and pharmacy drug insights to effectively manage overall cost of care.”

—Jim DuCharme, president and CEO



More than
\$2.7 billion

in client savings in 2017 as a result of Prime’s management tools

Based on internal Prime analysis

Specialty utilization growth was more than three times greater than traditional medicine and helped fuel double-digit specialty trend. Negative drug trend for traditional medicines was fueled by a nearly 9 percent reduction in unit cost. Specialty medicines saw unit costs increase by nearly 3 percent.

	Utilization (%)	Unit cost (%)	Total (%)
Overall	3.2	-3.4	-0.2
Traditional	3.2	-8.9	-5.7
Specialty	10.3	2.7	13.0

Trend analyses in this report were prepared and reviewed by Prime’s actuarial team.

Powerful upward forces in drug costs remain

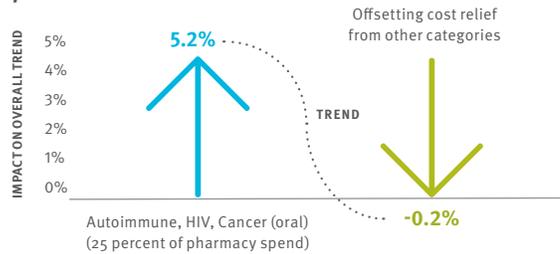
Double-digit trends continue in the most expensive categories

Drug Category	% of spend	Trend	Unit Cost
Autoimmune	14.0%	23.1%	\$4,785
HIV	5.6%	22.0%	\$1,814
Cancer (oral)	5.3%	19.3%	\$8,594

25 percent of pharmacy spend

Traditional spend Diabetes drugs retained first place among the most expensive drug categories in 2017. They saw ongoing increases in utilization, but Prime kept trend to single digits thanks to substantial negotiated savings. HIV medicines saw the highest trend (22 percent) among traditional drugs in the top ten, reflecting substantial increases in both unit cost and utilization. At -15 percent, pain medicine had the lowest trend among traditional drugs in the top ten. These results complement a 16 percent decrease in opioid claims over the past five years for Prime's commercial book of business. Today, Prime's Controlled Substance Management Program combines multiple tools into a comprehensive approach to help address the national opioid epidemic.

High-cost categories exert upward pressure on overall trend



Specialty spend The autoimmune category continued to be the primary driver of spend among specialty drugs. It had the highest trend (23 percent) among the top-ten categories, fueled by significant increases in both utilization and unit cost. The cancer (oral) category saw a similar pattern. Expenditures in both categories were further driven by heavy brand use. Hepatitis C trend continued to level off in 2017 as utilization declined as more people having been treated. The rapid pace of drug submissions for orphan conditions and oncology indications is expected to continue and will help maintain upward pressures in specialty trend.

Top-ten drug categories

Drug category	% of Spend*	Trend**
1. Diabetes	14.1%	2.2%
2. Autoimmune	14.0%	23.1%
3. HIV	5.6%	22.0%
4. Cancer (oral)	5.3%	19.3%
5. Multiple Sclerosis	4.8%	1.7%
6. Respiratory	4.0%	-7.0%
7. ADHD	3.8%	-6.4%
8. Pain	3.6%	-14.6%
9. Hepatitis C	3.1%	-22.3%
10. Anticonvulsant	2.5%	9.3%

*Total expenditures before rebates and inclusive of discounts **Bold = Specialty**
 **Change in PMPM spend 2016 to 2017 after rebates and discounts

Top-ten individual drugs

Drug	Condition	% of Spend*
1. Humira® Pen	Autoimmune	5.4%
2. Enbrel® Sureclick®	Autoimmune	2.3%
3. Harvoni®	Hepatitis C	2.2%
4. Lantus® SoloSTAR®	Diabetes	1.4%
5. Victoza®	Diabetes	1.3%
6. Vyvanse®	ADHD	1.3%
7. Stelara®	Autoimmune	1.3%
8. Novolog® Flexpen	Diabetes	1.3%
9. Novolog®	Diabetes	1.2%
10. Genvoya®	HIV	1.1%

All brand names are the property of their respective owners.

A pipeline of new, expensive drugs is driving upward cost pressure

Out of 46 new drugs (traditional and specialty) in 2017, 8 drugs drove overall trend by approximately 1 percent at an average annual cost of approximately **\$96,000**.

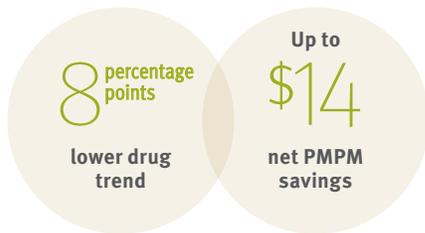
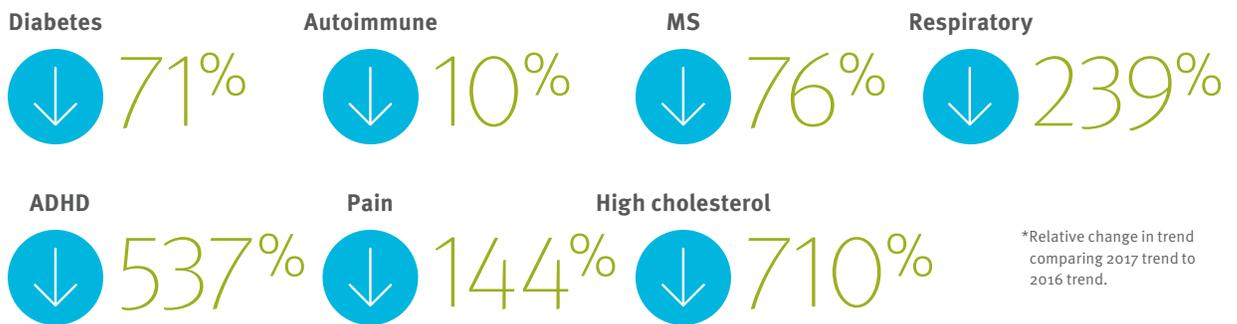


NEW DRUG PIPELINE

Based on internal Prime analysis

success stories

In 2017 Prime’s commercial clients saw significant trend reductions* in multiple categories. Increased use of Prime’s PBM tools and substantial negotiated savings helped drive these reductions.



NetResults™ formulary

Drug trend for clients who adopted Prime’s NetResults formulary in 2017 was 8 percentage points lower on average compared to clients not using this approach.

Total savings for lives covered by NetResults have ranged from \$10 – \$14 net PMPM in 2017.

Incremental negotiated savings

In 2017 commercial clients benefited from more than \$1.6 billion in incremental negotiated savings through Prime’s delivery of competitive rebates and pharmacy MAC pricing plus network savings fueled by client adoption of Walgreens-anchored networks.



Other value delivered

\$2 billion

Utilization Management savings, including prior authorization, step therapy and quantity limit programs, exceeded \$2 billion in total savings in 2017.

\$225 million

Prime’s GuidedHealth® analyses to address gaps in care and adherence generated more than \$225 million in total savings for our commercial clients.

\$123 million

Prime’s fraud, waste and abuse (FWA) efforts have generated more than \$154 million in total savings with \$123 million from actions taken on pharmacies due to noncompliance and denied network enrollments. Future enhancements to our FWA capabilities include advanced analytics leveraging integrated medical and pharmacy claims plus comprehensive investigations and client consultation that address **both** member and prescriber FWA.

Based on internal Prime analysis

Prime's PBM toolbox continues to grow and will create even greater impact in the year ahead.

Best in Care™ Our Best in Care disease-specific programs help manage costly chronic conditions and provide robust, comprehensive support through specially trained pharmacists, online resources and focused clinical programs. Prime offers Best in Care programs for autoimmune conditions, diabetes, high cholesterol, hepatitis C* and multiple sclerosis*. Programs for additional conditions are in development. These programs capitalize on our unique insights into how medical and pharmacy benefits can work together to strengthen outcomes and reduce costs.

*Anticipated late February 2018

CareCentered Contracting™ One way Prime is addressing rising drug costs is through CareCentered Contracting, an Outcomes and Value based program that ties the cost of a drug to how well it works. It aligns payers, manufacturers, members, and providers around the goal of improving health by helping to ensure drugs deliver the outcomes that they promise.

Prime has been a leader in outcomes-based and value-based strategies, establishing its first CareCentered Contracting agreement in 2010. This program continues to grow and addresses healthcare challenges such as adherence and total cost of care. CareCentered Contracting is focused on therapeutic areas making a large impact on healthcare spend: diabetes, multiple sclerosis, high cholesterol, and autoimmune.

CareCentered Contracting is supported through member educational efforts, targeted communications and channel management, with the ultimate goal of slowing disease progression and reducing total cost of care. Prime is uniquely positioned to evaluate the combined cost of pharmacy and medical on select therapies and the impact on overall health costs for the members we serve.

Patient-Centered Specialty Drug Management

With specialty drugs now exceeding fifty percent of total drug spend, Prime takes a holistic approach to effectively manage specialty costs. Our transparent model and ability to look across medical and pharmacy data differentiates Prime from other PBMs.

For example, our Integrated MedRx Opportunity Analytics package, in combination with Prime's team of dedicated therapy-specific pharmacists, leverages plan-specific data to bring forward actionable insights and generate meaningful savings. To help offset rising specialty costs in the medical benefit, our Reimbursement Solutions offering identifies savings opportunities in the physician office setting based on competitive drug reimbursement rates. Our Site of Care program focuses on shifting high-cost infusion patients from hospital outpatient facilities to lower cost sites such as home infusion, infusion centers or doctor's office. Prime's Medical Claim Edits capability is an evidence-based library of drug-specific rules and criteria that are designed to identify medical claims that are out of line with expected cost, quantity and clinical use. We're also analyzing new treatments that are challenging the status quo, like CAR-T cell and gene therapies.

Controlled Substance Management Program

Prime's Controlled Substance Management Program provides a multi-layered response to the national opioid epidemic. Using pharmacy and medical data to identify misuse and abuse, it combines our industry-validated controlled substance score with multiple programs. New predictive modeling in development will allow us to identify high-risk members even sooner.

Over the past five years Prime's industry-leading work around controlled substances helped contribute to a 71 percent decrease in commercial members identified as high-risk outliers,** 16 percent fewer opioid claims and reduced health care costs of at least \$1,500 PMPY.

**Members without cancer and a 6-month average morphine equivalent dose of 90mg or more who receive opioid prescriptions at more than three pharmacies AND from more than three prescribers OR more than five prescribers regardless of pharmacy total.

Prime Therapeutics LLC

800.858.0723

1305 Corporate Center Drive, Eagan, MN 55121

PrimeTherapeutics.com

METHODOLOGY

Trend Represents change for 2016 vs 2017 for Prime's commercial book of business (which includes Health Insurance Marketplace populations) for Total Costs (plan + member PMPM) inclusive of network discounts + tax + dispensing fees minus total rebates. Calculations include plans with 12 months of 2016 and 2017 data. Trend analyses in this report were prepared and reviewed by Prime's actuarial team.

Utilization Rate of change per member based on 30-day equivalent prescriptions.

Unit cost Rate of change in costs due to inflation and mix inclusive of discounts and rebates.

ATTACHMENT E

October 15, 2019

To: 2018 HB 4005 Rulemaking Advisory Committee
Jesse Ellis O'Brien
2018 HB 4005 RAC Members
Sent by Email to: Jesse.E.O'Brien@Oregon.gov

From: Robert Judge, Director of Pharmacy Services, Moda Health

Subject: Moda Health Comments on Preliminary Draft HB 4005 Rules

Dear Mr. O'Brien and members of HB 4005 RAC,

Thank you for providing Preliminary Draft HB 4005 Rules for review and feedback. I am providing feedback today on behalf of Moda Health as a participant in the Rulemaking Advisory Committee (RAC) for consideration by the Department of Consumer and Business Services' ("DCBS"). HB 4005 represents a major step forward in bringing consumers more information about drug costs by requiring greater transparency from manufacturers and insurers. In support of this objective, I am hopeful that my comments will help improve the clarity concerning the proposed Rules as DCBS continues its deliberation.

My comments concern the following sections of the proposed Rules:

- 836-200-0500 Definitions
- 836-200-0505 Form and Manner Requirements for Drug Pricing Reporting
- 836-200-0550 Assessments Against Prescription Drug Manufacturers
- 836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans

836-200-0500 Definitions

A key consideration for DCBS is assessing how best to establish the information required to be provided under HB 4005 and to ensure that parties understand what is expected to be provided. To this end, I am recommend the RAC consider the following additional definitions or clarifications to proposed definitions:

1. Addition to the definition for Reporting Manufacturer. HB 4005 requires manufacturers to report certain data on drugs that they market. This definition should include specificity around the manufacturer's drug. I propose that "holds the National Drug Code (NDC) for a prescription drug" be added to the definition.

Additionally, it is important to consider that many medications are marketed under different trade names in different countries. For example, Pfizer markets a chemically identical version of Viagra in New Zealand named Avigra. There are no provisions in the proposed rule for this consideration. This is especially important in consideration of the requirement to have manufacturers report

their 10 highest prices paid for the prescription drug in countries other than the United States as required under Section 2(3)(j) of HB 4005. Failure to include this in Definitions may expose the state to under-reporting by a manufacturer. DCBS should evaluate including a requirement that manufacturers include the chemical entity or biologic product in addition to the trade name when they report data.

2. "One-month supply" and "Course of treatment". The proposed definitions may be open to different interpretations so that data for drugs in therapeutic classes are reported differently. As a consequence, I recommend amending the definition to include the daily dosage under which the product was approved by the FDA. DCBS may want to consider changing the definitions for the above referenced terms to the following:
 - a. "One-month supply: The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for 30 days."
 - b. "Course of Treatment: The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than 30 days."

836-200-0505 Form and Manner Requirements for Drug Pricing Reporting

1. Additional consideration should be given to how a manufacturer will report data to ensure that such data is standard and easily analyzed by DCBS, sorted by manufacturer. Under General Requirements, item (1), it is proposed that manufacturers be directed to supply information by National Drug Code (NDC) and Group Product Identifier (GPI).

Requiring drug information by NDC will enable DCBS to capture both the labeler (manufacturer) and drug/strength/form. Specifically, DCBS should require manufacturers to supply 9-digit NDCs, which include the first 4 letters that represent the manufacturer, repackager, or distributor followed by the next 5 characters which represent the product code, and identifies the specific strength, dosage form (i.e., capsule, tablet, liquid) and formulation of a drug for a specific company. Requesting NDC data will allow DCBS to track price changes by drug and manufacturer.

Requiring drug information by GPI will allow DCBS to assess information by equivalent drug products (e.g., generics) that have the same active ingredients, strength, route, form, and therapeutic use. This will enable DCBS to assess individual manufacturer price movements in comparison with other generic manufacturers.

2. Prescription Drug Reporting - Price Increase, item (2)(f), should be reconsidered to require additional clarifying information from the manufacturer. In addition to requesting GPI data, DCBS should require a manufacturer to indicate whether the drug is one of the following:
 - a. An innovator multiple source drug;
 - b. A non-innovator multiple source drug; or

- c. A single source drug.

Definitions for these can be found in subparagraph (A) of paragraph (7) of subdivision (k) of Section 1396r-8 of Title 42 of the United States Code. This information will provide DCBS with a fuller understanding of the pricing and positioning for the product being reported.

836-200-0550 Assessments Against Prescription Drug Manufacturers

1. In consideration of any fee that is assessed on manufacturers for this program, it is understood the importance of establishing a fee basis that enables DCBS to carry out the requirements of HB 4005. The approach that is proposed in the draft rule makes consideration for ensuring that any such fee is predictable and consistent year to year, and is not solely tied to the number of manufacturers or filings by manufacturers in any given year. We support this approach.

836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans

1. We request that clarification or consideration be given to the following:
 - a. Items 2(l)(A), (B) and (C): Please clarify the data period for items A-C. Are insurers being asked to use the experience period that was used in the rate filing? We believe that this would make sense.
 - b. Item 2(l)(B), (C) and (D): The request that insurers include the “net impact of any rebate or other price concessions” on the Top 25 most costly drugs, the Top 25 drugs that have caused the greatest increase in total plan spending, and the impact of the costs of prescription drugs on premium rates should be removed as it is not required in the statute and is outside of the legislative authority given to the Department with HB 4005. Rebates are usually applied at rate setting to decrease premiums for all members.
 - c. Item 2(l)(D): Are insurers being asked for the portion of the proposed premium being attributed to prescription drugs? If so, this could be difficult to do accurately as it is dependent on the premium that will be required (e.g., the market average premium we are being requested to price to, or the projected premium we are expecting to receive). It would help to include a specific reference to the premium that is being referred to.

Additionally, because some plans receive rebates on a national level, rather than state-by-state from their PBMs, plans may not be able to report how rebates specifically impact the OR market. As a consequence, the impact of rebates on premiums will not be accurate as it will appear higher than it actually is given the denominator will be lower than it would be absent rebates. For this reason, rebates should be removed from this request.

Thank you for your consideration of these changes and clarifications.

Sincerely,



Robert Judge

Director of Pharmacy Services

Moda Health