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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 17-699 (BRM)(LHG) **PRO SE PLAINTIFF JULIA BOSS'S SUR-REPLY IN SUPPORT OF RESPONSE TO PLAINTIFFS' BRIEF IN OPPOSITION TO MOTION FOR RECONSIDERATION (ECF NO. 138)**

On April 6, 2018, I filed a response to Plaintiffs' brief in Opposition to Motion for Reconsideration (the "Reply"). (ECF No. 138.) Two new developments are specifically relevant to the fourth prong of my reply, i.e. whether "new information would warrant the Court's granting of my Motion for Reconsideration." (Reply at 9.)

INACCURATE STATEMENT OF FACT IN IN RE NOVO NORDISK SECURITIES LITIGATION

On August 16, 2018, Judge Martinotti issued an opinion[2] in the related case *In re Novo Nordisk Securities Litigation*, No. 3:17-cv-209-BRM-LHG (the "Securities Case"). That related case was

[2] ECF No. 99 in *In re Novo Nordisk Securities Litigation.* When no case is mentioned, the ECF number refers to *In re Insulin Pricing Litigation.*

filed by *In re Insulin Pricing Litigation*'s co-lead counsel James Cecchi in January 2017, supposedly on behalf of plaintiff Lehigh County Employees' Retirement System.[3] Certain statements of fact included in this opinion, if accepted as true, would undermine my Motion for Reconsideration—these must thus be addressed.

The Opinion states that "PBMs have **concealed the amounts of rebates they retain**, which in turn prevents insurance companies and other payors from knowing how much of a drug's cost consists of a payment to PBMs" (Opinion (ECF No. 99 in *In Re Novo Nordisk Securities Litigation*) ¶ 3.) between February 3, 2015, and February 2, 2017, inclusive (the "Class Period")." (*Id*. ¶ 2.) This statement is inaccurate. Payers have the capability to know the net prices of the drugs they pay for on behalf of their plan members; they also know how much of the drug's cost consists of payment to a PBM, and they have access to the vast amount of analytical data provided by a large array of commercial and public data aggregators.

For example, IQVIA (previously known as IMS Health) has reported "one of the largest and most comprehensive collections of healthcare information in the world" comprised of over 530 million non-identified patient records across 100+ international markets, with more than 3,000

[3] Lehigh County Employees' Retirement System (the "Fund") had not entered into a retainer agreement for the filing of this securities lawsuit as of January 11, 2017. Pursuant to their 2013 portfolio monitoring contract, Bernstein Litowitz Berger & Grossmann LLP ("BLB&G") would have needed to enter into a formal written retainer agreement with the Fund. BLB&G also knew or should have known that the County Executive could not contract and supervise a supplier, and file a lawsuit, on behalf of the Fund without a formal delegation from the Fund or Retirement Board. On December 24, 2016, Tom Mullen, the County Executive, did not have actual authority from the Retirement Board to retain BLB&G to file the January 11, 2017, lawsuit. According to an attestation from Catharine Roseberry, Senior Counsel in the Department of Law of Lehigh County, the Fund would not authorize the filing of a lawsuit against Novo Nordisk until May 10, 2018. A true and exact copy of the Attestation (Pennsylvania Office of Open Rocords, Docket No. AP 2018-0519) is attached as Exhibit C.

ready-to-use dynamic sources from EMR, hospital, pharmacy and claims data, through to genomics, mobile health and patient reported outcomes.[4] IQVIA's data set contains approximately 30 petabytes of proprietary data sourced from more than 120,000 data suppliers and covering over 900,000 data feeds globally for over 85% of the world's pharmaceuticals, as measured by 2016 sales. They manage one of the largest and most sophisticated information technology infrastructures in health care, processing over 70 billion health care records annually. IQVIA consulting services provide insights in drug pricing optimization "as well as pricing and market access." Outsourced research and development, real-world evidence and connected health and technology is now a $230 billion market.[5]

IQVIA Institute's *Medicine Use and Spending in the U.S.* report (April 19, 2018) relies on IQVIA Real-World Data Adjudicated Claims (PharMetrics Plus) covering 130 million non-identified lives in the U.S. in a single integrated database, updated quarterly since 2007, and on IQVIA Prescription Drug Data covering over 90% of dispensed prescriptions in the U.S.[6] Access to IQVIA's massive databases is available to only 5,000 corporate and institutional clients—payers, manufacturers, researchers and large consulting firms. IQVIA reported $7.8 billion in revenues in 2016[7] and $8 billion in 2017.[8]

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[4] https://www.iqvia.com/solutions/real-world-value-and-outcomes/realworld-data.

[5] Information on IQVIA can be found in its 10-K filing for 2017 at https://s22.q4cdn.com/924259526/files/doc_financials/2017/annual/IQVIA-2017-10K-Filed-(2).pdf.

[6] https://www.iqvia.com/institute/research-support.

[7] https://s22.q4cdn.com/924259526/files/doc_financials/quintiles_ims/2016/annual/QuintilesIMS_2016_Annual-Report_Final-(1).pdf.

[8] https://s22.q4cdn.com/924259526/files/doc_financials/quintiles_ims/2017/q4/IQVIA-Q4-2017-Earnings-Call-Slides-vFinal.pdf.

Payers, media outlets, researchers, sophisticated institutional investors—**and law firms**—also have access to net price information from smaller specialist data aggregators such as SSR Health[9] and financial analyses from large institutional investors and advisory firms such as Credit Suisse. In May 2015, Credit Suisse reported that "The three leading insulin companies, Lilly, Novo and Sanofi, have all shown an increases in rebates, which we assume reflects a continued pay-away of high list price rises for insulins to payers, and the high relative exposure to Medicare part D." (Exhibit D ¶ 23.) "IMS data suggest Novo, Lilly and Sanofi are the most

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[9] "Our US prescription brand net pricing data tool includes more than 10 years of quarterly analyses of gross and estimated net pricing trends in the US brand prescription pharmaceuticals market. Its underlying dataset includes the majority of active US brand prescription drugs – approximately 1,000 brands across more than 100 companies. With its ability to provide complete, standardized analyses of net pricing trends by industry, company, and therapeutic area, the SSR Health platform also enables subscribers to perform analyses customized to their unique requirements. Among the available data series are gross-to-net concessions, Medicaid versus non-Medicaid concessions, product roll-up to industry, therapeutic area and company levels, and product price per year (or course of therapy), all of which allow for in-depth comparisons across products and segments." From: https://www.ssrhealth.com/. See also SSR Health report *June 18, 2018 – Rx brand US net pricing as of 1Q18: Analysis of company level patterns* available to their paid customers at: http://www.ssrhealth.com/research-archive/. SSR Net estimated net prices are used by LJAF-funded ICER to performed its value-pricing assessments. See, e.g.: "Economic analyses in this report rely on pricing information from SSR Health LLC, which uses publicly disclosed data on net dollar sales and volume information to estimate average prices after typical discounts and rebates." https://icer-review.org/announcements/final-ms-report/; https://icer-review.org/announcements/pso-final-report/. SSR Health's rebate and net pricing information is also widely used by industry and media. See, e.g., Bloomberg, e.g, " Lilly offered discounts of 66 percent on Humalog last year, up from 23 percent in 2009, according to SSR Health estimates" at https://www.bloomberg.com/graphics/2016-drug-prices/; "Consider Humalog, an Eli Lilly & Co. insulin drug, which in recent years has more than tripled in price, to $275 per vial, drawing the ire of lawmakers, patients, and consumer activists. But the company doesn't keep even 20 percent of that list price. Most of it flows to middlemen in rebates and other discounts, according to SSR Health LLC, an investment research firm" at https://www.bloomberg.com/news/articles/2018-02-14/what-stands-between-bezos-buffett-and-dimon-and-a-health-care-fix; "To approximate the discounts, SSR Health subtracted the actual U.S. sales reported by the companies. Bloomberg compared the discounted monthly prices with list prices from 14 countries, using local data from IHS Inc., a data analysis and consulting firm, and other sources" at https://www.bloomberg.com/graphics/2015-drug-prices/.

exposed [to rebate pressure in Medicaid and Medicare Part D,] reflecting their diabetes sales." (Exhibit D ¶ 2.) "The very public exclusion of key drugs from important formularies effective from January 2014 and 2015 illustrated the growing power of purchasers to control physician prescribing, using buying power to drive incremental rebates." (Exhibit D ¶ 3.) As of April 2017, Credit Suisse reported that rebates accounted for 55% of Novo Nordisk's list prices, with net prices decreasing on average by 0.1%. (Exhibit E ¶ 11.) Novo Nordisk was however assessed as "neutral" because "diabetes is viewed as an area where investors are already familiar with the risk, which should be included in earnings forecasts… Experience from respiratory shows that PBMs extract value from a large category over multiple years. Credit Suisse forecasts continue to assume significant price pressure in US insulin." (Exhibit F ¶ 3.)[10] The pressure on price is such that AstraZeneca spends about 78% of its gross sales revenue on rebates and advertising, closely followed by Sanofi and Novo Nordisk (about 70%). For these two companies, rebates now amount to about 60% of gross sales revenue, on average. (Exhibit F ¶ 6.) The gross-to-net discount on Humalog and Novolog insulins was reported by Credit Suisse as 70% as of 2016. (Exhibit G ¶ 21.); IMS Health estimated the rebate on Lantus and Levemir to be c60% in 2016. (Exhibit I ¶ 14.) In 2018, the estimated rebate on Eli Lilly's Humalog was

[10] Credit Suisse also noted that although the price pressure in US insulin is well known and "diabetes is viewed as an area where investors are already familiar with the risk, [the pricing risk] should be included in earnings forecasts." (Exhibit F ¶ 3.) Although sophisticated institutional buyers, public and private payers know the estimated net price of analog insulins, the general investing public does not; any reference to a specific list price without disclosure of its effective rebate rate would be misleading. Rebate rate on insulin may be as high as 75%.

assessed at over 80% by Bloomberg (net realized price of less than **$55 per vial**) based on data from SSR Health LLC.[11]

The amount of available data is such that institutional investors can "conduct a drug-by-drug analysis to identify which companies would be most affected and evaluate the related EPS impact from greater pricing pressure going forward." (Exhibit F ¶ 7.) This analysis led Credit Suisse to conclude that "[a]mong Major Pharma names, recent launches and pipeline assets at Novo Nordisk are the most exposed to Medicare Part D [rebate pressure] as they are primarily focused on diabetes." (Exhibit F ¶ 9.) Furthermore, Novo Nordisk has also "the highest exposure to [added rebate risk caused by the transition of] dual eligibles [to Medicaid] given their focus on diabetes." (Exhibit F ¶ 10.) The influence of these federal government programs over drug pricing in the U.S. is now so overwhelming[12] that Credit Suisse concluded in 2016 that pharmaceutical companies have to increase rebates, and thus list prices "to sustain exposure to Medicare/Medicaid, as accessing patients becomes increasingly difficult through mechanisms such as formulary blocks. For a given level of exposure to Medicare/Medicaid of 30%, reported rebates have increased from c40% in '14 to c50% in '15. Novo and Sanofi are the most exposed, reflecting their diabetes sales." (Exhibit G ¶ 2; see also Exhibit I ¶ 11.)

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[11] https://www.bloomberg.com/news/articles/2018-02-14/what-stands-between-bezos-buffett-and-dimon-and-a-health-care-fix.

[12] The U.S. International Trade Commission had already recognized the market-making power of public payers in December 2000. See *Pricing of Prescription Drugs*, Investigation No. 3322-419, 2-7 (December 2000) ("Other U.S. Government programs have legislated drug pricing and reimbursement methodologies. With bargaining power similar to that of a large private buyer, the **U.S. Government can influence drug prices by requiring drug manufacturers to provide rebates** to States for Medicaid and the U.S. Department of Veterans Affairs drug purchases. This market power creates a market segment separate from that of consumers with no such influence.") [Emphasis added]

Credit Suisse estimated that about $179 billion was paid in 2016 to payers, PBMs and supply chain intermediaries,[13] up from $149 billion in 2015, an increase in "total effective discounts" of +336.6% since 2007 ($41 billion).[14] Public and private payers (30% and 50% respectively) captured 80% or $143.2 billion, 90% of which—about $128.9 billion, was passed back to payers. (Id. ¶ 12.)

The rebating system was initially perfected to serve public payers. The federal government negotiates discounted prices from pharmaceutical manufacturers for the large volume of drugs used by the Public Health Service, the Veterans' Administration and military personnel and their dependents. With a few exceptions, the price paid by the federal government under contracts is the lowest price available to any customer. But unlike the federal government, states did not buy drugs directly from manufacturers. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) thus established drug rebates so that these states could also take advantage of volume drug buying power.[15] Additionally, states are beginning to join interstate purchasing groups so they can achieve even greater efficiency in the acquisition of pharmaceuticals. The largest interstate Medicaid consortium is the Sovereign States Drug Consortium (SSDC), founded as a non-profit

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[13] Exhibit F ¶ 12. IMS Health reached a significantly lower estimate — $127 billion —but IMS Health's estimate may not include supply chain discounts. See IMS Health, *Medicines Use and Spending in the U.S.* (May 2017). While Credit Suisse's analysis suggest an accelerating rate of rebating, IMS Health has kept the effective rebating rate virtually unchanged since 2015 c28% or $128.6 billion. IQVIA Institute (formerly IMS Institute), *Medicine Use and Spending in the U.S.* (April 2018). Some industry experts believe rebates surpassed $153 billion in 2017, an estimate that is consistent with Credit Suisse's assessment. See, e.g., https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html

[14] Exhibit I ¶ 9.

[15] Express Scripts, Drug Trend 2002 Report, p. 138.

structure in October 2005. It is comprised of 15 states including Oregon and negotiates with manufacturers about $6.9 billion in annual drug spend.[16] To acquire even better volume pricing for their own state programs, some individual states combine their drug purchasing for several departments, such as employee health plans, health departments, prison systems and Medicaid. An example of this type of interstate bulk purchasing is the Northwest Prescription Drug Consortium managed by Moda Health on behalf of Washington's and Oregon's prescription drug programs (created in 2003). Oregon's Gov. Kate Brown testified to the U.S. Senate in early 2018 that "[s]ince 2007, groups that joined the [Northwest Prescription Drug] Consortium have seen savings on their pharmacy benefit programs, more aggressive prescription drug prices, 100% pass-through pricing on drug costs and manufacturer rebates, lower administrative costs and complete program transparency."[17]

On the employer side, transparent bulk purchasing entities such as Rx Collaborative, also founded in 2005, allow 297 large employers to access pharmacy benefits with 100% rebate pass-through on about $4.7 billion in annual drug spend.[18] Rx Collaborative contracts with Express Scripts and CVS Health on an annual open-book, triple-auditing basis (group-level claim audit, rebate audit and operational assessment). System and claim audits are performed by Caribou

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[16] https://www.rxssdc.org/sites/default/files/uploaded_files/RCY2019%20SSDC%20Fact%20Sheet_20180402_v2%20SL.pdf#overlay-context=node/105

[17] Kate Brown, Governor of Oregon, *Testimony before the Senate Committee on Health, Education, Labor and Pensions* (March 8, 2018), available at: https://www.help.senate.gov/imo/media/doc/Brown11.pdf.

[18] Rx Collaborative, *2016 Annual Report to Employers.* Available at: https://www.willistowerswatson.com/-/media/WTW/PDF/Insights/2017/04/rx-collaborative-2016-annual-report-to-employers.pdf.

Consulting. KPMG performs rebate audits of a statistically significant number of plans from both ESI and CVS to confirm whether the plans received "full pass through of all manufacturers' rebate."[19] Unsurprisingly, CVS Health recently disclosed that they "return over 95% of rebates to commercial clients and their members [and that] for Medicare Part D plans, effectively 100% of the rebates are passed through." (Exhibit J ¶ 2.) As recently acknowledged by Robert Judge, Director of Pharmacy Services of Moda Health,[20] only "2.3% of prescriptions that are dispensed have rebates associated with them so **it's a lot of dollars** going to a very small set of prescriptions." (Exhibit M ¶ 2.) [Emphasis added] CVS also clarified that they offer point-of-sale rebate pass-through as an option for all their insurer clients.[21] (Exhibit. J) As documented in T1DF's December 15, 2017, letter to members of the U.S. Senate H.E.L.P. Committee,[22] PBMs have offered this capability to payers since at least 2011. The recent disclosure from CVS led a respected expert to finally ask the question this Court ought now to litigate: "Are Plan Sponsors Now the Real Barrier…"? (See, generally, Exhibit L).

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[19] Id at 11.

[20] Joint Interim Task Force On Fair Pricing of Prescription Drugs, August 21, 2018. An accurate transcript of selected passages from that Task Force meeting, including an exchange between Mr. Judge and Dr. Neeraj Sood, is provided as Exhibit M. Full video and audio recording is available at: http://oregon.granicus.com/MediaPlayer.php?clip_id=25011.

[21] CVS Health Responds to Request for Information on Trump Administration's Blueprint to Lower Drug Prices (July 16, 2018). Available at: https://cvshealth.com/newsroom/press-releases/cvs-health-responds-request-information-trump-administrations-blueprint. Similarly, FierceHealthcare reported that a financial disclosure from Cigna indicates that Express Scripts retains approximately $400 million per year from rebates and passes on 95% of "purchase discounts, price reductions and rebates" back to payer clients. (Exhibit K, available at: https://www.fiercehealthcare.com/payer/cvs-caremark-express-scripts-pbm-pass-through-cigna-merger.) Expert Adam Fein independently estimated ESI's rebate retention rate as 6% in 2017. ESI projected a retention rate of 2% in 2018.

[22] https://www.t1df.org/news/2017/12/15/t1df-letter-to-us-senate-cost-sharing-crisis.

Manufacturer rebate pass-through to payers was already the norm in 2001.[23] (Exhibit P ¶ 9.) "Rebate" is mentioned on 63 pages of the 156-page report authored by PriceWaterhouseCooper ("PwC")— e.g. "Reduce ingredient cost by obtaining … rebates from pharmaceutical manufacturers. These discounts are obtained under contracts, and shared or passed on to clients. The cost of prescriptions, which average around $60.00, can be reduced as much as 30% to 35% by a PBM's programs.") In November 2001, the Kaiser Family Foundation defined 'rebate' as "an amount that the manufacturer of a drug **pays to an insurer or health plan** for each unit of drug dispensed."[24] [Emphasis added]

Payers have been concerned with the financial accounting of their pharmaceutical rebate receivables for two decades. GAAP provides a framework for offsetting claims expense with manufacturer rebates and related accounting of rebate receivables, but NAIC rejected the FASB's standards c2000. (To date, cost accounting of manufacturer rebate offset has remained unaddressed by NAIC and insurance commissioners). To fill the void left by the rejection of FASB's accounting standards, NAIC's Accounting Practices and Procedures Task Force started to work on an issue paper in March 2000 to address the statutory accounting treatment of

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[23] See, e.g., the report prepared by PricewaterhouseCoopers LLP (PwC) on the pharmacy benefit management (PBM) industry for the Health Care Financing Administration (HCFA): *Study of Pharmaceutical Benefit Management,* HCFA Contract No. 500-97-0399/0097 (June 2001) provided at Exhibit P.

[24] Kaiser Family Foundation, *Prescription Drug Trends: a chartbook update* (November 2001). See also *Prescription Drug Expenditures in 2000: The Upward Trend Continues,* a report by The National Institute for Health Care Management Research and Educational Foundation, 5 (May 2001) ("manufacturer rebates paid to some insurers," citing an interview with Katharine Levit, director of the National Health Statistics Group, Office of the Actuary, Health Care Financing Administration. (April 2001) The HCFA team estimates that bulk purchasers of prescription drugs saved an average of 10% in 1999 because of rebates.)

pharmaceutical rebate receivables. NAIC issued the final version of Statutory Issue Paper No. 107 in August 2001.[25] The Task Force left no ambiguity as to the insurer's responsibility for reporting accurate rebate information:

> "In some cases, the reporting entity determines the amount of the rebate due based on the actual use of various prescription drugs during the accumulation period and then invoices the pharmaceutical company. In other cases, an affiliated or unaffiliated pharmacy benefits management company may determine the amount of the rebate based on a listing (of prescription drugs filled) prepared for the reporting entity's review. **The reporting entity will confirm the listing and the pharmaceutical rebate receivables**. The pharmacy benefits management company will then collect the amount due from the pharmaceutical company for remittance to the reporting entity." (Exhibit N, ¶ 1.)

States also started in the early 2000s to issue temporary guidance to handle increasingly material pharmaceutical rebate receivables.[26]

Concurrently with the formalization of the regulatory accounting principles that now govern financial reporting of manufacturer rebates (and the negotiation of the final draft of what would

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[25] The initial version apparently endorsed insurers' common practice of treating manufacturer rebates as general revenue instead of categorizing them as asset offset to related expenses as otherwise required under GAAP standards. See *Interim Report of the HORBC Asset Codification Work Group To the NAIC Health Organizations Risk-Based Capital (E) Working Group* (December 2000).

[26] See, e.g., Nevada Division of Insurance, *Bulletin 01-007* (May 25, 2001); First Amendment to Part 83 of Title 11 of the Official Compilation of Codes, Rules and Regulations of the State of New York (Regulation No. 172), entitled *Financial Statement Filings and Accounting Practices and Procedures* (March 6, 2003).

become Medicare Part D[27]), the PBM industry came under "intense scrutiny from many Sources" "due to the combination of rapid growth in drug spending, a number of high profile legal investigations into PBM conduct, and their complex and often poorly understood business models." (Exhibit O, ¶ 1.) This is also the timeframe when economists started to pay attention to the PBM business model and its key component—the rebate-retention rate (the percentage of manufacturer rebates that is retained by the PBM rather than passed back or passed through to payer clients).[28] As of 2003, economist Lawrence Abrams documented that the rebate-retention rate for Express Scripts, the second largest independent PBM at the time, increased from 31.5% for fiscal years 2000 to 38% for FY 2002, thus threatening the very foundation of the soon to be enacted Medicare Part D legislation.

The response from regulators was swift. Between 2002 and 2008, more than 30 bills were introduced in 25 different states. (Exhibit O, ¶ 9.) The large number of investigations led Senator Mark Montigny, Chair of the Board of the National Legislative Association on Prescription Drug Prices, to state in a Letter to The Honorable Deborah Platt Majoras, Chair, Federal Trade Commission, dated May 11, 2005, that "[they knew] of no other market in which there has been such a significant number of prominent enforcement actions and investigations." (Exhibit O, ¶

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[27] Medicare Part D's "negotiated price" requires rebate pass-through to payers. See https://www.t1df.org/news/2018/01/16/t1df-comment-to-cms-negotiated-price.

[28] The term was coined by Larry Abrams in his seminal article, *Estimating the Rebate-Retention Rate Of Pharmacy Benefit Managers* (April 22, 2003). Available at: https://papers.ssrn.com/sol3/Delivery.cfm?abstractid=2850704.

6.) On April 26, 2004, the United States and 20 state attorneys general, including Oregon's,[29] agreed to a settlement of claims and alleged violations of unfair trade practice laws with Medco. The settlement, finalized in 2006 (the year Medicare Part D became effective), provided injunctive relief. In particular, Medco committed to disclose the amount of rebate it negotiated and its rebate retention rate. The settlement followed the framework of Medicare Part D and other regulatory proposals, but State regulators did not follow through at the State and Federal level. CMS final rule for Medicare Part D, issued in 2005, did not direct that payers pass all rebates through to Part D beneficiaries at the pharmacy point of sale.[30] By 2011, Medco's rebate retention rate had dropped to 12.2%. But contrary to the prediction of then U.S. Attorney Patrick Meehan, individual consumers' healthcare costs across the nation have not been positively impacted by the settlement.[31] This is the timeframe when Hagens Berman filed, on behalf of health plans and the American Federation of State County & Municipal Employees, among others, a lawsuit alleging that the largest PBMs had **failed to pass on rebates from drug manufacturers to payers** and that the PBMs developed a pricing system to inappropriately inflate prices set by the drug manufacturers, **pocketing secret payments from drug**

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[29] Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

[30] OPDP's mandate to give access to uninsured Oregonians to the low net price paid by insurers was similarly extinguished by Moda Health, with the implicit authorization of the Oregon Health Authority. See, https://www.bizjournals.com/portland/news/2018/06/13/type-1-diabetes-advocates-lambaste-oregon.html.

[31] Melissa Davis, *Medco Ponies Up to States*, TheStreet.com (April 27, 2004). Available at: http://www.thestreet.com/stocks/melissadavid/10156476.html.

manufacturers.[32] The case was withdrawn without prejudice in 2008 but only after Hagens Berman allowed defendant PBMs to seal the entire case record.

Since 2010, the Affordable Care Act has also required health insurance issuers to submit—subject to the penalties of the False Claim Act—pharmaceutical rebate data to calculate the Medical Loss Ratio (MLR) based on adjusted premium revenues, net of manufacturer rebates. Rebate information is therefore available by state and by insurer since 2011.[33] CMS asked NAIC to add an exhibit to its Annual Statement Blank, the reporting form used by most private insurers to report financial data. NAIC thus included Exhibit 3A – Analysis of Health Care Receivables Collected and Accrued.[34] This information is aggregated by NAIC and published as Supplemental Health Care Exhibit Reports (based off the new Supplemental Health Care Exhibit created as a tool to comply with the ACA MLR requirement).[35]

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[32] *American Federation of State County and Municipal Employees v. AdvancePCS, et al*.- Filed on March 18, 2003, in the Superior Court of California (Los Angeles)(Case No. BC 292227). 10 years later, Tom Sobol basically filed similar allegations, against different defendants, despite abundant evidence that industry circumstances had significantly changed.

[33] https://www.cms.gov/apps/mlr/mlr-search.aspx#/?state=OR&reporting_year=2011.

[34] Exhibit 3A relies on the definition of rebate receivable in SSAP No. 84, Certain Health Care Receivables and Receivables Under Government Insured Plans, for accounting guidance.

[35] Reports for the past 6 years are available at: https://www.naic.org/prod_serv_alpha_listing.htm#health_care_cost_guide. A review of the data aggregated by NAIC for 2010 would suggest under reporting by payers. Based on Medco's disclose retention rate and industry rebating average based on IMS Health data (known to underestimate manufacturer rebates), NAIC' Supplemental Health Care Exhibit Reports (2011) should have included about $74.5 million for the State of Oregon; Oregon private insurers reported only $29 million or 5.8% of the total drug spend. In 2010, the industry average was 14.8% based on IMS Health data. See Exhibit Q.

In the early 2000s, payers put in place the accounting standards, reporting requirements and auditing frameworks to capture most of the manufacturer rebate amounts. In addition to their increasing market power and close relationship with state regulators, the ACA gave payers a statutory tool to extract 100% rebate pass-through from PBMs, forcing PBMs to reinvent their business model. Since 2011, the mere allegation by counsel that "PBMs have concealed the amount of rebates they retain, which in turn prevents insurance companies and other payors from knowing how much of a drug's cost consists of a payment to PBMs" would amount to a "false statement of material fact" under New Jersey RPC 3.3(a)(1).

DEFECTIVE THEORY OF RECOVERY IN IN RE INSULIN PRICING LITIGATION

Second, defendants in the manufacturer-track litigation, *In re Insulin Pricing Litigation*, No. 3:17-cv-00699-BRM-LHG, filed on August 20, 2018, a Reply in Further Support of Motion to Dismiss the First Amended Complaint ("Response"). (ECF No. 190.) This filing also includes representations at pages 23-26 that pertain to the Motion for Reconsideration. These new representations must also be addressed.

Insulin manufacturers do not 'publish' AWP benchmarks. AWP benchmarks are proprietary pricing constructs published by third-party entities. As a result of *Lupron* and *AWP*, defendants have ceased to provide pricing data to the remaining publishers of the AWP benchmarks. First Data Bank discontinued the publication of Blue Book Average Wholesale Price (AWP) on September 28, 2011, as Medicaid and other government programs are transitioning to actual pass-through pricing methodologies.[36] TruvenHealth (a subsidiary of IBM Watson Health), still

[36] https://www.fdbhealth.com/fdb-medknowledge-drug-pricing/.

publishes its RED BOOK AWP, but none of the defendants provides AWP or a markup formula to calculate AWP for their insulin products.[37] Medi-Span, now Wolters Kluwer Clinical Drug Information's (WKCDI), warns that its AWP index "is not [in fact] an 'average' of actual wholesale prices. It is not derived from, does not reflect, and should not be assumed to represent, either (i) the actual prices paid for drug products in transactions between wholesalers (meant to include any party that buys drug products directly from a manufacturer) and their customers, or (ii) any discounts, rebates or other price reductions that wholesalers may offer to their customers in connection with those transactions."[38] WKCDI states that it publishes AWP information for a particular drug only if the drug's manufacturer directly reports to WKCDI (i) a Suggested Wholesale Price (SWP); (ii) a Wholesale Acquisition Cost (WAC) or Direct Price (DP); or (iii) in cases of over-the-counter products (OTC), a Manufacturer's Suggested Retail Price (MSRP)—but contrary to IBM Truven, WKCDI does not disclose a list of manufacturers that do not provide any pricing information to them.[39] It is thus doubtful that any currently published AWP index reflects pricing data actually provided by insulin manufacturers.

Second, coinsurance payments may or may not be based on AWP. Consumers do not know whether their insurer bases the amount of their coinsurance liabilities on actual ingredient costs plus negotiated dispensing fee (gross cost to plan, also called claims expense), net cost to plan, or some other proprietary or published pricing benchmark(s). A payer's Explanation of Benefits

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[37] http://truvenhealth.com/products/micromedex/product-suites/clinical-knowledge/awp-export.

[38] WKCDI's "Important Information About AWP Data" available at: http://www.wolterskluwercdi.com/sites/default/files/documents/WKH_AWP_Policy.pdf.

[39] http://www.wolterskluwercdi.com/sites/default/files/documents/WKH_AWP_Policy.pdf.

(EOB) generally labels the coinsurance amount as calculated in relation to a figure identified as "plan cost" or "cost to plan," without reference to the methodology or accounting standard used by the insurer to calculate that amount. Since PBM contracts are rarely disclosed, only discovery of PBMs acting as agents of payers or as fully-owned subsidiaries of the 10 largest payers would make it possible to ascertain the basis of the coinsurance amounts and "plan cost" figures presented by payers to their members.

Third, as documented above, I dispute "that the AWPs for defendants' analog insulin reasonably approximate actual average wholesale prices paid by pharmacies." (ECF No. 190, ¶ 24.) The only pricing data that "reasonably approximate actual average wholesale prices paid by pharmacies" are CMS's NADAC or Oregon's AAAC. In June 2010, State Medicaid Pharmacy Administrators, along with the National Association of State Medicaid Directors (NASMD), submitted to CMS the "Post AWP Pharmacy Pricing and Reimbursement" white paper in response to the change in availability of AWP caused by *Lupron* and *AWP*. They recommended, as a substitute for AWP, the National Average Drug Acquisition Cost (NADAC) produced by CMS under the authority of Section 1927(f) of the Social Security Act. The NADAC represents a national average invoice price derived from retail community pharmacies for drug products based on actual invoices from wholesalers and manufacturers.[40] Similarly, the Oregon Health Authority compensates (Medicaid) Oregon Health Plan's fee-for-service pharmacies according to

[40] See, e.g., https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-overview-operations.pdf.

an Average Actual Acquisition Cost (AAAC) reimbursement model. This pricing benchmark reflects the true acquisition cost for drugs and the cost of dispensing.[41]

Finally, the theory of recovery of the manufacturer-only litigation track, as currently articulated, is irreconcilable and mutually exclusive with the theory of recovery underpinning the PBM/payer litigation track my Motion for Reconsideration seeks to establish. I disagree with the representation of the manufacturer-only plaintiffs' theory as merely 'incoherent.' (ECF No. 190, ¶ 25.) It would, under any reasonable scenario, further injure the class rather than remediate its injury.

The first interpretation included in Defendants' response basically amounts to requesting that the Court impose the very price-fixing scheme plaintiffs accused defendants of in their initial complaint filed on February 2, 2017. Considering that current rebate levels to payers are c70% or greater, a mere 20% rebate would deliver unconscionable profits to insulin manufacturers without providing any guarantee that WAC would be re-set at current net price level or that net prices would be disclosed, thus magnifying rather than remediating the very injury plaintiffs purport to address. I would note here that the scheme proposed by Plaintiffs' co-lead counsel would result in a price per 10 ml vial of analog insulin consistent with ICER value-based price benchmark for insulin Degludec—$265 to $271.[42] (Exhibit S, ¶ 60.) Adding insult to injury, this

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[41] See, e.g., https://www.oregon.gov/oha/HSD/OHP/documents/aaac-qa.pdf; https://www.oregon.gov/oha/HSD/OHP/Pages/AAAC-Rates.aspx.

[42] The Institute for Clinical and Economic Review (ICER) is founded by the Laura and John Arnold Foundation (LJAF). LJAF also fund PORTAL, the organization of Aaron Kesselheim, a former board member of the Prescription Access Litigation (of which Tom Sobol was legal counsel) who has been retained by Hagens Berman as expert witness on several occasions. Dr. Kesselheim was also the academic advisor of Hannah Brennan.

approach would facilitate a transition to value-based pricing for new drugs pegged at current list price level, and a related transition to outcome-based rebating—i.e. an exponentially more opaque and complex pricing system that would further the injury to the class.

A second possible interpretation of the suggested theory of recovery would be to require insulin manufacturers to put in place a 20% copay assistance program on the model of Medicare Part D's Coverage Gap Discount Program. This approach would be equally catastrophic for the plaintiff class as actors would merely adjust prices as they did in the response to the AWP settlement. Given existing deep rebates to payers of over 70%, manufacturers would essentially be required to sell insulin at a loss if they were to keep list prices at current level and add a additional direct-to-consumer point of sale rebate of 20%. In the absence of any form of cap on list price, either direct or indirectly through net price disclosure, manufacturers would thus be incentivized to further inflate list prices, thus further injuring uninsured patients exposed to cash prices and insured patients via inflated coinsurance amounts and related claims expense upon which premium rate actuarial valuation is predicated in most states.

This is exactly what happened with the AWP benchmark after settlement. Most PBMs had price protection clauses that automatically adjusted upward their negotiated prices to account for the small correction in AWP negotiated by Hagens Berman. Furthermore, Hagens Berman's failure at that time to concurrently seek net price disclosure to protect consumers from the inherent abusive characteristic of any benefit design based on list prices (or AWP)—coupled with the rebate pass-through lawsuit Hagens Berman filed in 2003 and withdrew in 2008—have directly

contributed to the current insulin pricing crisis for consumers, while benefiting Hagens Berman's payer clients.

Patients with insulin-dependent diabetes must be protected from manufacturer defendants' inflated list prices, from PBMs/payers' failure to set coinsurance payments appropriately based on net prices, and from misguided remedies that could increase rather than remediate the class' injuries.

Respectfully submitted,

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