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SB 90: Injecting the Wrong Solution into the Insulin Market

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∗ J.D. Candidate, University of the Pacific, McGeorge School of Law, to be conferred May 2024; B.S. Business Administration, Supply Chain Management, 2020. Thank you to my family and friends for their continuous love and support. A special thanks to Carla Anglada for (somehow) convincing me that working full-time at a health plan during law school was a good idea. Finally, I dedicate this article to my mom, whose work ethic and kindness has taught me nurses are the true backbone of the health care system.

I. INTRODUCTION

Twenty-seven days—that is how long Alec Raeshawn Smith, a type 1 diabetic, survived after aging out of his parent's healthcare insurance plan.[1] Alec was a passionate outdoorsman, a Caribbean travel fanatic, and a devoted father.[2] He paid directly for insulin because he could not afford the high health insurance costs and earned too much to qualify for state subsidies.[3] When his latest prescription refill was $300 more than expected, he attempted to stretch his last supply of insulin until his next paycheck.[4] Unfortunately, this gamble cost him his life.[5]

Alec's story is just one of many.[6] Over 3 million people in California are diabetic.[7] Diabetes is regulated with insulin, a hormone that helps control blood sugar.[8] If not treated, the disease can result in strokes and heart and kidney failure.[9] One in four Americans with diabetes cannot afford the medication.[10]

SB 90 is one of California's various steps to ensuring insulin affordability.[11] The bill prohibits health insurers from imposing a deductible or copayment for insulin that exceeds thirty-five dollars for a thirty-day supply, alleviating the financial burden for some Californians.[12] Coupled with the other recently enacted legislative action, such as the Inflation Reduction Act (IRA) and California's CalRX Biosimilar Insulin Initiative (CalRX Initiative), SB 90 moves the insulin market in the right direction.[13] However, SB 90 ignores the root cause of insulin affordability, thus interrupting the natural competitive market and resulting in higher healthcare costs.[14] Although SB 90 takes a notable step in

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[1] *See* Elizabeth Snouffer, *Alec's Story: When the High Cost of Insulin Destroys Lives*, DIABETES VOICE (July 26, 2018), tinyurl.com/5n7ktway (on file with the *University of the Pacific Law Review*) (reading a statement from Nicole Smith-Holt, Alec's mother, during the 2018 Affordable Medicines Now conference).

[2] *Id*.

[3] *Id*.

[4] *Id*.

[5] *Id*.

[6] Michelle Llamas, *Study: Cost Forces 1.3 Million Americans with Diabetes to Ration Insulin*, DRUGWATCH (Oct. 19, 2022), https://tinyurl.com/2fa5hwsd (on file with the *University of the Pacific Law Review*) (finding that "16.5 percent of all adults with diabetes who take insulin ration").

[7] RUBIE GONZALEZ-PARRA, OFF. OF SEN. SCOTT WIENER, SENATE BILL 90 – INSULIN AFFORDABILITY ACT: FACT SHEET 1 (2023).

[8] Ryan Knox, *Insulin Insulated*, 7 J. L. & BIOSCIENCES 1, 4 (2020).

[9] Ana B. Ibarra, *California Lawmakers Try Again to Cap Insulin Costs*, CALMATTERS (Feb. 3, 2023), https://tinyurl.com/yc5ezb9f (on file with the *University of the Pacific Law Review*) ("Rationing insulin leads to poor control of diabetes and is linked in increased instances of strokes, heart failure, and kidney failure.").

[10] *Id*. (explaining that the United States 'average price for insulin is "$98.70 per vial, compared to $12 a vial in Canada"); *Biosimilar Insulin Initiative*, CALRX, https://calrx.ca.gov/biosimilar-insulin-initiative/ (last visited Apr. 7, 2024).

[11] *See* Ibarra, *supra* note 9 (explaining California has allocated $100 million in the 2022–23 budget to manufacture and distribute its own insulin).

[12] SB 90, 2023 Leg., 2023–2024 Sess. (Cal. 2023) (as amended on Mar. 21, 2023, but not enacted).

[13] CAL. HEALTH BENEFITS REV. PROGRAM, ANALYSIS OF CALIFORNIA SENATE BILL 90 HEALTH CARE COVERAGE: INSULIN AFFORDABILITY ii (2023).

[14] *See* Associated Press, *EXPLAINER: Why Is Insulin So Expensive and Difficult to Cap?*, U.S. NEWS (Aug. 5, 2022), https://tinyurl.com/5exw9tp9 (on file with the *University of the Pacific Law Review*) (asserting insurance plans will raise premiums to make up for the out-of-pocket cost cap).

decreasing insulin prices, the bill should be amended to regulate Pharmacy Benefit Managers (PBMs).[15]

II. LEGAL BACKGROUND

Skyrocketing insulin prices have caused concern for decades.[16] However, insulin cost issues are now at the forefront of healthcare discourse because of substantial annual price increases in recent years.[17] Section A details the history of insulin prices.[18] Section B reviews the players in the insulin industry.[19] Section C highlights recent state and federal legislative attempts to reduce insulin prices.[20] Section D reveals unprecedented market changes made by the State and drug manufacturers.[21]

A. Increasing Insulin Prices

Insulin was patented in 1923.[22] Subsequently, human insulin was introduced in 1982 for fourteen dollars per vial.[23] Prices increased to sixty dollars per vial by 2005.[24] By 2012, insulin cost $138 per vial.[25] From 2012 to 2016, the list price continued to increase by 20.7% annually, making diabetes the "most expensive chronic disease" in the United States.[26]

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[15] S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC 22, 25 (summarizing the reasons for high cost of insulin including barriers to entry and middlemen that benefit from a high list price).

[16] Tara O'Neill Hayes & Josee Farmer, *Insulin Cost and Pricing Trends*, AM. ACTION F. (Apr. 2, 2020) https://tinyurl.com/52dw9rtp (on file with the *University of the Pacific Law Review*) (listing the annual percent increases for insulin since 1991).

[17] *See* DEP'T OF MANAGED HEALTH CARE, PRESCRIPTION DRUG TRANSPARENCY REPORT (2021) (showcasing that three insulin drugs made the list of the top ten costliest pharmaceuticals in a 2021 report).

[18] Hayes & Farmer, *supra* note 16.

[19] *See* AHealthcareZ – Healthcare Finance Explained, *Pharmacy Benefit Managers (PBMs) Explained*, YOUTUBE (Sept. 3, 2022), https://www.youtube.com/watch?v=vT0NNXYjQ_Y (simplifying how insulin gets from the drug manufacturer to the patient).

[20] *See* Ibarra, *supra* note 9 (describing SB 473); *see also* Juliette Cubandki et. al, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023) https://tinyurl.com/y8cjeu24 (on file with the *University of the Pacific Law Review*) (discussing the contents of Inflation Reduction Act and its impact on insulin prices).

[21] *See* Ibarra, *supra* note 9 (describing the CalRX Biosimilar Insulin Initiative); *see also* Berkeley Lovelace, Jr., *For Many Insulin Users, New Price Cuts Will Be a 'Lifeline'*, NBC NEWS (Mar. 21, 2023) https://tinyurl.com/4fk9rksb (on file with the *University of the Pacific Law Review*) (describing the cost reduction from the big three insulin manufacturers).

[22] Irl B. Hirsch, *Insulin in America: A Right or a Privilege?* DIABETES J. (2016) (explaining that patents were sold to the University of Toronto for one dollar with the idea that cheap insulin would be available to all); Julia Belluz, *The Absurdly High Cost of Insulin, Explained*, VOX (Nov. 7, 2019), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive (on file with the *University of the Pacific Law Review*).

[23] Hirsch, *supra* note 22, at 130.

[24] *Id*.

[25] *Id*.

[26] Hayes & Farmer, *supra* note 16.

In 2021, the Food and Drug Administration (FDA) approved the first interchangeable insulin product, making waves across the diabetic community.[27] Because insulin is a biologic, the drug has been notoriously difficult to turn into a cheaper generic, or in insulin's case, a "biosimilar."[28] Since the market entry of the first biosimilar insulin, the average out-of-pocket cost for insulin prescriptions has decreased by fourteen percent for commercially insured Americans.[29] A likely explanation for this drop points to the introduction of a new product into the heavily concentrated market dominated by the big three drug manufacturers.[30] However, despite a miniscule drop in prices, the United States continues to have the highest price tags for insulin.[31] Yet, the drug manufacturers are not the biggest beneficiaries.[32] Rather, the middlemen, the PBMs, are earning the most from the disturbingly high costs.[33]

B. The Center of the Insulin Supply Chain: PBMs

Insulin prices are best understood by following the pharmaceutical supply chain, which is composed of two sides with one middleman: the PBM.[34] One side begins with the patient, who pays the health plan for insurance that may cover part or all of the drug cost.[35] The health plan determines what drugs are covered through formularies, which are maintained by PBMs.[36] On the other side, the drug manufacturer supplies the drugs to the wholesaler.[37] The wholesaler then sells the drugs to the pharmacy.[38]

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[27] *See FDA Approves First Interchangeable Biosimilar Insulin Product For Treatment Of Diabetes*, FOOD AND DRUG ADMIN. (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes (on file with the *University of the Pacific Law Review*).

[28] FOOD AND DRUG ADMIN., BIOSIMILARS: WHAT PATIENTS NEED TO KNOW 1–2 (2021) (explaining that there are two types of drugs: a chemical entity and a living organism, known as a biologic); *id*. (explaining that for a biologic to be replicated and approved as a biosimilar, "studies must show that there are no differences in the safety and effectiveness of biosimilars and original biologics," which is much more difficult than proving the same chemical composition as required with "generics.").

[29] John Ernst, *Price Controls Are Not The Solution For High Drug Costs*, SENATE RPC (Apr. 7, 2022), https://www.rpc.senate.gov/policy-papers/price-controls-are-not-the-solution-for-high-drug-costs (on file with the *University of the Pacific Law Review*).

[30] Ernst, *supra* note 29 ("Experts attribute the decline in prices to increased competition, as new insulin products have come to market.").

[31] Ibarra, *supra* note 9 ("Compared to other countries, the U.S. is known to have the highest price tags for insulin.").

[32] Karen Van Nuys et. al, *Who Is Really Driving Up Insulin Costs?*, USC SHAEFFER (Apr. 18, 2022), https://healthpolicy.usc.edu/article/who-is-really-driving-up-insulin-costs/ (on file with the *University of the Pacific Law Review*) (noting that specifically, by 2018, for every $100 spent on insulin, the manufacturer earnings had decreased to twenty-seven dollars, and the PBMs' share increased to fifty-three dollars).

[33] Van Nuys et. al, *supra* note 32 (explaining that PBMs must be regulated to fix the insulin market).

[34] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (explaining the players and their roles in the pharmaceutical supply chain).

[35] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (explaining that a patient may purchase insurance directly or through a plan sponsor such as an employer).

[36] Hayes & Farmer, *supra* note 16 (describing a drug formulary is a "list of prescriptions that are covered by a given insurance plan.").

[37] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (illustrating that a wholesalers' main function is to distribute drugs to the pharmacies).

[38] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19.

A PBM is paid by two parties.[39] First, a health plan pays a PBM an administrative fee for maintaining its drug formularies.[40] Second, the manufacturer pays a rebate to the PBM in exchange for preferred drug placement in a health plan's formulary.[41] The second exchange is causing insulin prices to skyrocket.[42] To continue making a profit while maintaining the rebate, the manufacturer drives up the list price.[43] Because patients' out-of-pocket costs are based on the list price, patients will continue to pay more as PBMs increase their profit.[44]

PBMs have protested current California regulation.[45] In 2018, California passed AB 315, which provided greater regulatory oversight of PBMs.[46] Specifically, AB 315 mandates PBMs act as fiduciaries to the health plans they sponsor.[47] Importantly, the United States Supreme Court has ruled PBMs do not owe a fiduciary duty under the Employee Retirement Income Security Act (ERISA).[48] ERISA is the federal law that "sets minimum standards for…health plans in private industry."[49] However, in *Rutledge v. PCMA*, the United States Supreme Court specified that state law regulating PBMs was not subject to federal preemption.[50] As long as the law "merely regulate[s] the cost of the items and services covered or the manner in which benefits must be provided," states may freely regulate PBMs.[51] This ruling allows California's AB 315, as well as any future regulation, to stand.[52]

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[39] *See Pharmacy Benefit Managers*, NAT'T ASSOC. OF INS. COMM'R (June 1, 2023) https://tinyurl.com/26juw9r2 (on file with the *University of Pacific Law Review*) (explaining that a PBM is a third-party intermediary between health plans and pharmaceutical manufacturers).

[40] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (demonstrating that a drug formulary is negotiated by a PBM).

[41] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (explaining that a rebate is a certain percentage of the drug's list price, usually around sixty, given to PBMs in order to ensure placement on the health plan's formulary).

[42] Hayes & Farmer, *supra* note 16 ("Competition among drug manufacturers … has driven ever-larger rebates, which naturally leads to high list prices.").

[43] Hayes & Farmer, *supra* note 16.

[44] Hayes & Farmer, *supra* note 16 (citing that, in 2015 to 2019, Eli Lilly reported the list price for insulin increased by twenty-seven percent while its net price decreased by fourteen percent).

[45] *See AB 315: A Conflict of Interest Threatening to Increase Drug Prices*, PCMA, https://www.pcmanet.org/wp-content/uploads/2017/12/PCMA-Fact-Sheet-CA-AB-315-Wood-2017-042517.pdf (last visited July 15, 2023) (on file with the *University of the Pacific Law Review*) (explaining the issues with AB 315 from the PBMs' perspective).

[46] Thomas Sullivan, *California Regulates Pharmacy Benefit Managers*, POL'Y & MED. (Jan. 7, 2019), https://www.policymed.com/2019/01/california-regulates-pharmacy-benefit managers.html (on file with the *University of the Pacific Law Review*).

[47] Tyrone Squires, *California Advances PBM "Transparency" Law*, TRANSPARENTRX (May 2, 2017), https://transparentrx.com/california-advances-pbm-transparency-law (on file with the *University of the Pacific Law Review*); *see Pharmacy Benefit Managers: Can They Return to Their Client-Centered Origins?*, ALTERUM (Jan. 2018), https://www.healthcarevaluehub.org/advocate-resources/publications/pharmacy-benefit-managers-can-they-return-their-client-centered-origins (on file with the *University of the Pacific Law Review*) (explaining that a "fiduciary duty is the legal obligation of one party to act in the best interest of another, for example, the best interest of the customer").

[48] *See Pharmacy Benefit Managers: Can They Return to Their Client-Centered Origins?*, *supra* note 47.

[49] *Id*.

[50] Michael A. Dowell, *State PBM Regulations Protecting Community Pharmacies*, U.S. PHARMACIST (Aug. 16, 2022), https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies (on file with the *University of the Pacific Law Review*).

[51] *Id*.

[52] *Id*.

C. Legislative Attempts at Reducing Insulin Prices

Both state and federal legislatures have been targeting insulin prices in the last few years.[53] First, California State Senator Patricia Bates sponsored SB 473 in 2022, which would have capped cost-sharing at fifty dollars for a thirty-day supply.[54] Unfortunately, the bill died in the California State Assembly due to the insurance industry lobbying against it.[55] The California Association of Health Plans claimed that cost-sharing caps create a one-size-fits-all approach to medical plans that reduced consumer choice.[56] Further, the California Chamber of Commerce opposed the caps, stating cost-sharing requirements drive up premiums for all enrollees.[57]

While California was unsuccessful, the United States Congress passed cost-sharing caps for Medicare patients through the IRA in 2022.[58] Similar to SB 90, the IRA limits monthly cost sharing for insulin to no more than "thirty-five dollars for Medicare beneficiaries."[59] However, because the IRA was pursued through budget reconciliation, the Senate Parliamentarian voted not to cover non-Medicare patients.[60] Thus, SB 90 will make up the difference by applying the same thirty-five dollar cap to California consumers that are not Medicare enrollees.[61]

D. Recent Market Changes

Adding more affordable options to the insulin market has been challenging because of the complicated regulatory requirements.[62] However, California and drug manufacturers are shifting the current dynamic.[63] First, in 2023, California allocated $100 million for the CalRX Initiative, which aims to make insulin available to all Californians regardless of insurance status.[64] While innovative, this

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[53] *See* Ibarra, *supra* note 9 (describing SB 473); Cubandki et. al, *supra* note 20 (discussing IRA impacts, including updates to insulin price caps and coverage of Part D and B).

[54] *See* Ibarra, *supra* note 9 (acknowledging SB 473's attempt to cap insulin costs in 2022).

[55] *See* Ibarra, *supra* note 9 (acknowledging SB 473's attempt to cap insulin costs in 2022 and the death of the bill resulting in insurance industry lobbying disagreeing that the bill does not address root causes).

[56] *Hearing on AB 97 Before the S. Health Comm.*, 2021 Leg., 2020–2021 Sess. (Cal. 2021) (on file with the *University of the Pacific Law Review*) (explaining the oppositions' side to cost-sharing caps for insulin on a similar bill in 2021).

[57] *Hearing on AB 97 Before the S. Health Comm.*, 2021 Leg., 2020–2021 Sess. (Cal. 2021) (on file with the *University of the Pacific Law Review*).

[58] Cubandki et. al, *supra* note 20 (discussing IRA impacts, including updates to insulin price caps and coverage of Part D and B).

[59] Cubandki et. al, *supra* note 20.

[60] Lorie Konish, *The Inflation Reduction Act Caps Costs for Medicare Patients on Insulin*, CNBC (Aug. 16, 2022), https://www.cnbc.com/2022/08/16/inflation-reduction-act-to-cap-costs-for-medicare-patients-on-insulin.html (on file with the *University of the Pacific Law Review*) (explaining that the vote to keep non-Medicare patients in the bill fell short three votes).

[61] GONZALEZ-PARRA, *supra* note 7.

[62] *See* Associated Press, *supra* note 14 (illustrating the regulatory requirements to enter the insulin market).

[63] *See* Ibarra, *supra* note 9 (referencing the CalRX Biosimilar Insulin Initiative); *see also* Grace Fernandez, *Why Eli Lilly's Insulin Price Cap Announcement Matters*, JOHNS HOPKINS (Mar. 13, 2023) https://tinyurl.com/4t28uub4 (on file with the *University of the Pacific Law Review*) (announcing Eli Lilly's insulin price cut).

[64] Ibarra, *supra* note 9 (asserting insulin products will cost no more than thirty dollars for ten milliliters, no matter their insurance).

initiative will need ongoing funding to sustain it and will likely not have the product on the market until 2025.[65]

Additionally, drug manufacturers made an unprecedented move in March 2023.[66] Eli Lilly announced it would lower its list price of insulin by seventy percent and cap copays at thirty-five dollars.[67] Novo Nordisk and Sanofi, the other two insulin manufacturers, shortly followed suit.[68] While many praise the long-awaited price reduction, others are concerned about potential long-term impacts.[69] Further, at a May 2022 United States Senate committee hearing, manufacturers and PBMs continued to blame each other for high costs, despite the recent drop in insulin prices.[70] Specifically, PBMs claimed drug manufacturers maintained monopolies that "seek the highest price point possible" and emphasized the need for competition and rebates to keep prices down.[71] Contrastingly, manufacturers pointed the blame towards PBMs.[72] Particularly, Sanofi stated the company attempted to reduce the price of insulin even before legislation.[73]

III. SB 90

Senator Scott Wiener introduced SB 90 to create stability for individuals struggling with costs of insulin.[74] The bill amends both the Health and Safety Code and the Insurance Code.[75] The Health and Safety Code governs health care service plan contracts, while the Insurance Code governs disability insurance policies.[76] Seeing how burdensome high insulin prices are for diabetic patients, Senator Wiener seeks to limit out-of-pocket costs.[77]

First, SB 90 amends Section 1367.51 of the Health and Safety Code.[78] Under this bill, a health care service plan may not require a deductible, coinsurance, or copayment that exceeds thirty-five dollars for a thirty-day supply of insulin.[79] Specifically, if a health care plan maintains a drug formulary, the thirty-five dollar cap only applies to insulin prescription drugs that are in Tier 1

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[65] Ibarra, *supra* note 9 (explaining "sufficient funding to go forward" will be a challenge).

[66] Lovelace, *supra* note 21 (describing how the big three insulin manufacturers were capping the cost of their insulin products).

[67] Fernandez, *supra* note 63.

[68] Lovelace, *supra* note 21.

[69] Michael Hiltzik, *Eli Lilly Is Slashing Insulin Prices, but Hold Your Applause*, L.A. TIMES (Mar. 17, 2023) https://tinyurl.com/4tf8sfwk 4fk9rksb (on file with the *University of the Pacific Law Review*) (asserting that the drug manufacturers' lowered prices do not target the true issue: PBMs).

[70] Michael Monostra, *US Senate Committee Questions Leading Pharmaceutical Companies, PBMs on Insulin Pricing*, HEALIO NEWS (May 12, 2023), https://www.healio.com/news/endocrinology/20230511/us-senate-committee-questions-leading-pharmaceutical-companies-pbms-on-insulin-pricing 4fk9rksb (on file with the *University of the Pacific Law Review*).

[71] *Id*. ("'Drug competition is ultimately what drives rebates, lower list prices and lower new costs.'").

[72] *Id*.

[73] *Id*.

[74] GONZALEZ-PARRA, *supra* note 7.

[75] Cal. SB 90, *supra* note 12.

[76] Cal. SB 90, *supra* note 12.

[77] GONZALEZ-PARRA, *supra* note 7 (emphasizing that insulin costs "[create] a financial burden that presents a barrier to accessing insulin").

[78] Cal. SB 90, *supra* note 12.

[79] Cal. SB 90, *supra* note 12.

and Tier 2.[80] This bill will apply to existing health care plans as of January 1, 2024, as well as new plans offered in the market as of January 1, 2025.[81]

The amendment to Section 1367.51 applies to Department of Managed Health Care (DMHC) regulated pharmacy benefits only.[82] For example, health insurers such as Blue Shield of California, Anthem Blue Cross, and Kaiser Permanente will be required to adhere to the cap.[83] As such, the bill does not regulate Medi-Cal managed care plans.[84] Additionally, the California Public Employees' Retirement System (CalPERS) health maintenance organization (HMO) enrollees will not be impacted because current cost sharing for insulin prescriptions are not higher than the thirty-five dollar cap.[85] Moreover, SB 90 ensures protections for those with high deductible health plans (HDHP).[86] Under this bill, a health care plan may not impose "a deductible, coinsurance, or any other cost sharing" on insulin for those members with HDHPs, "unless doing so would conflict with other federal requirements."[87]

Furthermore, SB 90 amends Section 10176.61 of the Insurance Code, extending the thirty-five dollar out-of-pocket cap to disability insurance policies that are regulated by the California Department of Insurance (CDI).[88] Because health insurers can have different plans, such as HMOs, preferred provider organizations (PPOs), and individual and family plans, the CDI and DMHC may overlap in the health insurers they regulate.[89] Thus, the same health insurers listed above will be subject to the language in Section 10176.61.[90] Additionally, like the amendment to Section 10176.61, the thirty-five dollar cap only applies to insulin prescription drugs that are within Tier 1 and Tier 2.[91] Applying only health and

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[80] Cal. SB 90, *supra* note 12; *What Is a Prescription Drug List?,* UNITED HEALTHCARE, https://tinyurl.com/f734zw8x (last visited May 26, 2023) (on file with the *University of the Pacific Law Review*) (explaining that Tier 1 is composed of the "least expensive drug options, often generic," and Tier 2 is composed of "higher price generic and lower-price brand-name drugs").

[81] Cal. SB 90, *supra* note 12.

[82] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii.

[83] CAL. DEP'T OF INS., HEALTH CARE PROVIDERS TO THE COMPLAINT PROCESS 2 (2020) (stating that "The CDI does not regulate Health Maintenance Organizations (HMOs) or certain PPOs, which fall under the Knox-Keene Act (i.e., Blue Cross of California or Blue Shield of California).").

[84] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii ("SB 90 only impacts DMHC-regulated pharmacy benefits.").

[85] *Id.* ("For CalPERS HMO enrollees, the impact on premiums is $0, because there are no enrollees for whom cost sharing for insulin prescriptions is higher than the cap at baseline."); Jason Gordon, *CalPERS – Explained*, THE BUS. PROFESSOR (Apr. 16, 2022), https://tinyurl.com/34yrdw6d (on file with the *University of the Pacific Law Review*) (explaining that CalPERS is an agency that is responsible for "managing health and pension benefits for public employees and retirees in California").

[86] Cal. SB 90, *supra* note 12.; *see High Deductible Health Plan*, U.S. CTR. FOR MEDICARE & MEDICAID SERV., https://tinyurl.com/3ta5vjys (last visited May 27, 2023) (on file with the *University of the Pacific Law Review*) (describing HDHPs as plans that have a lower monthly premium but higher deductible).

[87] Cal. SB 90, *supra* note 12.

[88] Cal. SB 90, *supra* note 12 ("A disability insurance policy … shall not imposed a copayment on an insulin prescription drug that exceeds thirty-five dollars ($35) for a thirty-day supply.").

[89] CAL. HEALTH CARE FOUND., CALIFORNIA HEALTH INSURERS: LARGE INSURERS REMAIN ON TOP 6–7 (2019) (comparing the distribution between health care insurers).

[90] *Id*.

[91] *What Is a Prescription Drug List?, supra* note 80.

disability insurance plans, this bill aims to cover those individuals who are not included under the IRA.[92]

IV. ANALYSIS

SB 90 is California's attempt at regulating insulin prices for the commercial market.[93] However, despite the potential immediate financial relief the bill provides, SB 90 benefits the drug manufacturers while failing to regulate the middlemen with the most impact on the market.[94] Section A pinpoints how SB 90 alleviates the financial burden of insulin for some Californians.[95] Section B explains how SB 90 pairs with existing law to ensure the greatest number of Californians are covered.[96] Section C discusses how the bill will result in higher healthcare costs and does not allow for healthy market competition.[97] Section D details that SB 90 does not account for further regulation of PBMs.[98]

A. SB 90 Alleviates Financial Burden of Insulin

SB 90 provides financial relief to thousands of diabetic Californians.[99] The cost of insulin is highly dependent on the type of insurance coverage the enrollee has.[100] Enrollees with copayments may only pay forty to sixty dollars a month.[101] However, those with an HDHP may be subject to insulin prices ranging from forty to four hundred dollars per vial.[102] With two to three vials required per month, insulin will cost at least $100 for a thirty-day supply.[103] SB 90 takes a notable step towards making insulin affordable for all insured Californians.[104] The cost-sharing cap applies no matter the type of DMHC-regulated or CDI-regulated insurance plan the patient is enrolled in.[105] Thus, SB 90 rightfully treats the applicable state-regulated plans equally, providing the same cost-sharing cap to all individuals with that type of health insurance.[106]

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[92] GONZALEZ-PARRA, *supra* note 7; *see* ASSISTANT SEC'Y FOR PLAN AND EVALUATION, OFF. OF HEALTH POL'Y INSULIN AFFORDABILITY AND INFLATION REDUCTION ACT: MEDICARE BENEFICIARY SAVINGS BY STATE AND DEMOGRAPHICS 1 (2023).

[93] Cal. SB 90, *supra* note 12 (naming the applicable policies).

[94] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii; *see* Van Nuys et. al, *supra* note 32 (explaining that PBMs must be regulated to fix the insulin market).

[95] *Infra* Part A.

[96] *Infra* Part B.

[97] *Infra* Part C.

[98] *Infra* Part D.

[99] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at 9 ("11.6% of the adult population in California has been diagnosed with diabetes.").

[100] *See* CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at 5 (explaining multiple forms of cost sharing across different insurance plans).

[101] Alyssa Hui, *California Plans to Lower Insulin Prices by Making Its Own*, VERYWELL HEALTH (July 13, 2022), https://www.verywellhealth.com/california-to-develop-its-own-insulin-5536962 (on file with the *University of the Pacific Law Review*).

[102] *Id*.

[103] *Id*.

[104] GONZALEZ-PARRA, *supra* note 7.

[105] Cal. SB 90, *supra* note 12.

[106] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at i.

Specifically, about 55,000 enrollees will benefit.[107] Average cost-sharing for insulin will drop from sixty-one dollars per prescription to an average cost-sharing of twenty dollars per prescription.[108] This results in a sixty-seven percent reduction in cost.[109] Given that one in four people report underusing insulin due to high prices, this cost reduction stemming from SB 90 prices insulin reasonably for thousands of Californians.[110] Additionally, SB 90 is particularly important for Californians with an HDHP.[111] By ensuring they will only pay the monthly cost-sharing, regardless if they have met their deductible, the bill protects those enrollees who pay the most for the life-saving drug.[112] For example, enrollees with out-of-pocket expenses for insulin may see annual savings of greater than $1,852.[113]

B. SB 90 Pairs Well with Existing Law

SB 90 is tailored to specific insurance policies, seemingly leaving some with high insulin prices.[114] However, coupled with other recently enacted legislation such as the IRA and the CalRX Initiative, the bill ensures consumers that were not included in federal and state legislation are provided relief in 2024.[115] Specifically, SB 90 covers state-regulated health insurance plans that were missed in the IRA.[116] Thus, the bill appropriately protects California consumers that do not benefit from federally regulated insurance plans.[117] This state-driven protection is particularly important as legislation for insulin cost-sharing caps is difficult to pass at the federal level.[118]

Additionally, SB 90 is associated with another California initiative that aims to reduce insulin prices—the CalRX Initiative.[119] The CalRX Initiative may be commended for its innovation, as it aims to reduce prices in a way that has never

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[107] *Id*.

[108] *Id*. at ii.

[109] *Id*.

[110] GONZALEZ-PARRA, *supra* note 7. *See generally Cost of Insulin*, WORLD POPULATION REV., https://worldpopulationreview.com/country-rankings/cost-of-insulin-by-country (last visited July 30, 2023) (illustrating that twenty dollars per month for insulin brings price down to costs similar to Chile, Mexico, and Japan).

[111] *Id*. at 5.

[112] *Id*.

[113] *Id*. at iii.

[114] Cal. SB 90, *supra* note 12.

[115] Cal. SB 90, *supra* note 12 (applying the law to existing health care service plan contracts or disability insurance policies starting on January 1, 2024).

[116] Cal. SB 90, *supra* note 12.

[117] GONZALEZ-PARRA, *supra* note 7.

[118] Skylar Jeremias, *$35 Insulin Cap for Private Sector Blocked from Budget Reconciliation Bill*, CTR. FOR BIOSIMILARS (Aug. 8, 2022), https://www.centerforbiosimilars.com/view/-35-insulin-cap-for-private-sector-blocked-from-budget-reconciliation-bill (on file with the *University of the Pacific Law Review*) (noting that the federal legislation cost-sharing cap for Medicare enrollees was originally proposed in March 2020 but failed three years ago).

[119] *See* Ibarra, *supra* note 9 (referencing the CalRX Biosimilar Insulin Initiative).

been done before.[120] However, California's ambitious goal of manufacturing its own insulin is fraught with issues, making SB 90 a significant bill on this year's slate.[121] Despite a promising market shift from the CalRX Initiative, the biosimilar insulin developed by California will need to pass regulatory approval, which is a strenuous process.[122] Although the FDA recently changed the classification of insulin from a drug to a biologic, the federal regulatory approval process can still take at least twelve months.[123] Additionally, sufficient funding will be required to maintain raw materials, facility maintenance, personnel costs, and more.[124] As the product is still at least two years from entering the market, SB 90 provides financial relief to consumers while an alternative option is being established.[125]

C. Hands of the Manufacturers

Another notable shift in the insulin market, alongside SB 90, are the voluntary price decreases that the top three insulin manufacturers agreed to.[126] In March 2023, Eli Lilly, Novo Nordisk, and Sanofi announced price cuts that would match the federal and state legislatures 'requests of thirty-five dollars for a thirty-day supply.[127] Drug manufacturers have touted this remarkable decrease was motivated by the need to help struggling Americans.[128] However, these reductions are not altruistic.[129] As a result of the Medicare Rebate Cap ending in January 2024, rebates owed by drug manufacturers will increase for brand-name insulin.[130] By adopting price cuts, manufacturers will avoid millions owed in rebates, thus increasing profits by several hundred million.[131]

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[120] Natalie Sainz, *Civica to Make California's Own Insulin Brand*, DIATRIBE LEARN (Apr. 3, 2023), https://diatribe.org/civica-make-californias-own-insulin-brand (on file with the *University of the Pacific Law Review*) (explaining that the CalRX Initiative "position[s] California as the first state to produce its own generic drugs").

[121] Phil Cicora, *California's Proposal To Manufacture Insulin Could Curb Prices, Improve Public Health*, UNIV. OF ILL. URBANA-CHAMPAIGN (Jan. 24, 2023), https://news.illinois.edu/view/6367/2121415057 (on file with the *University of the Pacific Law Review*).

[122] *Id*.

[123] U.S. FOOD & DRUG ADMIN., INFORMATION FOR PATIENTS ABOUT REGULATORY CHANGES FOR CERTAIN BIOLOGICAL PRODUCT MEDICATIONS 2 ("Like with all original biosimilar and interchangeable biological product applications, the FDA is committed to reviewing and either approving or providing a complete response within twelve months.").

[124] Cicora, *supra* note 121,

[125] Ibarra, *supra* note 9 (explaining CalRX is "expected to take at least two to three years").

[126] Lovelace, *supra* note 21.

[127] Lovelace, *supra* note 21.

[128] *Lilly Cuts Insulin Prices By 70% And Caps Patient Insulin Out-of-Pocket Costs At $35 Per Month*, LILLY (Mar. 1, 2023), https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket (on file with the *University of the Pacific Law Review*) ("Lilly is taking these actions to make it easier to access Lilly insulin and help Americans who may have difficulty navigating a complex healthcare system.").

[129] Hiltzik, *supra* note 69.

[130] Leemore S. Dafny, *Falling Insulin Prices—What Just Happened?*, 18 N. ENG. J. MED. 1636, 1638 (2023).

[131] Fraiser Kansteiner, *What Spurred Lilly, Novo, And Sanofi To Slash Insulin Prices?*, FIERCE PHARMA (Apr. 20, 2023), https://www.fiercepharma.com/pharma/impetus-behind-lilly-novo-and-sanofis-insulin-price-cuts-explained-report (on file with the *University of the Pacific Law Review*) (explaining that Eli Lilly is expected to save $430 million, while Novo Nordisk will save $350 million and increase earnings by $210 million).

Given that the price cuts are purely voluntary, analysis of SB 90 cannot rely on the reductions being permanent.[132] In fact, when questioned by the Senate Health Committee, only one drug manufacturer committed to not increasing insulin prices again.[133] The other two manufacturers left the option on the table.[134] Thus, SB 90, despite market shifts, ignores the root causes of insulin affordability.[135] Section 1 details the potential healthcare cost increase that can result from the cost-sharing cap.[136] Section 2 reviews how a cost-sharing cap disincentivizes manufacturers from producing and advertising cheaper generics.[137]

1. Higher Healthcare Costs

Although SB 90 may provide financial relief to those with private insurance, the bill will result in higher healthcare costs overall.[138] Specifically, a bill that mandates cost sharing for a single piece of a health benefit plan will not lead to "affordable or sustainable healthcare for all."[139] The cap on out-of-pocket costs for consumers shifts the burden of paying for insulin from the patients to the private insurers.[140] This shift in cost would cause insurers to increase premiums for all enrollees.[141]As a result of the price cap, total health insurance premiums paid by employers and employees would increase by $62.5 million.[142] At an individual plan level, total annual expenditures would increase by approximately $30 million for enrollees in DMHC-regulated and CDI-regulated policies.[143] Additionally, premiums for individual market health insurance would increase by $17 million.[144]

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[132] Hiltzik, *supra* note 69 (explaining that drug manufacturers were reluctant to lower prices in 2021 and only did so in 2023 because of multiple driving factors).

[133] Annika Kim Constantino, *Eli Lilly CEO Vows Not to Raise Insulin Prices Again, While Novo Nordisk And Sanofi Hedge*, CNBC (May 210, 2023), https://www.cnbc.com/2023/05/10/eli-lilly-novo-nordisk-sanofi-ceos-on-insulin-prices.html (on file with the *University of the Pacific Law Review*) (detailing that only Eli Lilly committed to "never increas[ing] the price of any insulin drug again").

[134] *Id*. (quoting Novo Nordisk stating "the company is committed to limited price increases to 'single digits'" and Sanofi stating that "the company has a 'responsible pricing policy'").

[135] *See* AHealthcareZ – Healthcare Finance Explained, *supra* note 19 (illustrating that the insulin supply chain is complicated with seven players).

[136] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at ii.

[137] Hayes & Farmer, *supra* note 16.

[138] *See* CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at i. (explaining that SB 90 would result in an increase of total health insurance premiums by over $60 million).

[139] Andrew Oxford, *California Moves Closer to Capping Insulin Prices With $35 Copay*, BLOOMBERG L. (June 20, 2023), https://www.bloomberglaw.com/bloomberglawnews/pharma-and-life-sciences/XFF592P8000000?bna_news_filter=pharma-and-life-sciences#jcite (on file with *University of the Pacific Law Review*) (citing the California Association of Health Plans' and Association of California Life Insurance and Health Insurance Company's argument against SB 90).

[140] Kao-Ping Chua & Rena M. Conti, *The Winners And Losers Of The Proposed Insulin Cost Cap*, MEDPAGETODAY (Apr. 8, 2022), https://www.medpagetoday.com/opinion/second-opinions/98123 (on file with *University of the Pacific Law Review*).

[141] *Id*.

[142] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii. (2023).

[143] *Id*. at ii–iii.

[144] *Id*. at iii.

Comparably, analysis on cost-sharing caps was completed on the IRA at a federal level.[145] A study evaluating the economic impact of the cap for Medicare patients found that the thirty-five dollar cap is "not cost-effective."[146] Although the cap for Medicare patients may save millions of Americans $500 per year, the provision in the IRA will also result in an increase of total medical costs by $5.6 billion over twenty years.[147] For the cap to be "cost-effective," the study concluded prices will need to roll back to pre-2010 levels.[148] The same logic applied at the federal level can be used for SB 90.[149] With the same cost-sharing cap of thirty-five dollars, the bill will similarly increase total medical costs by shifting the burden to private insurers—the byproduct being increased premiums for California enrollees.[150]

2. Negative Impacts to Generics

The recent FDA approval for biosimilar insulin brings hope to market competition within the drug manufacturing sector.[151] However, the short time lapse between the new market entry of biosimilars and implementation of cost-sharing caps leaves little time for that competition to take effect.[152] While a fourteen percent decrease in price is a positive change, any further substantial reductions in insulin spending are unlikely.[153] Patients are slow to adopt a new insulin, and a new product takes time to develop a meaningful presence in the market.[154] Thus, SB 90's cap overrides natural market competition that matures over time as cheaper products are introduced.[155]

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[145] *See* Hui Shao et. al, *Economic Evaluation Of The $35 Insulin Copay Cap Policy in Medicare And Its Implication for Future Interventions*, 45 DIABETES CARE 161, 161 (2022) (presenting a study reviewing IRA implications).

[146] *Id*.

[147] *Id*. (explaining that medical costs include incremental medical cost, incremental insulin cost, and additional gains in quality-adjusted life-years); *id*. (illustrating that, using the $500 per person per year savings that results from the price cap, the policy's incremental cost effectiveness ratio (ICER) determined the insulin cost-sharing cap must be even lower than thirty-five dollars to be cost effective).

[148] *Id.*

[149] *Id*. at 162 (implicating that the federal level has the same cost-sharing cap as California's bill).

[150] Andrew Lautz, *Senate Insulin Bill Would Help Relative Few, Could Raise Premiums and Taxpayer Costs*, NAT'L TAXPAYERS UNION (July 1, 2022), https://www.ntu.org/publications/detail/senate-insulin-bill-would-help-relative-few-could-raise-premiums-and-taxpayer-costs (on file with the *University of the Pacific Law Review*) (sharing that both legislative actions "limit out-of-pocket costs…but [do] not limit or control insulin *prices* by manufacturers, wholesalers, hospitals, or pharmacies").

[151] Ernst, *supra* note 29.

[152] *See* Hayes & Farmer, *supra* note 16 (illustrating that the first biosimilar insulin was produced in 2020, yet price caps were implemented at a federal level in 2023); *see also FDA Approves First Interchangeable Biosimilar Insulin Product For Treatment Of Diabetes*, *supra* note 27 (sharing that the first biosimilar insulin was not approved and ready for the market until 2021, leaving only a two year gap between market introduction and more legislative action).

[153] Hayes & Farmer, *supra* note 16.

[154] *Id*.

[155] *Id*. (noting that "the introduction of new, half-priced 'generic' insulin products has brought down the average price of most insulin prices").

By implementing a required price cap, the bill threatens an unregulated solution to the insulin price problem.[156] Rather, SB 90 does not give the more affordable biosimilar insulin the opportunity to rise within the market.[157] Instead, the bill creates a synthetic solution to insulin prices, which will inevitably raise healthcare costs overall.[158] SB 90 implements a price cap far too soon to allow for biosimilar insulin to create market competition and lower prices without government intervention.[159]

D. Lack of Regulation of PBMs

While SB 90's interference with natural market competition market is a concern, the bill's biggest shortcoming is its failure to address one of the biggest players in the insulin supply chain—the PBMs.[160] Between 2014 and 2015, the net price received by insulin manufacturers decreased by thirty-one percent.[161] Yet, the price of insulin did not change, proving that PBMs are "negotiating discounts…[but] not passing those savings onto patients."[162] Additionally, to further illustrate the substantial influence of PBMs, the Senate Finance Committee found that PBMs "create[] a vicious cycle of price increases that have sent [insulin] costs…through the roof."[163]

While California has attempted to regulate this part of the supply chain, requiring PBMs to owe a fiduciary duty is not enough.[164] Rather, SB 90 should be amended to require a partial pass-through of rebates at the point-of-sale.[165] This requirement would apply part of the total rebate to the list price of insulin at the time the patient purchases it, which would lower patient out-of-pocket spending directly.[166] For example, if the point of-sale-rebate is five percent, and the insulin is $100–the patient's insulin cost would be reduced by five dollars as a result of the point-of-sale rebate.[167]

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[156] *See id*. (emphasizing that a new product, such as cheaper, biosimilar insulin, takes time to gain market share).

[157] *See* Ernst, *supra* note 29 (explaining that only a few "generic" insulins were available on the market before the price cap was introduced at a federal level in 2022).

[158] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii (explaining the increase in premiums that will result from the price cap).

[159] Hayes & Farmer, *supra* note 16.

[160] *See* Van Nuys et. al, *supra* note 32 ("An investigation by the Senate Finance Committee found that PBMs are complicit in efforts to raise prices and rebates, noting that 'PBMs spur drug makers to hike list prices to secure primary formulary placement and greater rebate and fees.'").

[161] *Id*.

[162] *Id*.

[163] *Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies And PBMs That Keep Prices High*, S. COMM. ON FIN. (Jan. 14, 2021), https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high (on file with the *University of the Pacific Law Review*) ("PBMs use their size and aggressive negotiating tactics, like the threat of excluding drugs from formularies, to extract more generous rebates, discounts, and fees from insulin manufacturers.").

[164] Van Nuys et. al, *supra* note 32.

[165] Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, And Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y 360, 392 (2020).

[166] *Id*. at 394.

[167] Deana K. Bell & Karen L. Nixon, *Rebates at the Point of Sale*, ACTUARY (May 2020), https://www.theactuarymagazine.org/rebates-at-the-point-of-sale/ (on file with the *University of the Pacific Law Review*).

The rest of the rebate would be paid by drug manufacturers to health plans if sales to the plan's enrollees meet the market share thresholds negotiated by PBMs.[168] This change would allow health plans to trickle down the rebates to patients through various forms including decreasing co-pays or cost-sharing caps, or reimbursing the original patient with the earned rebate.[169] Rather than leave rebates in the hands of PBMs, a partial pass-through of the rebate at the point-of-sale would allow for the rebate to have immediate, positive impact on out-of-pocket spending.[170] With rebates having significant influence on drug list prices for the past several years, SB 90 fails to target the most influential player of the insulin supply chain.[171]

V. CONCLUSION

SB 90 provides much needed financial relief to patients not eligible for government-led healthcare programs.[172] Specifically, those with HDHPs will see an immediate decrease in cost for the life-saving drug.[173] Combined with the IRA and California's CalRX Initiative, SB 90 promises to balance insulin costs for individuals missed at the federal level while other state solutions are developed and brought to the market.[174] Collectively, the insulin initiatives, including SB 90, will likely reduce insulin costs for diabetics in California within the next year.[175]

However, while SB 90 assures cost-sharing prices decrease in the short-term, the bill fails to address the main source of insulin affordability.[176] Despite the surprising voluntary price cut by the drug manufacturers, making insulin affordable cannot depend on the oligopoly's limited promises.[177] Thus, SB 90's cost-sharing cap opens individuals up to potentially higher healthcare costs as a result of not waiting long enough to see market impacts of biosimilars.[178]

Additionally, SB 90 does not address PBMs despite their outsized role in driving up insulin prices.[179] Rather, the bill sidesteps the middlemen by pushing the cost-sharing to the private insurers.[180] To ensure outrageous insulin prices do not continue, SB 90 should be amended to mandate a partial pass-through of rebates at the point-of-sale.[181] While current law is a step in the right direction, rebates need to be reformed so that patients benefit the most.[182] While SB 90 injects

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[168] Shepherd, *supra* note 165, at 394.

[169] *Id*.

[170] *Id*. at 378–79 ("Health and Human Services (HHS) Secretary Alex Azar has identified drug markers' fear of retaliation from PBMs as a major impediment to reducing drug list prices.").

[171] *Id*. at 394.

[172] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at 5.

[173] CAL. HEALTH BENEFITS REV. PROGRAM, *supra* note 13, at iii.

[174] Cal. SB 90, *supra* note 12.

[175] Cal. SB 90, *supra* note 12.

[176] Van Nuys et. al, *supra* note 32.

[177] Hiltzik, *supra* note 69.

[178] Hayes & Farmer, *supra* note 16.

[179] Van Nuys et. al, *supra* note 32.

[180] Cal. SB 90, *supra* note 12.

[181] *See* Van Nuys et. al, *supra* note 32 (suggesting that PBMs are "complicit in efforts to raise prices and rebates" for themselves).

[182] Shepherd, *supra* note 165, at 394.

some regulation into the insulin market, more is required to fix the root causes of the insulin price crisis.[183]

[183] Van Nuys et. al, *supra* note 32.