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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ANN LEWANDOWSKI, on her own behalf, on behalf of all others similarly situated, and on behalf of the Johnson & Johnson Group Health Plan and its component plans, Plaintiff, v. JOHNSON & JOHNSON AND THE PENSION & BENEFITS COMMITTEE OF JOHNSON & JOHNSON, Defendants.	Case No. 3:24-cv-00671 **ORAL ARGUMENT REQUESTED**

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED CLASS ACTION COMPLAINT

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Defendants Johnson & Johnson ("J&J") and the Pension & Benefits Committee of Johnson & Johnson (together, "Defendants") respectfully submit this brief in support of their motion to dismiss the First Amended Class Action Complaint (Dkt. 44, the "Amended Complaint" or "AC").

INTRODUCTION

Johnson & Johnson is an innovative medicine and medical technology company with more than 130,000 employees worldwide. It proudly offers its employees an industry-leading benefits package, which includes robust medical, retirement, and other benefits ranging from adoption assistance and caregiver leave to mental health programs, military service benefits, and more.

As part of this benefits package, J&J sponsors the Johnson & Johnson Group Health Plan (the "Plan"), an optional benefits program through which J&J provides its employees with medical, dental, vision, and prescription drug coverage. Although employees who participate in the Plan contribute toward the cost of these benefits, J&J covers the vast majority of the costs. In 2022, for example, J&J contributed more than $800 million to the Plan – more than five times the total employee contributions. Accordingly, J&J has every incentive to negotiate the most favorable terms that it can for the Plan.

This case focuses on only one component of the Plan: the prescription drug benefit. The Plan offers generous prescription drug coverage. In general, after a

participant meets her annual deductible (which applies to both medical and drug costs combined), the Plan covers at least 80% of her prescription drug costs, and the participant pays as little as $0 and no more than $125 for a prescription – even for specialty prescriptions that would otherwise cost hundreds or thousands of dollars per fill. To administer the prescription drug component of the Plan, J&J has negotiated a contract with Express Scripts, Inc. ("ESI"), one of the three largest pharmacy benefit managers in the United States. ESI maintains a network of pharmacies from which employees can obtain prescription drugs, negotiates prices for those drugs, and manages the day-to-day operation of the Plan's prescription drug benefit.

Plaintiff elected to begin participating in the Plan after she was hired at J&J. She brings this suit under the Employee Retirement Income Security Act of 1974 ("ERISA"). Unlike the typical ERISA plaintiff, however, ***she does not claim that she was denied any benefits under the Plan***. Instead, Plaintiff primarily asserts that J&J breached ERISA's duty of prudence by entering into an agreement that allowed ESI to charge supposedly "excessive" prices for two limited categories of prescription drugs. In particular, Counts I and II of the Amended Complaint allege that the costs of 42 generic specialty drugs and 14 generic non-specialty drugs – out of the thousands available under the Plan – were too high, claiming that cheaper prices were available through online or neighborhood pharmacies. In

Count III, Plaintiff also claims that J&J's Pension & Benefits Committee (the "Committee") violated ERISA by failing to give her certain documents that she requested. All of the claims should be dismissed.

First, Plaintiff lacks Article III standing to assert the fiduciary duty claims. She received all of the benefits she was contractually entitled to receive – that is, prescription drug benefits at the cost and under the terms defined in the Plan documents. She has not alleged otherwise. Under *Thole v. U.S. Bank, N.A.*, 590 U.S. 538 (2020), she therefore cannot show an injury-in-fact traceable to Defendants' alleged imprudence. Moreover, Plaintiff's out-of-pocket costs under the Plan were completely unaffected by the challenged conduct. In each year in which she has been a participant in the Plan, Plaintiff has received tens of thousands of dollars (and in some years, well over one hundred thousand dollars) in medical benefits alone, such that in each year in which she has been a participant in the Plan, she reached the Plan's limit for out-of-pocket costs based on expenses unrelated to the prescription drug benefit. Stated differently, because of the Plan's cost-sharing obligations associated with her substantial medical (*i.e.*, non-drug-benefit-related) expenses, Plaintiff would have still paid the exact same out-of-pocket amount each year even if her prescription drugs through the Plan had cost nothing. She therefore has suffered no cognizable injury that can be traced to the challenged conduct.

Second, the Amended Complaint fails to state a claim. To adequately plead her fiduciary duty claims, Plaintiff must plead that Defendants' process for choosing a pharmacy benefit manager and negotiating the cost of drugs was imprudent. The Amended Complaint contains no facts whatsoever about that process. Plaintiff instead asks the Court to infer imprudence solely based on the prices of the 42 generic specialty drugs and 14 generic non-specialty drugs she challenges – among the thousands of prescription drugs covered by the Plan. But it is not enough to simply point to a fraction of the Plan's covered drugs and claim they were too expensive. A tiny subset of the results of Defendants' process cannot give rise to an inference of imprudence regarding that process overall. Instead, Plaintiff must at least allege that similar plans paid less overall for a comparable prescription drug program. The Amended Complaint fails to meet that burden. Plaintiff also does not state a claim as to Count III because she does not adequately allege a written request for documents under 29 U.S.C. § 1024(b)(4).

BACKGROUND

A. The Plan.

J&J has more than 130,000 employees worldwide who are engaged in the research and development, manufacture, and sale of healthcare products. AC ¶ 13. It provides medical, vision, dental, and prescription drug benefits to its employees,

retirees, and their family members through the Johnson & Johnson Group Health Plan. *Id.* ¶¶ 13–14; Ex. A, Plan Doc. §§ 1.02–03 & Schedule A.[1]

The Plan is self-funded, which means that instead of paying premiums to an insurance company, J&J bears direct financial responsibility for the cost of Plan benefits, including prescription drug benefits. *See* AC ¶¶ 14–15; Ex. A, Plan Doc. § 4.02. While Plan participants pay monthly premiums for their coverage (which are fixed as of the beginning of the year), as well as deductibles and co-pays,[2] those employee contributions pale in comparison to J&J's contributions. For example, in 2022, J&J paid more than $800 million in Plan costs, while participants contributed approximately $148 million. *See* AC ¶¶ 15, 192, 195; Ex. B, Summary Annual Rpt. at 1. Because J&J bears the lion's share of the Plan's costs, it has every incentive to negotiate the best deal it can for the overall package of covered benefits, including prescription drug benefits.

[1] The Plan documents attached to this motion (Exhibits A–D) are judicially noticeable at this stage because "the Complaint expressly references and relies upon the Plan." *Lipani v. Aetna Life Ins. Co.*, 2023 WL 3092197, at *6 (D.N.J. Apr. 26, 2023) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

[2] When this brief refers to "out-of-pocket costs," it means deductibles, co-insurance, and co-pays – not premiums, which are separate.

B. The Plan's Prescription Drug Benefit.

The Plan offers participants multiple medical plan options. Each option covers benefits for medical services and prescription drugs, including benefits that allow participants to obtain virtually any prescription drug approved for use in the United States. *See generally, e.g.*, Ex. D, Premier HSA Medical Plan Details Supplement.

For example, under the Premier HSA Medical Plan option (the "Premier HSA Plan"), a participant must pay an initial amount, called a "deductible," for most covered services. *Id.* at 4. The costs for both medical services and prescription drugs count toward the deductible. *Id.* Applicable law and IRS guidance provide that an HSA-eligible plan like the Premier HSA Plan must establish annual deductibles no less than a specified amount published by the IRS. The deductible established under J&J's Premier HSA Plan is the lowest amount permitted. Ex. E, Decl. ¶ 5(a).[3] Once a participant has met her annual deductible, the participant and the Plan share the costs of any services (known as "co-insurance"). For example, if a participant obtains a drug at an in-network retail pharmacy, she typically pays 20% of the cost of the drug, up to a maximum of

[3] The Court can consider this declaration (Exhibit E) for purposes of addressing whether the case should be dismissed under Rule 12(b)(1) for lack of Article III standing. *See, e.g.*, *Sharifi v. Township of E. Windsor*, 2023 WL 2182003, at *3 (D.N.J. Feb. 23, 2023).

$125 per prescription for a 30-day supply. Ex. C, Prescription Drug Coverage Details Supplement at 7. The Plan pays the remaining amount. *Id.* Thus, participants' payment for prescription drugs generally ranges from $0 up to a cap of $125 a month. *See id.* at 6–9.

The Plan further limits the total amount that the participant must pay by establishing a maximum out-of-pocket amount for each year. *See id.* at 6; Ex. D, Premier HSA Medical Plan Details Supplement at 10. This means that after a participant meets the annual deductible and pays a specified additional amount of co-insurance for medical services and prescription drug benefits combined, the participant pays nothing (and the Plan pays the entire amount) for covered healthcare expenses for the remainder of the year. *See* Ex. D, Premier HSA Medical Plan Details Supplement at 10.

C. The Role of ESI.

To administer the prescription drug portion of the Plan, J&J has contracted with Express Scripts, Inc., a pharmacy benefit manager ("PBM"). AC ¶ 93. ESI provides services to the Plan, such as negotiating with pharmacies where participants can obtain prescriptions at an in-network level of benefits and contracting with drug manufacturers to secure rebates. *See id.* ¶ 37. ESI also processes participants' claims. When a participant fills a prescription, ESI pays the

pharmacy for the prescription (minus any participant-paid amount), then later receives payment from the Plan. *See id.* ¶¶ 31–32, 37.

The Plan's overall prescription drug costs are negotiated between J&J and ESI, as is typical between a plan sponsor and a pharmacy benefit manager. *See id.* ¶ 41. As part of these negotiations, plan sponsors and pharmacy benefit managers often negotiate limits on the amount that a plan pays for categories of drugs based on a benchmark price, such as the "Average Wholesale Price" ("AWP"). *Id.* ¶¶ 42–43. For instance, to use Plaintiff's examples, plan fiduciaries and ESI might negotiate a limit on prices equal to "AWP minus 85%" for all generic drugs, "AWP minus 20%" for all branded drugs, and "AWP minus 15%" for all specialty drugs. *Id.* ¶ 44.

D. Plaintiff's Participation in the Plan.

Plaintiff Ann Lewandowski voluntarily elected to participate in the Plan, rather than obtain medical coverage through another source (such as a state or federal marketplace). Each year, she chose the Premier HSA Medical Plan option. *See* Ex. E, Decl. ¶ 4. She does not allege that she was improperly denied any benefits under the Plan or that she had to pay more than the Plan terms required. Rather, she claims that two categories of prescription drugs available under the Plan's terms were too expensive.

The first category consists of generic "specialty" drugs. *See, e.g.*, AC ¶ 5. Generally speaking, specialty drugs are used to treat complex or rare chronic conditions, require special handling or care, or historically were available only at hospitals, doctors' offices, or specialty pharmacy locations. *See id.* ¶ 77. The Amended Complaint challenges the prices of 42 such drugs. Plaintiff does not allege that she personally was prescribed or paid for any of them. *See, e.g.*, *id.* ¶¶ 104–16 (allegations about generic specialty drugs); *id.* ¶¶ 198–218 (allegations about Plaintiff).

The second category consists of generic "non-specialty" drugs. *See, e.g.*, *id.* ¶ 6. The Amended Complaint alleges that Plaintiff has filled prescriptions for 14 such drugs since August 2022 that were too expensive. *Id.* ¶¶ 124–25.

In addition to prescription drug benefits, Plaintiff received medical benefits through the Plan. *See, e.g.*, *id.* ¶¶ 212–16. Each year she was a participant (*i.e.*, 2022–2024), the Plan had a maximum out-of-pocket amount of $3,500 for in-network services. Ex. E, Decl. ¶ 5(d). Applicable law and IRS guidance provide a cap on the annual out-of-pocket maximum that HSA-eligible plans like the Premier HSA Plan are permitted to establish; for each year in which Plaintiff participated, the Premier HSA Plan's out-of-pocket maximum was considerably ***lower*** than that cap. *Id.* For each of those years, the Plan has provided substantial medical and drug benefits to Plaintiff, totaling more than $168,000 for 2022,

$197,000 for 2023, and $81,000 for 2024 (just through May). *Id.* ¶ 7. However, due to the maximum out-of-pocket cost limitation, Plaintiff's out-of-pocket cost in each of those years was restricted to $3,500; the Plan paid the rest. *Id.* ¶¶ 5(d), 6. Moreover, prescription drugs obtained under the prescription drug benefit comprised only a small fraction of Plaintiff's healthcare expenditures each year. Because of her significant medical expenditures, Plaintiff would have reached the maximum out-of-pocket amount each year even if the prices of the drugs she was prescribed were $0. *Id.* ¶¶ 7–10. In other words, the cost of prescription drugs had no impact on the cost-sharing amounts Plaintiff has paid for benefits under the Plan. *Id.*

E. The Amended Complaint.

Plaintiff filed this putative class action in February 2024, and filed an Amended Complaint in May 2024. The Amended Complaint asserts three claims under ERISA. Counts I and II are duplicative claims for breach of the fiduciary duty of prudence under 29 U.S.C. §§ 1132 (a) and 29 U.S.C. §§ 1132(a)(2)–(3) (ERISA Sections 502(a)(2) and 502(a)(3)), based on Plaintiff's theory that Defendants acted imprudently by failing to negotiate lower prices for the generic specialty drugs and generic non-specialty drugs at issue. AC ¶¶ 5–6, 230–35. Count III is a claim for failure to provide documents that Plaintiff allegedly requested under 29 U.S.C. § 1132(c) (ERISA Section 502(c)). AC ¶¶ 242–48.

Plaintiff's original complaint included a jury demand, which Defendants moved to strike; the Amended Complaint abandoned the jury demand.

ARGUMENT

I. Plaintiff Lacks Article III Standing for the Fiduciary Duty Claims.

Under Federal Rule of Civil Procedure 12(b)(1), Plaintiff "bears the burden of meeting the irreducible constitutional minimum of Article III standing" as to each claim in the Amended Complaint. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (quotation marks omitted). There are two kinds of challenges to Article III standing: "facial" and "factual" challenges. *Id.* at 243. A facial challenge "contests the sufficiency of the pleadings," *id.*, whereas a factual challenge "concerns the actual failure of a plaintiff's claims to comport factually with the jurisdictional prerequisites" of Article III, *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008) (citation and brackets omitted). Thus, in assessing a factual challenge to standing, courts "review evidence outside the pleadings" and "make factual findings." *Id.* at 145.

To meet the Article III standing requirements, Plaintiff must show that she (i) suffered an "injury in fact" that is (ii) "fairly traceable" to the challenged conduct, and (iii) likely to be "redressed" by a favorable judicial decision. *In re Schering Plough Corp.*, 678 F.3d at 244 (quoting *Lujan v. Defenders of Wildlife*,

504 U.S. 555, 560–61 (1992)). Injury-in-fact, the "[f]irst and foremost" of these elements, requires factual allegations showing that Plaintiff's injury is "concrete and particularized," as well as "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338–39 (2016) (quoting *Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 103 (1998), and *Lujan*, 504 U.S. at 560). "Concrete" means the injury is "real, and not abstract," and "particularized" means the injury "affect[ed] the plaintiff in a personal and individual way." *Id.* at 339–40 (cleaned up).

Plaintiff fails to meet the constitutional standing requirements for Counts I and II for three reasons. First, the gravamen of the claims is that Defendants acted imprudently by allegedly allowing ESI to charge excessive prices for generic specialty drugs and generic non-specialty drugs. *See, e.g.*, AC ¶¶ 5–6. But such a claim alleges no personal harm to Plaintiff, who does not claim she was denied any benefits to which she is entitled. Second, Plaintiff did not suffer any injury from the prescription drug costs she challenges. Even if prescription drugs had cost $0 under the Plan, Plaintiff would have paid the same amounts per year for her health benefits; lowering the prescription drug costs would have no effect on her. And third, Plaintiff lacks standing to challenge any of the generic specialty drugs she claims were too expensive – because she does not allege she was prescribed any of them.

A. Plaintiff Received All of the Benefits She Was Entitled to Receive Through the Plan.

In *Thole v. U.S. Bank*, the Supreme Court held that an ERISA plan participant lacks standing to challenge fiduciaries' alleged mismanagement of the plan if she received all of the plan benefits to which she was entitled. That holding controls and requires dismissal of the fiduciary duty claims here. Plaintiff "received all of [her] . . . benefits," has "no concrete stake in this dispute[,] and therefore lack[s] Article III standing." *Thole*, 590 U.S. at 547.

Thole involved a defined-benefit retirement plan. *Id.* at 540. "[A]s its name implies," a defined-benefit plan "consists of a general pool of assets" and is "one where the employee, upon retirement, is entitled to a fixed periodic payment." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 439 (1999). In other words, the employer bears the risks associated with managing the plan assets, while participants' benefits are defined in the Plan documents and "will not change, regardless of how well or poorly the plan is managed." *Thole*, 590 U.S. at 543. The plaintiffs in *Thole* claimed that their employer violated ERISA by making imprudent decisions about how to manage their defined-benefit plan's assets. *Id.* at 540–41. But even though their employer's decisions allegedly caused the plan to sustain losses, the plaintiffs had been paid all of the benefits they were "legally and contractually entitled to receive" under the terms of the plan, and they "would still receive the exact same monthly benefits" regardless of whether they won or lost

the suit. *Id.* The Court thus held that they failed to allege Article III standing. *Id.* at 541–42.

Plaintiff here lacks standing for the same reasons. Like a defined-benefit retirement plan, the J&J Plan has a general pool of assets held in a trust. AC ¶ 15. Participants' benefits, including the prescription drug benefit, are paid from those assets. *Id.* Benefits are "not tied to the value of the plan," but instead are "fixed" by the terms of the Plan documents, which operate "in the nature of a contract." *Thole*, 590 U.S. at 542–43. And as Plaintiff acknowledges (Dkt. 46 at 1), she received all of the prescription drug benefits she is "legally and contractually entitled to receive" under the Plan's terms. *Thole*, 590 U.S. at 540. She therefore "lack[s] Article III standing" to challenge alleged mismanagement of the Plan. *Id.* at 542; *see also, e.g.*, *Perelman v. Perelman*, 793 F.3d 368, 374 (3d Cir. 2015) (holding that "even if the defendants' dealings resulted in a diminution in Plan assets, they are insufficient to confer standing").

Plaintiff's conclusory allegation that Defendants' imprudence caused "higher premiums, higher deductibles, higher coinsurance, higher copays, and lower wages," AC ¶ 233, is speculative and thus cannot confer standing. The Amended Complaint claims that employee contributions into the Plan increased as Plan costs increased as a whole, *id.* ¶¶ 191–93, but it does not allege that the amounts of any premiums, deductibles, co-insurance, or co-pays were tied to

generic specialty or generic non-specialty drugs in particular. Nor does the Amended Complaint explain what those amounts might have been if Defendants had negotiated lower prices for those categories of drugs, or otherwise negotiated a different contract with ESI or another pharmacy benefit manager. Moreover, the deductible applicable to the Premier HSA Plan is the lowest amount permitted by the IRS. Ex. E, Decl. ¶ 5(a). That further belies Plaintiff's speculative claim that her deductible might have been lower if the costs of drugs had been lower. Plaintiff's theory that she might have received "a higher salary or additional benefits" is "far too speculative to serve as the basis for a claim of individual loss." *Horvath v. Keystone Health Plan E., Inc.*, 333 F.3d 450, 457 (3d Cir. 2003) (affirming dismissal of ERISA claims for lack of standing); *see also Lewis v. Gov't Emps. Ins. Co.*, 98 F.4th 452, 461 (3d Cir. 2024) ("Conjecture about how a negotiation might have played out . . . is not enough" for Article III standing); *Glanton ex. rel. ALCOA Prescription Drug Plan v. AdvancePCS Inc.*, 465 F.3d 1123, 1125 (9th Cir. 2006) (claims that plan sponsor might have reduced co-payments and deductibles if plan expenses were lower were insufficient for Article III standing).[4]

[4] Plaintiff also cannot rely on *Grasso v. Katz*, 2023 WL 4615299, at *2 (3d Cir. July 19, 2023), which deemed excessive expenses an injury in a completely different context: an abuse of process claim involving expenses arising from responding to subpoenas.

This Court recently rejected virtually identical allegations and dismissed ERISA claims for lack of Article III standing in *Knudsen v. MetLife Group, Inc.*, 2023 WL 4580406 (D.N.J. July 18, 2023), *appeal pending*, No. 23-2430 (3d Cir.). There, the plaintiffs were participants in a self-funded healthcare plan. *Id.* at *5. They claimed their employer violated ERISA by keeping drug rebates for itself instead of allocating them to the plan, on the theory that "[h]ad the drug rebates been properly allocated, Defendant may have reduced co-pays and co-insurance" paid by participants. *Id.* at *1 (quotation marks omitted). The Court rejected that theory because it was "speculative and conclusory," and it held that the plaintiffs lacked Article III standing because they had "no legal right to the general pool of Plan assets" and did "not contend that they did not receive their promised benefits." *Id.* at *5 (citing *Thole*, 590 U.S. at 543).

Other courts are in line with *Knudsen*: participants in self-funded healthcare plans lack Article III standing to bring ERISA claims for alleged mismanagement of the plan if they received all of the benefits they were legally entitled to receive under the plan's terms. *See Winsor v. Sequoia Benefits & Ins. Servs., LLC*, 62 F.4th 517, 523–29 (9th Cir. 2023) (plaintiffs lacked standing because they received "a fixed set of benefits as promised in plan documents"); *Gonzalez de Fuente v. Preferred Home Care of N.Y. LLC*, 858 F. App'x 432, 434 (2d Cir. 2021) (plaintiffs who claimed defendants' conduct resulted in "increased out-of-pocket

costs and reduced coverage" had no standing because they "received all of their promised health benefits so far") (brackets omitted); *Scott v. UnitedHealth Grp., Inc.*, 540 F. Supp. 3d 857, 861–65 (D. Minn. 2021) ("Like the plaintiffs in *Thole* . . . plaintiffs do not allege that they have submitted claims for healthcare expenses that have been wrongfully denied.").

Finally, the Amended Complaint's characterization of the claims as being brought not only on behalf of Plaintiff but also on behalf of the Plan as a whole (*see, e.g.*, AC ¶ 230) makes no difference. The Supreme Court in *Thole* considered the same argument and rejected it. "[To] claim the interests of others, the litigants themselves still must have suffered an injury in fact, thus giving them a sufficiently concrete interest in the outcome of the issue in dispute." 590 U.S. at 543 (cleaned up). Plaintiff lacks such an injury because she received all of the prescription drug benefits that she was "legally and contractually entitled to receive" under the terms of the Plan. *Id.* at 540.

B. Plaintiff Was Unaffected by the Costs of Prescription Drugs.

Even if Article III allowed Plaintiff to pursue claims for benefits beyond what she was entitled to receive under the Plan (it does not), she would still lack standing for an additional, independent reason: Plaintiff did not suffer any injury from the prices of prescription drugs obtained under the prescription drug benefit

because she would have paid the exact same amount in total out-of-pocket costs each year she has participated in the Plan, regardless of the cost of drugs.

The traceability requirement of Article III standing requires a plaintiff to show that the defendants' challenged conduct is the "but for" cause for her injury. *Davis v. Att'y Gen. United States*, 2024 WL 866034, at *4 (3d Cir. Feb. 29, 2024). To assess this element of standing, "a court must isolate and change one and only one variable," and ask whether plaintiff would be better off with that variable changed. *Id.* (quoting *LaSpina v. SEIU Pa. State Council*, 985 F.3d 278, 286 (3d Cir. 2021)). "[T]he variable to isolate and change is the conduct of the defendant the plaintiff challenges." *Id.*

Here, the "variable" to consider is the cost of the generic specialty drugs and generic non-specialty drugs that Plaintiff challenges. Even if higher cost-sharing amounts were a cognizable injury, the cost of the drugs that Plaintiff was prescribed had ***zero impact*** on Plaintiff's out-of-pocket expenses. Each year that Plaintiff participated in the Plan, her maximum out-of-pocket cost – that is, the maximum total amount she had to pay for her deductible plus any co-insurance – was $3,500 for all medical and drug benefits combined. Ex. E, Decl. ¶ 5(d). The Plan was responsible for all amounts beyond that for any covered health services and prescription drugs that Plaintiff received, as shown in the following table:[5]

[5] These figures are based on the data available to J&J as of the date of this motion.

Year	Allowed Amount	Deductible	Coinsurance	Patient Responsibility	Total Plan Responsibility
2022	$171,535	$1,400	$2,100	$3,500	$168,035
2023	$201,382	$1,500	$2,000	$3,500	$197,882
2024	$84,788	$1,600	$1,900	$3,500	$81,288

Id. ¶ 7. The "Allowed Amount" is the amount paid to providers for medical services and prescription drugs provided to Plaintiff. The "deductible" and "co-insurance" columns show the portion of the Allowed Amount for which Plaintiff was responsible. As the chart shows, in each year, Plaintiff's total out-of-pocket maximum was $3,500 – the Plan's limit. The last two columns of this table show the total portion of the Allowed Amount for health benefits that Plaintiff and the Plan had to pay, respectively. For example, for services provided in 2022, the Plan was responsible for $168,035 for healthcare services and products (including prescription drugs) provided to Plaintiff. Plaintiff was responsible for $3,500, her maximum out-of-pocket limit. *Id.* ¶ 8.

The vast majority of expenditures related to Plaintiff in each year were for medical services – not prescription drugs obtained under the prescription drug benefit. *Id.* ¶ 9. Because the maximum out-of-pocket limit applies to medical and prescription benefits combined, in each of 2022, 2023, and 2024 (just through May), Plaintiff would have reached her $3,500 maximum out-of-pocket limit based solely on the cost of her medical service expenses. *Id.* ¶¶ 9–10. In other words,

even if ESI had agreed to charge $0 for prescription drugs through the Plan, Plaintiff's total out-of-pocket expenses under the Plan would have been no less – and no more – than $3,500 each year. *Id.* ¶¶ 8–10.

Because the cost of prescription drugs under the prescription drug benefit had no impact on Plaintiff, these costs were not the cause of any injury, and she thus lacks standing. *Fischer v. Governor of New Jersey*, 842 F. App'x 741, 748 (3d Cir. 2021). Put differently, Plaintiff "still would have had to pay" each year an amount that was "equal to the amount" she actually paid, even if Plaintiff had been charged $0 for prescription drugs. *LaSpina*, 985 F.3d at 286. ESI's prescription drug costs thus were "not the 'but for' cause of [Plaintiff's] alleged injury, resulting in her lacking standing to pursue this claim." *Id.*

Plaintiff suggests that if the cost of prescription drugs were lower, it is possible that J&J might have set lower amounts for deductibles, co-insurance, and premiums. But that argument does not confer standing. The Amended Complaint has no factual allegations suggesting that those amounts would have been lower if generic specialty or generic non-specialty drug prices had been lower. Because the Court has "no way of knowing" the effect that those prices would have had on Plaintiff's out-of-pocket amounts, it "can only speculate," and "speculation is not enough to sustain Article III standing." *Finkelman v. Nat'l Football League*, 810 F.3d 187, 200 (3d Cir. 2016); *see also, e.g.*, *EJ MGT LLC v. Zillow Grp., Inc.*,

2021 WL 5754901, at *2 (3d Cir. Dec. 3, 2021) (affirming dismissal because "[c]onclusory allegations about the effect of" prices are insufficient for Article III standing).

C. Plaintiff Does Not Allege that She Paid for Any Generic Specialty Drugs or Was Affected By Other Challenged Conduct.

With regard to her allegations concerning generic specialty drugs, Plaintiff lacks standing for an additional, independent reason: she does not allege that she ever paid for – or was even prescribed – any of the 42 generic specialty drugs that were allegedly too expensive. *See* AC ¶¶ 104–16, 198–218. For similar reasons, she also lacks standing to pursue her theories that Defendants acted imprudently by "steering" participants toward Accredo (ESI's specialty pharmacy) and "failing to promote" generic drugs over branded drugs. *See id.* ¶¶ 129–38.

It is well-settled that a plaintiff who was unaffected by a defendant's conduct does not have standing to challenge that conduct. Instead, "[o]nly those plaintiffs who have been *concretely harmed*" by a defendant's alleged violations have standing. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 427 (2021); *see also, e.g.*, *Huber v. Simon's Agency, Inc.*, 84 F.4th 132, 152 (3d Cir. 2023) ("[R]egardless of whether the defendant violated the law, the plaintiff must establish that she herself suffered a concrete harm.").

Plaintiff lacks standing to challenge generic specialty drug prices under that rule. The Amended Complaint claims that 42 generic specialty drugs covered

under the Plan were too expensive. *See* AC ¶¶ 104–16. But it does not allege that Plaintiff ever purchased, attempted to purchase, or was prescribed any of those drugs. She therefore plainly did not suffer any injury-in-fact related to those prices that is traceable to Defendants' alleged imprudence. *Finkelman*, 810 F.3d at 195 (affirming dismissal for lack of Article III standing as "plainly correct" because plaintiff "never purchased" the allegedly overpriced tickets at issue).

Plaintiff's failure to allege that she paid purportedly inflated costs for generic specialty drugs distinguishes this case from others in which courts have concluded that a complaint adequately pleaded standing. For instance, in *Sweda v. University of Pennsylvania*, 923 F.3d 320 (3d Cir. 2019), and *Boley v. Universal Health Services, Inc.*, 36 F.4th 124, 131–32 (3d Cir. 2022), the plaintiffs claimed that investment options offered through their 401(k) retirement plans were imprudent because they allegedly underperformed or charged excessive fees. But the plaintiffs in those cases had each invested in one or more of the challenged investments. *Boley*, 36 F.4th at 131–32; *see also Sweda*, 923 F.3d at 334 n.10 ("[T]he complaint . . . indicate[s] that the named plaintiffs invested in the underperforming investment options."). Plaintiff makes no comparable allegation

here. She does not allege that she was ever prescribed even one of the allegedly overpriced generic specialty drugs identified in the Amended Complaint.[6]

Finally, Plaintiff's other two theories of imprudence fail for similar reasons. The Amended Complaint asserts that Defendants mismanaged the Plan by "agreeing to steer beneficiaries toward Express Scripts' mail-order pharmacy, Accredo," AC ¶ 129, and "failing to disincentivize the use of high-price branded drugs on the Plan's formulary in favor of lower-priced generics," *id.* ¶ 135. But Plaintiff does not allege that she personally was ever "steered" toward Accredo, or that she ever used a branded drug when a lower-priced generic version was available. She thus lacks Article III standing to assert these theories. *TransUnion*, 594 U.S. at 427–28.

II. The Amended Complaint Fails to State a Plausible Claim Under Rule 12(b)(6).

The Court should also dismiss the Amended Complaint in its entirety because it fails to state a plausible claim for relief.

[6] These cases are also distinguishable because they involved defined *contribution* plans rather than defined-benefit-type plans like those in *Thole* and this case. *Sweda*, 923 F.3d at 324; *Boley*, 36 F.4th at 128. As noted above, the *Thole* and J&J plans provide fixed benefits. The defined contribution plan benefits at issue in *Sweda* and *Boley*, in contrast, reflected the amount of each participant's contributions to her account along with investment gains and losses, the latter two of which depend directly on the performance of the plan investment options chosen by the fiduciaries. *Boley*, 36 F.4th at 128 n.2; *see also Thole*, 540 U.S. at 540.

First, Counts I and II fail to state a claim because the Amended Complaint does not plausibly allege that J&J had an imprudent process for selecting and negotiating with ESI. The Amended Complaint makes no factual allegations about that process. Instead, Plaintiff asks the Court to infer an imprudent process based on the prices of a tiny subset of generic specialty and generic non-specialty drugs – out of the thousands of drugs covered by the Plan. Those allegations are insufficient. To state a claim for imprudence, Plaintiff must allege facts showing that the overall package of prescription drugs that J&J negotiated with ESI was too expensive relative to a "meaningful benchmark" – that is, relative to a comparable package of prescription drug benefits for other similarly situated healthcare plans (*i.e.*, plans with coverage, access, or service needs similar to those of the J&J Plan). *Mator v. Wesco Distrib., Inc.*, 102 F.4th 172, 188 (3d Cir. 2024) (agreeing with other circuits that the question is whether "similar plans offer[] the same services for less") (quoting *Matousek v. MidAmerican Energy Co.*, 51 F.4th 274, 278–79 (8th Cir. 2022); *Matney v. Barrick Gold of N. Am.*, 80 F.4th 1136, 1148–49 (10th Cir. 2023) ("[T]o raise an inference of imprudence through price disparity, a plaintiff has the burden to allege a 'meaningful benchmark.'"). The Amended Complaint's selective drug-by-drug comparison fails to do that. Moreover, any notion of an imprudent process is implausible. When fiduciaries of a self-funded healthcare plan select and negotiate with a pharmacy benefit manager, they have

every incentive to negotiate the best overall deal for the plan (*i.e.*, for the universe of thousands of drugs covered), taking into account costs as well as qualitative factors, such as drug access and quality of services. That is especially so here, given that J&J bears direct financial responsibility for the vast majority of the Plan's costs.

Second, Count III does not adequately state a disclosure claim under 29 U.S.C. § 1024(b)(4) (ERISA Section 104(b)(4)). The statute requires a plaintiff to submit a written request for Plan documents. Plaintiff claims she did so on two occasions. But the Amended Complaint does not adequately allege that Plaintiff made a requisite written request on the first occasion, and the second occasion did not involve a request for documents covered by the statute.

A. Counts I and II Should Be Dismissed Because Plaintiff Does Not Plausibly Allege that Defendants Had an Imprudent Process for Negotiating Pharmacy Benefit Manager Services.

ERISA's duty of prudence turns on "process rather than the results." *McCaffree Fin. Corp. v. ADP, Inc.*, 2023 WL 2728787, at *13 (D.N.J. Mar. 31, 2023). Thus, to state a claim for breach of the fiduciary duty of prudence, Plaintiff's allegations must show that Defendants used an imprudent process in choosing ESI as the Plan's pharmacy benefit manager, and in negotiating with ESI with regard to categories of drug prices and other pharmacy benefit manager services. *See, e.g.*, *id.*

The Amended Complaint contains no allegations concerning the process by which the Plan selected or negotiated with ESI. Instead, Plaintiff asks the Court to infer imprudence based on a cherry-picked subset of results: the prices of 42 generic specialty drugs and 14 generic non-specialty drugs, out of the thousands of prescription drugs covered by the Plan. But "to raise an inference of imprudence through price disparity, a plaintiff has the burden to allege a 'meaningful benchmark.'" *Matney*, 80 F.4th at 1148–49; *accord Wesco*, 102 F.4th at 188. She is not entitled to an inference of imprudence "simply from the allegation that a cost disparity exists." *Matney*, 80 F.4th at 1148–49; *see also, e.g.*, *McCaffree*, 2023 WL 2728787, at *14 ("A high fee alone does not mandate a conclusion that . . . fees are excessive.") (citation omitted). In the context of plan services, a meaningful benchmark consists of an appropriate comparison between the cost charged to the challenged plan for a set of services overall – not merely a subset of services – and the cost of those same services to similarly situated plans, to show that similar plans "received the same services for less." *Krutchen v. Ricoh USA, Inc.*, 2022 WL 16950264, at *3 (E.D. Pa. Nov. 15, 2022), *appeal pending*, No. 23-1928 (3d Cir.); *accord Wesco*, 102 F.4th at 188; *McCaffree*, 2023 WL 2728787, at *14 ("[A]llegations that include a meaningful benchmark are those that plead similarly situated plans received the same services for less."). "[W]ithout a meaningful benchmark," Plaintiff cannot "create[] a plausible inference that the decision-

making process itself was flawed." *Matousek*, 51 F.4th at 280 (emphasis omitted); *accord Wesco*, 102 F.4th at 188 (agreeing with *Matousek*'s "articulation of the relevant law").

The Third Circuit has twice decided cases that illustrate what allegations are sufficient to allege a meaningful benchmark for the cost of plan services. Most recently, in *Mator v. Wesco*, the court held that plaintiffs had stated a claim when they alleged, among other things, "a table showing eleven plans that received recordkeeping services from other providers" and that paid between $31 and $53 per participant, while the plaintiffs' plan paid $154. 102 F.4th at 180–81. The court held that "the comparisons show the Plan paid well above what others did," and thus the complaint plausibly alleged imprudent conduct. *Id.* at 187. The *Wesco* court contrasted these allegations with those in other cases in which plaintiffs had relied on industry averages, which were insufficient to state a claim because they did not plausibly allege that services were sufficiently similar. *Id.* at 188; *accord Matney*, 80 F.4th at 1142–43, 1157–58 (industry averages were not a meaningful benchmark).

Similarly, in *Sweda*, the Third Circuit held that an inference of an imprudent process was warranted when a plan's recordkeeping fees were nearly $5 million and the complaint alleged that similar plans paid less than $1 million for the same set of services. 923 F.3d at 330; *see also McCaffree*, 2023 WL 2728787, at *14

(discussing *Sweda*). As in *Wesco*, the court held those allegations were sufficient because they adequately compared a challenged plan's fees to those of other, similarly situated plans.

Here, however, the Amended Complaint contains no such allegations (even after Plaintiff amended her complaint). Nowhere does it allege that similar plans paid less overall for a prescription drug program. It does not even make the insufficient allegation that the Plan paid more overall than some industry average. All that Plaintiff alleges is that specific individual drugs were available at a lower cost elsewhere; nowhere does she allege that other plans paid less for a similar suite of prescription drug services as the J&J Plan. That is what Plaintiff would have to allege to state a claim, including because the Plan's fiduciaries are acting on behalf of the Plan as a whole and its tens of thousands of participants, not a subset of participants who take only specific drugs. *See, e.g.*, *McCaffree*, 2023 WL 2728787, at *14.

The Amended Complaint thus fails to allege an appropriate benchmark. Allegations that some drugs might be available for less elsewhere do "not state a claim for breach of fiduciary duty with respect to excessive total plan costs" for prescription drugs. *Id.* at *15; *see also, e.g.*, *Albert v. Oshkosh Corp.*, 47 F.4th 570, 582 (7th Cir. 2022) (affirming dismissal of excessive-fee claims because complaint

lacked "detailed allegations providing a sound basis for comparison") (quotation marks omitted); *Krutchen*, 2022 WL 16950264, at *3 (similar).

While the Amended Complaint includes allegations about the practices of a handful of other companies' health plans, AC ¶¶ 177–89, none of these allegations suggest that any plan of comparable size, scope, and benefit levels pays less than the J&J Plan for the entire suite of prescription drug services. Most of these allegations simply describe measures that other plans took that may have resulted in certain cost savings for those plans, but without any suggestion that any of these plans paid less in total or even per person than the J&J Plan for prescription drugs as a whole. Moreover, none of these allegations suggest that the measures taken by other companies are ones that are commonly taken by plan fiduciaries; on the contrary, many of the paragraphs reflect alternative approaches, but do not demonstrate that any specific approach is inherently imprudent. There is also no suggestion that these other companies' plans had the same level of benefits, coverage, access, or service as the J&J Plan. *See, e.g.*, *id.* ¶ 179 (carve-out for specialty drugs); *id.* ¶ 180 (use of a pass-through PBM). In short, these allegations fail to provide a meaningful benchmark that would allow this Court to infer that J&J had a defective process for choosing or negotiating with ESI.

That failure is especially telling because the Amended Complaint suggests that examples of comparable plans that paid less overall for a prescription drug

program should be easy to find. The Amended Complaint points out that there are alternative, pass-through PBMs that pass through their cost for prescription drugs and charge only administrative fees for running the whole program. *Id.* ¶ 56. The Amended Complaint even points to a few plans that have switched to pass-through PBMs. *Id.* ¶¶ 179–82, 184–87. However, the Amended Complaint does not demonstrate that these plans offer benefits that are comparable to those offered under the J&J Plan at a lower cost. If such plans paid less overall for a prescription drug program, Plaintiff should be able to point to a large number of comparable plans that paid less. But Plaintiff still has not been able to identify even a single plan, even after she amended her complaint in response to Defendants' same arguments in the original motion to dismiss. *See* Dkt. 40-1 at 17–22. And the notion that switching to a pass-through PBM automatically results in cost-savings is belied by the fact that there is no allegation suggesting this is or was a common practice during the alleged class period.

Finally, Plaintiff claims that participants may have suffered lost wages, but that theory fails for the additional reason that it impermissibly seeks extracontractual damages. *See Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 147–48 (1985) (ERISA Section 502(a)(2) does not permit recovery of extracontractual damages). Plaintiff's theory appears to be that if the costs of the Plan were lower, J&J would have to contribute less money to the Plan, and might

have used those saved funds to increase employees' wages. But the wages that a Plan sponsor pays to its employees are not Plan benefits or paid from Plan assets, making them extracontractual. This is not a case in which an agreement specifically required plan savings to be used to increase wages; here, the notion that savings might be used to increase wages is pure speculation.

Ultimately, Plaintiff's desired inference of imprudence is fundamentally implausible. J&J's fiduciary and corporate interests are wholly aligned to get the best overall deal at a reasonable cost. And J&J did so. There is no common-sense reason to believe the J&J Plan's fiduciaries would not try to obtain the best overall deal for the Plan. On the contrary, J&J has every incentive to negotiate the best overall deal for Plan services because as a corporation it bears the majority of the Plan's healthcare expenditures. *Cf. Thole*, 590 U.S. at 545 (employers "are often on the hook for plan shortfalls," so "the last thing a rational employer wants or needs is a mismanaged [benefits] plan").

Consistent with those incentives, the obvious alternative explanation for the fact that some drugs allegedly have high prices is that those prices were simply part of the best overall deal Defendants could negotiate for the thousands of drugs covered by the prescription drug program as a whole. *See Wesco*, 102 F.4th at 184 & n.3 ("[T]he Rules require dismissal when fiduciary defendants offer an alternative explanation for their conduct that is 'obvious,' 'natural,' or simply

'more likely' than the plaintiff's theory of misconduct.") (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 567–68 (2007); *White v. Chevron Corp.*, 752 F. App'x 453, 454–55 (9th Cir. 2018) (affirming dismissal of prudence claim because "[s]omething more is needed, such as facts tending to exclude the possibility that [defendants'] alternative explanation is true"). While Plaintiff need not rule out *every* possible explanation for those prices, she must do more than point to an arbitrarily selected handful of drugs in two discrete categories. That is simply not enough to raise an inference of imprudence.

B. Count III Should Be Dismissed Because Plaintiff Does Not Allege that She Made a Proper Request Under 29 U.S.C. § 1024(b)(4).

In Count III, Plaintiff claims that the Committee violated Section 104(b)(4) of ERISA, which requires plan administrators to furnish copies of certain plan documents "upon written request of any participant or beneficiary." 29 U.S.C. § 1024(b)(4). If the Plan administrator does not respond to such a written request within 30 days, then Section 502(c) and Department of Labor regulations provide that a participant may be entitled to a penalty of no more than $110 per day, with the decision of whether to award any penalty to be determined in the Court's discretion. 29 U.S.C. § 1132(c)(1); 29 C.F.R. § 2575.502c-1; *see also* AC ¶ 244. Here, Plaintiff alleges that she made two such requests. First, she claims that she requested a single document on December 20, 2023, before this lawsuit was filed,

and that she received the wrong document in response. AC ¶¶ 204–06. Second, she requested the Plan's agreement with ESI on March 4, 2024, after this lawsuit was filed. *Id.* ¶ 209.

This tempest-in-a-teapot claim should be dismissed because the Amended Complaint does not allege facts showing that Plaintiff's requests satisfied the statutory requirements to trigger a potential penalty.

As to Plaintiff's first request, the Amended Complaint does not allege sufficient detail. It alleges that Plaintiff made "a typewritten request through [an] online portal messaging system" on the website of a third-party plan administrator, Alight. *Id.* ¶ 204. Although "a typed request" can sometimes be enough, courts have required more "specific allegations about the manner in which [the plaintiff] submitted the[] request." *Bafford v. Northrop Grumman Corp.*, 994 F.3d 1020, 1029–30 (9th Cir. 2021) (discussing the "written request" requirement under another ERISA provision, 29 U.S.C. § 1025(a)); *see also McDonough v. Horizon Blue Cross Blue Shield of N.J., Inc.*, 2011 WL 4455994, at *7 (D.N.J. Sept. 23, 2011) (dismissing Section 104(b)(4) claim for failure to allege a written request); *Cohen v. Independence Blue Cross*, 820 F. Supp. 2d 594, 608–09 (D.N.J. 2011) (same).

As to Plaintiff's second request, the claim fails because the document that Plaintiff requested – the Plan's contract with ESI – is not required to be produced

under Section 104(b)(4). Plaintiff contends that the ESI contract is an "instrument[] under which the plan is established or operated" under Section 104(b)(4), but it is well-settled that not every contract with a plan qualifies, and there is no reason to conclude that the ESI contract is such an instrument. *See, e.g.*, *Penwell v. Providence Health & Servs.*, 2021 WL 1222663, at *4 (W.D. Wash. Mar. 31, 2021) (rejecting requests for "a complete set of each of the contracts or agreements between the Plans and each Network Provider").

CONCLUSION

For these reasons, the Court should dismiss the Amended Complaint.

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Respectfully submitted,

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