

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: EpiPen ERISA Litigation,

Civ. No. 17-1884 (PAM/HB)

**MEMORANDUM AND ORDER**

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This matter is before the Court on Plaintiffs’ Motion for Class Certification, and Defendants’ Motions to Exclude Expert Witnesses. For the following reasons, Plaintiffs’ Motion is denied, and Defendants’ Motions are denied without prejudice as moot.

**BACKGROUND**

A full background of this matter is set forth in the Order on the Motions to Dismiss, In re EpiPen ERISA Litig., 341 F. Supp. 3d 1015 (D. Minn. 2018), and will not be repeated here. Facts relevant to a resolution of the instant Motions are detailed below.

In June 2017, Plaintiffs brought this lawsuit against Defendants,<sup>1</sup> who are the nation’s four largest pharmacy benefit managers (“PBMs”). The Consolidated Class Action Complaint (Docket No. 196) alleges that, because Defendant PBMs negotiated for rebates, discounts, and other fees with Mylan Pharmaceuticals and related entities, who market and sell EpiPens, Plaintiffs and the classes they sought to represent were forced to

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<sup>1</sup> Defendants are CVS Health Corporation, CaremarkPCS Health L.L.C, Caremark L.L.C., Caremark Rx L.L.C. (collectively, “CVS Caremark”), Express Scripts Holding Company, Express Scripts, Inc., Medco Health Solutions, Inc. (collectively, “Express Scripts”), UnitedHealthGroup, Inc., UnitedHealthcare Services, Inc., Optum, Inc., Optum Rx Holdings, LLC, OptumRx, Inc. (collectively, “Optum”), and Prime Therapeutics, LLC.

pay more for those EpiPens. According to Plaintiffs, in failing to ensure that individual EpiPen purchasers received the benefit of the rebates or discounts, the PBMs violated fiduciary duties imposed by the Employee Retirement Income Security Act (“ERISA”). Plaintiffs’ lone remaining claim arises under ERISA § 404(a), which provides that “a fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries.” 29 U.S.C. § 1104(1)(1). Plaintiffs contend that the PBMs failed to act “solely in the interest of” Plaintiffs and all similarly situated participants in ERISA-regulated health plans that used Defendants’ services.

Plaintiffs assert that the rebates Defendant PBMs negotiated with Mylan increased from a relatively small percentage of the list price of EpiPens—for example, four percent under CVS Caremark’s 2006 contract with Mylan—to at times more than 50 percent of EpiPen’s list price in the 2018 contract between CVS Caremark and Mylan. And each PBM also often received an administrative fee—usually between three percent and five percent—from Mylan for each EpiPen purchased by a plan participant. As with the rebates, the administrative fees have generally increased over the last decade. Plaintiffs allege that these ever-increasing rebates, fees, and other payments caused the list price of EpiPens to rise, which in turn caused Plaintiffs’ coinsurance and deductible payments, based on the list price of EpiPens, to go up exponentially.

Although there are five Plaintiffs remaining in this action,<sup>2</sup> only four of those Plaintiffs brought the instant Motion for Class Certification. These putative class

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<sup>2</sup> The docket lists Plaintiff Amy M. Khan as an active party, but she is not included in the discussion of class representatives or otherwise mentioned in the parties’ briefing.

representatives are:

- Susan Illis, whose health plan received PBM services from the Optum Defendants. Illis's daughter has food allergies that require Illis to purchase EpiPens.
- Elan and Adam Klein, a married couple, who received health benefits from a plan that used Prime Therapeutics as its PBM. The Kleins' son has food allergies that require them to purchase EpiPens.
- Emil Jalonen, the personal representative of the estate of Leah Weaver, one of the original Plaintiffs in this matter. Ms. Weaver died in 2018; her daughter has food allergies that require the purchase of EpiPens. Ms. Weaver's health plan received PBM services from both Express Scripts Defendants and CVS Caremark during the period in question.

In the instant Motion, Plaintiffs seek the certification of four nationwide classes, one for each Defendant PBM. These classes are substantively identical, with the exception of the class period for each class. The proposed class definitions are:

All current or former participants in, or beneficiaries of, any ERISA plan who, at any time between [either April 2010 or January 2007] and the present, paid a deductible and/or percentage coinsurance payment for one or more EpiPen(s) processed through their ERISA Plan(s) for which [the PBM] received from Mylan, on behalf of itself or a client, a rebate or other fee.

(Pls.' Supp. Mem. (Docket No. 518) at 48-49.) Plaintiffs ask the Court to certify these classes under Rule 23(b)(1)(A), which provides for class certification when "prosecuting separate actions by . . . individual class members would create a risk of inconsistent of varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the class." Fed. R. Civ. P.

23(b)(1)(A). In the alternative, Plaintiffs argue that certification of the more typical opt-out class is appropriate under Rule 23(b)(3).

## DISCUSSION

### A. Class Certification Standards

Although the Court does not consider the merits of Plaintiffs' substantive claims in assessing a motion for class certification, Plaintiffs bear the burden of establishing each prerequisite element to certification. See Gen. Tel. Co. v. Falcon, 457 U.S. 147, 161 (1982). In rigorously analyzing whether Plaintiffs have met their burden, the Court "may look past the pleadings . . . [to] understand the claims, defenses, relevant facts, and applicable substantive law. . ." Thompson v. Am. Tobacco Co., Inc., 189 F.R.D. 544, 549 (D. Minn. 1999) (quoting Castano v. Am. Tobacco Co., 84 F.3d 734, 744 (5th Cir. 1996)); Coopers & Lybrand v. Livesay, 437 U.S. 463, 469 (1978) (noting that analysis of a class certification motion "generally involves considerations that are enmeshed in the factual and legal issues comprising plaintiff's cause of action"). Ultimately, because of the fact-specific quality of the analysis, the Court exercises broad discretion in determining whether to certify a class under Rule 23. See Reiter v. Sonotone Corp., 442 U.S. 330, 345 (1979); Coleman v. Watt, 40 F.3d 255, 259 (8th Cir. 1994).

Plaintiffs seeking to certify a class must initially establish that: (1) the class is so numerous that joinder of all the members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a). "A district court

may not certify a class until it ‘is satisfied, after a rigorous analysis,’ that Rule 23(a)’s certification prerequisites are met.” In re Target Corp. Customer Data Sec. Breach Litig., 847 F.3d 608, 612 (8th Cir. 2017) (quoting Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 351 (2011) (internal quotation marks omitted)).

**1. Rule 23(a)**

Defendants do not dispute that each of the proposed classes is sufficiently numerous to warrant class treatment. Defendants argue that the proposed classes do not meet Rule 23(a)’s commonality, typicality, and adequacy requirements. The failure of the class to meet any one of Rule 23(a)’s requirements means that class certification is not appropriate.

a. Commonality

Rule 23 does not require that all questions of law and fact be common to every member of the proposed class. But commonality means that the Plaintiffs’

claims must depend upon a common contention—for example, the assertion of discriminatory bias on the part of the same supervisor. That common contention, moreover, must be of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.

What matters to class certification . . . is not the raising of common “questions”—even in droves—but rather, the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation. Dissimilarities within the proposed class are what have the potential to impede the generation of common answers.

Wal-Mart Stores, 564 U.S. at 350 (quotation omitted, emphasis in original).

The elements of Plaintiffs’ claims are not in dispute. Plaintiffs must allege that Defendants were fiduciaries of Plaintiffs’ ERISA plans with respect to the rebates/discounts Defendants received from Mylan, that Defendants breached their

fiduciary duties to the ERISA plan participants, and that Plaintiffs were injured as a result of the breach. Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 594 (8th Cir. 2009). As every court to address class certification in this context has held, Plaintiffs cannot establish that proof of these elements will be common to the entire class, and class certification of the broad classes Plaintiffs seek is therefore inappropriate. E.g., In re Express Scripts, Inc., PBM Litig., No. 4:05-MD-1672, 2008 WL 2952787, at \*17-22 (E.D. Mo. July 30, 2008); Mulder v. PCS Health Sys., 216 F.R.D. 307, 312-16 (D.N.J. 2003).

i. Fiduciary Status

ERISA provides that an individual or entity is a “fiduciary with respect to a plan” when that individual or entity “exercises . . . discretionary control respecting management of such plan.” 29 U.S.C. § 1002(21)(A). Plaintiffs emphasize that plan documents need not give the fiduciary such control; it is enough that the fiduciary exercises control. But “the threshold question is not whether the actions of some person employed to provide services under a plan adversely affected a plan beneficiary’s interest, but whether that person was acting as a fiduciary (that is, was performing a fiduciary function) when taking the action subject to complaint.” Pegram v. Herdrich, 530 U.S. 211, 226 (2000). “ERISA does not regulate fiduciaries at large, but only with respect to a particular plan.” Mulder, 216 F.R.D. at 313 (quotations omitted). Whether the PBMs were performing any fiduciary function with respect to EpiPen discounts and rebates will depend almost entirely on the terms of the individual plans.

Defendants’ fiduciary status is not susceptible of class-wide proof. Defendant PBMs managed pharmacy benefits for thousands of plans, each with its own specific

provisions governing the PBMs' behavior. For example, many plans required the PBMs to pass along 100% of any negotiated rebate or discount from Mylan, and sometimes 100% of the PBM's administrative fee, to the plan itself. The plan could use that rebate or discount to lower premiums across the board for all plan participants or apply it to participants' pharmacy benefits to keep costs down, if it so desired.<sup>3</sup> In such a situation, the PBMs had no fiduciary authority over the "action subject to complaint"—the alleged failure to provide the discounts directly to those purchasing EpiPens. The authority to determine to whom the rebates were paid rested solely with the plan. Thus, each plan's terms will be relevant and indeed crucial to determining the PBMs' fiduciary status as to that plan. See In re Express Scripts, 2008 WL 2952787, at \*18 ("[T]o ascertain the existence of discretion and control (and, in turn, fiduciary duty), the Court must . . . comb through and interpret the parties' bargains on an individualized basis.") This is not commonality under any definition of the term.

Plaintiffs allege that the PBMs were fiduciaries because their "common conduct, including [their] ongoing efforts to negotiate and collaborate with Mylan to obtain rebates and fees on EpiPen purchases by plan participants, constitutes discretionary control over plan 'management' or 'administration.'" (Pls.' Supp. Mem. (Docket No. 518) at 54

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<sup>3</sup> Plaintiffs argue that the PBMs should have passed any negotiated rebate directly to EpiPen purchasers at the point of sale. But Plaintiffs ignore whether such a credit would benefit these Plaintiffs to the detriment of other plan participants, because the plans often use rebates to lower premiums or other costs for all participants. And in any event, each PBMs' contract with each plan set the requirements for application of rebates; it was not the PBMs' responsibility to force the plans to provide those rebates directly to purchasers, or to negotiate that requirement with their clients.

(quoting 29 U.S.C. § 1002(21)(A)).) But while Plaintiffs repeatedly invoke the alleged “common” contract between each PBM and Mylan, that “common” contract cannot give rise to the alleged breach of fiduciary duty without further inquiry into what each specific contract between the PBM and the insurers provided. See In re Express Scripts, 2008 WL 2952787, at \*11 (finding no fiduciary status for PBM’s negotiation of rebates with drug manufacturers); see also Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 463, 475-76 (7th Cir. 2007) (finding PBM not a fiduciary when negotiating rebates with drug manufacturers or paying those rebates to plans).

Each PBM’s contract with Mylan cannot provide commonality for Plaintiffs’ claims. Even if the PBMs “negotiated with [Mylan] with respect to every plan [they] serviced, [the PBMs’] “services” differed markedly from plan to plan.” Mulder, 216 F.R.D. at 314. And it is the services provided that are relevant to establish Plaintiffs’ breach-of-fiduciary-duty claim, not the contracts’ “general ‘structure, untethered to claims of concrete harm.’” Id. (quoting Pegram, 530 U.S. at 234). Indeed, the common contracts’ relevance depends on the existence of a fiduciary duty in the first instance; that contract cannot establish such a duty. Id. at 316 (declining class certification because the contract between PBM and a drug manufacturer did not establish existence of fiduciary duty).

Not only did the percentage of the rebates and fees payable to each plan differ, but each plan’s control over its PBM’s rebate program also varied widely. These considerations “would affect whether [the PBM] was acting as an ERISA fiduciary with respect to those activities and with respect to each plan.” Id. at 315. Because evaluating each PBM’s fiduciary status depends largely on the terms of the contract between the PBM

and each plan, and because the terms of those contracts are as varied as the entities entering into the contracts, there can be no common proof of the existence of a fiduciary duty.

As Defendants note, at the motion-to-dismiss stage, Plaintiffs focused on the contracts between the PBMs and ERISA plans as providing support for their claims. Now, Plaintiffs ask the Court to ignore these same contracts, contending that they are irrelevant to determine the threshold questions at issue. But Plaintiffs cannot escape that the PBM/client contracts are the foundation for their claims, and because they vary from client to client, are not amenable to classwide proof. As one Court stated in declining to certify a class that sought to challenge one Defendant's use of rebates, "the parties' contracts illustrate the myriad of considerations that may affect the PBMs' discretion and/or fiduciary duty." In re Express Scripts, 2008 WL 2952787, at \*21; see also In re Express Scripts, Inc., PBM Litig., No. 4:05-MD-1672, 2015 WL 128073, at \* (E.D. Mo. Jan. 8, 2015) (declining to find Rule 23(a) commonality because "[t]here are variations regarding how the contracts addressed rebates").

ii. Breach

Even assuming, however, that Plaintiffs could establish Defendants' fiduciary status by means of common proof, Defendants' alleged breaches of any fiduciary duties would not present a common issue. To determine whether any Defendant breached its fiduciary duties, the Court would be required to examine the contract between each PBM and its customers to determine the extent of the PBM's discretion in negotiating with Mylan, and whether the PBM exercised that discretion in a way contrary to the expectations of the plan and its participants. See Mulder, 216 F.R.D. at 315; see also id. at 316 (noting that the

contractual “provisions made different guarantees to plan beneficiaries (such as the percentage of rebates to be paid to the plan rather than retained by [the PBM]) and therefore set forth distinct obligations on the part of [the PBM]”). Whether any Defendant breached its alleged ERISA-imposed duties to Plaintiffs’ plans is not susceptible of classwide proof.

In addition, common proof cannot establish what Plaintiffs allege was the PBMs’ failure to use the rebates “solely in the interest of” plan participants. (Reply Mem. (Docket No. 658) at 17.) If a particular contract required the PBM to pass through to the plan 100% of the rebates received, and the plan used the rebates to reduce premiums for every plan participant, or to reduce prescription drug prices for every plan participant, then the rebates were in fact used solely in the interest of plan participants. Plaintiffs allege that by not negotiating lower prices for EpiPen rather than entering into the rebate/fee program, PBMs violated their fiduciary duties to plan participants. But what Plaintiffs in fact assert is that the PBMs violated their alleged fiduciary duties to the class, not to all participants in Plaintiffs’ plans. Many if not most plan participants did not purchase EpiPens but nevertheless would have received the benefit of the plan applying EpiPen rebates to lower premiums and/or prescription drug prices across the board. Plaintiffs do not explain how the Court or a jury could decide whose interests are primary in that situation. Moreover, without reference to plan documents, it is impossible to tell whether, as the PBMs argue, the interests of the putative class are the same as the interest of plan participants who are not members of the putative classes.

The individual inquiries necessary to determine the existence and breach of fiduciary duty make class certification inappropriate.

iii. Injury

Finally, Plaintiffs cannot establish the injuries they suffered as a result of the alleged fiduciary breaches on a classwide basis. Plaintiffs attempt to circumvent the glaring differences in each named Plaintiff's EpiPen-purchasing experience by seeking disgorgement of Defendants' alleged ill-gotten gains rather than individual damages on behalf of class members. According to Plaintiffs, the factfinder need only multiply the PBM participants' total EpiPen purchases and multiply that number by the rebate each PBM negotiated with Mylan. Equity does not allow disgorgements of all profits but only those profits inequitably retained. Whether it was inequitable for any Defendant to retain a portion of the rebates or other fees will require reference to the contracts between each PBM and each plan. Despite Plaintiffs' arguments to the contrary, whether a PBM passed through a percentage of the Mylan rebates or the entire amount of the rebate will determine what profits would be subject to forfeiture. Indeed, what the plan contracts provided with respect to retention of rebates and other discounts is essential to determining the existence of injury, even before any determination of the amount of that injury.

iv. Conclusion

Plaintiffs have not demonstrated that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(1). "As directed by Rule 23 and applicable case law . . . class certification is not proper until all of Rule 23's prerequisites are met." In re Baycol Prods. Litig., 218 F.R.D. 197, 203 (D. Minn. 2003) (Davis, J.) (emphasis in original). Plaintiffs' Motion for Class Certification must be denied.

**B. Daubert**

Defendants ask the Court to exclude two of Plaintiffs' expert witnesses, Dr. Stephen W. Schondelmeyer and Dr. Stephan M. Levy. Because these expert witnesses offer testimony in support of Plaintiffs' Motion for Class Certification and the Court has determined that class certification is inappropriate, Defendants' Motions to Exclude those witnesses are moot. Defendants may renew their Daubert challenges to these experts' testimony if that testimony will be presented to the jury.

**CONCLUSION**

Accordingly, **IT IS HEREBY ORDERED that:**

1. Plaintiffs' Motion for Class Certification (Docket No. 517) is **DENIED**;
2. Defendants' Motion to Exclude Expert Testimony of Dr. Stephen W. Schondelmeyer (Docket No. 688) is **DENIED without prejudice**; and
3. Defendants' Motion to Exclude Expert Testimony of Dr. Stephan M. Levy (Docket No. 694) is **DENIED without prejudice**.

Dated: August 5, 2020

*s/ Paul A. Magnuson*  
Paul A. Magnuson  
United States District Court Judge