UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	**Case No. 1:17-md-2804-DAP**
This document relates to:	)	**Judge Dan Aaron Polster**
County of Webb v. Purdue Pharma, L.P. et al. **Case No. 1:18-op-45175-DAP (N.D. Ohio)**	)	
Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund, et al. v. Purdue Pharma L.P., et al. **Case No. 1:18-op-45446-DAP (N.D. Ohio)**	)	

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR LEAVE TO FILE JOINT MOTION FOR PRELIMINARY INJUNCTIVE RELIEF

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INTRODUCTION

The PBM Defendants[1] would have this Court believe that their role in the opioid crisis is passive. They portray themselves as hapless bystanders to the epidemic – mere claims processors, incapable of influencing the massive quantities of life-threatening opioid drugs being prescribed, distributed, reimbursed, and dispensed to the public. But the PBM Defendants are not bystanders. They manage prescription drug pharmacy benefits for nearly 90% of Americans and create standard national formularies that undergird reimbursement and dispensing requirements for every opioid prescription at issue in every case that has been filed in this multidistrict litigation and nationwide. Their opposition is a study in smokescreens and misinformation. *See* PBM Defs.' Obj. and Opp'n to Pls.' Mtn. for Leave to File Joint Mtn. for Prelim. Inj. Relief (ECF No. 67) ("PBM Opp'n").

The PBMs oppose a motion whose sole purpose is to establish the CDC Guideline as a baseline for standard PBM formularies. In every other environment, the PBMs have explicitly embraced the CDC Guideline as precisely that. *See* Mem. of Law in Supp. of Joint Mot. for Prelim. Inj. Relief ("Pls.' MOL") (ECF No. 45-3) at 10-13; Decl. of Joanne Cicala in Supp. of Joint Mot. for Prelim. Inj. Relief ("Cicala Decl.") (ECF No. 45-4) Exs. H-1 at 4; K-4 at 1; N-3 at 2. As a group of executives of one of the PBM Defendant's explain:

> [I]n the face of [the opioid] crisis . . . , we believe it is time to give greater weight to the CDC Guideline – based on patient care and safety. ***The CDC Guideline should become the default approach to prescribing opiates, a scenario in which physicians would have to seek exceptions for those patients who need more medication or longer duration of therapy. What is more, pharmacy benefit managers are better placed than others in the pharmacy supply chain to put this approach to the CDC Guideline into practice.***[2]

[1] The PBM Defendants are Caremark Rx, L.L.C.; CaremarkPCS Health, L.L.C.; Caremark, L.L.C.; and CaremarkPCS, L.L.C. (collectively, "Caremark"); Express Scripts, Inc. ("Express Scripts"); and OptumRx, Inc. ("OptumRx").

[2] Troyen Brennan (Executive Vice President and Chief Medical Officer of CVS Health), Richard Creager, Jennifer M. Polinski (Sr. Director, Evaluation and Public Health Analytics, CVS Health), *Pharmacy Benefit Management of*

When given an opportunity to make good on their public statements in this Court, the PBMs backtrack:

- The PBMs claim that the CDC Guideline is merely voluntary, and is intended only for physicians, not PBMs. PBM Opp'n at 3. Elsewhere, however, each of them expressly embraces the CDC Guideline as the appropriate standard for their opioid formulary treatment and related services. Pls.' MOL at 12-13. For example, Defendant OptumRx has stated that "[a]mong OptumRx members, approximately 65% of those who are prescribed a short acting opioid are considered new to therapy. Of these, 46% **are not in compliance with CDC prescribing guidelines**."[3] OptumRx goes on to describe how the PBMs' sophisticated analytics can help it "target the right people" among its members to assist.[4]

- The PBMs argue that their new and belatedly-launched commercial opioid management programs are consistent with the CDC Guideline (PBM Opp'n at Sec. IV) but do not specifically dispute ***any*** of Plaintiffs' details as to how those new programs fall short in critical areas such as requiring that non-opioid therapy be used before opioid therapy and, if opioids are prescribed, ensuring that the daily morphine equivalent dose not exceed 50 MME. Pls.' MOL at 14-23.

- The PBMs claim that they merely provide "formulary and other services to their clients" and "do not control their clients' formularies" (PBM Opp'n at 2-3), when their own opposition confirms that every client begins with the PBMs' standard baseline formularies that are the focus of Plaintiffs' motion. *See id.* at 7.

- The PBMs suggest to this Court that they operate pursuant to "thousands of individual contracts" (PBM Opp'n at 2) that are customized and varied, when they know that the vast majority of benefits – covering tens if not hundreds of millions of Americans – are governed by their standard formularies,[5] and when they themselves create powerful financial disincentives against deviation from those formularies. *See infra* at 7-8.

Opioid Prescribing: The Role Of Employers And Insurers, HEALTH AFFAIRS (Sept. 21, 2017) https://www.healthaffairs.org/do/10.1377/hblog20170921.062092/full/ (emphasis added).

[3] *See Opioid epidemic: Deflecting the curve*, OPTUM, https://www.optum.com/resources/library/deflecting-the-curve.html?s=rxopioid (last visited Nov. 19, 2018) (emphasis retained from original).

[4] *Id.*

[5] *See* Pls.' MOL at 19 ("more than 27 million [members] obtain their pharmacy benefit coverage through one of Express Scripts' standard formularies and more people use the [Express Scripts'] National Preferred Formulary than any other formulary in the U.S."); *see also CVS Health Announces 2018 Formulary Management Strategy*, CVS HEALTH (Aug. 1, 2017) cvshealth.com/thought-leadership/cvs-health-announces-2018-formulary-management-strategy ("[o]ur range of managed commercial formularies, including Standard Control Formulary, covers more than 31 million members.").

- The PBMs resist the notion that they are "gatekeepers" to prescription opioid medications (PBM Opp'n at 2-3), while elsewhere touting their ability to influence opioid utilization. Pls.' MOL at 6-7; Cicala Decl. Exs. H-3 at 1; K-4 at 1; N-1 at 1.

- The PBMs tell this Court that Plaintiffs misapprehend the CDC Guideline and that the CDC Guideline is directed only to primary care clinicians (PBM Opp'n at Sec. III) while simultaneously advertising that they provide services consistent with CDC Guideline. Cicala Decl. Exs. H-1 at 4; H-3 at 1; K-4 at 1-2; N-1 at 1; N-3 at 2-3.

- The PBMs tell this Court that they do not "distribute" or "sell" opioids (PBM Opp'n at 1), when their mail order pharmacies do both. *See* Pls.' MOL at 3-4.

- The PBMs claim that their "efforts to address opioid misuse and abuse remain one of the highest clinical priorities for each PBM" (PBM Opp'n at 1), even while their 2019 standard formularies award Oxycontin, one of the most highly addictive opioids, "preferred alternative" status for the Long-Acting Opioid Oral Analgesics drug class.[6]

Overall, the PBMs seek to minimize the pivotal role they have played in helping fuel the opioid crisis. They endeavor to portray themselves as mere claims administrators, subservient to physician orders and employer and health plan pharmacy benefit design. But the PBMs' own representations to their customers and investors reveal this is simply false. When not opposing Plaintiffs' motion, the PBMs cast themselves as change agents, who can improve the quality of drug use through patient screening and assessment, patient and provider education, and disease management programs. Cicala Decl. Exs. F-2, I-2, I-3, H-3, L, K-4, N-1. When courting customers and investors, they advertise themselves as organizations that can improve patient safety by maintaining comprehensive prescription records and implementing drug utilization reviews and alerts. *Id.* Exs. H-3, K-1, K-2, L, N-1, N-2, N-3. For nearly 90% of the United States population,

[6] *See 2019 National Preferred Formulary Exclusions*, EXPRESS SCRIPTS, https://www.express-scripts.com/art/pdf/Preferred_Drug_List_Exclusions2019.pdf; *Formulary Drug Removals*, CVS CAREMARK (Jan. 2019) crewconnect.vanguard.com/totalrewards/benefits/healthandwellness/prescription/drug_removals_list_2019.pdf, and *Jan. 1, 2019 Premium Formulary Exclusions*, OPTUMRX (2018) www.princeton.edu/hr/benefits/oe/communications/2019OptumRxFormularyExclusions.pdf.

PBMs claim to "provide pharmacy care that is clinically sound,"[7] "ensure that [they] provide access to safe and effective medications"[8] and help their customers "achieve better health outcomes."[9] And this is precisely the role the CDC Guideline contemplates for PBMs when calling for "identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans." Cicala Decl. Ex. B at 34. The PBMs' suggestion of passivity is absurd and would be a shock to all who have hired them.

Nor are their legal arguments any more convincing. They overstate the degree of success the law requires Plaintiffs to show and brush aside the Plaintiffs' clear demonstration of "serious questions going to the merits and irreparable harm which decidedly outweighs any potential harm to the defendant if the injunction is issued." Pls.' MOL at 26-29. The PBMs' remarks on irreparable injury are also misleading, claiming Plaintiffs have "offered no evidence" that the relief sought would have an impact on the crisis when the PBMs' own marketing materials extoll the benefits of their new inadequate opioid management programs. Pls.' MOL at 6-7. They could do far more if they used their undeniable market power to offer baseline formularies that fully tracked the CDC Guideline. *Id.* at 7. Moreover, the PBMs are virtually silent on the issue of harm flowing to them, and otherwise only identify illusory harm to providers and plans who can, respectively, satisfy or opt out of these controls with little administrative burden. The PBMs themselves acknowledge this, just not to this Court.[10] Because the relief sought is tailored to help abate perhaps the most severe public health crisis the country has ever faced, Plaintiffs readily meet their burden on this motion.[11]

[7] Cicala Decl. Ex. F-2 (CVS Caremark, *Formulary Development and Management at CVS Caremark*) at 1.
[8] *Id.* Ex. I-3 (Express Scripts, *Smart Formulary Management*) at 2.
[9] *Id.* Ex. N-3 (OptumRx, *OptumRx Opioid Risk Management*, 2018) at 4.
[10] *See Pharmacy Benefit Management of Opioid Prescribing: The Role Of Employers And Insurers*, *supra* note 2.
[11] When seeking a preliminary injunction, "[i]n general, the likelihood of success that need be shown will vary inversely with the degree of injury the plaintiff will suffer absent an injunction." *In re DeLorean Motor Co.*, 755 F.2d 1223, 1229 (6th Cir. 1985)

In the end, the Plaintiffs seek an injunction requiring that the PBMs implement formulary edits endorsed by the CDC that will help achieve this Court's objective to put "an effective system in place to monitor the delivery and distribution" of opioids. Tr. of R. at 5:9-10 (Jan. 9, 2018) (ECF No. 71). The PBMs' present resistance to a proposition they have themselves advanced elsewhere is entirely inconsistent with the assurance that they "share the Court's concern about prescription opioid abuse and addition." PBM Opp'n at 1. The PBMs have told the world they are "uniquely positioned to help address the opioid epidemic." Cicala Decl. Ex. N-2 at 9. It is time for them to do that.[12]

ARGUMENT

I. PLAINTIFFS' MOTION SATISFIES THE LEGAL STANDARD IN THIS CIRCUIT FOR INJUNCTIVE RELIEF

"Rule 65 normally requires the court to balance four familiar preliminary injunction factors: (1) the likelihood of success on the merits; (2) irreparable harm absent injunctive relief; (3) substantial harm to others from the proposed injunction; and (4) the broader public interest." *NCUA Bd. v. Jurcevic*, 867 F.3d 616, 622 (6th Cir. 2017). In this analysis, "[a] showing of 'probable irreparable harm is the single most important prerequisite.'" *Lucero v. Detroit Pub. Sch.*, 160 F. Supp. 2d 767, 801 (E.D. Mich. 2001) (quoting *Reuters Ltd. v. United Press Int'l., Inc.*, 903 F.2d 904, 907 (2d Cir. 1990)). Where this factor tips in plaintiffs' favor, it is "sufficient" to grant a preliminary injunction "if the plaintiff has raised questions going to the merits so serious, substantial, difficult, and doubtful as to make them a fair ground for litigation and thus for more deliberate investigation."[13]

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[12] The PBMs also contend that the relief sought by Plaintiffs' motion will interfere with the orderly process established by the Court. But Case Management Order One (ECF No. 232) requires a motion for leave prior to the filing of non-authorized motions and that is what Plaintiffs filed. This argument is a red herring and should be ignored.

[13] *Ne. Ohio Coal. v. Husted*, 696 F.3d 580, 591 (6th Cir. 2012) (quoting *Six Clinics Holding Corp. II v. Cafcomp Sys.*, 119 F.3d 393, 402 (6th Cir. 1997)); *see Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991).

A. The Plaintiffs Raise Serious Questions Going to the Merits and Are Likely to Succeed

The PBMs assert that Plaintiffs "do not even attempt" to satisfy the first factor of the test for preliminary injunction standard and ignore controlling authority (PBM Opp'n at 2), but it is the PBMs who have committed these errors, relying on mere semantics and unsupported assertions. Defendants' authorities establish only that injunctive relief is improper when a plaintiff has shown *no* likelihood of success on the merits.[14] But as Plaintiffs established in their opening brief, this Court may grant a preliminary injunction:

> [E]ven where the plaintiff fails to show a strong or substantial probability of ultimate success on the merits of his claim, but where he at least shows serious questions going to the merits and irreparable harm which decidedly outweighs any potential harm to the defendant if an injunction is issued.

Friendship Materials, Inc. v. Mich. Brick, Inc., 679 F.2d 100, 105 (6th Cir. 1982).[15] And, *in arguendo*, even if this were not sufficient, Plaintiffs' motion demonstrates a likelihood that core elements of their claims against the PBM Defendants will succeed on the merits. *Cf. Six Clinics Holding Corp., II v. Cafcomp Sys., Inc.*, 119 F.3d 393, 402 (6th Cir. 1997) (finding it was "not necessary to evaluate" the plaintiff's likelihood of success in proving breaches of fiduciary duty where plaintiff "demonstrated a likelihood of success on the central issue" of the defendant's fiduciary status).

To begin, were any case to present "serious, substantial, [and] difficult" questions that require deliberate investigation," it is this one. *Ne. Ohio Coal.*, 696 F.3d at 591. This Court said as

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[14] *See, e.g., Hall v. Edgewood Partners Ins. Ctr., Inc.*, 878 F.3d 524, 527 (6th Cir. 2017) ("As long as there is *some* likelihood of success on the merits, [the preliminary injunction] factors are to be balanced, rather than tallied.").

[15] As the Sixth Circuit itself has repeatedly observed, the "apparent disparity in the wording of the standard" – such as the inconsistent reference to a strong or substantial likelihood of success – merely reflects the circumstance that no single factor is determinative as to the appropriateness of equitable relief. . . . In general, the likelihood of success that need be shown will vary inversely with the degree of injury the plaintiff will suffer absent an injunction." *In re DeLorean Motor Co.*, 755 F.2d at 1229 (quoting *Metro. Detroit Plumbing & Mech. Contractors Ass'n v. Dep't of HEW*, 418 F. Supp. 585, 586 (E.D. Mich. 1976)); *see also Roth v. Bank of Commonwealth*, 583 F.2d 527, 537-38 (6th Cir. 1078)) (quoting same).

much at the January 2018 hearing, where it acknowledged the "interesting" and "complicated" legal questions and theories at play (Tr. of R. at 4:21-23 (Jan. 9, 2018)), stated that it was "not inclined to tackle legal issues without a full factual record" that would take significant time and resources to develop (*id.* at 12:15-16), but also made clear that its "objective is to do something meaningful to abate this crisis and to do it in 2018." *Id.* at 4:24-25. In other words, this crisis requires action now even if it will take far longer to fully resolve the pending litigation. Motions for preliminary injunction provide a tool in just such circumstances. At this stage, the Court is not required to "'resolv[e]' hotly contested issues of law," nor – reasonably – do Plaintiffs ask it to. *Nokes v. Miami Univ.*, 2017 U.S. Dist. LEXIS 136880, *26-27 (S.D. Ohio Aug. 25, 2017).

The centrality of the PBM Defendants to this multidistrict litigation cannot be overstated.[16] The PBMs do not, and cannot, dispute that they manage prescription drug benefits for nearly 90% of the U.S. population. Pls.' MOL at 1. Their argument that they do not "control" formularies because their clients may have the right to modify the standard offerings and thus do not serve as gatekeepers, therefore, is specious. It is also irrelevant to the relief requested in this motion, which focuses on PBMs' standard formulary offerings. The relief sought would merely guarantee that, when it comes to standard formularies, (and borrowing Caremark's executives' own language), "the CDC Guideline should become the default approach to prescribing opiates." *Pharmacy Benefit Management of Opioid Prescribing: The Role Of Employers And Insurers, supra* note 2. Conceding Plaintiffs' account in their moving papers (Pls.' MOL at 3-5, 13-23), the PBMs admit that they "develop a variety of standard national formularies that they make available to plan

[16] The fact that the Plaintiffs' Executive Committee chose not to name the PBMs should not distract from the reality of the PBMs' essential and embedded role in the pharmaceutical supply chain and the seriousness of the questions presented. Like all the other MDL defendants, the PBMs play a critical role in the supply of opioids to patients; no opioid would be reimbursed were it not on a PBM formulary.

sponsors," and that these serve as a starting point for all customers. PBM Opp'n at 7. But they do not disclose to the Court how routinely customers tend to adopt those standard formularies,[17] nor how routinely PBMs create disincentives against deviation from a standard formulary.[18]

Furthermore, as Plaintiffs also previously established, the PBMs have explicitly recognized their influential role in maintaining patient safety and, specifically, curtailing the opioid epidemic. For example, the PBMs have stated that their recently launched – but nonetheless inadequate – opioid management programs can "make a significant impact" on patient safety (Cicala Decl. Ex. K-4 at 2) and "help address the opioid epidemic." *Id.* Ex. N-2 at 9. The following statement from Caremark is consistent with these and other examples in Plaintiffs' moving papers:

> As the adverse consequences resulting from opioid misuse became apparent, employers sought the help of pharmacy benefit managers which responded by developing prospective (i.e., pre-dispensing) and retrospective utilization review programs to detect and intervene in unsafe prescribing of these addictive medications. Patients and prescribers who were engaged in unsafe behavior were identified and educated. Other interventions, in the form of member-specific drug limits, dispensing restricted to a single pharmacy, and prior authorization to ensure use for an appropriate diagnosis, were implemented – all programs shown to reduce opioid abuse. These programs had positive effects . . . .[19]

The CDC Guideline itself also expressly references the PBMs' embedded role as a partner in pain management and safe prescribing:

> CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic

[17] *See* Pls.' MOL at 19 ("more than 27 million [members] obtain their pharmacy benefit coverage through one of Express Scripts' standard formularies and more people use the [Express Scripts'] National Preferred Formulary than any other formulary in the U.S."); *see also CVS Health Announces 2018 Formulary Management Strategy*, CVS HEALTH, Aug. 1, 2017, cvshealth.com/thought-leadership/cvs-health-announces-2018-formulary-management-strategy ("[o]ur range of managed commercial formularies, including Standard Control Formulary, covers more than 31 million members.").

[18] *See* Adam J. Fein, Ph.D., *Optum, Aetna, Cigna and Prime Therapeutics Join the PBM Formulary Exclusion Party*, Drug Channels, Dec. 2, 2015, www.drugchannels. net/2015/12/optum-aetna-cigna-and-prime.html ("Formulary restrictions have emerged to block access to specific products. The restrictions affect the PBM's national formulary. Plan sponsors—the PBM's clients—that do not adopt the standard formulary face reduced rebates and/or higher plan costs.").

[19] *See Pharmacy Benefit Management Of Opioid Prescribing: The Role Of Employers And Insurers*, *supra* note 2.

> health records to assist clinicians' treatment decisions at the point of care; **identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans**; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice.[20]

If the PBMs had no control over the distribution of opioids, why do they and others tout the important role they can play in abating the opioid crisis? The PBMs' conflicting self-portrayals, in which their description of marketplace influence depends on their audience, unmistakably raise serious questions going to the merits.

Furthermore, even beyond the serious questions at issue in this litigation, Plaintiffs' injunction motion shows how PBMs have publicly defended their formulary placement practices while well aware that edits such as those requested here would likely reduce the flow of opioids to patients who should not be taking them. This conduct closely tracks core allegations of Plaintiffs' complaints, and "a party need only demonstrate a likelihood of success on the merits on the 'central issue' of a party's claims in order to satisfy this prong." *Skurka Aerospace, Inc. v. Eaton Aerospace, L.L.C.*, 781 F. Supp. 2d 561, 565 (N.D. Ohio 2011).[21]

B. The Plaintiffs and Broader Public Will be Irreparably Injured Without Action

At the beginning of these proceedings in January, this Honorable Court acknowledged that: "[w]hat's happening in our country with the opioid crisis is present and ongoing," and because of this crisis, "about 150 Americans are going to die today, just today[.]" Tr. of R. at 4:1-5 (Jan. 9, 2018). For this, the Court recognized that "everyone shares some of the responsibility, and no one

[20] Cicala Decl. Ex. B at 34 (emphasis added).

[21] As but one example, Plaintiff Webb County's Public Nuisance counts against the PBM Defendants allege, *inter alia*, that the PBM Defendants "knowingly, intentionally, recklessly and/or negligently failed to manage and/or monitor these plans to minimize the use and abuse of opioids" (Compl. ¶379); "knowingly and intentionally chose to include opioids on their formularies that were more addictive to users," (Compl. ¶ 380); and "knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse." (Comp. ¶386).

has done enough to abate it." *Id.* at 4:6-7. The Court was not without hope, however, expressing confidence that steps could be taken this year "to dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed" and to "make sure that the pills that are manufactured and distributed go to the right people and no one else[.]" *Id.* at 5:4-9.

The PBMs should not be excepted from this process, particularly given their statements to this Court that "efforts to address opioid misuse and abuse remain one of the highest clinical priorities for each PBM" and that they "share the Court's concern about prescription opioid abuse and addiction." PBM Opp'n at 1. Indeed, avoidance of further irreparable harm in this crisis ***requires*** the PBMs' shared prioritization and concern. But it is evident here that the PBMs' statements of concern ring hollow, as they resist taking the additional steps to tighten controls on opioid use and expand access to medication assisted treatment that are necessary for their standard formularies to be fully consistent with the CDC Guideline. As shown below, each PBM fails to refute ***any*** of Plaintiffs' examples of how each of its new standard commercial opioid management program fails to meet CDC standards and thereby effectively concedes that its program's purported alignment with the CDC Guidelines is inadequate. *See* Pls.' MOL at Sec. II.B(3).

Caremark does not dispute that its new opioid management program, launched nearly two years after the CDC Guideline was issued:

- Does not require step therapy prior to coverage of immediate release ("IR") opioids, as recommended by the CDC Guideline;
- Does not impose a 3-day limit for treatment of acute pain, as recommended by the CDC Guideline;
- Does not require prior authorization for up to 90MME daily, despite CDC Guidance that dosages at that level "should be avoided";
- Does not cover the higher-strength prescription dosages of the following nonopioid pharmacological options, useful in many step therapies: ibuprofen, topical lidocaine, amitriptyline, doxepin, desipramine, diflunisal, choline magnesium

trisalicylate, salsalate, etodolac, sulindac, indomethacin, celecoxib, meclofenamate and nabumetone; and

- Places no restrictions on the use of opioids outside of active care, end of life, and palliative care.

See Pls.' MOL at 14.

Express Scripts likewise does not dispute that it:

- Charges its customers for its new opioid management program;
- Has not installed an opioid management program across the board to all customers;
- Does not require prior authorization for IR opioids;
- Permits up to 200 MME daily without prior authorization;
- Does not impose a three-day limit for treatment of acute pain;
- Does not require step therapy prior to coverage of IR opioids; and
- Allows access to virtually every opioid analgesic on every ESI formulary available through its mail order pharmacy.

Id. at 21.

Finally, OptumRx does not dispute that it:

- Requires prior authorization for only some opioids that are placed on a limited number of commercial formularies;
- Does not require step therapy for IR opioids;
- Does not impose a 3-day limit for treatment of acute pain;
- Does not advise against patients' use of opioids to treat chronic pain;
- Permits patients who are not new to opioid therapy to receive 90 MME per day; and
- Charges its customers for its opioid management program.

Id. at 22-23.[22]

[22] OptumRx's opposition misquotes Plaintiffs as arguing its "standard formularies have 'no limits whatsoever surrounding the coverage of opioids" (a statement which OptumRx says is false). PBM Opp'n at 17. But Plaintiffs said that OptumRx's "generic centric formulary appears to have no limits whatsoever surrounding the coverage of opioids." Pls.' MOL at 22. OptumRx does not dispute that statement.

The relief requested by this motion seeks material changes to the PBMs' standard formularies that track closely to these deficiencies. Absent these changes, the PBMs' practices will continue to leave individuals at serious risk of addiction, overdose and – the most irreparable of all harms – death. For example:

- While the PBMs highlight their seven-day supply limits (PBM Opp'n at 13, 16, 18), research shows that the risk of long-term opioid use increases sharply after a mere five days of use.[23]

- While the PBMs allow dosages of up to 90–200 MME/day without prior authorization (PBM Opp'n at 14, 15, 18), the CDC Guideline itself highlights a study showing the hazard ratio for any overdose events more than doubling from 1.44 for 20–49 MME/day to 3.73 for 50–99 MME/day. Cicala Decl. Ex. B at 10.

- While the PBMs allow dosages of up to 90-200 MME/day without prior authorization, a Veterans Health Administration study found that chronic pain patients "who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day.)" *Id*. at 13.

- While the PBMs erect barriers to patients' access to opioids management programs such as by charging customers to use the programs, research shows that medication-assisted treatment can save lives but remains underutilized, in part because of insurance barriers.[24]

All of the foregoing research is consistent with Duke University's findings in February 2018 that "PBM strategies built on the CDC Guideline" are often compromised by "serious flaws or limitations" that reduce their effectiveness. [25] The Duke study specifically concluded that these

[23] Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66 MORBIDITY & MORTALITY WEEKLY REPORT 265 (March 17, 2017). https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s_cid=mm6610a1_w.

[24] *Medication-Assisted Treatment Improves Outcomes for Patients with Opioid Use Disorder*, THE PEW CHARITABLE TRUSTS (Nov. 2016), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder.

[25] Katie Greene et al, *Strategies for Promoting the Safe Use and Appropriate Prescribing of Prescription Opioids*, DUKE MARGOLIS CENTER FOR HEALTH POLICY (Feb. 15, 2018) https://healthpolicy.duke.edu/sites/default/files/atoms/files/landscape_analysis_-_opioid_safe_prescribing_strategies.pdf at 24.

deficiencies cause PBMs to overstate the impact of their programs "on outcomes beyond short-term prescribing measures, including cost-effectiveness or outcomes related to patient care."[26]

In short, continued inaction by the PBMs to address the shortfalls in their standard formularies will cause irreparable injury to Plaintiffs and the greater public, as overdose deaths continue unabated and more individuals, families, and communities are swept into the scourge of addiction. Certainly, there can be no dispute that addiction and death constitute irreparable injury in its gravest form.[27] The injury to the Plaintiffs in this multidistrict litigation is likewise substantial and will not be "fully compensable" by any eventual money damages. *Basicomputer Corp. v. Scott*, 973 F.2d 507, 511 (6th Cir. 1992). For example, in Webb County, like many other cities and counties across the nation, fiscal strain on governmental functioning caused by the opioid crisis will have lasting and even permanent negative effects.[28] As the country has seen occur in Flint, Michigan, public health crises can exacerbate fiscal crises and these effects are long-lasting and difficult to quantify.[29]

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[26] *Id.*

[27] *See, e.g.*, *Blum v. Caldwell*, 446 U.S. 1311, 1315-16 (1980) (declining to stay an injunction that would cost the state $150 million per year when "[o]n the other side of the balance are the life and health of the members of this class"); *Concerned Pastors v. Khouri*, 844 F.3d 546, 549 (6th Cir. 2016) ("Flint residents continue to suffer irreparable harm from the lack of reliable access to safe drinking water."); *Hadix v. Caruso*, 2005 U.S. Dist. LEXIS 25295, *19, 2005 WL 2671289 (W.D. Mich. Oct. 19, 2005) ("The observable consequence of the deficient medical care at issue have been avoidable death, illness, pain and aggravation of disease. As a matter of law, such injuries constitute irreparable injury.").

[28] Webb County alleged in its Complaint that it "has been required to allocate substantial public monies and resources to combat the opioid crisis in Webb County and deal with its fall out." Compl. ¶165 (ECF No. 1); *see also* Compl. ¶¶166-181. Even if Webb's expenditures can be calculated and repaid in the form of damages, the money was and continues to be taken away from other public uses, the harm to which is not readily calculable. *See Basicomputer Corp.*, 973 F.2d at 511.

[29] Paul Egan & Kathleen Gray, *Budget director: Flint water crisis impact unknown*, DETROIT FREE PRESS (updated Jan. 15, 2016, 10:28 AM), https://www.freep.com/story/news/local/michigan/2016/01/13/budget-director-flint-water-crisis-impact-unknown/78741892/.

C. Neither PBMs, Plans, nor Providers Will Suffer Substantial Harm

The PBMs offer nothing of any weight on the other side of the scale, making only cursory reference to administrative costs they might incur and otherwise advancing a flimsy argument about burden to plans and providers.

Already having publicly embraced the CDC Guideline, the PBMs' perfunctory reference to administrative burdens is unconvincing. However insufficient the steps they have already taken are in substance, the PBMs have failed to show how the additional steps proposed by Plaintiffs' motion would add significant cost to their operations, much less be cost-prohibitive. For example, how does the requirement that non-opioid therapy be used before opioid therapy amount to a meaningful burden when the CDC Guideline makes clear that opioid therapy should be a last resort? Cicala Decl. Ex. B at 16-19. And, if opioids are prescribed, why not ensure that the daily morphine equivalent dose does not exceed 50MME in the ordinary course, given the extraordinary risks of addiction and overdose at higher levels? *Id.* at 16.

PBMs' protestations to the contrary, the requested relief also would not burden plans or bar patients from receiving or doctors from prescribing medically necessary care. Rather, it simply seeks to change the **default rules** for opioid coverage to ensure they are consistent with the CDC's recommendations for physician prescribing, and to make addiction and overdose treatments more accessible. Plans that do not wish to implement these changes are free to opt out. And while the changes require providers to take some additional steps in order to deviate from the default opioid prescribing practices recommended by the CDC, this is precisely the point of the CDC Guideline. Caremark's own executives have stated that:

> [P]rescriber autonomy and respect for the physician-patient relationship are of paramount importance. However, there is little evidence to show that past opioid

> prescribing habits are necessary or appropriate, and there is a great deal of evidence that they have produced significant harm.[30]

The PBMs hinge their opposition on the hope that this Court will believe imposition of formulary controls in the form of quantity limits, step therapies, and prior authorization requirements unduly burdens clinician prescribing practices even though PBMs implementation of such controls for a wide range of drugs is inherent in formulary construction. Providers are well-versed in these basic protocols, and the minor expenditures of "time and energy" that the requested changes will impose on them are far from enough to show "substantial harm." *Concerned Pastors for Soc. Action v. Khouri*, 217 F. Supp. 3d 960, 978-979 (E.D. Mich. 2016) (internal brackets and quotation marks omitted) (quoting *United States v. Edward Rose & Sons*, 384 F.3d 258, 264 (6th Cir. 2004)).[31]

CONCLUSION

Plaintiffs' motion identifies critical steps towards stemming this crisis and should be granted. This is a case, like the one in Flint, Michigan, where "the public interest at stake . . . is fundamental." *Concerned Pastors for Soc. Action*, 217 F. Supp. 3d at 979 (quoting *United States v. Alisal Water Corp.*, 431 F.3d 643, 656 (9th Cir. 2005)). In such circumstances, "equitable powers assume an even broader and more flexible character than when only a private controversy is at stake." *Id.* (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398, 66 S. Ct. 1086, 90 L. Ed. 1332 (1946)). Plaintiffs respectfully submit that the real potential for the relief sought herein to help stem this crisis is far more serious and substantial than the PBM Defendants' dubious claims of burden and helplessness.

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[30] *See Pharmacy Benefit Management of Opioid Prescribing: The Role Of Employers And Insurers*, *supra* note 2.

[31] The PBMs also ignore that one of the requests for relief specifically seeks the **removal** of these types of limits to the extent PBMs currently impose them on opioid overdose agents and medication-assisted treatment so to expand access to these life-saving drugs.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2018, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the attorneys of record at their e-mail addresses on file with the Court.

/s/ Joanne Cicala
Joanne Cicala