EXHIBIT 3

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)**	)	

MEMORANDUM OF LAW IN SUPPORT OF
JOINT MOTION FOR PRELIMINARY INJUNCTIVE RELIEF

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I. INTRODUCTION

At the start of proceedings in January, this Honorable Court stated that:

> [M]y objective is to do something meaningful to abate this crisis and to do it in 2018…. I'm confident we can do something to dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed. Just dramatically reduce the quantity, and make sure that the pills that are manufactured and distributed go to the right people and no one else, and that there be an effective system in place to monitor the delivery and distribution, and if there's a problem, to immediately address it and to make sure that those pills are prescribed only when there's an appropriate diagnosis, and that we get some amount of money to the government agencies for treatment. Because sadly, every day more and more people are being addicted, and they need treatment.

Transcript of Record at 4-5, *In: re National Prescription Opiate Litigation*, (Jan. 9, 2018) (ECF No. 71). However, while settlement discussions continue, procedural corrections by manufacturers and wholesalers are contemplated and a few cases are prepared for bellwether trials,[1] prescription opioids continue to flow into our communities and Americans continue to die at the rate of over 134 people every day.[2] One mechanism to address the urgency of abating the opioid epidemic has been hiding in plain sight for months.

By this motion, Plaintiffs, the County of Webb, Texas ("Webb"), Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund, and Employer Teamsters Local Nos. 175 & 505 Retiree Health & Welfare Fund (collectively "Plaintiffs"), seek an injunction directing the nation's three largest pharmacy benefit managers ("PBMs" or the "Big Three") – Caremark, Express Scripts, and OptumRx, which control as much as eighty-nine percent (89%) of America's drug benefits (private and public)[3] – to immediately adjust their formularies to impose restrictions on opioids consistent with the March 2016 *CDC Guideline for Prescribing Opioids For Chronic Pain*

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[1] *See* Transcript of Record at 24-25, *In: re National Prescription Opiate Litigation*, (Aug. 2, 2018) (ECF No. 854).

[2] *See* NIH, *Overdose Death Rates*, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (estimating more than 49,000 opioid related deaths in 2017).

[3] NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, *PBM Resources*, http://www.ncpanet.org/advocacy/the-tools/pbm-resources (last visited Aug. 28, 2018).

– *United States, 2016* ("CDC Guideline"), consistent with the PBMs' own statements of support for the CDC Guideline, and reflective of all current medical literature regarding the dangerous and addictive nature of these drugs.

Webb has endeavored – since its case was filed in January 2018 – to alert the Plaintiff Co-Leads, the Plaintiff Executive Committee and this Court of the PBMs' unique role in abating the opioid crisis. *See* Declaration of Joanne Cicala, dated September 14, 2018 ("Cicala Decl.") at Ex. A (collection of communications to PEC and Court). Those efforts have been ignored. This motion is required to bring the Court's attention to the fact that it has a tool readily available that will help implement the Court's declared objective.

The Big Three were named by Webb as defendants in its case. *See* Amended Complaint, *County of Webb v. Purdue Pharma, L.P. et al.,* Case No 1:18-cv-45175 (N.D. Ohio), ("Am. Compl.") (ECF No. 32) ¶¶ 158-189. Since Webb's initial filing on January 25, 2018, other plaintiffs in this MDL and beyond have similarly been including the Big Three together with the manufacturers and wholesalers named in the bellwethers.[4] The PBMs' role as gatekeepers to the vast majority of prescription opioids – through their formularies and plan designs – is undeniable.[5] Confirming Webb's allegations, the Big Three now expressly admit that they have the ability to abate the opioid crisis. *See infra* Section II(A). To borrow OptumRx's own language, the PBMs are "uniquely positioned to help address the opioid epidemic." Cicala Decl. Ex. N-2 at 9; *see also, infra* Section II(A).

[4] The Federal and State opioid cases that have included PBMs as defendants to date include: (i) *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); (ii) *City of Springfield, MO v. Purdue Pharma, L.P., et al.,* Case No. 1:18-op-45899-DAP (N.D. Ohio); (iii) *City of Huntington, WV, et al. v. Express Scripts Holding Company*, Case No. 1:18-op-45984-DAP (N.D. Ohio); and (iv) *Jefferson County, et al. v. Purdue Pharma L.P., et al.*, Case No. 1822-CC10883 (22nd Judicial Cir. Court, St. Louis City, MO).

[5] Matthew Kandrach, *PBM stranglehold on prescription drug market demands reform*, THE HILL, May 2, 2017, http://thehill.com/blogs/pundits-blog/healthcare/331601-pbm-stranglehold-on-prescription-drug-market-demands-reform.

Importantly, this motion does not address the merits of Webb's allegations regarding PBM complicity in creating the opioid epidemic. That is an issue for another day. This motion is focused on the PBMs' express acknowledgements that their power in the marketplace uniquely positions them – right now – to control the flow of opioids, opioid reversal agents, and opioid addiction treatment medications, and their failure, nonetheless, to leverage that power to full effect.

Despite their unique position, despite their acknowledgement of the epidemic, despite their articulated commitment to drug safety and the CDC Guideline, the PBMs are still not doing all they (easily) can to halt the improper dispensing of opioids and expand access to treatments for opioid overdose and addiction. It is true that each of the Big Three recently have begun offering opioid management programs for certain customers that they claim (falsely) are consistent with the CDC Guideline. *See infra* Section II(B)(2). And it is no surprise that their new opioid management programs are having some positive impact for the customers who pay for them. *See infra* Section II(A). But, the relief sought by this motion remains necessary because the PBMs' corrections do not apply across the board and still fall woefully short of the CDC Guideline and all current medical literature regarding the highly dangerous properties of opioids. *See infra* Section II(B)(3).

None of the Big Three's new opioid management programs are consistent with the CDC Guideline – they still permit the largely unchecked prescribing of opioids for chronic pain (the CDC says opioids are not proven effective for chronic pain); still provide seven-day quantity limits for acute pain (when the CDC says "three days or less will often be sufficient"[6] and the PBMs themselves acknowledge that "a few days"[7] can make a difference in whether one becomes addicted); still permit opioid prescriptions to be delivered through mail-order pharmacies for

[6] Cicala Decl. Ex. B (CDC, *CDC Guideline for Prescribing Opioids For Chronic Pain – United States, 2016*) at 16.
[7] *Id.* Ex. N-3 at 2.

conditions outside of active cancer, end-of-life or palliative care (which typically supply maintenance drugs for chronic conditions; it is well-established that except for active cancer, end-of-life or palliative care, opioids should not be dispensed for chronic pain); do not adhere to CDC MME/day[8] recommendations; do not cover high dosage nonopioid alternatives; do not require step therapies; and do not require prior authorizations for the most commonly prescribed immediate-release opioids. *See infra* Section II(B)(3). At the same time, the PBMs also continue to impose unnecessary restrictions on access to treatments for opioid overdose and addiction. *Id.*

Hence, this motion remains necessary. This motion seeks the imposition of (1) step therapies requiring nonpharmacologic (*e.g.*, cognitive behavioral therapy ("CBT")) and/or nonopioid pharmacologic (*e.g.*, non-steroidal anti-inflammatory drugs ("NSAIDs")) therapy *before* any opioids – immediate- or extended-release – are dispensed for chronic pain outside of active cancer, palliative or end-of-life care; (2) default three-day quantity limits for opioid treatment of acute pain; seven-day quantities only available subject to strict prior authorization; (3) adherence to the CDC MME limits; and (4) expanded access to nonopioid pain alternatives, and pharmacologic treatments for opioid overdose and addiction.

Each of these adjustments will impact the ease with which opioids and opioid overdose and addiction treatments are dispensed into our communities. Each of these adjustments are, and always have been, within the PBMs' control. Each is consistent with the CDC Guideline and current industry understanding regarding the dangers of prescription opioids. Each may be implemented easily with what is known in PBM parlance as a coding "edit." That edit will better enable this Court to achieve what it has stated to be its primary objective from day one.

Critically, the relief sought will not disturb the Court's plan for the bellwether cases. It will

[8] MMEs are morphine-milligram equivalents.

not disturb the discovery process or the provisions of any ruling or order. It will not disturb any of the more long-term responses to the opioid crisis that are being considered and implemented at the federal level (executive, legislative and agency). This motion presents a constructive step that may be taken now. It will protect the public while permitting those in genuine need of opioid treatment for short-term acute pain treatment or active cancer, end-of-life or palliative care to receive that therapy. And it will permit the Court to achieve that which it has wanted since January 2018.

Plaintiffs respectfully request that this joint motion for injunctive relief be granted.

II. STATEMENT OF FACTS

A. AN ORDER DIRECTING THE PBMS TO IMMEDIATELY RESTRICT OPIOID COVERAGE AND EXPAND ACCESS TO PHARMACOLOGIC TREATMENTS FOR OPIOID OVERDOSE AND ADDICTION WOULD MEANINGFULLY ABATE THIS CRISIS

PBM formularies drive which drugs enter the marketplace. They determine what drugs (a) will be available (or not available) to patients; (b) for what diagnosis; (c) in what quantities; (d) at what level of cost-sharing; (e) and subject to what utilization management terms and conditions. *See* Am. Compl. (ECF No. 32) ¶ 16. The Big Three that are the subject of this motion manage the drug benefits for nearly 238 million people.[9] In this powerful role, the Big Three hold themselves out as "provid[ing] pharmacy care that is clinically sound,"[10] "ensur[ing] that [they] provide[] access to safe and effective medications"[11] and helping their customers "achieve better health outcomes."[12]

[9] *See PBM Resources, supra* note 3.

[10] Cicala Decl. Ex. F-2 (CVS Caremark, *Formulary Development and Management at CVS Caremark*) at 1.

[11] *Id.* Ex. I-3 (Express Scripts, *Smart Formulary Management*) at 2.

[12] *Id.* Ex. N-3 (OptumRx, *OptumRx Opioid Risk Management*, 2018) at 4.

Recently, the Big Three have acknowledged the immense risks and harms posed by prescription opioids – including overdose,[13] misuse,[14] and addiction[15] – and have implemented new opioid management programs in response, although only at extra cost to their customers.[16] Given their market power and "unique[] position[]," in the marketplace,[17] it is no surprise, and consistent with Webb's allegations (Am. Compl. at ¶¶13, 15-17, 193, 263, 329-352), that the PBMs' new opioid management programs are beginning to impact opioid flow for participating customers.

For example, Caremark describes how clients who:

> implemented our opioid utilization management program in 2017 had a number of positive results, including that the number of patients new to opioid therapy with an acute condition who received more than a seven day supply of an opioid *decreased 70 percent*. For those clients, the number of patients new to opioid therapy who receive a seven-day supply or less *is now nearly 94 percent*.

Cicala Decl. Ex. H-3 at 1 (emphases added).

Express Scripts similarly boasts of its ability to influence opioid usage among customers paying for its new plan:

> In the first 90 days since the program began on September 1, 2017, we observed a nearly 60% reduction in the average days supply for patients receiving an opioid prescription for the first time, from 18.6 days supply per prescription claim before the launch of the program, to 7.5 days supply per claim after the start of the program….

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[13] *See id.* Ex. H-1 at 3 ("61% of all drug overdose deaths involved a prescription opioid" and "[p]rescription opioids account for approximately 70% of fatal prescription drug overdoses"); *id.* Ex. K-1 at 2 ("90+ people die on an average day from an opioid-related overdose"); and *id.* Ex. N-3 at 1 ("[e]very 16 minutes there is a death from opioid overdose" and "21% increase in drug overdose deaths [between] 2015-2016").

[14] *See id*. Ex. H-1 at 3 ("[i]n an average month, 4.3M Americans used painkillers for nonmedical reasons"); *id.* Ex. N-3 at 1 ("4.5 million Americans abuse opioid prescription painkillers"); and *id.* at 3 ("45% of 'first fill' scripts nationally are not in compliance with CDC guidelines").

[15] *See id.* Ex. H-1 at 3 ("[a]s many as 25% of patients receiving Rx opioids long-term in a primary care setting struggle with addiction"); *id.* Ex. K-1 at 2 ("2 million people are addicted to prescription narcotics" and "[t]he odds of continuing opioid use after one year are 20% after receiving a ten-day supply"); and *id.* Ex. N-3 at 2 ("opioid dependence can start in just a few days").

[16] *See id*. Exs. H-1 – H3, K-1 – K-4, N-1 – N-3.

[17] *See id.* Ex. N-2 at 9.

> Nearly 96% of patients prescribed an opioid for the first time started with a 7-day supply or less.

Id. Ex. K-4 at 1.

OptumRx likewise proclaims that since launching its Opioid Risk Management program on July 1, 2017 with 400 clients (out of 65 million served)[18] it has "delivered the following improvements: [i] 82 percent decrease in prescriptions above the CDC guideline recommended dose of 50mg morphine equivalent dose (MED) per day for first-fill acute prescriptions; [ii] 65 percent decrease in prescriptions for first-fill acute opioid treatment written above the maximum 7-day supply; [iii] 68 percent decrease in prescriptions for current chronic opioid utilizers issues for >90mg MED; and [iv] 14 percent reduction in average dose across all opioid prescriptions." *Id.* Ex. N-1 at 1.

But, as set forth below, the PBMs' new opioid management programs still fall far short of the CDC's recommendations for prescribing opioids that have been in effect since March 2016. Express Scripts itself acknowledges that, "[s]eeing these types of results at such an early stage shows that by working together with our clients and introducing innovative ways to protect the safety of patients, *we have the ability to make a significant impact.*" *Id.* Ex. K-4 at 2 (emphasis added). Imagine the impact if the Big Three implemented programs that were fully consistent with the CDC Guidelines across the board for all they serve.

B. THE CDC GUIDELINE SETS FORTH EVIDENCE-BASED RECOMMENDATIONS FOR OPIOID PRESCRIBING THAT SHOULD – BUT CURRENTLY DO NOT – FORM THE BASIS FOR PBM OPIOID MANAGEMENT PROGRAMS

1. The CDC Guideline Sets Forth Evidence-Based Recommendations on Opioid Prescribing

[18] *See* Alex Reger, *Heath Insurers and Pharmacy Benefit Managers: Information on Size, CEO Salaries, and Fiduciary Relationships,* Research Report - Office of Legislative Research (Conn.), Mar. 1, 2018 at 3.

The CDC issued its CDC Guideline on March 18, 2016 for the treatment of chronic pain. Cicala Decl. Ex. B at 1.

The CDC Guideline provides that:

> *Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.* Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate….
>
> *Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain.* In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain….
>
> Nonopioid pharmacologic therapies are not generally associated with substance use disorder, *and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications*….
>
> *Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy* []. *While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant*….
>
> The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent.

Id. at 16-19 (emphases added).

For the treatment of acute pain, the CDC Guideline states that:

> Acute pain can often be managed without opioids….[w]hen opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. *Three days or less will often be sufficient; more than seven days will rarely be needed*….

Id. at 16, 24, *et seq.* (emphasis added).

The CDC Guideline further recommends that when opioids are used outside of active

cancer, palliative and end-of-life care, patients should receive the lowest effective dosage and that "holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages." *Id.* at 23. The CDC Guideline advises that increasing dosages to ≥ 90 MME/day "should [be] avoid[ed]." *Id.* at 16.

Additionally, the CDC Guideline advises that clinicians should make certain harm-reducing pharmacologic treatments available alongside behavioral therapy to address overdose and addiction. Specifically, the CDC Guideline instructs clinicians to offer naloxone, an opioid antagonist used to quickly reverse severe respiratory depression, when risk factors for opioid overdose are present, including when patients are prescribed dosages of opioids ≥ 50 MME/day. *Id.* at 16, 28-29. The CDC Guideline further directs clinicians to "offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder." *Id*. at 16. Buprenorphine and methadone "have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin." *Id.* at 14. And, buprenorphine has been found to prevent relapse in patients with prescription opioid addiction. *Id.* at 32. "Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in non-pregnant adults." *Id.* at 33.

The CDC also issued supporting materials that briefly reiterate its primary recommendations and emphasize certain key points.[19] All of this reflects the fact that there is

[19] For example, a two-page prescription opioid fact sheet states expressly that "opioids are not first-line or routine therapy for chronic pain…." *See id.* Ex. D ("CDC Fact Sheet") at 1. (emphasis added). It also states that: "[w]hen opioids are needed for acute pain, prescribe no more than needed" and "[w]hen opioids are used for acute pain….[t]hree days or less will often be sufficient; more than seven days will rarely be needed." *Id.* at 2 (emphasis added). It reaffirms that clinicians should avoid increasing dosage beyond 50 MME/day. *Id.*

Similarly, a four-page summary document, again makes clear: "[n]onopioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care." *See id.* Ex. C ("CDC Guideline Summary") at 2. "OPIOIDS ARE NOT FIRST-LINE THERAPY…. Nonpharmacologic therapies and nonopioid medications include: nonopioid

simply no evidence that long-term opioid use is an effective treatment for chronic pain.

> *The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception….*
>
> *Whereas the benefits of opioids for chronic pain remain uncertain, the risks of addiction and overdose are clear.* Although partial antagonists such as buprenorphine may carry a lower risk of dependence, prescriptions opioids that are full mu-opioid receptor agonists – nearly all the products on the market – are no less addictive than heroin. Although abuse-deterrent formulations may reduce the likelihood that patients will inject melted pills, these formulations are no less addictive and do not prevent opioid abuse or fatal overdose through oral intake….
>
> The prevalence of opioid dependence may be as high as 26% among patients in primary care receiving opioids for chronic non-cancer-related pain.

Id. Ex. E (Thomas R. Frieden, M.D., M.P.H. & Debra Houry, M.D., M.P.H., *Reducing the Risks of Relief – the CDC Opioid-Prescribing Guideline*, 374 THE NEW ENGLAND JOURNAL OF MEDICINE 16 (2016)) at 1501-02 (emphases added).

2. The CDC Guideline's Recommendations Can Be Readily Implemented by the PBMs, as Their Own Statements Acknowledge

The CDC Guideline, while explicitly making recommendations as to physician prescribing practices, readily translates into coverage guidelines that can and should be implemented by PBMs. Indeed, the Big Three have vocally embraced the CDC Guideline as applicable to their practices and now market themselves (falsely) as offering opioid management programs that are CDC consistent.

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medications such as acetaminophen, ibuprofen, or certain medications that are also used for depression or seizures." *Id.* at 3. The CDC Guideline Summary also underscores that the CDC's objective is "Promoting Patient Care and Safety." *Id.* at 1. It highlights on page 1 that:

> [m]any Americans suffer from chronic pain. These patients deserve safe and effective pain management. Prescription opioids can help manage some types of pain in the short term. However, we don't have enough information about the benefits of opioids long term, and we know that there are serious risks of opioid use disorder and overdose—particularly with high dosages and long-term use.

First, the CDC Guideline makes clear that opioids should be dispensed only rarely for chronic pain, thereby endorsing a form of utilization management known as "step therapy," whereby a clinician must attempt to treat a condition with one therapy before an alternative will be covered. Specifically, the CDC Guideline provides that: "[n]onpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain," and that "[s]everal nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain." Cicala Decl. Ex. B at 16-17. The CDC Fact Sheet similarly states that "opioids are not first-line or routine therapy for chronic pain." *Id.* Ex. D at 1. Consistent with these recommendations, PBMs can impose step therapy rules that require clinicians to first treat chronic pain with nonpharmacologic and/or nonopioid pharmacologic therapy and only prescribe opioids if these therapies are ineffective. Even Purdue Pharma has now acknowledged that step therapy should precede opioid use for chronic pain.[20]

Second, the CDC Guideline stresses that opioids should be dispensed sparingly for acute pain, affirming that a three-day supply will be adequate for most patients suffering from acute pain and that "only rarely" will seven days be needed. *Id.* Ex. B at 16, 24, *et seq.* PBMs can implement this recommendation by imposing a default three-day quantity limit on opioid prescriptions for acute pain, and only covering a seven-day quantity subject to strict prior authorization approval. Indeed, in this vein, a number of States and State Medicaid programs have taken it upon themselves to impose three to five-day limits on opioid prescriptions.[21]

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[20] *See* Purdue Pharma, *We make prescription opioids. And we want to limit their use*, https://www.purduepharma.com/corporate-social-responsibilities/ongoing-efforts-to-help-address-the-opioid-crisis/open-letter/ (last accessed Aug. 24, 2018).

[21] *See, e.g.*, Florida (Fla. Stat. Ann. § 456.44 (2018)), Tennessee (Tenn. Code Ann. §63-1-164 (2018)), Kentucky (KY H.B. 333 (amending Ky. Rev. Stat. Ann. §218A.205, 2017)), Minnesota (SF 2a (2017)), New Jersey (N.J. Stat. Ann. § 24:21-15.2 (N.J. 218th First Annual Sess., L. 2018, c. 54 (except c. 48) and J.R. 5)), North Carolina (Strengthen Opioid Misuse Prevention Act of 2017, H.B. 243, N.C. Sess. Laws 2017-74 (N.C. 2017) (enacted)) and Arizona (Arizona Opioid Epidemic Act, 2018 S.B. 1001/H.B. 2001, 2018 Ariz. Sess. Laws 284 (Ariz. 2018) (enacted)).

Third, whether for acute or chronic pain, the CDC Guideline provides key dosage benchmarks that can be incorporated into PBM formularies. Consistent with the recommendation that "Clinicians . . . should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 [MME]/day, and . . . should avoid increasing dosage to ≥ 90 MME/day," PBMs can require prior authorization to increase dosages to ≥ 50 MME/day and exclude coverage for dosages ≥ 90 MME/day. *Id*. Ex. B at 16.

Fourth, the CDC Guideline endorses expanding access to pharmacologic treatments for opioid overdose and addiction. In so doing, it also notes that "patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited." *Id.* at 32. Physician surveys also identify prior authorization and quantity limits[22] as frequent barriers to such treatments.[23] PBMs can help expand access by ensuring that they cover the range of treatments currently available (i.e., at least one formulation each of naloxone, methadone, buprenorphine, and naltrexone) and eliminate prior authorization requirements and quantity limits for all those treatments that are covered. To reduce financial barriers to treatment, PBMs can place at least one formulation of each type of treatment on the lowest tier of their formulary and/or waive cost-sharing for such treatments.

The PBMs' own documents confirm the important role they play in implementing the CDC Guideline. For example, nearly one year after the CDC Guideline was issued, Caremark publicly acknowledged that, "*[p]harmacy benefit managers (PBMs) play an important role in*

[22] The CDC has issued guidance subsequent to March 2016 clarifying that the CDC Guideline dosage thresholds "are based on overdose risk when opioids are prescribed for pain and should not guide dosing of medication-assisted treatment for opioid use disorder." CDC, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf (last viewed Aug. 29, 2018))

[23] Troy Parks, *AGs called on to help stop prior authorization for MAT*, AMA WIRE, Feb. 8, 2017, https://wire.ama-assn.org/ama-news/ags-called-help-stop-prior-authorization-mat; David Kan, MD, DFASAM, *Insurance Barriers to Accessing Treatment of Opioid Use Disorders Identified by California Physicians*, CALIFORNIA SOCIETY OF ADDICTION MEDICINE, Nov. 2016, https://www.csam-asam.org/sites/default/files/pdf/misc/insurance_barriers_mat_2016_final.pdf.

implementing the CDC [G]uideline, and helping ensure access and patient safety" and assured its customers that it had "taken a thoughtful, evidence-based approach to implementing the CDC guideline into our utilization management (UM) criteria with consideration of the needs of those with chronic pain, as well as the potential for harm from these powerful medications." *Id*. Ex. H-1 at 4 (emphasis added). Caremark also assured the public that its, "*UM criteria reinforce [the CDC] principles and encourage appropriate use of opioids by patients and prescribers. They provide coverage that fosters safe use of opioids, consistent with the … CDC [G]uideline,* to support plans helping members on their path to better health." *Id.* at 5 (emphasis added). Express Scripts similarly boasts that its Advanced Opioid Management program "is based on CDC prescribing guidelines" and "promot[es] greater compliance with CDC guidelines." *Id.* Ex. K-4 at 1. OptumRx likewise claims that its "utilization management edits are tightly aligned with Centers for Disease Control (CDC) prescribing guidelines." *Id.* Ex. N-3 at 2.

Unfortunately, however, as set forth in Section II(B)(3), *infra*, the Big Three's statements of concern are hollow and their assurances of fostering "safe use of opioids" consistent with the CDC Guideline are false. The Big Three's utilization management criteria – to this day and despite all their talk – fall far short of meeting the CDC Guideline.[24]

3. The PBMs Are Still Not Controlling Opioid Usage Consistent with the CDC Guideline

All statements to the contrary, none the Big Three PBMs' opioid management programs or standard formularies are consistent with the CDC Guideline or their own promotional materials.

[24] Researchers at the Johns Hopkins Bloomberg School of Public Health concur. Their June 22, 2018 study *Prescription Drug Coverage for Treatment of Low Back Pain Among US Medicaid, Medicare Advantage, and Commercial Insurers* found widespread failures to apply evidenced-based utilization management rules to discourage opioid use including failures to impose quantity limits and prior authorization and failures to require step therapies. Dora H. Lin, MHS, et al, JAMA NETWORK OPEN, Jun. 22, 2018, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685625

None require step therapy or prior authorization prior to reimbursing for the most commonly prescribed immediate-release opioids. *See infra* Sections 3(a)-(b). None impose three-day quantity limits on any opioids when prescribed for acute pain. *Id.* None limit dosages to ≤ 50 MME/day absent prior authorization or exclude coverage of dosages ≥ 90 MME/day. *Id.* None uniformly cover all four types of pharmacologic treatment for overdose and addiction without financial or procedural barriers. *Id.*

In short, the PBMs may be finally saying "all the right things" when it comes to acknowledging the dangers of opioids and the need for tight controls. But the unfortunate reality is that over two years after the CDC Guideline was issued, the Big Three still have not uniformly installed available edits to their standard plan designs that are in line with the CDC Guideline, their own documents and all currently available medical literature.

Each of the Big Three's current standard formularies and opioid management programs are examined in detail in the Cicala Declaration, submitted together herewith and incorporated herein. below:

a. Caremark

According to the Drug Channels Institute, CVS Health (Caremark) was the highest-ranking PBM in 2017 with over twenty-five percent (25%) of the industry market share.[25] It currently covers more than 94 million lives.[26]

Caremark says the following about its "Formulary Development and Management":

> Development and management of drug formularies is an integral component in the pharmacy benefit management (PBM) services CVS Caremark provides to health plans and plan sponsors. Formularies have two primary functions: 1) *to help the*

[25] Adam J. Fein, Ph.D., *The Outlook for Pharmacy Benefit Management: Evolution or Disruption*, DRUG CHANNELS INSTITUTE, Mar. 5, 2018http://drugchannelsinstitute.com/files/PBMI-PBM_Outlook-Drug_Channels-Fein-Mar2018 - Handouts.pdf, at 2.

[26] CVS Health, *CVS Health at a Glance*, https://cvshealth.com/about/facts-and-company-information (last visited on Aug. 23, 2018).

> *PBM provide pharmacy care that is clinically sound* and affordable for plans and their plan members; and 2) to help manage drug spend through the appropriate selection and use of drug therapy.

Cicala Decl. Ex. F-2 at 1 (emphasis added).

Caremark has three basic formularies: Standard Control, Advanced Control, and Value. *See Id.* Ex. F-1 at 3. A wholly owned subsidiary (SilverScript) also manages two basic formularies for Medicare Prescription Drug Plans ("PDPs"), Choice and Plus.[27] Each of Caremark's basic formularies include opioids. *See id.* at Exs. G-1 – G-6.

Contrary to the CDC Guideline, Caremark's Standard Control formulary contains no step therapies, prior authorization requirements or quantity limits for opioids on its face. *See id.* Ex. G-1 at 1. It imposes no three-day limitations for acute pain. *Id.* It does not limit the use of opioids for chronic pain outside active cancer, end-of-life and palliative care. *Id.* The prescribing guide for the Standard Control formulary refers clinicians to 2017 prescribing guidelines, but even those do not require nonopioid step therapies for treatment of chronic pain or three-day limits for acute pain. *See id.* Ex. G-2 at 11. And, although it covers methadone, and multiple buprenorphine and naloxone treatments, it does not cover any naltrexone treatments and it is unclear what utilization management or cost-sharing requirements may apply. *See id.* Ex. G-1 at 1, 3. Finally, Caremark's Standard Control formulary does not even 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. *Id.*

Much like Caremark's Standard Control formulary, Caremark's Advanced Control formulary contains no step therapies, prior authorization requirements or quantity limits for opioids

[27] SilverScript, *Overview of 2018 SilverScript Plans*, https://www.silverscript.com/learn/plans-overview.aspx (last visited on Aug. 23, 2018)

on its face. *See id.* Ex. G-3 at 1. It does cover naltrexone, although as with the Standard Control formulary, it is unclear what terms apply. *Id.* at 4. And, as with the Standard Control Formulary, the Advanced Control formulary does not include many of the following prescription nonopioid pain treatment alternatives: capsaicin, diflunisal, choline magnesium trisalicylate, salsalate, etodolac, sulindac, indomethacin, meclofenamate and nabumetone. *Id.*

Indeed, Caremark's Value Formulary contains no step therapies for any immediate release opioids. *Id.* Ex. G-4 at 9-10. It has prior authorization requirements for some opioids, but not the most widely used opioids: hydrocodone-acetaminophen, oxycodone-acetaminophen and codeine-acetaminophen.[28] *Id.* at Ex. G-4. And, the Value Formulary points to the same lax 2017 opioid prescribing guidelines. *Id.* at 19. In contrast, this formulary imposes both prior authorization and/or quantity limits on the majority of pharmacologic treatments for opioid addiction and overdose. *Id.* at 10, 22-23. And, this Value formulary (like Caremark's other commercial offerings) excludes an array of nonopioid pain relief options including: topical lidocaine, choline magnesium trisalicylate, salsalate, indomethacin, celecoxib and meclofenamate. *Id.*

Likewise, Caremark's Medicare PDP formularies have no prior authorization requirements for opioids except fentanyl-related products, and no step therapies for any opioids. *See id.* Exs. G-5 at 8-10 and G-6 at 8-10. As with Caremark's other formularies, they impose dosage and quantity limits but these exceed the CDC Guideline's recommendations for MME per day. For example, Caremark sets a 360 tabs/30 day limit for all strengths of Hydrocodone-acetaminophen (5-325mg,

[28] *See* NIH, National Institute on Drug Abuse, *Most Commonly Used Addictive Drugs*, https://www.drugabuse.gov/publications/media-guide/most-commonly-used-addictive-drugs ("commonly prescribed opioids include hydrocodone (e.g., Vicodin®), oxycodone (e.g., OxyContin®), morphine, fentanyl, and codeine."); *see also*, Theodore J. Cicero; Matthew S. Ellis; Hilary L. Surratt; Steven P. Kurtz, *Factors influencing the selection of hydrocodone and oxycodone as primary opioids in substance abusers seeking treatment in the United States*, 154 PAIN 12 at 2639–2648 (2013) ("Our results showed that oxycodone and hydrocodone were the drugs of choice in 75% of all patients.").

7.5-325mg, 10-325mg), one of the most widely overprescribed opioids.[29] But even at the lowest dosage (5mg), this exceeds the CDC-recommended dosage limit of 50 MME/day. The following chart explains how Caremark's current hydrocodone Medicare quantity limits far exceed the CDC Guideline with respect to this highly abused drug:

Hydrocodone-acetaminophen, 360 tab per 30 days[30]	**Strength**	**MME [31]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.0	12	**60 MME**
7.5-325mg	7.5mg	1.0	12	**90 MME**
10-325mg	10mg	1.0	12	**120 MME**

Caremark is similarly lax when it comes to imposing limits on the other most commonly prescribed opioid – oxycodone-acetaminophen.[32] Caremark's current Medicare quantity limits of 360 tablets/30 days for the 5-325mg, 7.5-325mg, and 10-325mg strengths of Oxycodone completely ignore the CDC Guideline.

Oxycodone-acetaminophen, 360 tab per 30 days[33]	**Strength**	**MME[34]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.5	12	**90 MME**
7.5-325mg	7.5mg	1.5	12	**135 MME**
10-325mg	10mg	1.5	12	**180 MME**

[29] Seago S, Hayek A, Pruszynski J, Newman MG, *Change in prescription habits after federal rescheduling of hydrocodone combination products*, 29(3) PROCEEDINGS (BAYLOR UNIVERSITY MEDICAL CENTER) 268-270 (2016) ("hydrocodone/acetaminophen products are by far the most popular formulation and were the most frequently prescribed drug from 2007 to 2011."); *see also*¸ Lydia Ramsey, *The 10 most popular prescription drugs in the US*, BUSINESS INSIDER, Dec. 28, 2017, https://www.businessinsider.com/common-popular-prescription-drugs-us-2017-7 ("Vicodin is the most popular drug in the US").

[30] Cicala Decl. Exs. G-5 at 9 and G-6 at 9.

[31] CMS Conversion Chart, *Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors*, CENTERS FOR MEDICARE & MEDICAID SERVICES, Aug. 2017, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-Aug-2017.pdf

[32] *See* U.S. Department of Health & Human Services, Office of Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, HHS OIG DATA BRIEF, OEI-02-17-00250 (July 2017) at 2 ("The most commonly prescribed opioids were tramadol, hydrocodone-acetaminophen (including the brand-name version, Vicodin), and oxycodone-acetaminophen (including the brand-name version, Percocet).")

[33] Cicala Decl. Exs. G-5 at 10 and G-6 at 10.

[34] *See* CMS Conversion Chart, *supra* note 31.

Caremark applies the same limits to the widely used acetaminophen-codeine, again ignoring the CDC Guideline.

Acetaminophen-codeine, 400 tablets per 30 days[35]	Strength	MME[36]	Tabs/day	MME/day
300-30mg	30mg	0.15	13.33	**59.99 MME**
300-60mg	60mg	0.15	13.33	**119.97 MME**

Additionally, Caremark's Medicare PDP formularies impose quantity limits and/or prior authorization requirements on the majority of pharmacologic treatments for opioid addiction and overdose. *Id.* Exs. G-5 at 9, 34-35 and G-6 at 9-10, 36. These treatments, including generics, are also all listed on Tier 3 or higher of the formulary. *Id.* This designation is associated with copays of at least $35 or coinsurance rates typically exceeding 33%. *Id.* Exs. G-5 at 5-7 and G-6 at 5-7.

Even with its new Opioid Utilization Management Program, Caremark does not require step therapy as a pre-condition for coverage of immediate-release opioids. *See id.* Ex. H-2. Caremark does not impose three-day limits on opioids prescribed for acute pain, or require prior authorization when opioids are prescribed for chronic pain. *Id.* Caremark limits the quantity of opioids prescribed per day, but only to 90 MME/day,[37] a quantity the CDC says, should be avoided. *See id.* Ex. B at 16, 22, 23. Caremark does not require prior authorization prior to covering immediate-release opioids (i.e., hydrocodone-acetaminophen, oxycodone-acetaminophen, codeine-acetaminophen). *Id. at* Exs. G-1 – G-6. And, Caremark merely allows for an "emergency supply" of buprenorphine-naloxone products while it processes prior authorization, rather than broadly waiving such requirements. *See id.* Ex. H-1 at 6.

b. Express Scripts

[35] Cicala Decl. Exs. G-5 at 8 and G-6 at 8.

[36] *See* CMS Conversion Chart, *supra* note 31.

[37] Cicala Decl. Ex. H-2.

Express Scripts "provides pharmacy benefits to 83 million members. Of these, more than 27 million 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* Cicala Decl. Ex. I-1 at 1.

Express Scripts explains that their standard formularies are "governed by our National Pharmacy & Therapeutics Committee (the 'P&T Committee'), a panel of independent physicians and pharmacists in active clinical practice, representing a variety of specialties and practice settings and typically with major academic affiliations." *Id.* Ex. I-2 at 11. Express Scripts touts that the "the P&T Committee considers the drug's safety and efficacy," and the company "fully compl[ies] with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy." *Id.* Express Scripts further states that, "we re-evaluate our National Preferred Formulary on an annual basis. We look at the formulary first from a clinical perspective *to ensure that it provides access to safe and effective medications in all therapy classes*." *Id.* Ex. I-3 at 2 (emphasis added).

And yet, to this day, and notwithstanding the CDC Guideline and everything that is now known about the addictive properties of opioids and opioid over-prescribing, every standard commercial Express Scripts formulary contains no restrictions whatsoever on the majority of opioids covered – no quantity limits, no step therapies, no prior authorization requirements. *Id.* Exs. J-1 – J-5. Express Scripts recently updated its National Preferred Formulary to exclude coverage for two long-acting opioid oral analgesics (Opana ER and Oxycodone ER) and two narcotic analgesics (Buprenorphine Patches and Butrans) but, even there, Express Scripts presents no fewer than six "preferred alternatives," each of which are highly addictive opioids available in extended-release forms. *Id.* Ex. J-2 at 1. The National Preferred Formulary indicates that certain naloxone (Narcan nasal spray) and buprenorphine Suboxone Sublingual Film and Zubsolv

sublingual tablets) treatments are available, but does not list any methadone or naltrexone treatments. *See id.* Exs. J-1 and J-2. And, as with Caremark, despites its articulated commitment to step therapies, the Express Scripts National Preferred formulary does not cover numerous highly effective prescription nonopioids including: doxepin, desipramine, diflunisal, choline magnesium trisalicylate, etodolac, sulindac, indomethacin, and meclofenamate. *Id.*

Express Scripts' Medicare PDP formularies are likewise lax. They impose prior authorization requirements for certain opioids but most immediate-release opioids are not subject to step therapy or prior authorization requirements. *Id.* Exs. J-3 – J-5. There are also some quantity and dosage limits in place but, as with Caremark, these limits exceed the CDC Guideline. *Id.* Ex. J-3 at 21-22; J-4 at 20-22; and J-5 at 20-22. The following charts explains how Express Scripts' current hydrocodone and oxycodone Medicare quantity limits far exceed CDC Guidance with respect to these highly abused drugs:

Hydrocodone-acetaminophen, 372 tablets per 31 days[38]	**Strength**	**MME [39]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.0	12	**60 MME**
7.5-325mg	7.5mg	1.0	12	**90 MME**
10-325mg	10mg	1.0	12	**120 MME**

Oxycodone-acetaminophen, 372 tablets per 31 days[40]	**Strength**	**MME[41]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.5	12	**90 MME**
7.5-325mg	7.5mg	1.5	12	**135 MME**
10-325mg	10mg	1.5	12	**180 MME**

Like Caremark, Express Script's Medicare PDP formularies impose prior authorization and/or quantity limits on the majority of covered pharmacologic treatments for opioid addiction

[38] *See id.* Exs. J-3 at 22; J-4 at 21; and J-5 at 21.

[39] *See* CMS Conversion Chart, *supra* note 31.

[40] *See* Cicala Decl. Exs. J-3 at 22; J-4 at 22; and J-5 at 22.

[41] *See* CMS Conversion Chart, *supra* note 31.

and overdose. *Id*. Exs. J-3 at 22, 23; J-4 at 21, 22; and J-5 21-22, 23. These treatments are listed on Tiers 2 through 4 of the formularies, *id.*, indicating that at least some non-nominal cost-sharing is required, *id.* Exs. J-3 at vi; J-4 at vi; and J-5 at vi ("[u]se Tier 1 drugs for the lowest copayments"). And, as in the commercial contexts, the Express Scripts Medicare formulary does not include a number of the following prescription nonopioids useful in a step therapy context: choline magnesium trisalicylate, indomethacin, meclofenamate and nabumetone. *Id.*

Even with its Advanced Opioid Management Program, Express Scripts does not impose a three-day limit for first-time users dealing with acute pain; does not require step therapy prior to covering immediate-release opioids; and does not require prior authorization for immediate-release opioids. *See id.* Exs. K-1 – K-4. Express Scripts limits the dosage of opioids prescribed per day, but only to 200 MME/day, more than double the dosage which the CDC Guideline says should be avoided. *See id.* Ex. K-3 at 1. Moreover, this program – self-described as a "comprehensive solution" that "significantly reduces inappropriate selection and excessive dispensing of opioids," particularly for those taking an opioid for the first time[42] – reportedly has a fee of $0.30 PMPM.[43] For a client with 10,000 members, this translates to a yearly cost of approximately $36,000 – a significant amount, especially for public payors.

Additionally, nowhere does any Express Scripts formulary advise that opioids are inappropriate for chronic pain treatment outside active cancer, end-of-life or palliative care. *See id.* Exs. K1 – K4. To the contrary, virtually every opioid analgesic on every Express Scripts formulary (commercial or Medicare) is available through its mail order pharmacy. *Id.* Exs. J-1 – J-5. Mail order pharmacies are used most commonly for maintenance drugs and the treatment of

[42] *See* Cicala Decl. Ex. K-4 at 1.

[43] *See id.* Ex. K-2 (Express Scripts Contract).

chronic conditions.[44] The CDC made clear over two years ago that opioids are not proven effective for chronic pain. *See id.* Ex. B at 16-19.

c. OptumRx

According to the Drug Channels Institute, OptumRx (UnitedHealth) was the third highest ranking PBM in 2017 with twenty-two (22%) of the industry market share.[45] Recent OptumRx publications indicate that it provides pharmacy services to 65 million Americans. Cicala Decl. Ex. L at 1.

OptumRx offers five basic formularies,[46] each of which includes opioids. *Id.* at Exs. M-1 – M-5. OptumRx's 2018 Generic Centric Formulary appears to have no limits whatsoever surrounding the coverage of opioids. *Id.* Ex. M-3 at 7-9. OptumRx's other commercial formularies require prior authorization only on some opioids, not including the most popular immediate-release drugs. *See id.* at Exs. M-1 – M-5. They also do not appear to require step therapy for immediate-release opioids or a three-day limit for acute pain treatment. *Id.* They do not advise against the dispensing of opioids for chronic pain. *Id.* OptumRx currently limits immediate-release opioids for patients new to opioid therapy to 49 MME a day.[47] However, patients not new to opioid therapy may receive 90 MME per day,[48] a limit the CDC Guideline recommends should avoided. OptumRx's Medicare PDP formularies do not appear to have any prior authorization requirements

[44] James Chan, PharmD, PhD; and O. Kenrik Duru, MD, MSHS, *Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes,* AJMC (Nov. 2013) at 882-887 ("Mail order pharmacies are widely used to deliver medications in the United States, with up to one-third of chronic illness medications delivered by mail."); s*ee also* Constance Horgan, Brigid Goody, David Knapp, and Leslye Fitterman, *The Role of Mail Service Pharmacies,* HEALTH AFFAIRS (Fall 1990) at 67 ("One such alternative is mail service pharmacies, which generally concentrate on processing new and renewal prescriptions for maintenance drugs through the mail.")

[45] Adam J. Fein, Ph.D., *supra* note 25.

[46] OptumRx, *Formulary and drug lists*, June 5, 2018, https://professionals.optumrx.com/resources/formulary-drug-lists.html

[47] OptumRx, *Quantity Limit Changes on Short-Acting Opioids,* last updated May 23, 2018, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/SAOQuantityLimits.pdf.

[48] *Id.*

for most long-acting opioids or widely used opioids such as hydrocodone/acetaminophen, oxycodone/acetaminophen and codeine/acetaminophen, instead imposing prior authorization requirements for only a very limited number of immediate-release branded opioids. *See id*. Ex. M-6 at 10-15. These formularies have very few quantity limits, as well, including no apparent limits on the popular opioids identified above. *Id.* Without such quantity limits, OptumRx does not appear to limit Medicare reimbursement for acute pain treatment to three days. *Id*.[49]

Like Express Scripts, OptumRx offers its OptumRx Opioid Risk Management program for an additional fee. Only through enrollment in that program, for extra money, will its commercial customers receive services that OptumRx's falsely claims are compliant with the CDC Guideline. Even in its Opioid Risk Management Program, OptumRx does not appear to limit acute treatment to three-days and does not require step therapy for opioid treatment of chronic pain. *Id.* Ex. N-3.

III. RELIEF REQUESTED

Plaintiffs seek entry of an order directing the Big Three to make immediate edits to their formularies, consistent with the CDC Guideline, effective immediately:

> 1. For chronic pain[50] outside of active cancer, palliative and end-of-life care, no opioids are covered in the first instance. Step therapy using nonpharmacologic therapies[51] and nonopioid medications must be completed first.

[49] OptumRx generally offers better access to pharmacologic treatments for opioid overdose and addiction than its competitors. It covers at least one formulation of the four types of treatments without prior authorization on Tier 1 of its Essential Health Benefits Base Formulary, as well as its Medicare PDP formulary. *See id.* Exs. M-1 at 13, 15; M-6 at 11, 16. It, however, does impose quantity limits on some treatments (*id.*) and even Tier 1 drugs may come with cost-sharing obligations that could limit treatment uptake. *Id.* Exs. M-1 at 5 ("[u]se Tier 1 drugs for the lowest out-of-pocket costs.") and M-6 at 3 (similar); *see also, id.* Ex. M-2 at 5 (establishing a "Tier LC" below Tier 1, that provides "lowest-out-of-pocket costs" for certain generics). OptumRx's Generic Centric Formulary offers a more limited selection of drugs and none at the lowest tier level, but still has at least one formulation of all four-types of treatments without prior authorization or quantity limits. *Id.* Ex. M-3 at 8, 12. Its Select Standard Formulary is more stringent, requiring prior authorization for the one form of methadone covered, imposing quantity limits on buprenorphine treatments, and offering the only version of naloxone covered, branded Narcan, on Tier 2. *Id.* Ex. M-4 at 6, 7.

[50] The CDC Guideline defines chronic pain as pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition). *See id.* Ex. B at 19.

[51] Nonpharmacologic therapies include CBT, exercise therapy, interventional treatments, and multimodal pain treatment. Nonopioid medications include NSAIDs (e.g., acetaminophen or ibuprofen), or certain medications that are also used for depression or seizures.

2. For acute pain, any opioid, including the widely abused immediate-release opioids hydrocodone-acetaminophen, oxycodone-acetaminophen and codeine-acetaminophen, may only be covered for three-days. Prior authorization is required for any acute pain opioid prescriptions beyond this three-day limit.

3. Given overdose risks, prescription coverage is limited to amounts where daily dosages do not meet or exceed 50 MME/day absent prior authorization, and coverage should be excluded for dosages of greater than or equal to 90 MME/day.

4. To prevent overdose and treat opioid addiction, cover at least one formulation each of naloxone, methadone, buprenorphine and naltrexone on the lowest formulary tier or otherwise waive cost-sharing for such treatments. Eliminate prior authorization requirements and quantity limits for all formulations of such treatments that are covered.

Each of these edits is within the PBMs' control and consistent with the CDC Guideline the PBMs acknowledge they should follow.

IV. ARGUMENT

A. THE CIRCUMSTANCES PRESENTED SATISFY THE CRITERIA FOR GRANTING THE RELIEF SOUGHT

The PBM Defendants are still not implementing edits consistent with the CDC Guideline and their own public statements regarding the dangers of opioid use. They are still not doing all they can to decrease the improper flow of opioids to the public and to reduce the number of deaths related to opioid- addiction. Given the PBMs' admitted control over opioid use, *see supra* Section II(B), an order from this Court directing them to immediately tighten their opioid controls while simultaneously increasing access to overdose and treatment therapies can reasonably be expected to reduce the number of Americans becoming addicted to opioids and dying opioid-related deaths. An affirmative (or "mandatory") injunction is appropriate when "the currently existing status quo itself is causing one of the parties irreparable injury, [then] it is necessary to alter the situation so as to prevent the injury." *United Food & Commer. Workers Union, Local 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 348 (6th Cir. 1998) (*quoting Stenberg v. Cheker Oil Co.*, 573 F.2d

921, 925 (6th Cir. 1978)).[52] Clearly, the status quo is causing irreparable injury. With a few computer "edits", some of that injury may be avoided.

When determining whether to grant a request for a preliminary injunction, the court considers four factors: "(1) the likelihood of plaintiff's success on the merits; (2) whether the injunction will save the plaintiff from irreparable injury; (3) whether the injunction would harm others; and (4) whether the public interest would be served by the injunction." *In re DeLorean Motor Co.*, 755 F.2d 1223, 1228 (6th Cir. 1985); *see also Taverns for Tots, Inc. v. City of Toledo*, 307 F. Supp. 2d 933, 939 (N.D. Ohio 2004). The factors are not prerequisites to be met, but must be balanced. *See In re DeLorean Motor Co.*, 755 F.2d at 1229.[53]

> [N]o single factor is determinative as to the appropriateness of equitable relief. In addition to assessing the likelihood of success on the merits, the court must consider the irreparability of any harm to the plaintiff, the balance of injury as between the parties, and the impact of the ruling on the public interest. 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.

Id. at 1229 (*quoting Metro. Detroit Plumbing & Mech. Contractors Ass'n v. Dep't of HEW*, 418 F. Supp. 585, 586 (E.D. Mich. 1976)).[54] This "traditional preliminary injunctive standard – the balancing of equities" applies equally to mandatory preliminary injunctions and injunctions

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[52] The Sixth Circuit has held that there is no difference in the legal standard for mandatory and prohibitory preliminary injunctions and explicitly rejected other jurisdictions' heightened standards. *See United Food*, 163 F.3d at 348.

> "[T]he focus always must be on prevention of injury by a proper order, not merely on preservation of the status quo" … We therefore see little consequential importance to the concept of the status quo, and conclude that the distinction between mandatory and prohibitory injunctive relief is not meaningful. Accordingly, we reject the Tenth Circuit's "heavy and compelling" standard and hold that the traditional preliminary injunctive standard -- the balancing of equities -- applies to motions for mandatory preliminary injunctive relief as well as motions for prohibitory preliminary injunctive relief.

Id. (*quoting Stenberg*, 573 F.2d at 925).

[53] *See also, Project Vote v. Blackwell*, 455 F. Supp. 2d 694, 700 (N.D. Ohio 2006) (*quoting In re Eagle-Picher Indus., Inc.*, 963 F.2d 855, 859 (6th Cir. 1992)); *Grand Trunk W. R.R. v. Bhd. of Maint. of Way Emples. Div.*, No. 3:06-cv-1749, 2006 U.S. Dist. LEXIS 82247, at *6-7 (N.D. Ohio Nov. 9, 2006).

[54] *See also, Roth v. Bank of Commonwealth*, 583 F.2d 527, 536-37 (6th Cir. 1978), cert. dismissed, 442 U.S. 925, 99 S. Ct. 2852 (1979); *Friendship Materials, Inc. v. Mich. Brick, Inc.*, 679 F.2d 100, 105 (6th Cir. 1982); *Project Vote*, 455 F. Supp. 2d at 700.

preserving the status quo. *United Food,* 163 F.3d at 348.

"The degree of proof necessary for each factor used in determining whether to grant preliminary injunctive relief depends on the strength of plaintiff's case on the other factors." *Grand Trunk W. R.R.*, 2006 U.S. Dist. LEXIS 82247, at *7. Although the party seeking a stay must usually show a strong or substantial likelihood of success, a motion for injunctive relief might be granted if the movant could show "serious questions going to the merits and irreparable harm which decidedly outweighs any potential harm to the defendant if an injunction is issued." *In re DeLorean Motor Co.*, 755 F.2d at 1229 (*quoting Friendship Materials*, 679 F.2d at 105).

There is ample precedent in this Circuit for granting injunctive relief to avoid irreparable harm where there are serious questions on the merits, as here. *See Carpenter-Barker v. Ohio Dep't of Medicaid*, No. 1:15-cv-41, 2018 U.S. Dist. LEXIS 24686 (S.D. Ohio Feb. 15, 2018) at *10 (the court considered the four factors involved in deciding whether to grant a stay and determined that the plaintiff was unlikely to prevail on the merits. Nevertheless, the court granted an injunction based on the plaintiff's allegations that her daughter might suffer irreparable harm "in the form of institutionalization, injury, or death if her [private duty nursing] hours are reduced before her appeal has been resolved."); *see also Taverns for Tots*, F. Supp 2d at 944-946 (court issued injunction where "[t]he balance of harms weigh[ed] strongly in favor of granting [such] relief").

All factors weigh in favor of granting the relief sought here.

1. Plaintiffs Will Likely Succeed on the Merits and Regardless, Have Demonstrated Serious Questions Going to the Merits with the Balance of Hardships in Plaintiffs' Favor

To satisfy the first prong of the preliminary injunction analysis:

> [I]t is not necessary that the plaintiff's right to a final decision, after a trial, be absolutely certain, wholly without doubt; if the other elements are present (I. e., the balance of hardships tips decidedly toward plaintiff), it will ordinarily be enough that 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.

Roth, 583 F.2d at 536-37 (quoting *Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740 (2d Cir. 1953)); *see also J&G Invs., LLC v. Fineline Props.*, No. 5:06 CV 2461, 2006 U.S. Dist. LEXIS 88472, at *11-12 (N.D. Ohio Dec. 7, 2006); *Stile v. Copley Twp.*, 115 F. Supp. 2d 854, 859 (N.D. Ohio 2000).

> The purpose of the ["balance of hardships"] test is to underscore the flexibility which traditionally has characterized the law of equity. It permits the district court, in its discretion, to grant a preliminary injunction even 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, 679 F.2d at 105; *see also Office Depot, Inc. v. Impact Office Prod., LLC*, No. 1:09-cv-2791, 2010 U.S. Dist. LEXIS 143884, at *8 (N.D. Ohio Dec. 30, 2010).

This motion has presented the disconnect between the CDC Guideline and the PBMs' current formularies and has presented the PBMs' own assessment of their control and influence over opioid prescriptions. In addition, the exhibits to the Cicala Declaration reveal the PBMs' knowledge – based on their own data – that their pharmacy plans are not consistent with the CDC Guideline. For example, OptumRx boldly reports its knowledge that "45% of 'first fill' [opioid] scripts nationally are not in compliance with CDC guidelines." Cicala Decl. Ex. N-3 at 3. This presentation clearly raises questions going to the merits of the moving parties' allegations that are "so serious, substantial, … as to make them a fair ground for litigation and thus for more deliberate investigation." *Roth*, 583 F.2d at 536-37.

But even if the Court did not agree, the balance of hardships test overwhelmingly weighs in Plaintiff's favor given the lives being lost to opioid addiction and the PBMs' admitted ability to impact opioid flow. *See Carpenter-Barker*, 2018 U.S. Dist. LEXIS 24686 at *14-15 (given the life or death stakes involved, injunction was granted even though plaintiff unlikely to prevail on the

merits); *see also* Cicala Decl. Exs. O-1 – O-9 (collection of recent articles regarding ongoing deaths).

2. Irreparable Injuries will Continue if no Injunctive Relief is Granted

An injury is irreparable if it cannot be compensated by money damages. *See Office Depot*, 2010 U.S. Dist. LEXIS 143884, at *7. Clearly, the injuries caused by the opioid crisis – to Plaintiffs, individuals suffering from opioid addiction, their families and greater communities nationwide – are often irreparable. The relief sought here is narrowly tailored to prevent further addiction and reduce deaths. The PBMs' own documents confirm their awareness that "opioid dependence can start in just a few days" and that "it's important to stop opioid abuse before it starts." Cicala Decl. Ex. N-3 at 4. The meaningful edits sought by this motion will help reduce the chances of addiction and death. The PBMs' own conduct since the CDC Guideline was issued in March 2016 reveals that, absent this injunction, the PBMs will not install these edits across the board; rather they will make some of them available to only some of their customers and often at price. Plaintiffs respectfully submit that more wide-spread relief is required to halt the ongoing irreparable injury.

3. Granting the Injunction Will Not Cause Serious Harm to the PBM Defendants

The PBMs have expressly acknowledged their "important role in implementing the CDC guideline, and helping ensure access and patient safety." Cicala Decl. Ex. H-1 at 4. Indeed they have described themselves as "uniquely positioned to help address the opioid epidemic." *Id.* Ex. N-2 at 9. Plaintiffs agree.

The relief sought merely directs the PBMs to do that which they agree they can do to abate the epidemic: follow the CDC Guidelines regarding opioid prescribing. Lives will be saved as a result. Any economic harm to the PBMs is outweighed by public health, safety and welfare

concerns.

4. It is in the Public Interest to Abate the Opioid Epidemic

This Court has made clear from day one of this MDL that abating the opioid epidemic, including by restricting the flow of opioids into our communities and expanding treatment access, is a top priority and a matter of significant public interest because of the direct correlation with public safety and public health. The relief sought by this motion is narrowly tailored to abate that flow and ensure only those genuinely needing opioid treatment for acute pain, cancer treatment, and palliative care are prescribed opioids, while expanding access to overdose and addiction treatments. Nothing in this motion disturbs the larger litigation picture in the MDL, nor would this motion interfere with any federal activity (legislative, executive or agency) focused on long-term responses to the opioid crisis. This motion presents a constructive step that may be taken in the short-term.

B. THE COURT CAN AND SHOULD DISPENSE WITH ANY BOND REQUIREMENT

"The Sixth Circuit has repeatedly held that a district court, in its discretion, may dispense with the requirement for a bond under Fed. R. Civ. P. 65(c)." *See Moltan Co. v. Eagle-Picher Indus.*, 55 F.3d 1171, 1176 (6th Cir. 1995) ("While we recognize that the language of Rule 65(c) appears to be mandatory, and that many circuits have so interpreted it, the rule in our circuit has long been that the district court possesses discretion over whether to require the posting of security"); *Wright v. City of Cincinnati*, 450 F. Supp. 2d 831, 841 (S.D. Ohio 2005) (same). As observed in *Wright*, this circuit has routinely determined that a bond is unnecessary in cases without financial risk to the defendant.[55]

[55] *See Wright*, 450 F. Supp. 2d at 41 (No bond required because no financial risk; fees withheld from plaintiffs paycheck could be paid if injunction were improperly granted); *Urbain v. Knapp Bros. Mfg. Co.*, 217 F.2d 810, 815-

As described above, the relief requested here can be obtained through straightforward computer edits to the Big Three's formularies. Defendants cannot reasonably argue that such edits present financial risk, particularly where the purpose thereof is to render the Big Three's own public statements regarding CDC compliance more accurate. Movants' genuinely limited financial resources also weigh against a bond requirement. *See Mamula v. Satralloy, Inc.*, 578 F. Supp. 563, 579 (S.D. Ohio 1983) ("Pursuant to the Court's authority under Rule 65(c) to order the proper amount of security, in consideration of the financial condition of the plaintiffs, the likelihood of their success on the merits, the defendant's admission of its obligation to maintain the plan, and the remoteness of any damage to defendant if the order should be deemed wrongfully granted, the Court will not require the filing by the plaintiffs of a bond."); *see also Bailey v. AK Steel Corp.*, No. 1:06cv468, 2006 U.S. Dist. LEXIS 68298, at *38-39 (S.D. Ohio Sep. 22, 2006) (Even though granting the injunction would cost AK Steel a significant amount of money the defendant provided no estimate; court waived bond based on the age and financial means of the plaintiffs and their likelihood of success).

V. CONCLUSION

This court must weigh all the foregoing factors. On balance, these factors weigh in support of granting the injunctive relief sought. Plaintiffs have shown that absent an injunction, the PBMs will not adjust their formularies and plan designs for all customers consistent with the CDC Guideline of March 2016.

16 (6th Cir. 1954) (Party enjoined from proceeding with a trial prior to decision in a similar case; no bond required because "no material damage will ensue to appellants from the failure of the District Judge to require bond of appellees").

Date: September 14, 2018

Respectfully submitted,

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LOCAL RULE 7.1(f) CERTIFICATION

The Court's April 11, 2018 Case Management Order One, Section 2(h) states that the page limitations applicable to complex cases shall apply to the length of memoranda filed in support of motions. Under Rule 7.1(f), memoranda relating to dispositive motions in complex cases may not exceed thirty (30) pages.

I, Joanne Cicala, hereby certify that this *Memorandum of Law in Support of Joint Motion for Preliminary Injunctive Relief* complies with Local Rule 7.1(f) of the United States District Court for the Northern District of Ohio and the page limitations set forth therein.

Respectfully submitted,

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