#### COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.	SUPERIOR COURT CIVIL ACTION NO.
COMMONWEALTH OF MASSACHUSETTS,	)
Plaintiff,	)
V.	)
INJURED WORKERS PHARMACY, LLC.	)
Defendant.	)
	)

# **COMPLAINT**

# I. INTRODUCTION

- 1. Defendant Injured Workers Pharmacy ("IWP") is a Massachusetts-based mail-order pharmacy that dispenses and ships prescription drugs, including controlled substances, across the nation, primarily to workers who have been injured on the job.
- 2. Like all other pharmacies, IWP has a legal obligation to dispense only those controlled substance prescriptions that have a legitimate medical purpose. This is necessary to protect its patients and to make sure that the drugs it dispenses are not diverted onto the black market.
- 3. The evidence gathered during the Attorney General's investigation demonstrates that IWP failed to implement adequate dispensing safeguards and dispensed and shipped controlled substance prescriptions without sufficient regard for their legitimacy, including:
  - a. prescriptions for large quantities of opioids, for high doses, for long periods of time;

- opioid prescriptions in dangerous combinations with other controlled substances, including other opioids, benzodiazepines (like Valium), and muscle relaxants;
   and
- c. controlled substance prescriptions written by prescribers whose prescriptions bore numerous red flags and who were later sanctioned for inappropriate prescribing.
- 4. IWP drove this prescription volume in part by making payments for new patient referrals, including to law firms representing personal injury plaintiffs and injured workers.
- 5. IWP's conduct violated Massachusetts law and regulations, including G.L. c. 93A ("the Massachusetts Consumer Protection Act").

# II. JURISDICTION AND VENUE

- 6. This Court has jurisdiction over the subject matter of this suit pursuant to General Laws chapter 93A, § 4 and chapter 214, § 1.
- 7. This Court has jurisdiction over IWP because it is incorporated in Massachusetts and its primary place of business is in Massachusetts.
- 8. Venue is proper in Suffolk County pursuant to General Laws chapter 93A section 4 because IWP has consented to venue here.

# **III.PARTIES**

- 9. The plaintiff is Attorney General Maura Healey, who brings this action in the public interest in the name of the Commonwealth of Massachusetts.
- 10. Defendant IWP is a licensed retail pharmacy that dispenses prescription drugs almost exclusively on a mail-order basis. IWP is incorporated in Massachusetts and has its principal

place of business at 300 Federal Street in Andover, Massachusetts. IWP primarily fills prescriptions for patients covered by workers' compensation insurance, which pays the medical expenses for workers who are injured or become ill in the course of their employment. In addition to a national salesforce of about 40-50 sales representatives, IWP employs approximately 200 staff in its Andover location.

### IV. BACKGROUND FACTS

# A. IWP Must Comply With Affirmative Legal And Regulatory Obligations When Dispensing Controlled Substances

- 11. Due to the risks associated with controlled substances, pharmacies like IWP are subject to various state and federal dispensing requirements aimed at protecting patient and public safety and reducing misuse and diversion of controlled substances.
- 12. Massachusetts law imposes on doctors and other prescribers a responsibility to properly prescribe controlled substances. It further imposes on pharmacies and pharmacists a "corresponding responsibility" to fill only legitimate prescriptions issued in the "the usual course of professional treatment."
- 13. Pharmacies and pharmacists filling controlled substance prescriptions are further required to: (a) "verify the prescription by telephonic or other means," and not "fill a prescription for which verification cannot be obtained"; (b) conduct drug utilization reviews ("**DURs**"); and

<sup>&</sup>lt;sup>1</sup> See G.L. c. 94C, § 19(a) ("A prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of section one and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties [under the Massachusetts CSA].").

<sup>&</sup>lt;sup>2</sup> See G.L. c. 94C, § 18.

<sup>&</sup>lt;sup>3</sup> DURs are a standard pharmacy practice required by Massachusetts pharmacy regulations. *See* 247 CMR 9.07. DUR regulations require pharmacists to review prescriptions before dispensing to identify, among other things:

(c) deliver controlled substance prescriptions only to a "verified address" in the state of residence of the person for whom the prescription was written.<sup>4</sup> Taken together, these state law requirements are designed to keep patients safe and are important safeguards against illegal diversion of prescription drugs.

# B. IWP Failed To Implement Adequate Safeguards Against Improper Dispensing

- 14. Because IWP's business is national, the Massachusetts IWP staff involved in reviewing and dispensing prescriptions generally lack personal familiarity with the many out-of-state prescribers, patients and communities they serve. Accordingly, it was even more important that IWP adhere to legal requirements and implement and follow effective policies and practices for verifying the legitimacy of controlled substance prescriptions, meet the corresponding responsibility imposed upon pharmacists, and guard against diversion.
- 15. IWP did not implement effective safeguards against improper dispensing. Rather, IWP created an operation that prioritized dispensing speed and shipments to new patients (referred to internally at IWP as "new patient ships").
- IWP did not implement adequate policies or procedures for monitoring, flagging, or 16. blocking controlled substance prescriptions written by prescribers who were: engaged in suspicious pattern prescribing; prescribing dangerously high doses of opioids; or prescribing dangerous fentanyl drugs.<sup>5</sup> Nor did IWP implement adequate systems for requiring its pharmacists to verify all controlled substance prescriptions.

prescriptions that would result in consumption of the drug in amounts outside of a medically appropriate range; therapeutic duplication; drug-disease contraindication; drug-drug interactions (including highly dangerous combinations of drugs such as the "holy trinity" - an opioid, benzodiazepine, and muscle relaxant - that is almost never medically appropriate); incorrect drug dosage or duration of drug treatment; drug-allergy interactions; clinical abuse or misuse; and any significant change in drug, dose, or directions.

<sup>&</sup>lt;sup>4</sup> See G.L. c. 94C, § 18(d½)(6).

<sup>&</sup>lt;sup>5</sup> IWP did not implement a reliable system for checking the validity of prescribers' DEA controlled substances licenses until in or around June 2018.

17. Instead, IWP pressured pharmacists to dispense prescriptions at unsafe rates using a dispensing process that divided responsibility for filling each prescription among up to four pharmacists and pharmacy technicians, such that no one assumed complete responsibility for ensuring compliance with IWP's legal obligations.

# C. IWP Created A Program Known As "Gold Not Enrolled" To Increase New Patient Ships And Shortcut Existing Safeguards

- 18. IWP created a program, in effect from 2008 to about March 2017, that required pharmacists to fill and ship new patient prescriptions (including controlled substance prescriptions) written or referred by "gold" level referral sources (i.e., certain doctors and lawyers) the day they came in, before IWP staff had spoken with patients to confirm their demographic information (including their address) or had verified they had a workers' compensation claim.
- 19. Under the Gold Not Enrolled program, IWP did not contact the patient to verify the delivery address. Instead, IWP's enrollment staff would attempt to verify the patient's address online. IWP paid bonuses to enrollment staff based on number of new patient ships, which included all prescriptions filled under the Gold Not Enrolled program.
- 20. IWP eventually eliminated Gold Not Enrolled on April 1, 2017, citing difficulties verifying and collecting from certain Gold Not Enrolled patients' insurance.
- 21. For a short time beginning in February 2018, IWP reintroduced Gold Not Enrolled for drugs other than schedule II controlled substances called GNE 2.0 "to accelerate [New Patient Ships] from well-known referral sources" while acknowledging that the "Poor data quality" of patient addresses was a "program risk." Senior management and finance personnel selected the "gold" referral sources "based on various financial drivers (profitability, \$ collected)."

22. IWP dispensed and shipped thousands of controlled substance prescriptions under Gold Not Enrolled and GNE 2.0 without sufficient compliance safeguards.

# D. IWP Filled Thousands Of Dangerous Controlled Substance Prescriptions Without Sufficient Regard For Their Legitimacy

- 23. IWP's dispensing and sales policies and practices effectively precluded IWP from meeting its corresponding responsibility and complying with statutory mandates. As a result, IWP filled and shipped:
  - a. thousands of prescriptions written by prescribers whose prescribing behaviors bore red flags and who were ultimately disciplined, indicted or convicted for improper opioid prescribing. IWP did not stop dispensing their prescriptions until long after their suspicious prescribing behaviors were or should have been apparent to the pharmacy staff filling them and sales staff visiting their offices.
  - b. thousands of dangerous, high-dose prescriptions that exceeded relevant prescribing guidelines.<sup>6</sup>
  - c. thousands of prescriptions for fentanyl formulations known to be especially dangerous known as Transmucosal Immediate-Release Fentanyl ("TIRF")<sup>7</sup>.
     Many of these prescriptions were from prescribers whose prescriptions bore

<sup>&</sup>lt;sup>6</sup> In March 2016, the Centers for Disease Control and Prevention released guidelines for the prescribing and dosing of opioids for chronic pain—the predominant condition among IWP's patients. The CDC recognized that prior recommendations had "considerable variability" in their specific recommendations, by, for example, providing a range of maximum dosing thresholds of 90 MME per day to 200 MME per day. The CDC conducted a "systematic review of the scientific evidence" and obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. Ultimately, the CDC recommended that "[c]linicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 [MME]/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day."

<sup>&</sup>lt;sup>7</sup> TIRF drugs are 50 to 100 times stronger than morphine. TIRF drugs are approved by the Food and Drug Administration solely to manage breakthrough pain in adults with cancer who are taking other opioid medicines around-the-clock for pain. Fentanyl, like morphine, heroin, and other opioids is highly addictive and poses a significant risk of addiction, overdose, and death. Patients prescribed TIRF drugs for even a short period of time are at a significantly increased risk for these outcomes.

- multiple red flags and who were ultimately disciplined, indicted or convicted of improper opioid prescribing; and
- d. thousands of prescriptions for dangerous combinations of drugs even though these combinations are key indicators of drug misuse and potential overdose, and are almost never medically appropriate. These deadly drug combinations included the "holy trinity" – a combination of an opioid, a benzodiazepine, and a muscle relaxant – as well as combinations of opioids and benzodiazepines.
- 24. IWP filled these prescriptions without sufficient regard for their legitimacy.

# E. IWP Used Unlawful Sales Tactics

25. IWP's business depended on prescribers all over the country sending prescriptions to IWP, rather than to local pharmacies. IWP generated that business using, *inter alia*, unfair and unlawful sales tactics.

# (i) IWP Incented Its Sales Reps To Engage In Unlawful Conduct

- 26. IWP used a team of sales representatives (40-50 at any given time) to generate sales by visiting prescribers and other "referral sources" across the country, e.g., workers' compensation and personal injury attorneys.
- 27. IWP did not utilize its sales representatives to identify and report red flags about the doctors they were visiting; it did not train, require or incent its sales representatives to identify or report red flags regarding the prescribers they visited. Rather, it paid them largely on the basis of "new patient ships" the "key driver of [IWP's] continued financial success and growth" and it armed them with large expense accounts to woo referral sources.

7

<sup>&</sup>lt;sup>8</sup> In 2014, the Substance Abuse and Mental Health Services Administration ("**SAMHSA**") warned that "when combined with other drugs that depress CNS activity, such as alcohol or opioid pain relievers … benzodiazepines may present serious or even life-threatening problems. Concerns exist about the increasing number of patients prescribed both benzodiazepines and opioids."<sup>8</sup>

28. IWP's incentive compensation structure, compounded by a lack of IWP oversight and control over sales representatives and their expense accounts, had predictable results. To meet their quotas and earn more bonus compensation, IWP sales representatives used unfair sales tactics and pressured enrollment and pharmacy staff to process and dispense prescriptions faster.

# (ii) IWP Paid For Patient Referrals

- 29. It is unlawful to make a payment in exchange for a recommendation or referral for the purchase of a good or service that will be paid for in whole or in part by a health care insurer. *See* G.L. c. 175H § 3, G.L. c. 118E § 41. Paying for referrals can also be an unlawful, unfair method of competition or unfair or deceptive act or practice. *See* G.L. c. 93A § 2.
- 30. IWP entered into multiple payment arrangements with personal injury and workers' compensation law firms and other businesses to buy new patient referrals.
- 31. IWP disguised these referral payment arrangements by calling them "marketing agreements" and "sponsorships." One such "marketing agreement" with a Massachusetts personal injury and workers' compensation law firm called for IWP to pay \$4,000 per month in exchange for "plac[ing] a direct link to IWP's website on [the law firm's] website for information purposes about pharmacy services." Internal communications reveal that IWP was not paying the law firm for "traffic on [its] website" but rather for "getting them 40 cases" each month. IWP paid that law firm more than \$90,000 for hundreds of patient referrals from 2017 to 2019. Those referrals generated more than \$1.2 million revenue for IWP.

# V. CLAIMS

# COUNT ONE UNFAIR AND DECEPTIVE ACTS AND PRACTICES IN VIOLATION OF G.L. c. 93A § 2

- 32. The Commonwealth realleges each allegation above.
- 33. G.L. c. 93A, § 4 authorizes the Attorney General to bring an action to enjoin a defendant from engaging in a method, act, or practice that violates G.L. c. 93A, § 2.
- 34. On March 3, 2020, the Attorney General notified IWP of her intention to file this suit and offered them an opportunity to confer, in conformance with G.L. c. 93A.
- 35. IWP engaged in unfair or deceptive acts or practices in the conduct of trade or commerce in violation of G.L. c. 93A, including, without limitation, by:
  - Failing to implement adequate policies and procedures to safeguard against improper and unlawful dispensing;
  - Filling dangerous controlled substance prescriptions without sufficient regard for whether they were issued for a legitimate medical purpose;
  - c. Filling controlled substance prescriptions without verifying them;
  - d. Filling prescriptions without conducting an adequate Drug Utilization Review;
  - e. Shipping prescriptions without verifying the patient's address; and
  - f. Using unfair sales tactics, including paying health care providers, attorneys, and others in exchange for new patient referrals.
- 36. IWP's conduct was knowing and willful.
- 37. Each unfair or deceptive act was a distinct violation of G.L. c. 93A.

# PRAYER FOR RELIEF

WHEREFORE, the Commonwealth respectfully requests that this Court grant the following relief:

- Enter a final judgment against IWP;
- b. Declare that IWP engaged in unfair and deceptive acts and practices in violation of G.L. c. 93A, § 2;
  - c. Permanently enjoin IWP from further violations of G.L. c. 93A, § 2;
- d. Order IWP to pay a civil penalty of up to \$5,000 for each violation of G.L.
  c. 93A;
- e. Award the Attorney General's Office the reasonable costs of investigation and litigation of such violations, including reasonable attorney's fees; and
  - f. Grant such other relief for the Commonwealth as the court deems just and proper.

Dated: June 24, 2020

Respectfully Submitted, COMMONWEALTH OF MASSACHUSETTS By its Attorney MAURA HEALEY ATTORNEY GENERAL

Gillian Feiner, BBO No. 664152 Senior Enforcement Counsel David Kim, BBO No. 703568 Matthew Lashof-Sullivan, BBO No. 695922 Office of the Attorney General Health Care & Fair Competition Bureau One Ashburton Place Boston, MA 02108

Tel: 617-680-8297 gillian.feiner@mass.gov