



MAURA HEALEY
ATTORNEY GENERAL

THE COMMONWEALTH OF
MASSACHUSETTS
OFFICE OF THE ATTORNEY GENERAL

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December 16, 2021

BY HAND

Michael Joseph Donovan, Civil Clerk
Suffolk County Superior Court for Civil Business
Suffolk County Courthouse, 12th Floor
3 Pemberton Square
Boston, Massachusetts 02108

RECEIVED

DEC 16 2021

SUPERIOR COURT-CIVIL
MICHAEL JOSEPH DONOVAN
CLERK/MAGISTRATE

Re: *Comm. v. Collegium Pharmaceutical, Inc.*

Dear Clerk Donovan:

Enclosed, please find for in the above-referenced case the following documents:

1. Civil Cover Sheet
2. Assurance of Discontinuance

Thank you for your attention to this matter.

Very truly yours,


/s/Michael Wong

BBO #568875

Assistant Attorney General

Enclosure.

Cc: Barry Boise, Esq.
Callan Stein, Esq.

CIVIL ACTION COVER SHEET		DOCKET NUMBER	Trial Court of Massachusetts The Superior Court		
			COUNTY	Suffolk Superior Court (Boston)	
Plaintiff Commonwealth of Massachusetts			Defendant: Collegium Pharmaceutical, Inc.		
ADDRESS: Office of the Attorney General			ADDRESS: 100 Technology Center Dr. #300		
One Ashburton Place, Boston, MA 02108			Stoughton, MA 02072		
Plaintiff Attorney: Michael Wong			Defendant Attorney: Callan Stein		
ADDRESS: Office of the Attorney General			ADDRESS: Troutman Pepper Hamilton Sanders LLP		
One Ashburton Place, Boston, MA 02108			19th Floor, High St. Tower		
			125 High St., Boston, MA 02110-2736		
BBO: 568875			BBO: 670569		
TYPE OF ACTION AND TRACK DESIGNATION (see instructions section below)					
CODE NO.	TYPE OF ACTION (specify)	TRACK	HAS A JURY CLAIM BEEN MADE?		
AB1	Assurance of Discontinuance		<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
*If "Other" please describe: _____					
Is there a claim under G.L. c. 93A? Is there a class action under Mass. R. Civ. P. 23?					
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
STATEMENT OF DAMAGES PURSUANT TO G.L. c. 212, § 3A					
The following is a full, itemized and detailed statement of the facts on which the undersigned plaintiff or plaintiff's counsel relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.					
TORT CLAIMS					
A. Documented medical expenses to date					
1. Total hospital expenses _____					
2. Total doctor expenses _____					
3. Total chiropractic expenses _____					
4. Total physical therapy expenses _____					
5. Total other expenses (describe below) _____					
Subtotal (1-5): \$0.00					
B. Documented lost wages and compensation to date _____					
C. Documented property damages to date _____					
D. Reasonably anticipated future medical and hospital expenses _____					
E. Reasonably anticipated lost wages _____					
F. Other documented items of damages (describe below) _____					
TOTAL (A-F): \$0.00					
G. Briefly describe plaintiff's injury, including the nature and extent of injury: _____					
CONTRACT CLAIMS					
<input type="checkbox"/> This action includes a claim involving collection of a debt incurred pursuant to a revolving credit agreement. Mass. R. Civ. P. 8.1(a).					
Item #	Detailed Description of Each Claim				Amount
1.					
Total					
Signature of Attorney/Unrepresented Plaintiff: X Michael Wong <i>Michael Wong</i>			Date: December 15, 2021		
RELATED ACTIONS: Please provide the case number, case name, and county of any related actions pending in the Superior Court.					
CERTIFICATION PURSUANT TO SJC RULE 1:18					
I hereby certify that I have complied with requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods of dispute resolution.					
Signature of Attorney/Unrepresented Plaintiff: X Michael Wong <i>Michael Wong</i>			Date: December 15, 2021		

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
CIVIL ACTION NO.

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff,

v.

COLLEGIUM PHARMACUTICAL, INC.,

Defendant.

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SUPERIOR COURT-CIVIL
MICHAEL JOSEPH DONOVAN
CLERK/MAGISTRATE

**ASSURANCE OF DISCONTINUANCE
PURSUANT TO G. L. C. 93A, SECTION 5**

I. INTRODUCTION

1. In or around January 2018, pursuant to G.L. c. 93A, § 6, the Commonwealth of Massachusetts, through Attorney General Maura Healey, commenced an investigation of Collegium Pharmaceutical, Inc.'s sale and promotion of opioids in Massachusetts from the time Collegium launched its extended-release oxycodone product, Xtampza ER, until the Effective Date (the "Covered Conduct").

2. Based on the investigation, the AGO is prepared to allege that Collegium engaged in certain unfair and deceptive conduct in connection with marketing and selling Xtampza in Massachusetts, including through its Speaker Programs and In-Person Detailing as those terms are defined in Section II, *infra*, in violation of G.L. c. 93A § 4.

3. Collegium has cooperated with the AGO's investigation.

4. Collegium ceased Speaker Programs about Xtampza in Massachusetts, in March 2018.

5. Collegium ceased In-Person Detailing about Xtampza in Massachusetts, effective December 1, 2021.

6. In lieu of litigation, the Attorney General accepts this Assurance of Discontinuance ("Assurance") on the terms and conditions contained herein, pursuant to G.L. 93A § 5.

7. The Massachusetts Attorney General's Office and Collegium ("Parties") voluntarily enter into this Assurance without trial or adjudication of any issue of fact or law.

8. Collegium denies each of the AGO's allegations, and further denies that any of those allegations, standing alone or together with others, constitutes a violation of G.L. 93A. Collegium denies that it violated any laws or regulations, or that it engaged in any wrongdoing.

9. Collegium enters this Assurance for settlement purposes only. Collegium enters this Assurance to resolve the AGO's investigation without the risk and expense of litigation.

II. DEFINITIONS

10. "AGO" means the Massachusetts Attorney General's Office.

11. "Collegium" means Collegium Pharmaceutical, Inc., including its current and former officers, directors, employees, parents, subsidiaries, affiliates, agents, successors, and assigns.

12. “In-Person Detailing” means a practice where an individual, acting on behalf of Collegium, communicates face-to-face, in person, with a physician or other health care professional licensed to prescribe medications about a drug or disease state during the health care professional’s working day, including mealtimes.

13. “Speaker Programs” means any event, including a breakfast, lunch, or dinner, sponsored by Collegium at which a physician or other health care professional makes a speech or presentation to other health care professionals about a drug or a disease state.

14. “Effective Date” means the date this Assurance is fully executed by the parties.

15. “Xtampza” means the prescription medication Xtampza ER (oxycodone) for oral use.

III. THE AGO’S ALLEGATIONS

Based upon its investigation, the AGO alleges that Collegium violated G. L. c. 93A, § 2 by engaging in the following conduct:

16. Since May 2016, Collegium has manufactured and sold Xtampza, a powerful extended-release opioid that contains the same active ingredient—oxycodone—as Oxycontin. The U.S. Drug Enforcement Administration classifies Xtampza as a Schedule II narcotic. Since launching Xtampza, Collegium sales representatives have promoted Xtampza to Massachusetts prescribers face to face more than 5,000 times.

17. Collegium misled Massachusetts doctors about Xtampza’s risks and appropriate uses, at various times, by deceptively marketing it as a safer and more responsible choice than other opioids and improperly marketing it to treat acute pain, primarily through In-Person Detailing and Speaker Programs.

18. In other times, Collegium sales representatives obscured Xtampza's risks and overcame prescribers' concerns about the risks of addiction, overdose and death, including by deceptively telling doctors that Xtampza's abuse-deterrent formulation – which was designed to make Xtampza more difficult to crush or dissolve in water – could prevent intentional misuse, making Xtampza a “safe” and “responsible” choice.

19. Collegium's sales representatives also deceptively stated and implied to certain prescribers that Xtampza's abuse-deterrent properties made it safer and less subject to diversion than OxyContin, even though Xtampza has the same active ingredient (oxycodone) with the same risk of addiction, overdose, and death.

20. Email correspondence among Collegium sales staff describing sales representative “success stories” confirm that this deceptive tactic – pitching Xtampza as a safe and responsible alternative to other opioids – was successful, including in Massachusetts.

21. In addition to deceptively marketing Xtampza as safer than other opioids, Collegium unfairly and deceptively marketed Xtampza to orthopedists and surgeons as an appropriate initial treatment for acute, short-term pain, without regard for relevant CDC guidelines calling for doctors to prescribe immediate-release opioids for short-term use instead of extend-release/long-acting (“ER/LA”) opioids like Xtampza.

IV. ASSURANCES

22. In the interest of fully and finally resolving the AGO's Investigation, Collegium provides the AGO the following assurances (“Assurances”):

23. Collegium will not engage in unfair or deceptive marketing in Massachusetts.

24. Collegium will not resume Speaker Programs about Xtampza in Massachusetts.

25. Collegium will not resume In-Person Detailing about Xtampza in Massachusetts.

26. Collegium will publicly disclose online, on a quarterly basis beginning with respect to the first quarter of 2022 and continuing until such time as Collegium no longer sells Xtampza in Massachusetts, the following: (i) the number of prescriptions of Xtampza, categorized by dosage strength, that are filled during such period in Massachusetts and nationally; and (ii) the number of morphine milligram equivalents, or MMEs, associated with the prescriptions disclosed pursuant to clause (i), categorized by dosage strength, for the relevant quarterly period in Massachusetts and nationally.

V. PAYMENT TO COMMONWEALTH

27. Within seven days after the Effective Date, Collegium shall pay to the Commonwealth a total of \$185,000 which payment shall be made by an electronic fund transfer to an account or accounts identified by the Commonwealth and shall be designated as for the costs of investigation, including attorneys' fees. Such payment shall be designated as follows: (1) \$125,000 to be deposited into a trust fund maintained by the AGO that shall be expended, within the sole discretion of the Attorney General, to support (a) the Local Consumer Aid Fund, G.L. c. 12, § 11G; (b) the Municipal Naloxone Bulk Purchase Trust Fund, G.L. c. 12, § 2RRRR; or (c) the Opioid Recovery and Remediation Fund, G.L. c. 10, § 35000; and (2) \$60,000 for the costs of investigation, including attorneys' fees.

VI. RELEASE

18. In consideration of this Assurance, the Commonwealth of Massachusetts releases, discharges, and agrees not to proceed with or institute a civil action or proceeding for, any violations of Chapter 93A or any other consumer protection or unfair trade practice laws, RICO

laws, public nuisance laws together with any related common law and equitable claims for damages or other relief against Collegium Pharmaceutical, Inc., including but not limited to an action or proceeding seeking restitution, injunctive relief, fines, penalties, multiple damages, attorneys' fees or costs, for any acts or practices based on the Covered Conduct prior to the Effective Date. This Assurance does not resolve and shall not be deemed a waiver of any other actual or potential claims the Commonwealth may have against Collegium Pharmaceutical, Inc., such as any administrative liability that Collegium Pharmaceutical, Inc. or liability that any other person and/or entity may have to the Commonwealth not expressly covered by the release in this paragraph, including, but not limited to Medicaid claims and state false claims violations.

VII. GENERAL PROVISIONS

19. This Assurance represents the entire agreement between the AGO and Collegium concerning the matters addressed herein. This Assurance supersedes and prior agreements, understandings, communications, or stipulations between the Parties.

20. This Assurance shall be binding on Collegium and the AGO.

21. This Assurance shall be governed by and interpreted in accordance with the laws of the Commonwealth of Massachusetts. This Assurance confers no standing or other legal rights on any party other than the AGO and Collegium.

22. This Assurance shall be filed in the Superior Court of Suffolk County. The Superior Court has and shall retain jurisdiction over this Assurance.

23. Nothing in this Assurance shall prevent the AGO from enforcing the obligations and Assurances set forth in Sections IV herein. This Assurance does not resolve any claims by

any party other than the Commonwealth. This Assurance similarly does not resolve any actual or potential claims by the Commonwealth against any other parties.

24. This Assurance shall not relieve Collegium of any obligations to comply with all applicable current and future federal, state, and local laws and regulations.

25. This Assurance is not intended to impair any right of action that any other person or entity might have against Collegium.

26. This Assurance is not intended to be, and shall not be, construed or used as a waiver or limitation of any defense otherwise available to Collegium in any pending or future legal or administrative action or proceeding, except as provided in G.L. c. 93A, § 5.

27. Except for purposes of its enforcement, if necessary, no part of this Assurance shall be construed or admitted into evidence in any proceeding as an admission of liability by Collegium, and any such liability is expressly denied by Collegium.

28. By virtue of the provisions of G.L. c. 93A, §5, evidence of a violation of the terms of this Assurance by Collegium after the Effective Date shall constitute prima facie evidence of a violation of Chapter 93A, § 2, in any civil action or proceeding subsequently commenced against Collegium, as applicable, by the AGO.

29. Except as provided in Section VI. above, nothing in this Assurance shall be interpreted to limit the Commonwealth's authority to issue a CID, bring a lawsuit under G.L. c. 93A, s. 4 against Collegium or proceed otherwise, to the extent such authority exists under applicable law.

30. Prior to bringing an action to enforce an alleged violation of this Assurance, the AGO will provide Collegium at least fourteen (14) days' written notice that identifies the

conduct that is alleged to violate this Assurance. Collegium may provide a written response to the AGO during the fourteen-day period before the AGO files suit

31. Collegium shall comply with all reasonable written inquiries and requests from the AGO regarding the implementation of the terms contained within this Assurance.

32. Collegium hereby accepts the terms and conditions of this Assurance and waives any right to challenge the validity and binding effect of this Assurance in any action or proceeding.

33. Any notices or communications required to be transmitted between the

34. AGO and Collegium pursuant to this Assurance shall be provided in writing by first class mail, postage prepaid, and by electronic mail to the parties or successors as follows, unless otherwise agreed in writing to the following:

To the AGO

Michael W. Wong
Assistant Attorney General
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
Michael.W.Wong@mass.gov

To Defendant

Shirley Kuhlmann
Executive Vice President & General Counsel
Collegium Pharmaceutical, Inc.
100 Technology Center Drive, Suite 300
Stoughton, MA 02072
skuhlmann@collegiumpharma.com

35. The Assurance, including any time period within which a party must perform or begin to perform or complete an obligation, may be amended upon written agreement of all parties.

36. The undersigned represents that he/she is duly authorized to execute this Assurance on behalf of and to bind Collegium to all provisions of this Assurance, and on behalf of Collegium, he/she voluntarily enters into this Assurance.

APPROVED FOR DEFENDANT:

By: Shirley Kuhlmann
Name: Shirley Kuhlmann
Title: Executive Vice President & General Counsel
Date: December 15, 2021

By: Callan Stein

Callan Stein (BBO #670569)
Katherine Stark (BBO #696618)
Troutman Pepper Hamilton Sanders LLP
19th Floor, High Street Tower
125 High Street
Boston, MA 02110-2736

Barry Boise
Troutman Pepper Hamilton Sanders LLP
3000 Two Logan Square
Philadelphia, PA 19013

Date: December 15, 2021

APPROVED AND SUBMITTED by:

COMMONWEALTH OF MASSACHUSETTS
Maura Healey, Attorney General

Michael W. Wong (BBO # 568875)
Assistant Attorney General
Health Care Division
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
617-963-2918
Michael.W.Wong@mass.gov

Date: [] 2021

APPROVED FOR DEFENDANT:

By: _____
Name: Shirley Kuhlmann
Title: Executive Vice President & General Counsel
Date: [] 2021

By: _____

Callan Stein (BBO #670569)
Katherine Stark (BBO #696618)
Troutman Pepper Hamilton Sanders LLP
19th Floor, High Street Tower
125 High Street
Boston, MA 02110-2736

Barry Boise
Troutman Pepper Hamilton Sanders LLP
3000 Two Logan Square
Philadelphia, PA 19013

Date: [] 2021

APPROVED AND SUBMITTED by:

COMMONWEALTH OF MASSACHUSETTS
Maura Healey, Attorney General

/s/Michael Wong _____

Michael W. Wong (BBO # 568875)
Assistant Attorney General
Health Care Division
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
617-963-2918
Michael.W.Wong@mass.gov

Date: December 15, 2021

CERTIFICATE OF SERVICE

I, Michael W. Wong, of the Office of the Attorney General, hereby certify that a true copy of the foregoing document was served upon counsel for Defendant by mail and e-mail on December 16, 2021.

/s/Michael Wong
Assistant Attorney General