

EXHIBIT E

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE SUBOXONE (BUPRENORPHINE
HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION**

THIS DOCUMENT RELATES TO:

All Direct Purchaser Class Actions

MDL No. 2445

Master File No. 2:13-MD-2445-MSG

**Declaration of Stuart E. Des Roches in Support of
Direct Purchaser Class Plaintiffs' Motion for Attorneys' Fees, Reimbursement of
Expenses, and Incentive Awards for the Named Plaintiffs**

I, Stuart E. Des Roches, subject to the penalties of perjury provided by 28 U.S.C. § 1746, hereby declare as follows:

I am a managing member of the law firm Odom & Des Roches, LLC (“ODR”), co-counsel for the Direct Purchaser Class Plaintiffs (“DPC Plaintiffs”) in the above-captioned case. I submit this declaration in support of Direct Purchaser Class Plaintiffs’ Motion for Attorneys’ Fees, Reimbursement of Expenses, and Incentive Awards for the Named Plaintiffs.

Firm Background and Experience.

1. ODR has engaged in antitrust litigation for many years, including twenty-five (25) years of litigating antitrust cases on behalf of individual and classes of plaintiffs who purchase FDA-approved drugs directly from pharmaceutical manufacturers. ODR was a member of the litigation team that first challenged reverse payments on behalf of the direct purchaser class starting in 1998, and later challenged for the first time other types of conduct, such as product-hopping, improper Orange Book listings, and the filing of sham Citizen Petitions and patent lawsuits, all of which artificially delay or impair market entry of less-expensive generic drugs in contravention of the antitrust laws and the Hatch-Waxman regulatory scheme that governs prescription drugs in the United States (collectively, “Hatch-Waxman antitrust cases”).

2. In particular, the firm has extensive experience with: (a) the Hatch-Waxman Act and the Medicare Modernization Act (“MMA”), as well as associated regulations, guidances, manuals, practices and procedures pertaining to the filing,

maintenance, and FDA approval of Abbreviated New Drug Applications (“ANDA” or “ANDAs”) filed by generic drug manufacturers and New Drug Applications (“NDA” or “NDAs”) filed by branded drug manufacturers; (b) operational issues associated with the processes and procedures employed by pharmaceutical manufacturers in preparing for, launching, and maintaining commercial quantities of pharmaceutical products on the U.S. market; and (c) organizing, preparing for and being trial-ready in Hatch-Waxman antitrust cases.

3. ODR’s attorneys and paralegals leveraged their Hatch-Waxman antitrust experience in this case to efficiently and effectively assist in evaluating this case prior to filing, conducting fact and expert discovery, engaging in motion practice, commencing extensive trial preparations, and participating in multiple mediation processes that resulted in the settlement presented to this Court for approval.

Work in this Case.

4. From the outset of this case, the efforts of co-counsel for the DPC Plaintiffs were organized, coordinated, and monitored by Co-Lead Counsel. Most of the class counsel representing the DPC Plaintiffs in this case have worked together for 25 years on Hatch-Waxman antitrust cases. Efforts here were generally divided into issue teams according to the expertise that each firm has built over the years, with each issue team interacting with other teams to ensure that overall strategies were consistent throughout and that key facts were developed and exploited across all aspects of the case, which was particularly important in that the DPC Plaintiffs alleged that the defendant engaged in an inter-connected, over-arching scheme in violation of Section 2 of the Sherman Act. Co-

counsel for the DPC Plaintiffs worked together to devise and implement an overall litigation plan and ensured that all litigation tasks were appropriately staffed, pursued, and executed in an effective manner.

5. Prior to filing this case, ODR conducted research and analysis pertaining to Indivior's product hop from Suboxone Tablets to Suboxone Film by evaluating, *inter alia*, Citizen Petitions filed by Indivior and oppositions thereto, FDA's publicly-available review package relating to Suboxone Film, and other public information relating to the relative safety of tablet versus film dosage forms and child-resistant bottles versus unit-dose packaging in terms of accidental pediatric exposures and abuse, misuse, and diversion. ODR also evaluated certain causation-related issues, including the prospects that generic pharmaceutical manufacturers could and would have earlier launched less-expensive generic versions of Suboxone Tablets "but for" the FDA's mandated shared Risk Evaluation and Mitigation Strategies ("shared REMS") requirement and Indivior's September 2012 Citizen Petition filed with the FDA regarding Suboxone Tablets.

6. After filing of the case and its transference to this Court, ODR was part of the team effort that successfully opposed Indivior's comprehensive Fed.R.Civ.P. Rule 12 motion to dismiss and the undersigned took the lead in presenting arguments to this Court during the hearing on that matter on behalf of the DPC Plaintiffs.

7. Once discovery commenced, and at the direction of Co-Lead Counsel, ODR was responsible for portions of the case involving, *inter alia*: (a) the regulatory background underlying and pertaining to Suboxone Tablets and Film, and generic versions thereof; (b) regulatory exclusivities Indivior possessed in connection with its

Suboxone Tablet NDA, as well as FDA’s mandated shared REMS requirement; (c) the ANDAs filed by generic competitors to Indivior’s Suboxone Tablets, namely Amneal and Actavis; (d) the failed negotiations between Indivior and Amneal/Actavis (and other manufacturers of buprenorphine-containing products) regarding the shared REMS requirement, and the subsequent FDA waiver of that requirement in terms of Indivior’s participation; (e) Indivior’s September 2012 Citizen Petition, oppositions thereto, and FDA’s ruling thereon and referral to the Federal Trade Commission (“FTC”); (f) the readiness, ability, and willingness of Amneal and Actavis to enter the market earlier and/or enter with greater volumes of generic Suboxone Tablets than they actually launched and sold “but for” Indivior’s over-arching scheme; (g) the legal framework and FDA regulations governing comparative marketing and promotional efforts for pharmaceuticals (which was a component of evaluating Indivior’s false marketing statements and illegal promotion of its film product, as part of its product hop scheme); and (h) advice obtained by Indivior from third-party regulatory consultants that revealed the intent, operation, and purpose of their product hop scheme.

8. More specifically, Amneal and Actavis’ “readiness, willingness and ability” to enter the market earlier with greater volumes of product comprised gathering evidence regarding and evaluations of: (a) earlier FDA regulatory approval of the Amneal/Actavis ANDAs in light of the shared REMS negotiations with Indivior and Indivior’s September 25, 2012 Citizen Petition regarding Suboxone Tablets; (b) commercial manufacturing capabilities and supplies; (c) business incentives and objectives; and (d) business strategies to counteract Indivior’s launch of Suboxone Film.

This work necessarily required ODR to have an in-depth understanding of the nature and details of the REMS negotiations that occurred between Indivior and Actavis/Amneal (and others), as well as the nature of the requests and supporting data in Indivior's Citizen Petition filed in September 2012. ODR also conducted discovery regarding other generic competitors potentially delayed by the scheme, and which also provided information on the shared REMS negotiations and Indivior's actions, communications, and efforts relating thereto.

9. In order to understand the interrelatedness of the component parts of Indivior's scheme, it was also necessary for ODR to coordinate efforts with co-counsel to assist in other aspects of the case, particularly the timing and types of efforts undertaken to force the market switch from Suboxone Tablets to Suboxone Film over a period of time (and prior to formal withdrawal of Suboxone Tablets), the nature of Indivior's false marketing statements, Indivior's scientific support (or lack thereof) for their unlawful and misleading comparative marketing and promotional efforts, discovery of Indivior's development partner and supplier on this drug product (Monosol/Aquestive Therapeutics), and related whistleblower/relator cases and criminal matters involving Suboxone and Indivior.

10. Consistent with the above discovery (and eventual trial responsibilities), ODR took multiple depositions of party and non-party fact witnesses in the case. In total, ODR actively participated in 16 of the approximately 53 fact depositions taken by all parties in this case – in most instances, taking the lead in the examinations on behalf of all plaintiffs. Specifically, ODR deposed the following:

Name	Party	Date(s)
Andry, Gerald	Third Party – Roxane/West Ward Senior Director of Regulatory Medical Affairs	Jan. 23, 2018
Clissold, Dave	Third Party – Indivior’s outside regulatory counsel	Apr. 11, 2018
Crossley, Mark	Indivior’s current CEO (and former CFO)	Aug. 29, 2023
Edwards, Candis	Third Party – Amneal Senior Vice President of Regulatory Affairs/Compliance	Oct. 5, 2017
Gopu, Kishore	Third Party – Teva Director of REMS Operations	Feb. 21, 2018
Higgin, Michelle	Third Party – PharmaDirections Managing Principal (Indivior’s outside regulatory consultant)	Jun. 20, 2018
Jadeja, Janek	Third Party – Actavis Director of Regulatory Affairs	Sep. 14, 2017 & Oct. 3, 2017
Kendall, Keith	Third Party – Monosol/Aquestive Therapeutics CEO	Aug. 30, 2018
Kinard, Robin	Third Party – PPD project manager regarding the BTOD REMS	Aug. 1, 2019
Luce, Jim	Third Party – Amneal Executive Vice President of Sales & Marketing	Aug. 30, 2018
McLeod, Suzanne	Third Party – Roxane/West Ward Manager of REMS and Drug Safety	Jan. 23, 2018
Pastore, Jill	Third Party – Teva Senior Director of Regulatory Affairs	Feb. 21, 2018
Patel, Alpesh	Third Party – Amneal Vice President of Global Regulatory Affairs	Aug. 31, 2017
Pollock, Robert	Third Party – Lachman Consultants Executive Vice President (Monosol/Aquestive Therapeutics’ outside regulatory consultant)	Aug. 7, 2018
Schobel, Mark	Third Party – Monosol/Aquestive Therapeutics CEO and President	Aug. 22, 2018 & Aug. 23, 2018
Yang, Ju	Indivior Global Head of Regulatory Affairs	Apr. 4, 2023

11. ODR also attended the depositions of other fact witnesses, and assisted the examining attorneys for those depositions with preparation for and/or taking of the depositions.¹

12. ODR further assisted in other discovery tasks, including: (a) drafting numerous requests for production, interrogatories, and third-party subpoenas; (b) participating in meet-and-confer processes with multiple generic ANDA filers regarding their responses and objections to discovery requests; (c) assisting in the review of 6-7 million pages of documents obtained from Indivior and third parties, which was an especially substantial undertaking; (d) constructing an efficient deposition strategy that identified key witnesses with relevant knowledge of the facts while minimizing the total number of depositions plaintiffs would have to take in the case; and (e) engaging and working with experts.

13. Regarding experts, ODR worked closely with two highly-qualified experts specializing in the pharmaceutical industry and the Hatch-Waxman Act regulatory scheme, Ms. Deborah Jaskot and Prof. Patricia Zettler. Ms. Jaskot, a former executive with over 30 years of pharmaceutical regulatory affairs experience, opined regarding the general regulatory framework pertaining to brand and generic drug products, whether there were regulatory impediments to earlier final approval of the ANDAs of Amneal and Actavis, as well as the merits of Indivior's September 2012 Citizen Petition. Prof. Zettler,

¹ Fact witnesses, Dr. Tim Baxter (Indivior Global Medical Director), Lenn Murrelle (Venebio President and CEO), and Nicholas Reuter (Indivior Manager of Risk Mitigation and Public Policy).

who at the time was teaching at the Moritz College of Law (Ohio State University) and was recently named Deputy General Counsel for U.S. Department of Health and Human Services, opined regarding issues involving FDA's required shared REMS for buprenorphine-containing products, the FDA regulations concerning the marketing and promotion of prescription drugs, and Indivior's lack of scientific evidence to support its promotional safety claims relating to Suboxone Tablets and Film.

14. ODR was also responsible for preparing Ms. Jaskot and Prof. Zettler for their depositions and defending their three depositions (Prof. Zettler was deposed twice). In addition, ODR was primarily responsible for deposing those experts put forward by Indivior to counter Ms. Jaskot and Prof. Zettler, namely Sheldon Bradshaw and Nicholas Fleischer (Mr. Fleischer was also deposed twice). ODR also participated in the deposition of Dolores Curtis on related issues, in conjunction with the state attorneys general. In total, ODR either took or defended 7 of the approximately 29 expert depositions in the case. In addition, ODR also attended the depositions of an additional two expert witnesses, and assisted the examining attorneys for those depositions with preparation for and/or taking of the deposition.²

15. ODR was tasked to lead the oppositions to *Daubert* motions filed by Indivior seeking to exclude the opinions of Ms. Jaskot and Prof. Zettler, assisted with any causation-related aspects of other *Daubert* oppositions, and assisted in drafting and

² Indivior's expert Lenn Murrelle (who was also deposed separately as a fact witness) and DPC Plaintiffs' expert Dr. Laurence Westreich.

editing Plaintiffs' affirmative *Daubert* motion seeking to exclude certain opinions of Indivior's experts, Sheldon Bradshaw and Nicholas Fleischer.

16. ODR was also involved in drafting aspects of Plaintiffs' opposition to Defendants' motion for summary judgment, Plaintiffs' responses to Defendants' statements of material facts submitted in support of their motions for summary judgment, and Plaintiffs' responsive statement of facts opposing summary judgment.

17. ODR was also part of the core team that engaged in extensive trial preparations and was prepared to materially participate in all aspects of trial. Those trial efforts started in the Fall of 2022 and continued until the matter was settled through a mediation process in October 2023.

18. The undersigned was designated as the lead trial lawyer, while firm member Dan Chiorean was designated to lead the direct or cross examination of several fact and expert witnesses. Our firm's paralegal, Kimberly Fontenot, was designated as the lead paralegal for the combined, multi-firm trial team.

19. These trial responsibilities required ODR attorneys and paralegals to be involved in extensive trial preparations, including (a) organizing and overseeing the entire trial team; (b) negotiating deadlines and sequencing with Indivior regarding pre-trial deliverables; (c) creation of and quality control over an extensive exhibit list, and associated preparation of the actual exhibits for trial use; (d) deciding which fact and expert witnesses to present as well as the ordering of those witnesses; (e) designating deposition testimony of witnesses who would not be available to testify live during trial; (f) researching the evidentiary bases for introduction of, or opposition to, key pieces of

testimony and exhibits; (g) preparing for the examination of fact and expert witnesses, including preparing expert witnesses for their testimony; (h) selecting trial vendors for various technical needs; (i) researching and selecting a hotel and war room for counsel, paralegals, and other support staff; (j) preparing the opening statement; (k) structuring a mock jury focus session; (l) working with jury and demonstrative-graphics consultants; and (m) coordinating and leading the overall team of paralegals for trial preparations.

20. Finally, ODR through the undersigned was a core member of the DPC Plaintiffs' settlement and mediation team. This work involved, among other things, working closely with Co-Lead Counsel (Mr. Gerstein in particular) in charge of settlement negotiations on behalf of the DPC Plaintiffs, drafting portions of mediation statements and other communications, and engaging with the mediator.

ODR's Fees and Expenses.

21. Contained below is a chart demonstrating the time spent on this case by each ODR attorney and paralegal, and the lodestar calculation based on the firm's 2023 billing rates. The schedule was prepared from contemporaneous daily time records regularly prepared and maintained by all attorneys, paralegals, and staff at our firm, which are available for the Court's *in camera* inspection if necessary. The chart reports the time spent on the case from its inception until October 31, 2023. This does not include time spent preparing documentation for this motion. The total number of hours expended on this litigation by the firm is 16,569.65 and the total lodestar for the firm is \$10,062,603.75.

Name	Position	Hours	2022 Rate (\$/ Hour)	Lodestar (\$)
Stuart Des Roches	Partner	3000.5	\$985.00	\$2,955,492.50
Andrew Kelly	Partner	59.75	\$930.00	\$55,567.50
Chris Letter	Partner	364.5	\$765.00	\$278,842.50
Dan Chiorean	Partner	3121.65	\$700.00	\$2,185,155.00
Craig Glantz	Associate	65.75	\$650.00	\$42,737.50
Annie Schmidt	Associate	1986.5	\$525.00	\$1,042,912.50
Christopher Stow-Serge	Associate	97.5	\$550.00	\$53,625.00
Amanda Hass	Associate	179.0	\$525.00	\$93,975.00
Caroline Hoffmann	Associate	574.25	\$450.00	\$258,412.50
John Fitzpatrick	Associate	3367.5	\$400.00	\$1,347,000.00
TJ Maas	Of Counsel	1479.25	\$750.00	\$1,109,437.50
Kimberly Fontenot	Paralegal	1478.75	\$290.00	\$428,837.50
Amy Kennelly	Paralegal	794.75	\$265.00	\$210,608.75
TOTAL		16,569.65		\$10,062,603.75

22. In addition to the lodestar, our firm has also incurred a total of \$1,191,296.97 in un-reimbursed expenses reasonably and necessarily incurred in connection with the prosecution of the litigation. The expenses and costs incurred in this action are reflected in the firm’s detailed Work-In-Progress (“WIP”) Report, which is also available to the Court for *in camera* inspection upon request. The WIP Report is prepared from expense vouchers, check records, receipts, and other source materials and are an accurate recordation of the actual expenses and costs incurred. No “premium” or other additional charge has been added to these figures. The breakdown of the un-reimbursed costs and expenses is as follows:

Expense	Amount
Travel/Hotel/Meal Expenses	\$80,753.98
Service of subpoenas	\$1,894.01
Filing fees or other court costs	\$40.00
Litigation fund contributions	\$1,090,000.00
Reproduction Costs	\$16,155.57
Postage	\$1,386.36
Legal Research (Pacer)	\$887.10
Miscellaneous (FDA- Freedom of Info Request)	\$179.95
TOTAL	\$1,191,296.97

23. The expenses incurred in this action are also reflected on the books and records of our firm. These books and records are prepared from expense vouchers, receipts and other source material and accurately record the expenses incurred.

Executed this 27th day of December, 2023.

/s/ Stuart E. Des Roches
Stuart E. Des Roches