IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re: : Chapter 11

INSYS THERAPEUTICS, INC., et al., : Case No. 19-11292 (JTD)

Liquidating Debtors.¹ : (Jointly Administered)

Objection Deadline: April 28, 2023,

at 4:00 p.m. (ET)

Hearing Date: May 9, 2023,

at 11:00 a.m. (ET)

MOTION BY LIQUIDATING TRUSTEE TO APPROVE SETTLEMENT WITH CERTAIN FORMER DIRECTORS OF THE DEBTORS PURSUANT TO 11 U.S.C. § 105(a) AND FEDERAL RULE OF BANKRUPTCY PROCEDURE 9019

William H. Henrich, as Liquidating Trustee (the "<u>Trustee</u>") of the Insys Liquidation Trust (the "<u>Liquidation Trust</u>"), the successor-in-interest to Insys Therapeutics, Inc. and its co-debtors (collectively, the "<u>Debtors</u>"), files this motion (the "<u>Motion</u>"), pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019, for entry of an order, substantially in the form attached as <u>Exhibit A</u>, approving a proposed settlement of the Trustee's claims against certain former directors of the Debtors. In support of this Motion, the Trustee states as follows:

INTRODUCTION

1. The Debtors played a key role in the national opioid crisis. Specifically, the Debtors sold and marketed a highly addictive and inherently dangerous fentanyl-based spray in violation of multiple federal and state statutes. This misconduct exposed the Debtors to hundreds of civil and criminal actions, resulting in the criminal convictions of at least eight high-ranking

¹ The Liquidating Debtors in these cases, along with the last four digits of each Debtor's federal tax identification number, are Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659); Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155).

corporate executives, a \$225 million settlement with the federal government, and the financial collapse of the Debtors into bankruptcy.

- 2. In this Motion, the Trustee requests approval of a proposed Settlement Agreement (the "Settlement Agreement"), which is attached as **Exhibit B**, with four former directors of the Debtors (the "Settling Defendants"), who are defendants in a pending lawsuit by the Trustee.
- 3. The Settlement Agreement, which is the culmination of extensive, arm's-length negotiations between the Trustee and Settling Defendants, is an excellent result for several reasons. First, the Settlement Agreement allows the Trustee to obtain a stipulated judgment against the Settling Defendants for \$175 million, which is a substantial portion of the damages sought by the Trustee in his existing lawsuit. Second, the Settlement Agreement allows the Trustee to collect an initial \$2.35 million payment toward that stipulated judgment, consisting of: (a) an \$850,000 payment by the Settling Defendants from their personal assets; and (b) a \$1.5 million payment from the only insurance policy which has agreed to provide coverage for the Trustee's claims, thereby exhausting that policy. Third, the Settlement Agreement allows the Trustee to take an assignment of claims from the Settling Defendants against their other insurance policies, which have \$90 million in remaining coverage limits, but have declined to provide coverage for the Trustee's claims. Fourth, the Settlement Agreement authorizes the Trustee to seek a coverage determination and recovery of the stipulated judgment's remaining balance (\$172.65 million) from those insurance policies. Fifth, the Settlement Agreement requires the Settling Defendants to cooperate with the Trustee's pursuit of that recovery from the policies. Sixth, the Settlement

² The Settling Defendants are Patrick Fourteau, Pierre Lapalme, Steven Meyer, and Brian Tambi.

Agreement permits the Trustee to continue pursuing his claims against the non-settling directors of the Debtors, who are the most culpable actors here.³

4. In sum, the Trustee believes that the Settlement Agreement should be approved under Rule 9019 as being fair, equitable, and in the best interests of the bankruptcy estate, its creditors, and other parties-in-interest.

JURISDICTION AND VENUE

- 5. The Court has jurisdiction to consider this Motion pursuant to 28 U.S.C. §§ 157(a) and 1334(b), and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware dated February 29, 2012. This Motion presents a core proceeding within the meaning of 28 U.S.C. § 157(b)(2)(A) and (O).
- 6. Venue for this Motion and proceeding are proper before this Court pursuant to 28 U.S.C. §§ 1408 and 1409.
- 7. The legal predicates for the relief requested in this Motion are 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019. Pursuant to Rule 9013-1(f) of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware, the Trustee consents to entry of final orders or judgments by this Court if it is determined that the Court, absent consent of the parties, cannot enter final orders or judgments consistent with Article III of the United States Constitution.

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³ Indeed, in affirming the criminal conviction of one of the non-settling directors, the First Circuit stated as follows: "The facts of this mammoth case . . . tell a chilling tale of suffering that did not need to happen. It involves a group of pharmaceutical executives who chose to shunt medical necessity to one side and shamelessly proceeded to exploit the sickest and most vulnerable among us – all in an effort to fatten the bottom line and pad their own pockets." *United States v. Simon*, 12 F.4th 1, 14-15 (1st Cir. 2021) (affirming the conviction of John Kapoor and others).

BACKGROUND

A. The Bankruptcy Case

- 8. On June 10, 2019 (the "<u>Petition Date</u>"), the Debtors filed voluntary petitions for relief under chapter 11 of the Bankruptcy Code, thereby commencing these bankruptcy cases.
- 9. On January 14, 2020, the Debtors filed the Second Amended Joint Chapter 11 Plan of Liquidation of Insys Therapeutics, Inc. and Its Affiliated Debtors (Docket 1095) (the "Plan"), which provided for: (a) the formation of the Liquidation Trust; (b) the appointment of the Trustee for the Liquidation Trust; and (c) the retention by the Liquidation Trust of certain causes of action held by the Debtors, including causes of action against their former directors and officers.
- 10. On January 16, 2020, this Court entered an order confirming the Plan (Docket No.1115). The Plan subsequently became effective on February 18, 2020.

B. The D&O Action

11. Following his appointment, the Trustee investigated potential causes of action held by the Liquidation Trust against the former directors and/or officers of the Debtors (the "<u>D&Os</u>"). As part of his investigation, the Trustee analyzed the allegations in an existing pre-petition action filed by certain shareholders asserting derivative claims against the D&Os in the Delaware Court of Chancery (the "<u>D&O Action</u>"). *See In re Insys Therapeutics Inc. Derivative Litigation*, C.A. No. 12696-JTL (Del. Ch.).⁴ The Trustee also analyzed documents and other information gathered from the Debtors and various third parties. Based upon his investigation, the Trustee ultimately determined that the Liquidation Trust had viable claims against the D&Os.

⁴ The D&O Action was filed in August 2016, but it was stayed in November 2017 due to: (a) the pendency of a federal securities class action against one of the Debtors and certain former directors and officers of the Debtors; and (b) the pendency of criminal indictments against certain former directors and officers of the Debtors.

- 12. On June 10, 2021, the Trustee filed a motion in the D&O Action requesting that:
 (a) one of the Debtors—Insys Therapeutics, Inc. ("Insys")—be realigned as the plaintiff in the action; and (b) the Trustee be substituted as the real party in interest in the action. The Delaware Court of Chancery entered an order granting the Trustee's motion on June 11, 2021.
- 13. The Trustee prepared a draft amended complaint (the "Amended Complaint"), which is attached as **Exhibit C**, to be filed the D&O Action. In the Amended Complaint, the Trustee alleges that:
 - a. Two of the D&Os—John Kapoor ("<u>Kapoor</u>") and Michael Babich ("<u>Babich</u>")—implemented an unlawful three-part scheme for selling and marketing the Debtors' pharmaceutical product, SUBSYS® ("<u>Subsys</u>"), a fentanyl-based spray approved by the U.S. Federal Drug Administration (the "<u>FDA</u>") for treatment of cancer patients: (i) bribing doctors to write more Subsys prescriptions, even where not medically appropriate or necessary; (ii) directing the Debtors' salesforce to pressure doctors into writing prescriptions for stronger doses of Subsys than medically indicated or FDA-approved; and (iii) defrauding third-party insurers and government payors into covering the costs of medically unnecessary or otherwise unlawful Subsys prescriptions.⁵
 - b. The remaining D&Os—the Settling Defendants—failed (i) to implement sufficient board-level monitoring of compliance risks involving the sale and marketing of Subsys; and (ii) to respond to "red flags" regarding the apparent non-compliant activity surrounding Subsys.

The Trustee further alleges in the Amended Complaint that this misconduct caused the Debtors to suffer substantial damages, including almost \$150 million in out-of-pocket costs, a \$225 million settlement with the federal government, and literally billions of dollars in criminal, civil, and regulatory liabilities.

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⁵ As reflected in **Exhibit D**, Kapoor and Babich were criminally convicted for their roles in the unlawful sale and marketing of Subsys. Kapoor was convicted of engaging in a racketeering conspiracy and was sentenced to 66 months in prison, three years of supervised release, and ordered to pay restitution and forfeiture. Babich pleaded guilty to mail and wire fraud charges and was sentenced to 30 months in prison, three years of supervised release and ordered to pay restitution and forfeiture.

- 14. Before filing the Amended Complaint and pressing forward in the D&O Action, the Trustee offered to participate in mediation with the D&Os in a good-faith attempt to resolve the action. The D&Os, in turn, accepted the Trustee's offer. The Trustee and the D&Os then scheduled the mediation for late November 2021, and they retained Layn Phillips, a well-respected former federal district judge with experience in opioid-related cases,⁶ to serve as the mediator.
- 15. The Trustee and the D&Os invited the insurers (the "<u>Insurers</u>"), which had issued multiple director-and-officer liability insurance policies to the Debtors, to attend this mediation. Specifically, the Insurers had issued the following policies (collectively, the "Policies"):
 - a. Policy No. 02-157-02-94 issued by National Union Fire Insurance Company of Pittsburgh, Pa. and its excess policies, which provide up to \$25 million in aggregate coverage for the 2013-14 policy period (collectively, the "2013-14 Tower");
 - b. Policy No. 04-808-77-07 issued by National Union Fire Insurance Company of Pittsburgh, Pa. and its excess policies, which provide up to \$40 million in aggregate coverage for the 2014-15 policy period (collectively, the "2014-15 Tower"); and
 - c. Policy No. 01-301-26-48 issued by National Union Fire Insurance Company of Pittsburgh, Pa. and its excess policies, which provide up to \$40 million in aggregate coverage for the 2015-16 policy period (collectively, the "2015-16 Tower").

Only one of the Insurers—Old Republic Insurance Company, which had issued an excess policy in the 2013-14 Tower and 2014-15 Tower—agreed to attend the mediation. The other Insurers, however, declined to attend the mediation and denied that they were required to defend or indemnify the D&Os under the 2013-14 Tower, the 2014-15 Tower, or the 2015-16 Tower.

⁶ Judge Phillips served as one of the court-appointed mediators in the Purdue Pharma bankruptcy case.

⁷ In fact, one of the Insurers in the 2013-14 Tower—XL Specialty Insurance Company—recently filed a declaratory judgment action in Arizona state court, asserting that its policy does not provide coverage for the D&O Action. *See XL Specialty Ins. Co. v. Kapoor, et al.*, Case No. CV2023-005006 (Ariz. Sup. Ct., Maricopa County).

16. In October and November 2021, the Trustee and the D&Os exchanged substantial mediation briefing—including opening briefs, reply briefs, and supporting exhibits—totaling more than 1,700 pages. On November 22, 2021, the Trustee and the D&Os engaged in arm's-length negotiations in a full-day mediation session with Judge Phillips. Following the mediation session, the Trustee and at least some of the D&Os engaged in further arm's-length negotiations through Judge Phillips or one of his colleagues in late 2021 and most of 2022. Their negotiations ultimately resulted in the Settlement Agreement.

C. The Settlement Agreement

- 17. The Settlement Agreement includes the following key terms:⁸
 - a. <u>Bankruptcy Court Approval.</u> The Settlement Agreement shall become effective on the date that this Court's order approving the agreement pursuant to Federal Rule of Bankruptcy Procedure 9019 has become a final order (the "<u>Effective Date</u>"). If this Court does not approve the Settlement Agreement, then: (i) the agreement shall not become effective; (ii) the parties shall revert to their positions immediately prior to the execution of the agreement; and (iii) the agreement and any related drafts thereof, correspondence, or negotiations between the parties shall not be used for any purpose and shall not be admissible for any purpose in the D&O Action or any other action or proceeding.
 - b. <u>Stipulated Judgment.</u> The parties to the Settlement Agreement shall seek the entry of a \$175 million stipulated judgment against the Settling Defendants in the D&O Action (the "<u>Judgment</u>") through the process set forth in the Settlement Agreement. The parties agree that the terms of the Judgment are fair, reasonable, and a good-faith compromise of the claims against the Settling Defendants in the D&O Action, and have been negotiated at arm's-length based on each party's objective assessment of various factors, including: (i) the strength of the Trustee's claims; (ii) the amount of damages associated with the Trustee's claims; (iii) the litigation risks to all parties; and (iv) the amount of attorney's fees and expenses necessary to prosecute and defend against the Trustee's claims.

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⁸ This summary is provided solely for ease of reference and is qualified in its entirety by reference to the Settlement Agreement, the actual terms of which are controlling here. *See* Ex. B.

If the Judgment is determined by any court of competent jurisdiction to be invalid or set aside on any grounds, including it being an unreasonable settlement, being based on fraud, or being based on collusion, then: (i) the underlying claims and defenses shall be reinstated between the parties; (ii) the parties shall revert to their positions immediately prior to the execution of the Settlement Agreement in all other respects, including the return of the Settlement Payment (as defined below) by the Trustee; (iii) the Settlement Agreement, the Judgment, and any related drafts thereof, correspondence, or negotiations between the parties shall not be admissible for any purpose in the D&O Action or any other action or proceeding; and (iv) the parties shall use their best efforts to negotiate in good faith and at arm's length in an attempt to cure any deficiency in the Judgment that caused it to be invalidated or set aside.

- c. <u>Settlement Payment.</u> Within twenty (20) calendar days after entry of the Judgment, the Settling Defendants shall pay, or shall cause to be paid by their insurers, the total sum of \$2.35 million (the "<u>Settlement Payment</u>"), which sum is comprised of the following: (i) \$1.5 million from Policy No. CUG 35844 issued by Old Republic Insurance Company; and (ii) \$850,000 from the Settling Defendants. The Settlement Payment shall be made by wire transfer to the Trustee's counsel, and the Settlement Payment shall be treated as a credit to the Judgment.
- Release of Claims. The Settling Defendants fully and finally release d. the Trustee, the Liquidation Trust, and the Debtors, as well as their present and former law firms and attorneys, together with all of their present and former members, partners, limited partners, associates, employees, agents, officers, directors, related entities, fiduciaries, trustees, contractors, independent contractors, consultants, experts, attorneys, owners, assigns, heirs, spouses, executors, administrators, and representatives (collectively, the "Insys Released Parties") from any and all claims relating to the Debtors, including, without limitation, Claim No. 451, Claim No. 452, Claim No. 524, Claim No. 525, and any other claims filed or scheduled on behalf of the Settling Defendants in these bankruptcy cases. Further, the Settling Defendants covenant and agree: (i) not to sue any of the Insys Released Parties; and (ii) not to directly or indirectly aid any person or entity in suing any of the Insys Released Parties in any matter concerning the Debtors. Nothing in this provision, however, shall be construed as releasing any of the Insurance Claims (as defined below).

- e. <u>Covenant Not to Execute.</u> The Trustee agrees: (i) not to execute on the Judgment against the Settling Defendants and to seek recovery on the Judgment only from the Insurers on the Policies (other than two policies issued by Old Republic Insurance Company); (ii) the Judgment shall resolve all claims that the Liquidation Trust may have against the Settling Defendants, known or unknown, and that, upon resolution of the Insurance Claims (as defined below), the Settling Defendants shall be released of any and all claims to the fullest extent permitted by law; and (iii) unless a court of competent jurisdiction invalidates the Judgment, the Trustee shall not attempt to sue or otherwise collect any funds in addition to the Settlement Payment from any of the Settling Defendants.
- f. Assignment of Claims. Upon entry of the Judgment and without need of further documentation, the Settling Defendants convey and assign to the Trustee, on behalf of himself and the Liquidation Trust, any and all claims and/or causes of action that the Settling Defendants have under the Policies (except for two policies issued by Old Republic Insurance Company), including, without limitation, claims for failure to pay defense costs, to indemnify, and/or to settle and for bad faith under the Policies (except for two policies issued by Old Republic Insurance Company) (collectively, the "Insurance Claims"). Any settlement of the Insurance Claims shall include standard releases of the Liquidation Trust and the Settling Defendants.
- Stay and Dismissal. The parties shall see the stay and/or dismissal g. of the D&O Action and another pending action under the following terms: (i) within five (5) calendar days after the Effective Date, the Trustee shall intervene in, and file a motion seeking to dismiss without prejudice, a shareholder derivative action similar to the D&O Action pending in New York; (ii) within five (5) calendar days after the entry of the Judgment, the parties shall file a motion seeking to stay the D&O Action against the Settling Defendants; (iii) the Trustee shall file a notice in the D&O Action stating that there has been a full and complete satisfaction of the Judgment within ten (10) calendar days after the earlier of the following: (a) the full and complete satisfaction of the Judgment; or (b) the final resolution of the Insurance Claims; and (iv) the Trustee shall file a motion seeking to dismiss with prejudice the Trustee's claims against the Settling Defendants in the D&O Action within ten (10) calendar days after the earlier of the following: (a) the full and complete satisfaction of the Judgment; or (b) the final resolution of the Insurance Claims.
- h. <u>Further Cooperation.</u> Each of the Settling Defendants agrees to cooperate with the Trustee in connection with the D&O Action, any

of the Trustee's claims against other parties in the D&O Action or other proceedings, and any action involving the Insurance Claims, including by: (i) voluntarily responding to the Trustee's reasonable requests for documents and other information; (ii) voluntarily appearing and participating in interviews on reasonable notice with the Trustee's counsel for up to five (5) total hours; (iii) voluntarily appearing and providing testimony on reasonable notice for a deposition and a pre-deposition meeting (without need of subpoena) with the Trustee's counsel; and (iv) voluntarily appearing and providing testimony at trial (without need of subpoena). The Trustee shall reimburse the Settling Defendants and their counsel for any reasonable out-of-pocket travel costs that they incur in complying with the Trustee's requests for cooperation.

18. The Settlement Agreement has been approved by the ILT Board, which provides oversight of the Liquidation Trust pursuant to the Plan.

RELIEF REQUESTED

19. By this Motion, pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019, the Trustee requests entry of an order (a) approving the Settlement Agreement substantially in the form attached as **Exhibit A**; and (b) authorizing the parties to take any and all actions necessary to effectuate the Settlement Agreement.

BASIS FOR RELIEF REQUESTED

- 20. The Court has the authority to "approve a compromise or settlement" pursuant to Federal Rule of Bankruptcy Procedure 9019(a). To exercise this authority, the Court must determine that the proposed settlement is "fair and equitable." *Will v. Northwestern Univ. (In re Nutraquest, Inc.)*, 434 F.3d 639, 644 (3d Cir. 2006) (quoting *Protective Comm. for Indep. Stockholders of TMT Trailer Ferry, Inc. v. Anderson*, 390 U.S. 414, 424 (1968)).
- 21. In evaluating the fairness and equity of a proposed settlement, the Court must "assess and balance the value of the claim that is being compromised against the value to the estate of the acceptance of the compromise proposal." *Myers v. Martin (In re Martin)*, 91 F.3d 389, 393

(3d Cir. 1996). Specifically, the Court must consider the following factors: (a) the probability of success in litigation; (b) the likely difficulties in collection; (c) the complexity of the litigation involved and the expense, inconvenience, and delay necessarily attending to it; and (d) the paramount interest of creditors. *Martin*, 91 F.3d at 393. The Court also may consider "the extent that the settlement is truly the product of arms-length bargaining, and not fraud or collusion." *In re Tribune Co.*, 464 B.R. 126, 155 (Bankr. D. Del. 2011).

22. Each of these factors supports approval of the Settlement Agreement.

A. Probability of Success in the Litigation

Amended Complaint. First, the Trustee asserts *Caremark* claims for breach of fiduciary duty, alleging that the Settling Defendants: (a) failed to implement board-level monitoring of the compliance risks involving the sale and marketing of Subsys; and (b) to respond to "red flags" regarding the non-compliant activity surrounding Subsys. *See* Ex. C ¶ 123-224, 252-256. Second, the Trustee asserts corporate waste claims against the Settling Defendants, alleging that they caused the Debtors to waste corporate assets by: (a) approving or allowing severance payments to former employees who had engaged in illegal conduct and other misconduct; and (b) approving or allowing advancement of defense costs to former directors, officers, and employees who had engaged in illegal conduct and other misconduct. *See id.* ¶ 213-218, 229-230, 257-260. The Trustee further alleges that the Settling Defendants caused the Debtors to suffer substantial damages, including almost \$150 million in out-of-pocket costs, a \$225 million settlement with the federal government, and literally billions of dollars in criminal, civil, and regulatory liabilities. *See id.* ¶ 225-234, 255, 260.

- 24. The Settling Defendants raise several defenses to the Trustee's claims, including that the Trustee allegedly cannot satisfy the rigorous standard for proving *Caremark* claims or corporate waste claims. *See Espinosa v. Zuckerberg*, 124 A.3d 47, 67 (Del. Ch. 2015) (explaining that the standard for a corporate waste claim "is extreme and rarely satisfied"); *In re Caremark Int'l Deriv. Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996) (stating that a *Caremark* claim "is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment"). The Trustee, however, believes that the egregious facts here support compelling *Caremark* and corporate waste claims against the Settling Defendants.
- 25. Nonetheless, the Trustee recognizes that the probability of success—though seemingly very good—remains subject to risk and uncertainty. After all, the D&O Action has not advanced beyond the pleadings stage yet. The Trustee, therefore, asserts that some risk-based discount is appropriate in resolving the underlying claims at this early stage—namely settling for a \$175 million stipulated judgment to resolve claims for almost \$150 million in out-of-pocket losses and billions of dollars in additional liabilities. This settlement amount is certainly within the reasonable range of litigation possibilities in the D&O Action. *See In re Washington Mut., Inc.*, 442 B.R. 314, 328 (Bankr. D. Del. 2011) ("The court does not have to be convinced that the settlement is the best possible compromise, but only that the settlement falls within the reasonable range of litigation possibilities.").

B. Difficulties in Collection in the Litigation

26. Even if he were to prevail on his claims, the Trustee would likely encounter difficulties in collecting a judgment against the Settling Defendants. The Settling Defendants contend that they are insured for the Trustee's claims under the Policies in the 2013-14 Tower, the 2014-15 Tower, and/or the 2015-16 Tower. However, the Insurers under the Policies—other than

Old Republic Insurance Company—deny that they are required to defend or indemnify the D&Os under the 2013-14 Tower, the 2014-15 Tower, or the 2015-16 Tower. Old Republic Insurance Company has agreed to defend and/or indemnify the D&Os under Policy No. CUG 35844 in the 2013-14 Tower, but that policy has been severely depleted by defense costs and settlements to approximately \$1.5 million in remaining proceeds.

- 27. The Trustee could potentially pursue post-judgment collection efforts against any assets held by the Settling Defendants, but that would be a long, difficult, and uncertain process. As an initial matter, the Settling Defendants would likely appeal any adverse judgment, thereby delaying the Trustee's post-judgment collection efforts. *See, e.g., In re Key3Media Grp., Inc.*, 336 B.R. 87, 97 (Bankr. D. Del. 2005) (noting that "[t]he collection of a judgment could be further delayed by the potential for appeal by the Defendant" in weighing the "difficulties in collection" factor), *aff'd*, No. 03-10323, 2006 WL 2842462 (D. Del. Oct. 2, 2006). Following the eventual resolution of any appeal, the Trustee would need to engage in costly post-judgment collection efforts against each of the Settling Defendants. At least one of the Settling Defendants, moreover, resides in Canada, which would likely complicate the Trustee's post-judgment collection efforts.
- 28. Given these challenges, it is reasonable to conclude that the Trustee would have difficulty collecting anything from the Settling Defendants beyond the available insurance proceeds—assuming that coverage can be established—under any of the Policies. *See, e.g., Donovan v. Robbins*, 752 F.2d 1170, 1182 (7th Cir. 1985) ("[B]ecause it is so difficult to collect large judgments from individuals unless they have insurance coverage, it is natural and ordinarily reasonable for a plaintiff to settle for the limits of that coverage.").

C. Complexity, Expense, and Delay of the Litigation

29. The Trustee would face a complex, lengthy, and expensive process in litigating his claims against the Settling Defendants. The claims raise difficult questions regarding the operations of a large, former public company over a period of several years. These questions would require costly expert analysis and testimony related to liability, causation, and damages. These questions, moreover, would likely not be ripe for decision on dispositive motions, thereby requiring a lengthy, expensive trial and possibly subsequent appeal.

D. Paramount Interest of Creditors as to the Litigation

30. The Trustee believes that the paramount interest of creditors would be served by the Settlement Agreement. The proposed settlement would avoid substantial costs, delays, and risks of litigating against the Settling Defendants. The settlement—for a stipulated judgment of \$175 million—would allow the Trustee to liquidate his claims against the Settling Defendants for a substantial portion of the amount in controversy, receive an assignment of their claims related to the coverage dispute regarding the Policies, and seek to recover directly from the Policies with cooperation from the Settling Defendants. Plus, the proposed settlement would yield an initial cash payment of \$2.35 million to the Trustee from the Settling Defendants and one of their insurers, which payment will be applied to the stipulated judgment. Finally, the proposed settlement would allow the Trustee to proceed with his claims against the non-settling defendants in the D&O Action—Kapoor and Babich—who are certainly the most culpable actors here.

E. Arm's-Length and Good-Faith Settlement Negotiations as to the Litigation

31. The Settlement Agreement is the product of arm's-length and good-faith negotiations spanning over a one-year period. The Trustee and the Settling Defendants participated in mediation with Layn Phillips—a well-respected former federal district court judge

who had successfully mediated other opioid-related cases—on November 22, 2021. Judge Phillips has submitted a supporting declaration, which is attached as **Exhibit E**. As described in his declaration, the parties submitted detailed mediation statements and supporting documents addressing key factual and legal issues related to liability, causation, and damages. *See* Ex. E ¶ 7. The parties subsequently engaged in extensive arm's-length, good-faith negotiations during a full-day mediation with Judge Phillips, where they exchanged multiple rounds of offers and counteroffers. *See id.* ¶ 8. After more than ten (10) hours of negotiations, the Trustee and the Settling Defendants had still not reached a settlement. *See id.* However, the Trustee and the Settling Defendants continued to engage in arm's-length negotiations through Judge Phillips or one of his colleagues in late 2021 and most of 2022. *See id.* ¶ 9. Their negotiations ultimately resulted in the Settlement Agreement. *See id.*

32. Thus, given this extensive and extended settlement process, the Settlement Agreement is clearly the product of arm's-length negotiations. Indeed, as Judge Phillips attests in his declaration, this settlement is "the product of arm's-length, good-faith negotiations and represents a fair and reasonable outcome with respect to the underlying claims." *Id.* ¶ 10.

NOTICE

33. The Trustee has provided notice of this Motion to the following: (a) the United States Trustee for the District of Delaware; (b) counsel to the Settling Defendants; (c) counsel to the non-settling defendants in the D&O Action; (d) counsel to the Insurers under the Policies; and (e) all parties entitled to notice under Federal Rule of Bankruptcy Procedure 2002. In light of the relief requested in this Motion, the Trustee submits that no other or further notice is necessary.

CONCLUSION

WHEREFORE, the Trustee respectfully requests entry of the proposed order, substantially in the form attached as **Exhibit A**, (a) approving the Settlement Agreement; (b) authorizing the parties to take any and all actions necessary to effectuate the Settlement Agreement; and (c) granting such other and further relief as the Court deems just and proper.

Dated: April 14, 2023

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Matthew O. Talmo

Derek C. Abbott (No. 3376)
Matthew O. Talmo (No. 6333)
1201 N. Market Street, 16th Floor
P.O. Box 1347
Wilmington, DE 19899
Telephone: (302) 658-9200
dabbott@morrisnichols.com
mtalmo@morrisnichols.com

Counsel to the Liquidating Trustee of the Insys Liquidation Trust

-and-

REID COLLINS & TSAI LLP

Eric D. Madden (admitted *pro hac vice*)
Michael J. Yoder (admitted *pro hac vice*)
1601 Elm Street, Suite 4200
Dallas, TX 75201
Telephone: (214) 420-8900
emadden@reidcollins.com
myoder@reidcollins.com

-and-

Keith Y. Cohan (admitted *pro hac vice*)
Ryan M. Goldstein (admitted *pro hac vice*)
Morgan M. Menchaca (admitted *pro hac vice*)
1301 S. Capital of Texas Hwy, C-300
Austin, TX 78746
Telephone: (512) 647-6100
kcohan@reidcollins.com
rgoldstein@reidcollins.com
mmenchaca@reidcollins.com

Special Litigation Counsel to the Liquidating Trustee of the Insys Liquidation Trust

IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

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(Jointly Administered)

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PLEASE TAKE NOTICE that on April 14, 2023, William Henrich, as Liquidating Trustee (the "<u>Trustee</u>") of the Insys Liquidation Trust (the "<u>Liquidation Trust</u>"), filed the Motion by Liquidating Trustee to Approve Settlement with Certain Former Directors of the Debtors Pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019 (the "<u>Motion</u>").

PLEASE TAKE FURTHER NOTICE that objections, if any, to the Motion must be (a) in writing and served on or before **April 28, 2023, at 4:00 p.m. (ET)** (the "Objection Deadline"); (b) filed with the Clerk of the Bankruptcy Court, 824 N. Market Street, 3rd Floor, Wilmington, Delaware 19801; and (c) served so as to be received on or before the Objection Deadline by the undersigned counsel.

PLEASE TAKE FURTHER NOTICE that only objections made in writing and timely filed and received, in accordance with the procedures above, will be considered by the Bankruptcy Court at such hearing.

PLEASE TAKE FURTHER NOTICE THAT A HEARING ON THE MOTION WILL BE HELD ON May 9, 2023, AT 11:00 A.M. (ET) VIA VIDEOCONFERENCE OR IN PERSON BEFORE THE HONORABLE JOHN T. DORSEY OF THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE.

The Liquidating Debtors in these cases, along with the last four digits of each Debtor's federal tax identification number, are: Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659), Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155).

IF YOU FAIL TO RESPOND IN ACCORDANCE WITH THIS NOTICE, THE COURT MAY GRANT THE RELIEF REQUESTED IN THE MOTION WITHOUT FURTHER NOTICE OR HEARING

Dated: April 14, 2023

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Matthew O. Talmo

Derek C. Abbott (No. 3376)
Matthew O. Talmo (No. 6333)
1201 N. Market Street, 16th Floor
P.O. Box 1347
Wilmington, DE 19899
Telephone: (302) 658-9200
dabbott@morrisnichols.com
mtalmo@morrisnichols.com

Counsel to the Liquidating Trustee of the Insys Liquidation Trust

-and-

REID COLLINS & TSAI LLP

Eric D. Madden (admitted *pro hac vice*)
Michael J. Yoder (admitted *pro hac vice*)
1601 Elm Street, Suite 4200
Dallas, TX 75201
Telephone: (214) 420-8900
emadden@reidcollins.com
myoder@reidcollins.com

-and-

Keith Y. Cohan (admitted *pro hac vice*)
Ryan M. Goldstein (admitted *pro hac vice*)
Morgan M. Menchaca (admitted *pro hac vice*)
1301 S. Capital of Texas Hwy, C-300
Austin, TX 78746
Telephone: (512) 647-6100
kcohan@reidcollins.com
rgoldstein@reidcollins.com
mmenchaca@reidcollins.com

Special Litigation Counsel to the Liquidating Trustee of the Insys Liquidation Trust

Exhibit A

IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re: : Chapter 11

INSYS THERAPEUTICS, INC., et al., : Case No. 19-11292 (JTD)

Liquidating Debtors.¹ : (Jointly Administered)

ORDER GRANTING MOTION BY LIQUIDATING TRUSTEE
TO APPROVE SETTLEMENT WITH CERTAIN FORMER DIRECTORS
OF THE DEBTORS PURSUANT TO 11 U.S.C. § 105(a) AND
FEDERAL RULE OF BANKRUPTCY PROCEDURE 9019

Upon consideration of the Motion by the Liquidating Trustee to Approve Settlement with Certain Former Directors of the Debtors Pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019 (the "Motion");² and this Court having jurisdiction to consider the Motion and the relief requested therein in accordance with 28 U.S.C. §§ 157 and 1334 and the Amended Standing Order of Reference from the United States District Court for the District of Delaware dated as of February 29, 2012; and consideration of the Motion and the relief requested therein being a core proceeding pursuant to 28 U.S.C. § 157(b); and venue being proper in this district pursuant to 28 U.S.C. §§ 1408 and 1409; and due and proper notice of the Motion having been provided to all parties-in-interest; and it appearing that no other or further notice need be provided; and this Court having determined that the relief sought in the Motion is in the best interests of the Debtors' estates, their creditors, and all other parties-in-interest; and this Court having determined that the legal and factual bases set forth in the Motion establish good cause for the relief granted herein; and this Court having determined that the Settlement Agreement is the

¹ The Liquidating Debtors in these cases, along with the last four digits of the Debtor's federal tax identification number, is Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659); Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155).

² Capitalized terms not otherwise defined herein shall have the same meanings ascribed to them in the Motion.

result of good-faith, arms-length negotiations, is within the reasonable range of litigation possibilities in the D&O Action, and is fair, equitable, and in the best interests of the Debtors' estates, their creditors, and other parties in interest; and upon the proceedings had before this Court and after due deliberation and sufficient cause appearing therefor,

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

- 1. The Motion is hereby GRANTED.
- 2. The Settlement Agreement and all terms set forth therein are authorized and approved by the Court pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019(a).
- 3. The Trustee and the Settling Defendants, as applicable, are hereby authorized to execute, deliver, implement, and perform their respective obligations under the Settlement Agreement, including the conveyance and assignment of the Insurance Claims for pursuit by the Trustee.
- 4. The Court shall retain jurisdiction with respect to all matters arising from or related to the implementation or interpretation of this Order.

Exhibit B

SETTLEMENT AGREEMENT

This SETTLEMENT AGREEMENT (the "<u>Agreement</u>") is entered into as of March 17, 2023, by and between the following parties (collectively, the "<u>Parties</u>," and each separately, a "<u>Party</u>"): (a) William H. Henrich, as the Liquidation Trustee of the Insys Liquidation Trust (the "<u>Trustee</u>"), the duly authorized successor-in-interest to Insys Therapeutics, Inc. and its subsidiaries (collectively, "<u>Insys</u>"); and (b) Patrick Fourteau, Pierre Lapalme, Steven Meyer, and Brian Tambi (collectively, the "<u>Settling Defendants</u>").

WHEREAS, on August 26, 2016, certain Insys stockholders filed a Verified Derivative Complaint in C.A. No. 12696-JTL (the "<u>First Action</u>") in the Delaware Court of Chancery, asserting certain claims against the Settling Defendants and other defendants;

WHEREAS, on February 2, 2017, a certain Insys stockholder filed a Verified Derivative Complaint in C.A. No. 00078-TMR (the "Second Action") in the Delaware Court of Chancery, asserting certain claims against the Settling Defendants and other defendants;

WHEREAS, on March 2, 2017, the First Derivative Action and the Second Derivative Action were consolidated under C.A. No. 12696-JTL (the "<u>Consolidated Action</u>") in the Delaware Court of Chancery;

WHEREAS, on November 30, 2017, the Court entered an order staying the Consolidated Action pending the resolution of ongoing criminal proceedings involving Insys and certain of its former executives, including other defendants in the Consolidated Action;

WHEREAS, on June 10, 2019, Insys filed bankruptcy cases in the U.S. Bankruptcy Court for the District of Delaware (the "<u>Bankruptcy Court</u>"), which cases were jointly administered under Case No. 19-11292 (the "<u>Bankruptcy Case</u>");

WHEREAS, on January 16, 2020, the Bankruptcy Court entered an order in the Bankruptcy Case confirming the Second Amended Joint Chapter 11 Plan of Liquidation of Insys Therapeutics, Inc. and Its Affiliated Debtors (the "Plan"), which retained certain of Insys's potential claims and causes of action for enforcement by the Trustee as a representative of the bankruptcy estate pursuant to 11 U.S.C. § 1123(b)(3);

WHEREAS, on June 11, 2021, the Delaware Court of Chancery entered an order in the Consolidated Action substituting the Trustee as the plaintiff and real party in interest in that action;

WHEREAS, the Settling Defendants are entitled to coverage for their defense or settlement of the Consolidated Action under one or more of the following insurance policies (collectively, the "<u>Policies</u>"): (a) Policy No. 02-157-02-94 issued by National Union Fire Insurance Company of Pittsburgh, Pa., along with its excess policies, which provided up to \$25 million in aggregate coverage limits for policy year 2013-14; (b) Policy No. 04-808-77-07 issued by National Union

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¹ The excess policies for the 2013-14 policy year are: (a) Policy No. ELU129710-13 issued by XL Specialty Insurance Company; and (b) Policy No. CUG 35844 issued by Old Republic Insurance Company.

Fire Insurance Company of Pittsburgh, Pa., along with its excess policies,² which provided up to \$40 million in aggregate coverage limits for policy year 2014-15; and (c) Policy No. 01-301-26-48 issued by National Union Fire Insurance Company of Pittsburgh, Pa., along with its excess policies,³ which provided up to \$40 million in aggregate coverage limits for policy year 2015-16;

WHEREAS, the insurers on the Policies—with the exception of Policy No. CUG 35844 issued by Old Republic Insurance Company—have denied requests by the Settling Defendants to provide coverage for the defense or settlement of the Consolidated Action;⁴

WHEREAS, on November 22, 2021, the Trustee, the Settling Defendants, and the other defendants in the Consolidated Action participated in a full-day mediation session with former United States District Judge Layn Phillips;

WHEREAS, in late 2021 and most of 2022, the Trustee and the Settling Defendants engaged in extended post-mediation settlement discussions through Judge Phillips;

WHEREAS, the Trustee and the Settling Defendants have each decided to enter into this Agreement to avoid the expense, inconvenience, uncertainty, and delay of litigation and to compromise, settle, and resolve the Trustee's claims against the Settling Defendants in the Consolidated Action and other matters as specifically set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing recitals, the mutual covenants and promises contained in this Agreement, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

- 1. <u>Incorporation of Recitals.</u> The Parties each attest to the accuracy of the foregoing recitals and incorporate them by reference as if set forth fully herein.
- **2.** Bankruptcy Court Approval. This Agreement shall be subject to approval by the Bankruptcy Court under Federal Rule of Bankruptcy Procedure 9019. Within ten (10) calendar days after the execution of this Agreement, the Trustee shall file a motion seeking such approval, give notice to all known Trust beneficiaries and any person known or reasonably known to assert claims against the Settling Defendants, and take reasonable steps to publish notice as directed by the Court. If the Bankruptcy Court does not approve this Agreement, then: (a) this Agreement shall not become effective; (b) the Parties shall revert to their positions immediately prior to the execution of this Agreement; and (c) this Agreement (including the Stipulation and all other exhibits thereto) and any related drafts thereof, correspondence, or negotiations between the Parties shall not be used

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² The excess policies for the 2014-15 policy year are: (a) Policy No. ELU133984-14 issued by XL Specialty Insurance Company; (b) Policy No. FD1481166 issued by Certain Underwriters at Lloyd's, London/Beazley Insurance Company; and (c) Policy No. CUG 36623 issued by Old Republic Insurance Company.

³ The excess policies for the 2015-16 policy year are: (a) Policy No. 01-301-33-48 issued by National Union Fire Insurance Company of Pittsburgh, Pa.; (b) Policy No. FD1581166 issued by Certain Underwriters at Lloyd's, London/Beazley Insurance Company; and (c) Policy No. DOX10006981200 issued by Endurance American Insurance Company.

⁴ Policy No. 02-157-02-94 issued by National Union Fire Insurance Company of Pittsburgh, Pa. for the 2013-14 policy year was previously exhausted through prior payments.

for any purpose and shall not be admissible for any purpose in the Consolidated Action or any other action or proceeding.

- **3.** Effective Date. This Agreement shall become effective on the date that the Bankruptcy Court's order approving the Agreement has become a final order (the "Effective Date") because: (a) no motion for reconsideration regarding the order has been timely filed within fourteen (14) calendar days after the date of the entry of the order, as required by Federal Rule of Bankruptcy Procedure 9023; (b) no notice of appeal regarding the order has been timely filed within fourteen (14) calendar days after the date of the entry of the order, as required by Federal Rule of Bankruptcy Procedure 8002(a); and (c) if a notice of appeal or motion for reconsideration of the order has been timely filed, as required by Federal Rule of Bankruptcy Procedure 9023 or Federal Rule of Bankruptcy Procedure 8002(a), then such appeal or motion has been denied with prejudice and the order is not subject to further timely appellate review.
- **4. Stipulated Judgment.** The Parties shall seek the entry of a stipulated judgment in the Consolidated Action through the following process:
 - (a) Within five (5) calendar days after the Effective Date, the Trustee shall file the Motion to Lift Stay (the "<u>Lift Stay Motion</u>"), which is attached hereto as <u>Exhibit A-1</u>. The Settling Defendants shall consent to and shall not oppose the Lift Stay Motion.
 - (b) Within five (5) calendar days after the Lift Stay Motion has been granted, the Trustee shall file the Motion for Leave to File Amended Complaint (the "Motion for Leave"), which is attached hereto as Exhibit A-2. The Settling Defendants shall consent to and shall not oppose the Motion for Leave.
 - (c) Within five (5) calendar days after the Motion for Leave has been granted, the Parties shall file the Stipulation for Entry of Judgment (the "Stipulation"), which is attached hereto as Exhibit A-3 (the "Judgment").

The Parties agree that the terms of the Judgment are fair, reasonable, and a good-faith compromise of the claims against the Settling Defendants in the Consolidated Action, and have been negotiated at arm's-length, based on each Party's objective assessment of various factors, including: (a) the strength of the Trustee's claims; (b) the amount of damages associated with the Trustee's claims; (c) the litigation risks to all Parties; and (d) the amount of attorney's fees and expenses necessary to prosecute and defend against the Trustee's claims.

If the Stipulation or the Judgment is determined by any court of competent jurisdiction to be invalid or set aside on any grounds, including it being an unreasonable settlement, being based on fraud, or being based on collusion, then: (a) the underlying claims and defenses shall be reinstated between the Parties; (b) the Parties shall revert to their positions immediately prior to the execution of this Agreement in all other respects, including the return of the Settlement Payment by the Trustee to Old Republic Insurance Company and the Settling Defendants; (c) this

Agreement, the Stipulation, the Judgment, and any related drafts, correspondence, or negotiations between the Parties shall not be admissible for any purpose in the Consolidated Action or any other action or proceeding; and (d) the Parties shall use best efforts to negotiate in good faith and at arm's length in an attempt to cure any deficiency in the Judgment that caused it to be invalidated or set aside. The Parties understand and agree that nothing in this paragraph is intended to limit or in any way qualify the Trustee's unconditional agreement in Paragraph 7 of this Agreement not to execute upon any stipulated judgment except against the insurers on the Policies, nor intended to limit or otherwise affect any insurance claim or recovery against those insurers.

- **5.** <u>Settlement Payment.</u> Within twenty (20) calendar days after entry of the Judgment, the Settling Defendants shall pay, or shall cause to be paid by their insurers, the total sum of two million, three hundred and fifty thousand dollars (\$2,350,000) in cash (the "<u>Settlement Payment</u>") to the Trustee, which is comprised of the following:
 - (a) \$1,500,000 from Policy No. CUG 35844 issued by Old Republic Insurance Company; and
 - (b) \$850,000 from the Settling Defendants, to be paid as follows:

(i) Patrick Fourteau: \$250,000
 (ii) Pierre Lapalme: \$250,000
 (iii) Steven Meyer: \$250,000
 (iv) Brian Tambi: \$100,000

The Settlement Payment shall be made by wire transfer to the Trustee's counsel, pursuant to the wire instructions and Form W-9 attached hereto as <u>Exhibit A-4</u>. The Settlement Payment shall be treated as a credit to the Judgment. The failure of any Settling Defendants to pay their required portion of the Settlement Payment shall not negate, nullify, or otherwise eliminate any obligation of any other Settling Defendants. Moreover, this Agreement shall remain in full force and effect with respect to each of the Settling Defendants on a defendant-by-defendant basis.

6. Release by the Settling Defendants. The Settling Defendants, on behalf of themselves and their respective successors and assigns, hereby forever irrevocably, unconditionally, fully, and finally release, acquit and discharge the Trustee, the Insys Liquidation Trust, and Insys, as well as their present and former law firms and attorneys, together with all of their present and former members, partners, limited partners, associates, employees, agents, officers, directors, related entities, fiduciaries, trustees, contractors, independent contractors, consultants, experts, attorneys, owners, assigns, heirs, spouses, executors, administrators, and representatives (collectively, the "Insys Released Parties") from any and all claims relating to Insys, including, without limitation, Claim No. 451, Claim No. 452, Claim No. 524, Claim No. 525, and any other claims filed or scheduled on behalf of the Settling Defendants in the Bankruptcy Case. Further, the Settling Defendants, on behalf of themselves and their respective successors and assigns, covenant and agree: (a) not to sue any of the Insys Released Parties; and (b) not to directly or indirectly aid any person or entity in suing any of the Insys Released Parties in any matter concerning Insys. Nothing in this paragraph, however, shall be construed as releasing any of the Insurance Claims as defined in Paragraph 8 of this Agreement.

- Covenant Not to Execute by the Trustee. The Trustee, on behalf of himself and the Insys Liquidation Trust, as well as their respective successors and assigns, covenants and agrees: (a) not to execute on the Judgment against the Settling Defendants and to seek recovery on the Judgment only from the insurers on the Policies, other than from Policy No. CUG 35844 and Policy No. CUG 36623 issued by Old Republic Insurance Company, as set forth in Paragraph 5 of this Agreement; (b) the Judgment shall resolve all claims that the Insys Liquidation Trust, and all of its predecessors or successors (including Insys and its affiliates), may have against the Settling Defendants, known or unknown, and that, upon resolution of the Insurance Claims (as defined in Paragraph 8 of this Agreement), the Settling Defendants shall be released of any and all such claims to the fullest extent permitted by law; and (c) unless a court of competent jurisdiction invalidates the Judgment for the reasons described in Paragraph 4 of this Agreement or for any other reason, the Trustee shall not attempt to sue or otherwise collect any funds in addition to the Settlement Payment from any of the Settling Defendants. The Parties stipulate and agree that this Paragraph 7 is a material term of the Settlement Agreement.
- **8.** <u>Assignment of Claims.</u> Upon the entry of the Judgment and without need of further documentation, the Settling Defendants convey and assign to the Trustee, on behalf of himself and the Insys Liquidation Trust, as well as their respective successors and assigns, any and all claims and/or causes of action that the Settling Defendants have under the Policies, except for Old Republic Policy No. CUG 35844 and Policy No. CUG 36623, including, without limitation, claims for failure to pay defense costs, to indemnify, and/or to settle and for bad faith under the Policies, except for Old Republic Policy No. CUG 35844 and Policy No. CUG 36623 (collectively, the "Insurance Claims"). Any settlement of the Insurance Claims will include standard releases of the Insys Liquidation Trust and the Settling Defendants.
- **9.** <u>Stay and Dismissal.</u> The Parties shall seek the stay and/or dismissal of the Consolidated Action and another pending action under the following terms:
 - (a) Within five (5) calendar days after the Effective Date, the Trustee shall file the following motions in *Ravansari v. Kapoor et al.*, Case No. 1:18-cv-7026 (S.D.N.Y.): (a) a motion seeking to substitute the Trustee as plaintiff and the real party in interest in the action; and (b) a motion seeking the dismissal without prejudice of the action. The Settling Defendants shall consent to and shall not oppose these motions.
 - (b) Within five (5) calendar days after the entry of the Judgment, the Parties shall file a motion seeking to stay the Consolidated Action with respect to the Trustee's claims against the Settling Defendants.
 - (c) The Trustee shall file a notice in the Consolidated Action stating there has been a full and complete satisfaction of the Judgment within ten (10) calendar days after the earlier of the following: (a) the full and complete satisfaction of the Judgment; or (b) the final resolution of the Insurance Claims.

- (d) The Trustee shall file a motion seeking the dismissal with prejudice of the Trustee's claims against the Settling Defendants in the Consolidated Action within ten (10) calendar days after the earlier of the following: (a) the full and complete satisfaction of the Judgment; or (b) the final resolution of the Insurance Claims.
- 10. Further Cooperation. Each of the Settling Defendants agrees to cooperate with the Trustee in connection with the Consolidated Action, any of the Trustee's claims against other parties in the Consolidated Action or other proceedings, and any action involving the Insurance Claims, including by: (a) voluntarily responding to the Trustee's reasonable requests for documents and other information; (b) voluntarily appearing and participating in interviews on reasonable notice with the Trustee's counsel for up to five (5) total hours; (c) voluntarily appearing and providing testimony on reasonable notice for a deposition and a pre-deposition meeting (without need of subpoena) with the Trustee's counsel; and (d) voluntarily appearing and providing testimony at trial (without need of subpoena). To the extent that any Settling Defendant's health status makes it overly burdensome for him to appear in person at trial, the Trustee shall work in good faith and use best efforts to ensure that said Settling Defendant may appear remotely. The Trustee shall reimburse the Settling Defendants and their counsel for any reasonable out-of-pocket travel costs that they incur in complying with the Trustee's requests for cooperation.
- 11. <u>Fees, Costs, and Expenses.</u> The Parties shall bear their own attorney's fees, costs, and expenses incurred in connection with the Consolidated Action. Nonetheless, in any action or proceeding to enforce this Agreement, the prevailing party shall be entitled to recover its reasonable attorney's fees, costs, and expenses from the other parties to such action or proceeding.
- **12.** <u>Notice.</u> Any notice to be provided to the Parties under this Agreement shall be delivered by U.S. mail and electronic mail to the following persons:
 - (a) If to the Trustee:

Eric D. Madden Reid Collins & Tsai LLP 1601 Elm Street, Suite 4200 Dallas, TX 75201 emadden@reidcollins.com

-and-

Alan D. Halperin Halperin Battaglia Benzija, LLP 40 Wall Street, 37th Floor New York, NY 10005 ahalperin@halperinlaw.net

(b) If to Patrick Fourteau:

Joshua A. Goldberg
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
jgoldberg@pbwt.com

(c) If to Pierre Lapalme:

Jonathan Bunge
Daniel Lombard
Quinn Emanuel Urquhart & Sullivan LLP
191 N. Wacker Drive, Suite 2700
Chicago, IL 60606
jonathanbunge@quinnemanuel.com
daniellombard@quinnemanuel.com

(d) If to Steven Meyer:

Jonathan Bunge
Daniel Lombard
Quinn Emanuel Urquhart & Sullivan LLP
191 N. Wacker Drive, Suite 2700
Chicago, IL 60606
jonathanbunge@quinnemanuel.com
daniellombard@quinnemanuel.com

(e) If to Brian Tambi:

W. Gordon Dobie Winston & Strawn LLP 35 W. Wacker Drive Chicago, IL 60601 wdobie@winston.com

4. Additional Representations and Warranties. Each of the Parties represents and warrants that: (a) he has negotiated this Agreement at arm's length; (b) he participated in jointly drafting this Agreement and that any rule which construes ambiguities against the drafter is of no force or effect here; (c) he is represented by competent counsel who has had an opportunity to review the Agreement; (d) he enters into this Agreement knowingly and voluntarily; (e) the person executing this Agreement is legally competent and able to execute this Agreement; and (f) the person executing this Agreement has the power and authority to enter into this Agreement. Further, the Trustee represents and warrants that the Insys Liquidation Trust will not pursue, or cooperate in the pursuit of, any claims against the Settling Defendants except as explicitly

contemplated by Paragraph 4 of this Agreement, and is not aware of any other party that intends to pursue claims against the Settling Defendants.

- 14. <u>Complete Agreement.</u> Each of the Parties agrees that: (a) this Agreement constitutes the full and complete agreement among the Parties regarding the subject matter of this Agreement; (b) this Agreement supersedes any prior oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement; and (c) there are no oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement, except as expressly stated herein. This Agreement can be amended or modified only in a writing executed by the Parties.
- 15. Governing Law and Venue. This Agreement shall be governed by, interpreted under, and enforced in accordance with the laws of the State of Delaware, without regard to its conflict of laws principles. The sole and exclusive venue for any action, proceeding, or dispute regarding this Agreement shall be brought in a court of competent jurisdiction in the State of Delaware, and the Parties waive any right to challenge the propriety of such venue and the right to seek permissive transfer from such venue to any other venue.
- 16. Execution. The Parties agree that: (a) this Agreement may be executed in multiple counterparts, each of which shall be deemed to be and have the same force and effect of an original, and all of which taken together shall constitute and be construed as a single, binding agreement; and (b) a photocopied or PDF-scanned signature on this Agreement shall be deemed to be and have the same force and effect of an original signature.

IN WITNESS WHEREOF, and intending to be legally bound, each of the Parties has caused this Agreement to be executed as of the date set forth above.

INSYS LIQUIDATION TRUST	PATRICK FOURTEAU
By William H. Henrich	By: Patrick Fourteau
Title: Liquidation Trustee	Date:
Date: 3/30/2023	PIERRE LAPALME
	By: Pierre Lapalme
	Date:

contemplated by Paragraph 4 of this Agreement, and is not aware of any other party that intends to pursue claims against the Settling Defendants.

- Complete Agreement. Each of the Parties agrees that: (a) this Agreement constitutes the full and complete agreement among the Parties regarding the subject matter of this Agreement; (b) this Agreement supersedes any prior oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement; and (c) there are no oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement, except as expressly stated herein. This Agreement can be amended or modified only in a writing executed by the Parties.
- 15. Governing Law and Venue. This Agreement shall be governed by, interpreted under, and enforced in accordance with the laws of the State of Delaware, without regard to its conflict of laws principles. The sole and exclusive venue for any action, proceeding, or dispute regarding this Agreement shall be brought in a court of competent jurisdiction in the State of Delaware, and the Parties waive any right to challenge the propriety of such venue and the right to seek permissive transfer from such venue to any other venue.
- 16. Execution. The Parties agree that: (a) this Agreement may be executed in multiple counterparts, each of which shall be deemed to be and have the same force and effect of an original, and all of which taken together shall constitute and be construed as a single, binding agreement; and (b) a photocopied or PDF-scanned signature on this Agreement shall be deemed to be and have the same force and effect of an original signature.

IN WITNESS WHEREOF, and intending to be legally bound, each of the Parties has caused this Agreement to be executed as of the date set forth above.

INSY	S LIQUIDATION TRUST	PATRICK FOURTEAU
		Paller Faul
	William H. Henrich Liquidation Trustee	By: Patrick Fourteau Date: 03/27/2023
		PIERRE LAPALME
		By: Pierre Lapalme Date:

contemplated by Paragraph 4 of this Agreement, and is not aware of any other party that intends to pursue claims against the Settling Defendants.

- Complete Agreement. Each of the Parties agrees that: (a) this Agreement constitutes the full and complete agreement among the Parties regarding the subject matter of this Agreement; (b) this Agreement supersedes any prior oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement; and (c) there are no oral or written agreements, representations, or understandings among the Parties regarding the subject matter of this Agreement, except as expressly stated herein. This Agreement can be amended or modified only in a writing executed by the Parties.
- 15. Governing Law and Venue. This Agreement shall be governed by, interpreted under, and enforced in accordance with the laws of the State of Delaware, without regard to its conflict of laws principles. The sole and exclusive venue for any action, proceeding, or dispute regarding this Agreement shall be brought in a court of competent jurisdiction in the State of Delaware, and the Parties waive any right to challenge the propriety of such venue and the right to seek permissive transfer from such venue to any other venue.
- 16. Execution. The Parties agree that: (a) this Agreement may be executed in multiple counterparts, each of which shall be deemed to be and have the same force and effect of an original, and all of which taken together shall constitute and be construed as a single, binding agreement; and (b) a photocopied or PDF-scanned signature on this Agreement shall be deemed to be and have the same force and effect of an original signature.

IN WITNESS WHEREOF, and intending to be legally bound, each of the Parties has caused this Agreement to be executed as of the date set forth above.

INSY	S LIQUIDATION TRUST	PATRICK FOURTEAU
By: Title: Date:	William H. Henrich Liquidation Trustee	By: Patrick Fourteau Date:
		By: Pierre Lapalme Date: 03/39/2033

STEVEN MEYER, Mye				
By:	Steven Meyer / 20 2 3			
Date:	4/3/2023			
BRIA	N TAMBI			
By:	Brian Tambi			
Date:				

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By: Date:	Steven Meyer	

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BRIAN TAMBI

STEVEN MEYER

By: Brian Tambi

Exhibit C

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

WILLIAM H. HENRICH, as Trustee of : the Insys Liquidation Trust, :

Plaintiff,

V. : C A No. 12

JOHN N. KAPOOR,
MICHAEL L. BABICH,
PATRICK P. FOURTEAU,
PIERRE LAPALME, STEVEN
MEYER, BRIAN TAMBI, and
THEODORE H. STANLEY,

Defendants.

C.A. No. 12696-JTL

TRUSTEE'S AMENDED VERIFIED COMPLAINT

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William H. Henrich, in his capacity as Liquidating Trustee (the "<u>Trustee</u>") of the Insys Liquidation Trust (the "<u>Trust</u>") under the confirmed Chapter 11 Plan for Insys Therapeutics, Inc. ("<u>Insys</u>"), hereby files this Amended Verified Complaint, and alleges as follows.

I. NATURE OF ACTION

- 1. In this action, the Trustee seeks to hold Insys's former directors and officers accountable for the crippling consequences that the company suffered due to their shocking malfeasance. That misconduct exposed Insys to hundreds of civil and criminal actions involving billions of dollars in third-party claims, driving the company into bankruptcy in June 2019.
- 2. Insys was a specialty pharmaceutical company that developed, sold, and marketed a highly addictive and inherently dangerous fentanyl spray, SUBSYS® ("Subsys"). Fentanyl—a synthetic opioid that is 50 times more powerful than heroin and 100 times more powerful than morphine—is a Schedule II controlled substance with high potential for abuse and dependence. The U.S. Federal Drug Administration ("FDA") approved Subsys solely for treatment of cancer patients suffering persistent pain that was not ameliorated by other prescription pain medications, referred to as "breakthrough" pain.
- 3. Shortly after Subsys was launched for commercial sale in March 2012, Insys's founder, chairman, and controlling stockholder, John D. Kapoor ("Kapoor")

and the protégé whom he installed as the company's CEO, Michael Babich ("Babich"), implemented an unlawful scheme to sell and market Subsys. Their illicit scheme was pervasive and multi-faceted, but it involved three primary components.

- 4. The first major component of the Kapoor-Babich unlawful scheme involved bribing doctors to write an increasingly greater number of Subsys prescriptions, even where not medically appropriate or necessary. The bribes were made under the pretense of being "speaker fees" as part of a "speaker program," in which doctors supposedly were to extoll the virtues of Subsys to other doctors. But in reality, the speaker program was a sham from the start. Doctors were paid speaker fees for events that they never attended, and their fees were directly tied to the number of prescriptions that they wrote. Shockingly, Kapoor and Babich even directed Insys personnel to create a return on investment, or "ROI," analysis, to monitor the number of prescription "bangs" for the amount of speaker fee "bucks." And Kapoor and Babich made sure that doctors who did not live up to their end of the corrupt, quid pro quo bargain were excluded from further participation in the socalled "speaker program."
- 5. The second major component of the Kapoor-Babich criminal scheme involved directing Insys's salesforce to pressure doctors into writing prescriptions for stronger doses of Subsys than medically indicated (because higher-strength doses were more lucrative for the company). Babich, with Kapoor's blessing, instructed

Insys's salesforce to pressure doctors to write stronger prescriptions, and tied their bonuses to the strength of prescriptions written, known as the "effective dose." This marketing strategy of increasing the strength of dose, referred to as "titration," was so pervasive that the company played a satirical rap video at its national sales meeting in which Insys salesmen—wearing tuxedos with sunglasses and dancing alongside a person in a Subsys canister costume—boasted about the practice, rapping: "I love titrations. Yeah, that's not a problem."

The third major component of the Kapoor-Babich illicit scheme was to 6. defraud third-party insurers (in addition to governmental payors) into covering the costs of medically unnecessary or otherwise unlawful Subsys prescriptions. Kapoor and Babich oversaw the creation of Insys's in-house department, referred to as the "insurance reimbursement center" or "IRC," to facilitate authorizations from insurance carriers for Subsys prescriptions (regardless of medical need). Insys employees were instructed to fill out necessary insurance paperwork for prescribing doctors, and then to converse by telephone with insurers without indicating their Insys affiliation and while delivering carefully crafted—and fraudulent—scripted answers to questions that insurers might ask. The so-called "spiel" that Insys employees were instructed to follow was discussed widely among Insys management, and Kapoor himself personally participated in drafting different versions of the "spiel."

- 7. Given its pervasive and systemic nature, the Kapoor-Babich scheme did not remain hidden, and it sparked a series of whistleblower complaints, government investigations, media reports, and criminal prosecutions of Insys employees and corrupt doctors. Eventually, in October 2017, Kapoor and Babich were criminally indicted in a superseding indictment for violating 18 U.S.C. § 1962(d) (racketeering conspiracy), 18 U.S.C. § 1349 (mail fraud conspiracy and wire fraud conspiracy for scheme to defraud insurers), and 18 U.S.C. § 371 (conspiracy to violate the Anti-Kickback Statute) in *United States v. Babich et al.*, No. 16-CR-10343 (D. Mass.) (the "Criminal Action").
- 8. The Criminal Action confirmed the illegality of the Kapoor-Babich scheme. On January 9, 2019, Babich pleaded guilty to conspiracy to commit mail fraud and wire fraud (18 U.S.C. § 307) and to mail fraud (18 U.S.C. § 1341). On May 12, 2019, following a lengthy criminal trial at which Babich and others testified over the course of many days, Kapoor was convicted for violating the federal RICO statute (18 U.S.C. § 1962(d)) by devising a scheme to bribe doctors to prescribe Subsys and to defraud insurers to cover the prescription costs. Kapoor's landmark conviction for criminal racketeering was subsequently affirmed by the U.S. Court of

Appeals for the First Circuit in a blistering 141-page opinion.¹

- 9. By June 2019, at least eight high-ranking Insys executives—including its Chairman (Kapoor) and CEO (Babich)—had been criminally convicted. The company therefore waived the white flag. On June 5, 2019, Insys agreed to pay \$225 million to settle the federal government's civil and criminal investigations, with the company's wholly owned subsidiary pleading guilty to mail fraud. Just five days later, Insys collapsed into bankruptcy.
- 10. All told, the vast criminal scheme perpetrated by Kapoor and Babich generated dozens of criminal convictions of former Insys executive and employees, and corrupt Subsys-prescribing doctors. Insys itself has faced dozens of government investigations, enforcement actions, and criminal and civil proceedings, and hundreds of civil suits collectively seeking billions of dollars. Consequently, Insys has been oft-described in media reports as the "poster child" of a pharmaceutical company plagued by wrongful opioid sales and marketing practices.
 - 11. None of the shocking malfeasance that befell Insys would have been

¹ The First Circuit, for example, stated: "The facts of this mammoth case . . . tell a chilling tale of suffering that did not need to happen. It involves a group of pharmaceutical executives who chose to shunt medical necessity to one side and shamelessly proceeded to exploit the sickest and most vulnerable among us—all in an effort to fatten the bottom line and pad their own pockets." *United States v. Simon et al.*, 12 F.4th at 1, 15 (1st Cir. 2021).

possible had it not been for the total failures by Insys's board of directors to implement any sort of compliance or monitoring function at the company. Indeed, Insys's directors turned a blind eye to known risks, known regulatory compliance obligations in the pharmaceutical industry, the inherent risks involved in the sale and marketing of opioids (and a notoriously dangerous one, in fentanyl, at that), and numerous "red flags" of potential compliance issues brought to their attention. Again and again, Insys's directors failed to act in good faith to implement even the most minimal safeguards against illegality, or to ensure that the few token gestures they did take were implemented effectively, as the following examples illustrate.

- 12. <u>First</u>, Insys's directors failed to implement any internal audit function, to hire any full-time regulatory compliance personnel, or to hire in-house legal counsel until 2014, long after the Subsys launch in early 2012 and implementation of the Kapoor-Babich unlawful sales and marketing scheme.
- 13. Second, although Insys's directors retained a part-time compliance consultant, they ignored his specific recommendations to ensure that the company's sales and marketing practices were lawful. The directors did not request or receive any information from this consultant until a July 2013 board meeting. At that board meeting, the consultant specifically advised the board that Insys needed to hire a full-time general counsel and compliance officer given the inherent risks in selling Subsys and his observations about concerning promotional and reimbursement

practices. The consultant also stressed the need to conduct an internal audit both of the "speaker program" and of the IRC. But Insys's directors ignored those recommendations.

- 14. <u>Third</u>, Insys's directors failed to implement any board-level compliance monitoring, any regular processes or protocols for management reports to the board on compliance issues, or any internal reporting system through which employees could bring compliance concerns to the board's attention.
- even upon receiving a federal governmental subpoena in December 2013 that indicated a possible whistleblower regarding Insys's ongoing practices. Shortly after receiving the subpoena, Insys's directors held a board meeting at which the part-time compliance consultant reiterated his concerns regarding possible systemic unlawful activity related to the speaker program. Although the directors formed a special committee to explore compliance issues, the special committee did absolutely nothing until over eighteen months later (in August 2015). And even when the special committee re-constituted itself and finally started to meet, it was not independent or well-functioning; Kapoor himself was present at many special committee meetings and continued to steer the company's actions from outside the special committee framework.
 - 16. Fifth, in early 2014, the only Insys director without any financial

entanglements or prior business relationships with Kapoor expressed concerns to his fellow board members that the board was "turning a blind eye" to potential unlawfulness and the concerns raised by Insys employees over the speaker program (and in particular, the ROI analysis seeking to quantify the effectiveness of *quid pro quo* payments). Yet Insys's directors did nothing.

- 17. Sixth, Insys's directors failed to take any action in response to glaring "red flags" of possible illegality that came to their attention beginning in May 2014. Early that month, the leading Subsys prescriber in the entire country was charged with health care fraud and Controlled Substance Act violations. Just five days after Insys's directors were informed of that arrest, *The New York Times* published an article noting that "questions are emerging about how [Subsys] is being sold, and to whom." Once again, however, Insys's directors brushed off the concerns raised as isolated issues and did nothing to investigate or to ensure that misbehaving salesforce members were not pushing Subsys to be prescribed inappropriately.
- 18. Seventh, Insys's directors failed to act in response to concerns expressed in a June 2014 board meeting by a recently hired compliance director for the company. Although this compliance director had no prior pharmaceutical industry experience and was relatively young and inexperienced, it was obvious even to her that the IRC's practices were inappropriate. At a June 2014 board meeting, this compliance director specifically informed Insys's directors that she believed that

the IRC was committing insurance fraud. Yet Insys's directors brushed off her concerns and failed to take any investigatory or monitoring efforts to ensure that the IRC was operating appropriately.

- 19. <u>Eighth</u>, Insys's directors failed to perform any investigation when Kapoor and Babich retaliated against an internal whistleblower by firing him in August 2014. The board was informed of the firing, and that it had been at the direction of Kapoor and Babich. But the board did absolutely nothing to explore the surrounding circumstances, which would have revealed Kapoor's implementation of the ROI analysis of bribes paid to doctors in the "speaker program."
- 20. <u>Finally</u>, Insys's directors failed to implement investigatory or monitoring initiatives even when the company itself received a federal criminal subpoena in September 2014.
- 21. In sum, Insys's directors did nothing to ensure that the company complied with applicable laws in its strictly regulated, high-risk industry, even after "red flags" of possible unlawful activity were brought to their attention. Instead, they stood back and let Kapoor run Insys as he saw fit—even when that entailed misguided efforts to try to shield Kapoor from criminal liability as his subordinates were criminally charged from 2015 through 2017. Insys's directors did not act in good faith in carrying out their duties of care as directors, nor did they act in what they subjectively believed to be in Insys's best interests. Rather, they were enablers

who, motivated by their relationships with and loyalty to Kapoor, gave him carte blanche to author one of the darkest chapters of the opioid crisis.

II. PARTIES

A. PLAINTIFF

22. The Trust is a Delaware statutory trust. The Trust was created, and the Trustee was appointed, pursuant to an order by the U.S. Bankruptcy Court for the District of Delaware confirming the Chapter 11 plan of liquidation (the "Plan") in Insys's bankruptcy case.² Under the Plan, certain claims and causes of action belonging to Insys, including the claims asserted in this action, were vested in the Trust for prosecution by the Trustee as a representative of the bankruptcy estate pursuant to 11 U.S.C. § 1123(a)(5), (a)(7), and (b)(3)(B). The Trustee, therefore, has standing to pursue the claims asserted in this action. On May 11, 2021, the Court granted the Trustee's Motion to Realign and Substitute Party in this action and substituted the Trustee as the plaintiff to pursue claims formerly brought derivatively on behalf of Insys.

B. DEFENDANTS

23. Defendant John N. Kapoor ("<u>Kapoor</u>") is the founder of Insys. He served in the following positions at Insys: (a) as a member of its board of directors

² In re Insys Therapeutics, Inc., et al., Case No. 19-11292 (Bankr. D. Del.).

from its formation until October 2017; (b) as Executive Chairman from June 2006 to October 2017; and (c) as President and Chief Executive Officer from November 2015 to January 2017. Kapoor holds a doctorate in medical chemistry from the University of Buffalo. On May 2, 2019, Kapoor was convicted by a jury for engaging in a racketeering conspiracy (18 U.S.C. § 1962(d)) with other Insys executives. Kapoor was sentenced to 66 months in prison followed by three years of supervised release. His conviction was subsequently affirmed by the U.S. Court of Appeals for the First Circuit. Kapoor is currently serving his prison sentence.

24. Defendant Michael L. Babich ("Babich") served in the following positions at Insys: (a) as a member of its board of directors from 2008 to November 2015; (b) as President from November 2010 to November 2015; and (c) as Chief Executive Officer from March 2011 to November 2015. He also served as the Chief Operating Officer and as a member of the board of directors for Insys Pharma, Inc. ("Insys Pharma"), a wholly owned subsidiary of Insys, from March 2007 to November 2010. Before joining Insys, Babich worked closely with Kapoor at EJ Financial Enterprises Inc. ("EJ Financial"), a venture capital firm controlled by Kapoor. Babich began working for EJ Financial in 2001, at the age of 25, and became close with Kapoor. Kapoor paid for Babich's pursuit of an MBA degree during his time at EJ Financial. Following Babich's receipt of an MBA in 2007, Kapoor hired him at Insys Pharma. Kapoor later installed Babich as CEO of Insys

in March 2011. On January 9, 2019, Babich pleaded guilty to one count of conspiracy to commit mail fraud and wire fraud (18 U.S.C. § 307) and one count of mail fraud (18 U.S.C. § 1341). Babich was sentenced to 30 months in prison followed by three years of supervised release. Babich is currently serving his prison sentence.

- 25. Defendant Patrick P. Fourteau ("Fourteau") served as a member of Insys's board of directors from March 2011 to October 2017. He also served as a member of Insys Pharma's board of directors from August 2007 to November 2010. From 2003 to 2008, Fourteau served as President and Chief Executive Officer of Sciele Pharma, Inc. ("Sciele"), a company that Kapoor founded and controlled. Fourteau also served as a member of Sciele's board of directors—along with Kapoor and Defendant Pierre Lapalme—from 2004 to 2008.
- 26. Defendant Pierre Lapalme ("<u>Lapalme</u>") served as a member of Insys's board of directors from March 2011 to June 2019. He also served as a member of Sciele's board of directors—along with Kapoor and Fourteau—from 2000 to 2008.
- 27. Defendant Steven Meyer ("Meyer") served in the following positions at Insys: (a) as Chairman of its board of directors from January 2017 to June 2019; and (b) as a member of its board of directors from November 2010 to June 2019. He also served as a member of Insys Pharma's board of directors from August 2007 to November 2010. Meyer—along with Kapoor and Defendant Brian Tambi—also

served as a member of the board of directors of Akorn, Inc. ("Akorn"), another pharmaceutical company in which Kapoor held a substantial ownership interest, from 2009 to 2020.

- 28. Defendant Brian Tambi ("<u>Tambi</u>") served as a member of Insys's board of directors from November 2010 to May 2018. From August 2007 until November 2010, Tambi served as a member of Insys Pharma's board of directors. Tambi—along with Kapoor and Meyer—also served as a member of Akorn's board of directors from 2009 to 2020
- 29. Theodore Stanley ("Stanley") served as a member of Insys's board of directors from March 2013 to July 2017, when he passed away at the age of 77 after this action was commenced. The Trustee is no longer pursuing claims against Stanley or his estate.
- 30. As members of Insys's board of directors during the relevant period, Kapoor, Babich, Fourteau, Meyer, Lapalme, and Tambi are collectively referred to as the "Defendants." Because they did not serve as Insys's officers at any point (unlike Kapoor and Babich), Fourteau, Meyer, Lapalme, and Tambi are collectively referred to as the "Outside Directors."

III. FACTUAL BACKGROUND

A. KAPOOR AND BABICH IMPLEMENT A CRIMINAL SCHEME.

- 1. <u>Insys Develops Subsys</u>, a Powerful Painkiller for Cancer Patients.
- 31. Insys was a specialty pharmaceutical company in the business of developing and marketing novel pharmaceutical products. Its most promising—and only commercially significant—product was Subsys, which Insys launched for sale in March 2012. Subsys helped alleviate pain suffered by cancer patients when less powerful painkilling medications failed, a pain known as "breakthrough" pain. It did so by administering a synthetic opioid called fentanyl through an under-the-tongue (sublingual) spray.
- 32. Subsys has a novel delivery system. Upon its launch, Subsys was the sixth product in a specific class of drugs which administer fentanyl through mucus membranes. That class of drugs is technically referred to as the Transmucosal Immediate-Release Fentanyl ("<u>TIRF</u>") class. Among TIRF drugs, Subsys was the first-ever sublingual spray.
- 33. Subsys is a strong pain suppressant. Its primary chemical compound, fentanyl, is quite potent—50 times more powerful than heroin and 100 times more powerful than morphine. As such, it is classified as a Schedule II controlled substance with high potential for abuse and dependence. And when fentanyl is

released into mucus membranes, as through TIRF drugs like Subsys, its potency is enhanced by a rapid release of the opioid into the patient's bloodstream.

- 34. Based on the unique delivery system and high potency of Subsys, the FDA recognized its inherent potential for abuse and overdose. Specifically, in January of 2012, the FDA approved Subsys for commercial sale while also limiting the purposes and manner for which Subsys could be prescribed.
- 35. The purposes for which the FDA approved Subsys were narrow. Subsys was permitted only for the management of breakthrough pain in adult cancer patients who were already receiving and tolerant to around-the-clock opioid therapy. Under 21 U.S.C. § 301 *et seq.* and 42 U.S.C. § 262 *et seq.* and their implementing regulations, Insys was permitted to market Subsys only for this specific, on-label use. Subsys was expressly <u>not</u> permitted (*i.e.* contraindicated) for use in the management of acute or postoperative pain, headaches or migraines, and dental pain.
- 36. The strength of the doses in which Subsys could be prescribed was also constrained by the FDA. "The initial dose of SUBSYS to treat episodes of breakthrough cancer pain" was "always" to be 100 mcg—the smallest available dose. And doctors seeking to increase a patient's dose strength could do so only under limited circumstances. As a prerequisite, physicians had to find that the current dose failed to treat the breakthrough pain episode adequately for several

consecutive episodes. If that were so, physicians were permitted to prescribe only the next tiered dose.

2. <u>Insys's Sale and Marketing of Subsys Is Heavily Regulated.</u>

- 37. Insys sold Subsys within a heavily regulated industry for controlled substances and the sale of pharmaceutical products. As such, Insys was subject to extensive statutes and regulations, at both the state and federal level, applicable to the manufacturing, sale, and marketing of Subsys. Compliance with all such laws was mission critical for Insys to succeed in its business model. Insys's sale and marketing of Subsys was subject to at least three, well-known statutory and regulatory regimes.
- 38. <u>First</u>, under the False Claims Act, "any person" incurs civil liability for knowingly presenting or causing to be presented to the federal government a "false or fraudulent claim for payment or approval." 31 U.S.C. § 3729. The law attaches similar liability for any person who knowingly makes, uses, or causes to be made or used, a material "false record or statement" related to a false or fraudulent claim. *Id*. Parallel state laws prohibit similar conduct.
- 39. Second, under the federal Anti-Kickback Statute, it is unlawful for a drug manufacturer to bribe doctors to sell its drug (or for a doctor to accept such a bribe). That is, it is illegal for anyone to offer, make, or accept payment pr other remuneration in exchange for the referral of any product for which payment is sought

from any federal healthcare program. 42 U.S.C. § 1320a-7b(b). A violation of the Anti-Kickback Statute can result in civil or criminal liability. And under the Patient Protection and Affordable Care Act, a violation of the Anti-Kickback Statute is a false claim for purposes of the False Claims Act.

- 40. Third, various federal statutes and regulations make it illegal for drug companies to market drugs for "off-label" use. As described above with Subsys, the FDA approves drugs for specific uses (called "indications"). Although doctors may legally prescribe drugs outside of their approved indications, it is illegal for manufacturers to market a drug for off-label indications. *See, e.g.*, 21 U.S.C. §§ 301 *et seq.*; 42 U.S.C. §§ 262 *et seq.*, 21 U.S.C. § 331(a), (d); 42 U.S.C. § 262(a)(1), (b); 21 C.F.R. § 601.12.
- 41. Even though these statutory and regulatory limitations are well-known within the pharmaceutical industry, Kapoor and Babich implemented a pervasive criminal scheme that flagrantly violated these and other legal limitations.

3. The Multifaceted Kapoor-Babich Scheme Is Implemented.

42. Soon after Subsys was launched in early 2012, Kapoor and Babich implemented their multifaceted criminal sales and marketing scheme. They did so because Subsys's lackluster initial results—panned by Kapoor as the "worst fl***Jing launch in pharmaceutical history"—were inadequate to satiate their greed. Kapoor and Babich demanded that sales increase at all costs, regardless of

the legality of methods or the harm inflicted on the public and Insys itself. The pervasive scheme they devised to criminally and fraudulently increase Subsys revenues involved three primary components: (1) a "speaker program" to mask bribes to doctors; (2) deployment of a corrupt Insys salesforce to pressure doctors to write medically inappropriate prescriptions for stronger doses, referred to as the "effective" doses, and (3) development of an in-house insurance fraud program, the IRC.

a. The Sham "Speaker Program" to Disguise Bribes to Doctors.

43. In August 2012, Kapoor and Babich launched a "speaker program" designed to induce doctors to write more Subsys prescriptions by offering them bribes in the form of "speaker fees" and other perks, tied *quid pro quo*, to the number of prescriptions written by those doctors (the "Speaker Program"). On paper, the Speaker Program was a peer-to-peer educational program through which doctors and other medical providers would share their experiences prescribing Subsys with other potential prescribers. But in reality, the Speaker Program was a way for Kapoor, Babich, and the salesforce they installed to funnel bribes to prescribing doctors through "speaker fees" that totaled thousands of dollars per event. The speaking events were merely a pretense for the Speaker Program's true purpose: to put money in the pockets of prescribers in exchange for their willingness to prescribe more Subsys to their patients, regardless of medical necessity.

- 44. Four aspects of the Speaker Program reflect that it was not a genuine marketing effort, but rather an utter farce designed to disguise what amounted to illegal kickbacks to doctors. First, the Speaker Program paid out exorbitant benefits to doctors that were tied to the number of Subsys prescriptions written by the participating speakers themselves, not by their audience members (reflecting that building brand awareness was not the real motive). Second, Kapoor and Babich implemented a tracking program to quantify and correlate the amount of money paid to doctors in speaker fees and their Subsys prescriptions—a "return on investment" or "ROI" analysis. Third, Kapoor and Babich ensured that their underlings and corrupt salesforce representatives intentionally targeted top "performing" doctors in the Speaker Program who wrote the most Subsys prescriptions—doctors to whom they referred as "whales." Fourth, Kapoor and Babich consciously sought out subordinate officers and salesforce foot soldiers who would implement the Speaker Program, despite its flagrant illegality.
- 45. <u>First</u>, the Speaker Program paid out exorbitant benefits that were directly tied to the number of Subsys prescriptions written by the participating doctor, and not some metric related to building brand awareness. Doctors prescribing Subsys could earn over \$100,000 or more per year in bribes disguised as so-called "speaker fees," regardless of whether anyone attended their purported speaking events or whether or not the events were even held. In addition, speakers

were lavished with expensive meals, drinks, and travel reimbursements, as inducements to write more prescriptions. The cash "speaker fees" and other perks were not tied to building brand awareness, as no analysis was performed on prescriptions written by attendees. Rather, payments and other benefits provided to doctors were dependent on the number of prescriptions written by the supposedly speaking doctors. In fact, salesforce representatives expressly required doctors to write a minimum number of Subsys prescriptions to continue to receive the "speaker fee" bribes and kickbacks.

- 46. Further reflective of the sham and illegitimate nature of the Speaker Program, the Insys salesforce falsified attendance records, listed inappropriate attendees and venues, and posted excessive costs. Indeed, salesforce members were specifically instructed that participating doctors who were leading prescribers, like Dr. Gavin Awerbuch (arrested in 2014), should be paid regardless of whether they attended events or gave speeches.
- 47. None of this was by accident, and Kapoor himself made clear to the company's Executive Vice President of Sales, Alec Burlakoff ("Burlakoff"), that the true purpose of the Speaker Program was to line doctor's pockets as a *quid pro quo* for more Subsys prescriptions. Burlakoff testified in the Criminal Action that, in September 2012, he had a "detailed conversation" with Kapoor and Babich in which "their objectives were once again reiterated to [Burlakoff]—they made sure that

there was no way that [he] could mistake their message" that "paying the doctors w[ould] result in an increase in prescriptions."

- 48. Following that conversation, and in order to convey Kapoor's message, Burlakoff sent an email to the entire Insys salesforce (with Kapoor blind-copied) regarding the Speaker Program. Burlakoff specifically instructed the salesforce: "If you cannot guarantee that this program will yield positive results [*i.e.*, speakers producing prescriptions], the program should not take place."
- 49. Second, Kapoor and Babich instructed their underlings to quantify and track whether doctors participating in the Speaker Program were living up to their end of the corrupt bargain and writing more Subsys prescriptions in exchange for the payments they received. In September 2012, Kapoor directed Matthew Napoletano ("Napoletano"), the company's Vice President of Marketing, to analyze the ratio of expenditure to revenue from each speaker's prescriptions of Subsys (the "ROI Analysis"). Napoletano understood that Kapoor wanted a 2:1 ratio. That is, Kapoor demanded that for every dollar that Insys spent on a particular speaker, it must generate two dollars of revenue from Subsys prescriptions written directly by that speaker. The ROI Analysis was focused purely on a *quid pro quo* return in prescriptions from the speaking doctors themselves, and not on any general increase in market share due to enhanced brand awareness.

- 50. Napoletano initially objected to Kapoor's demand to prepare and maintain the ROI Analysis. At meetings with Kapoor that included Babich and Burlakoff, Napoletano stated that, based on the "pharma code" and certain "statutes," "[e]verybody knows that you don't track speakers." Napoletano was so impassioned about the topic that at one meeting he dared to yell at Kapoor, screaming his dissent to conducting the analysis. The meeting ended with Napoletano fearing for his job.
- Shortly thereafter, Napoletano ceded to Kapoor's demands to avoid 51. getting fired. Specifically, Napoletano sent a presentation to Babich and Burlakoff on December 10, 2012, with a cover email stating, "let's discuss if this is what we want to share with [Kapoor] tomorrow" The presentation was entitled "Speaker Bureau Assessment," and explicitly calculated the return on investment for the Speaker Program. That is, for each individual physician in the program, it compared the fees paid to that doctor with the net revenue he/she had personally generated by writing Subsys prescriptions. Two days later, Napoletano emailed Babich and others the same presentation (along with a second entitled "2013 Proposed Marketing Budget") in an email with a single line of text: "To send to The attachments included slides analyzing "Speaker ROI," [Kapoor]..." explained that speakers with less than 2:1 ROI had been "flagged," and identified candidates to "soft delete" from the Speaker Program.

- 52. After sending that email intended for Kapoor, Napoletano met with Kapoor, Babich, and Burlakoff to review the ROI Analysis presentation. As Babich testified in the Criminal Action, at that meeting they assessed each doctor, line by line, to determine what they should do with certain speakers going forward based upon the revenue generated.
- 53. Despite his obedience to Kapoor, Napoletano continued to express discomfort with performing the ROI Analysis to Babich. Babich testified that Napoletano was in Napoletano's "office screaming that we're all going to go to jail, that he should have never ran the return on investment report." Ignoring Napoletano's desperate warnings, Babich told him to keep performing the analysis because it was what Kapoor wanted.
- 54. Third, Kapoor and Babich directed and ensured that the Insys salesforce targeted top performing physicians in the Speaker Program. With the blessing of Kapoor and Babich, Burlakoff instructed the salesforce to give speaker programs to high prescribers and "hold them accountable" for prescribing more Subsys in exchange for Speaker Program payments. The salesforce (and management) referred to these high prescribers as "whales." Babich bluntly testified that whales were "the physicians that we knew that, if you gave them money, their scripts would go up."

- 55. Kapoor, Babich, Burlakoff, and others frequently discussed the productivity of whales on management calls, which occurred at 8:30 a.m. each day.
 - 56. Babich testified in the Criminal Action that:

[Kapoor] bought into the fact that we should target these whales Because remember at the end of the day the goal was to get money in the hands of physicians any way possible, and it was a cheaper way to do it.

The prosecutor then asked: "I want you to be crystal clear about this. Mr. Babich, when you're talking about getting money into the hands of doctors, what are you referring to?" Babich responded: "To bribe them to write the product."

- 57. Because the true goal of the Speaker Program was bribery (not education), the salesforce was specifically instructed not to be concerned with whether physicians were qualified to speak about Subsys in an educational setting. For example, Babich forwarded to Burlakoff an email summarizing a salesforce member's interactions with Dr. Paul Madison, a high prescriber and participant in the Speaker Program: "Dr. Madison runs a *very shady pill mill and only accepts cash...* He basically *just shows up to sign his name on the prescription pad*, if he shows up at all ... I call on him frequently." Burlakoff then instructed the salesforce member to "make good on our commitment to utilize Dr. Madison as a *Subsys thought leader*" with speaking programs "as much as once a week."
- 58. And when doctors receiving speaker fees did not write enough prescriptions, salesforce members were instructed to proactively challenge those

doctors to write more prescriptions or even drop them from the Speaker Program. Such exclusions began even early on in the Speaker Program. For example, on November 9, 2012, Babich emailed Burlakoff and Napoletano that Dr. Steve Fanto—another high-decile prescriber of Subsys—"needs to start crankin or he gets taco bell."

- 59. Fourth, Kapoor and Babich implemented the illicit Speaker Program through conscious hiring decisions to bring in unscrupulous, financially desperate, and/or sufficiently inexperienced or unsophisticated salesforce employees who would partake in the flagrantly wrongful behavior that the Speaker Program entailed. Kapoor and Babich referred to such salesforce minions hired to implement their scheme as "PHDs," standing for "poor, hungry and driven."
- and Babich turned to Burlakoff. Kapoor and Babich hired Burlakoff in 2012 after he specifically told them, during his job interview, of a similar sham speaker program to bribe doctors that Burlakoff had employed when he had worked as one of the top salespeople at Cephalon, Inc. ("Cephalon"). Cephalon's illegal marketing tactics resulted in a \$425 million settlement with the federal government in 2008. Despite their knowledge of Burlakoff's prior involvement in these illegal tactics, Kapoor and Babich hired Burlakoff because his experience made him a perfect fit for spearheading the illicit Speaker Program that they hoped to implement at Insys.

- On the Speaker Program and building a sales team "upon a 'win at all cost' foundation."
- 62. Upon Burlakoff's promotion, Kapoor and Babich directed Burlakoff to build his "win at all cost" sales team. Burlakoff zealously followed those orders, hiring a slew of regional and district sales managers and sales associates who were the right sort of people for the dirty job. Consistent with the guidance and direction from Kapoor and Babich, Burlakoff specifically recruited people he believed would be willing and capable of taking part in illicit sales tactics, including improper payments and perks provided to physicians through the Speaker Program.
- 63. One of the first regional sales managers that Burlakoff hired was Sunrise Lee ("Lee"), an exotic dancer whom Burlakoff first met at a strip club. Burlakoff said he recruited Lee because she was a "great listener" and "more of a 'closer." Because Lee lacked pharmaceutical experience and a college education, Burlakoff helped Lee falsify her resume to obtain the job at Insys.
- 64. Burlakoff also recruited employees from his former employer, Cephalon. He did so because he knew they would be willing and well-equipped to

help execute the illegal Speaker Program. Between 2013 and 2016, Burlakoff recruited at least 15 employees from Cephalon to join Insys. And Kapoor and Babich also hired personnel from Cephalon. For instance, they hired Joseph Rowan ("Rowan") from Cephalon as a district manager because, during his time as a sales representative at Cephalon, Rowan developed a "tremendous" relationship with a massive "pill mill" operator in Mobile, Alabama.

65. In short, the illegality surrounding the Speaker Program was not the result of random acts by a handful of "bad apple" employees gone rogue. Rather, Kapoor and Babich deliberately implemented all aspects of the program, hired Burlakoff to help spearhead it because of his prior experience in executing a similar illegal speaker program at Cephalon, and ensured that Insys staffed its salesforce with "poor, hungry, and driven/dumb" individuals who would heedlessly execute the Speaker Program despite the flagrant illegality it entailed in exchange for bonuses.

b. The Effective-Dose Scheme to Increase Sales.

66. A salesforce made up of "PHD" members also executed the second major component of the Kapoor-Babich scheme, dubbed the effective-dose strategy, through which doctors were pressured to write prescriptions for stronger doses of Subsys than medically indicated (or permitted under the FDA-approved prescribing parameters for Subsys). Kapoor and Babich implemented the effective-dose strategy

despite its illegality (and the physical risks it posed to patients) because Insys was paid far more for higher strength doses of Subsys (e.g., 1200 mcg and 1600 mcg) than for lower strength doses (e.g., 100 mcg).

- 67. Kapoor and Babich implemented the effective-dose strategy starting in mid-2012. By July 2012, Babich was sending salesforce-wide emails informing them that the five salesforce representatives with the highest number of prescriptions for 600 meg or stronger would receive extra cash bonuses. And in August 2012, Kapoor and Babich made clear that pressuring doctors to prescribe higher strength doses was an imperative for the salesforce. On August 29, 2012, Kapoor emailed Babich, Napoletano, and others: "[W]e need to move patients to higher doses from 100mcg.... We will monitor on a daily basis, based on the report from Sean [Yu, the Vice President, Business Intelligence] the success of our effective dose message" That same day, Babich emailed all regional sales managers and blind-copied Kapoor: "Our number 1 goal right now is effective dose and having reps promote 60 units of the low strength is not going to cut it."
- 68. The effective-dose scheme, like the Speaker Program, was not merely the random acts of a few rogue sales representatives. Rather, it was a core component of the Kapoor-Babich unlawful scheme. The effective-dose strategy was so pervasive, in fact, that it featured prominently in a satirical rap music video,

entitled "Great by Choice," that was played at the Insys national sales meeting in 2015 (which Kapoor and Babich attended).

69. In the video, Insys salesforce representatives dance and rap next to a person dressed in a Subsys canister costume. The label on the Subsys costume displayed a prominent 1,600 microgram label—the highest dose of Subsys available. In the video, the salesforce employees brag about pushing doctors to increase the dosage of Subsys that they were prescribing for any given patient, a process known as "titration," rapping: "I love titrations. Yeah, that's not a problem. I got new patients, and I got a lot of 'em. If you want to be great, listen to my voice. You can be great, but it's your choice."



The video ends with a cameo by Burlakoff—a well-known and powerful personality among the company's salesforce—lifting the Subsys costume from his body and repeating the chorus pushing "titration." In other words, the video not only boasted about the widespread practice of encouraging doctors to write improperly strong

prescriptions for Subsys, but also encouraged salesforce representatives to choose to become "great" by pushing "titration."

70. To further ensure that Insys's salesforce was incentivized to pursue the effective-dose strategy as much as possible, Kapoor and Babich implemented a "pay for performance" compensation model. The pay-for-performance model that Kapoor and Babich implemented differed from pharmaceutical industry norms in two respects. First, because salesforce members were given a less-than market-rate base salary (about 20-30% below "big pharma" salaries), they were paid a significant percentage of their compensation through performance bonuses. Second, unlike most pharmaceutical companies, those performance bonuses were "uncapped," meaning that the bonuses had no upper limit. Burlakoff testified in the Criminal Action that the unusual compensation structure Kapoor implemented for corrupt salesforce members meant they were "highly incentivized to sell," as it led to quarterly six-figure bonuses for some salesforce members.

c. The Insurance Fraud Scheme Involving the IRC.

71. The third main component of the Kapoor-Babich scheme to unlawfully boost revenues from medically unnecessary and otherwise illicit Subsys prescriptions was the insurance reimbursement center ("IRC"). The IRC was Insys's in-house department devoted to securing coverage approvals from insurance companies. But the IRC and its activities were far from standard in the industry.

Rather, through the IRC and its personnel, Kapoor and Babich implemented a pervasive scheme of lying to insurers to secure insurance coverage for Subsys patients to cover the significant costs of medically unnecessary (and often illegal) Subsys prescriptions.

- 72. Many health insurance companies require patients to obtain prior authorization from the insurers before agreeing to cover the costs of prescriptions for TIRF medications, like Subsys. Such prior authorizations can be obtained by the prescribing physicians either directly from the insurer or through an entity specializing in the practice of obtaining such approvals, such as a pharmacy benefit manager ("PBM"). In general, patients must obtain and present a specific medical diagnosis to obtain a prior authorization. Moreover, many insurers will not agree to cover the costs of expensive drugs (like Subsys) until the patient has tried and failed less expensive, preferred medications.
- 73. In effect, therefore, standard health insurance industry practices surrounding prior authorizations serve as an indirect check on improper Subsys prescriptions. Because: (1) insurance carriers would only agree to cover the costs of Subsys with a prior authorization and (2) the prior authorization process required a medical diagnosis and effort to try alternative medications, insurance carriers frequently denied reimbursement requests for inappropriate Subsys prescriptions.

- 74. The hurdles necessary to obtain prior authorizations and the lack of insurance company reimbursement absent such authorizations posed a significant obstacle to the overall Kapoor-Babich scheme. As early as 2012, Kapoor and Babich became concerned that prior authorization requests for Subsys were being denied at high rates. Consequently, Kapoor and Babich sought a potential end-run to the problem and began exploring the viability of creating an in-house reimbursement center that could assist Subsys-prescribing physicians in getting prior authorizations for Subsys patients.
- 75. Kapoor and Babich tapped Michael Gurry ("Gurry"), the company's Vice President for Managed Markets, to spearhead that initiative. On September 14, 2012, Gurry sent Kapoor and Babich an email attaching a "SUBSYS Prior Authorization Action Plan." The attachment detailed a five-phase plan to, among other things, train sales employees on the prior authorization process and dynamics, create a "tool kit" for employees to use to obtain prior authorizations, and hire a prior authorization specialist. The goal of the plan was "increas[ing] pull through of SUBSYS prescriptions."
- 76. In furtherance of the plan, in October 2012, Gurry hired Elizabeth Gurrieri ("Gurrieri") as a prior authorization specialist to run a pilot program for what would later become the IRC. The pilot program proved successful in gaining higher rates of prior authorization approvals. Following the success of the pilot

program, Gurry led a full launch of the IRC in January 2013. Gurrieri was subsequently promoted to Manager of Reimbursement Services in March 2013.

- 77. The IRC consisted of a team of Insys employees with the formal title of "prior authorization specialists" who placed calls to insurers. Their sole responsibility was to help obtain coverage approval for as many Subsys prescriptions as possible, regardless of medical necessity.
- For the IRC to function, Insys first needed permission from physicians 78. to allow the IRC to submit prior authorization requests for them. That is, Insys needed doctors to expressly "opt in" to allowing Insys to submit prior authorization requests on their behalf. To do so, physicians were generally required to fill out "opt-in" forms, which formally granted a third party the authority to seek prior authorization on behalf of the physician and the patient. These forms were required by federal law to be filled out by the physicians themselves. But at the behest of Kapoor, Babich, and their corrupt subordinates like Burlakoff, Gurry and Gurrieri, Insys salesforce members and other employees routinely filled out the opt-in forms themselves and merely had the physicians sign the completed form. testified at the Criminal Action that she repeatedly heard Kapoor and Burlakoff demand that Insys employees "make sure the [necessary] boxes are checked" on the opt-in forms "and then have the doctor sign [the completed form]."

- 79. Several efforts were made to conceal from insurance companies that the IRC representatives were Insys employees. For instance, the IRC operated out of a separate building that lacked any signage to indicate it was owned or operated by Insys. Also, IRC representatives were instructed to tell insurers that they were calling "from" a particular physician's office. Further, IRC representatives were instructed to say "reimbursement center" instead of "Insys reimbursement center" when they answered the phone. As Gurrieri testified in the Criminal Action, IRC representatives took these measures "because when insurers would call back the [IRC representatives] [saying] that they needed more information, if we were answering it as Insys Therapeutics, they wouldn't want to speak to us because we were a third party and not the physician's office."
- 80. Kapoor and Gurry also encouraged IRC representatives to "maneuver" around questioning from insurance companies—*i.e.*, to lie—in order to ensure they received insurer approvals for Subsys. For instance, when Subsys was prescribed for off-label uses, insurance companies would typically ask IRC representatives if the patient was suffering with "breakthrough cancer pain"—the FDA's on-label indication—and deny coverage if the answer was "no." Gurry instructed Gurrieri to "maneuver through the questions about cancer" and "find ways to answer questions in a manner that would gain approval," stressing his philosophy that they should always "ride the gray line" between telling the truth and lying.

- 81. In keeping with Gurry's instructions, Gurrieri even developed a "question-and-answer" list ("Q&A List") for the IRC representatives. This list contained questions commonly asked by insurance companies and answers to those questions that were designed to lead to approval. IRC representatives were instructed to provide answers to questions based on the guidelines set forth in the Q&A List, regardless of whether a particular answer was truthful for a given patient.
- For example, one of the misleading responses on the Q&A List was 82. referred to by the IRC representatives as the "spiel"—a script that IRC representatives were instructed to use when insurers asked whether Subsys was being prescribed to treat breakthrough cancer pain. In the original version of the "spiel," when asked whether Subsys was being prescribed for the management of breakthrough cancer pain, IRC representatives were instructed to say: "Yes, this patient does have breakthrough pain." In a subsequent version of the "spiel," IRC representatives were instructed to answer the same question by saying: "The physician has stated that Subsys is approved for treating breakthrough cancer pain, so he is treating that breakthrough pain under [insert diagnosis code]." While the "spiel" was revised from time to time, its purpose always was to suggest to insurers that a Subsys prescription was for the treatment of breakthrough cancer pain, even though frequently it was not.

- 83. Gurry and Burlakoff, among others, regularly discussed the fact that IRC representatives were using the "spiel." And Kapoor also personally helped in drafting versions of the spiel.
- As another example of the systemic fraud put in place at the IRC with 84. the knowledge and blessing of Kapoor and Babich, Gurry and Gurrieri instructed IRC representatives to lie to insurers regarding the medications patients had previously "tried and failed." Because Subsys was very costly and there were cheaper alternatives on the market, insurers would often ask what medications a patient had already tried and failed before approving a Subsys prescription. Some insurance companies even had a specific list of medications that they required a patient to have tried and failed. To get around this, Gurrieri developed a list of the tried-and-failed medications certain insurance companies required before approving Subsys. Gurrieri discussed this list with Gurry. At Gurry's direction, Gurrieri provided this list to the IRC representatives. Gurrieri instructed them that, when asked by an insurer which medications a patient had tried and failed, they were to recite the names of the tried-and-failed medications on Gurrieri's list—regardless of what the patient's medical records stated.
- 85. Finally, Gurry and Gurrieri also instructed IRC representatives to provide diagnosis codes to insurers that were likely to lead to approval, even if the patient's medical records did not suggest the diagnosis was accurate. In particular,

Gurry and Gurrieri trained IRC representatives to use cancer-related diagnosis codes to provide the impression that a patient suffered from cancer, regardless of whether that was true or not.

- 86. To ensure that IRC representatives were incentivized to go along with these fraudulent practices, Gurry, at Kapoor's direction, created a pay structure to reward IRC representatives who gained prior authorization approvals with incentive bonuses. Every week, Gurry would establish a minimum number of approvals, referred to as a "gate," that the entire group of IRC representatives had to meet before any of them could be eligible for a bonus. Once the "gate" number was satisfied, IRC representatives were paid a bonus based on how many approvals they obtained from insurers. Like the compensation structure for salesforce members, this structure created improper incentives for IRC representatives to engage in fraudulent practices to obtain approvals.
- 87. Although Kapoor and Babich let Gurry and Gurrieri spearhead the fraudulent practices that permeated every facet of the IRC's operations, Kapoor and Babich were nevertheless fully aware of and approved the IRC's illegal practices. Indeed, according to Gurrieri's testimony, Insys's management "constantly asked" for and received regular updates about whether the fraudulent methods being employed at the IRC were successful in obtaining prior authorizations. Kapoor and

Babich also routinely discussed the IRC's operations with other members of Insys's management during the company's daily 8:30 a.m. management call.

- 88. Moreover, Kapoor took additional steps to closely monitor the IRC's "success" in obtaining prior authorizations by pressing Gurrieri for precise details and data regarding IRC's operations. For instance, in June 2014, Kapoor told Gurrieri to create a spreadsheet listing the "main" insurers with whom the IRC dealt, along with information such as "what was required to get an approval . . . [w]hether the approved compliance spiel would work with those payers, what tried and failed medications would work to gain approval, and . . . what diagnosis codes would help to get an approval."
- 89. On top of closely monitoring the IRC's performance in obtain prior authorizations, Kapoor had a habit of making his passion about IRC's approval rates known. Kapoor regularly screamed his demands and expectations to Gurry and Gurrieri during daily calls, and delivered express instructions to Gurry to relay to IRC representatives. In particular, Kapoor demanded that the IRC representatives take measures to increase the approval rate for prior authorization requests, and on numerous occasions stressed that his goal was for the IRC to achieve a 100% approval rate. According to Gurrieri, Kapoor "was extremely hostile" and put an extraordinary amount of pressure on the IRC personnel to achieve that objective. In

fact, Kapoor expressed the belief that they had to "game" the insurance companies to get them to pay for Subsys prescriptions, regardless of the propriety of doing so.

90. Eventually, Kapoor became so obsessed with monitoring the IRC's success in obtaining prior authorizations that Kapoor had the IRC hire someone whom Kapoor then instructed to report IRC performance metrics directly back to himself. According to Gurrieri's testimony in the Criminal Action, this individual essentially acted as a "spy" for Kapoor within the IRC.

4. The Kapoor-Babich Scheme Culminates in Criminal Convictions.

91. The criminal scheme implemented by Kapoor and Babich ultimately unraveled as the government secured guilty pleas from many salesforce members and Speaker Program doctors who had effectuated the scheme. The government methodically moved from these lower-ranking participants up the chain, all the way to Kapoor and Babich, the chief architects of the vast criminal scheme. By 2019, dozens of individuals associated with Insys—including Kapoor, Babich, and Burlakoff—had been convicted of federal crimes, including racketeering. And as of the drafting of this complaint, the government continues to pursue doctors who prescribed Subsys in exchange for bribes from corrupt members of Insys's salesforce.

a. <u>Kapoor, Babich, and Other Senior Management Are</u> <u>Convicted of Criminal Racketeering.</u>

92. On December 6, 2016, Babich, Burlakoff, Gurry, Lee, Rowan, and

Richard Simon ("Simon") were indicted in the Criminal Action. The original Indictment contained four counts: (1) racketeering conspiracy (against all six defendants), (2) mail fraud conspiracy (against Babich, Burlakoff, Simon, Lee, and Rowan), (3) wire fraud conspiracy (against Babich and Gurry), and (4) conspiracy to violate the anti-kickback law (against Babich, Burlakoff, Simon, Lee, and Rowan).

- 93. On October 24, 2017, Kapoor was added as a defendant in the First Superseding Indictment in the Criminal Action, joining the original defendants. Kapoor was charged with all four counts in the First Superseding Indictment, unchanged from the original Indictment.
- 94. On September 11, 2018, the government filed a Second Superseding Indictment returned by the grand jury. In the Second Superseding Indictment, the government charged all seven defendants, including Kapoor and Babich, with racketeering conspiracy. The government included the following predicate acts or racketeering activity: mail fraud, distribution of controlled substances in violation of the Controlled Substances Act ("CSA"), honest services mail fraud, wire fraud, and honest services wire fraud.
- 95. On November 28, 2018, Burlakoff became the first high-ranking Insys executive to plead guilty when he entered a guilty plea to one count of racketeering conspiracy. Burlakoff also agreed to cooperate with the government.

- 96. On January 9, 2019, and shortly in advance of the trial in the Criminal Action, Babich pleaded guilty to one count of conspiracy to commit mail fraud and wire fraud and one count of mail fraud and agreed to cooperate with the government.
- 97. Babich pleaded guilty to a conspiracy that existed "between at least May 2012 and December 2015." As part of his plea agreement, Babich and the government submitted an agreed statement of facts. The statement provided that Babich, "in concert with, and at the direction of his superior John Kapoor," used the Speaker Program "to bribe medical professionals to prescribe Subsys to as many patients as possible," without regard to the risks posed to patients. Further, the statement provided that Kapoor and Babich "directed IRC employees" to "provide false and misleading information to insurance companies and PBMs to obtain authorization and payments for Subsys."
- 98. On January 17, 2019, a 53-day trial commenced against the five remaining defendants: Kapoor, Gurry, Simon, Lee, and Rowan. During the trial, Babich and Burlakoff testified alongside many other former Insys employees, including Napoletano, Gurrieri, and Davis. Kapoor did not take the witness stand.
- 99. On May 2, 2019, the jury found all five defendants guilty of a racketeering conspiracy. With respect to the predicate racketeering acts, the jury found that the defendants committed honest services mail fraud, honest services wire fraud, mail fraud, wire fraud, and that they violated the CSA.

- 100. Following post-trial motions, the District Court held that the government had not presented sufficient evidence that the defendants intended for doctors to prescribe Subsys for non-legitimate uses. As a result, the Court vacated the jury's findings on the predicate acts of honest services fraud and the violation of the CSA. The Court otherwise declined to vacate the jury's findings on the mail fraud and wire fraud predicates to the racketeering conspiracy convictions and denied the defendants' motions for a new trial.
- 101. On January 22, 2020, Babich was sentenced to 30 months in prison and 3 years of supervised release. Babich is currently serving his prison sentence.
- 102. On January 23, 2020, Kapoor was sentenced to 66 months in prison, 3 years of supervised release, a fine of \$250,000, restitution of \$59.7 million, and forfeiture of \$1.9 million. Kapoor is currently serving his prison sentence.
- 103. On January 21–23, 2020, Burlakoff, Gurry, Simon, Lee, and Rowan were sentenced to prison terms ranging from one to three years, and three years of supervised release. Gurry, Simon, and Rowan were also ordered to pay forfeiture and restitution.
- 104. Following their sentencing, Kapoor, Gurry, Simon, Lee, and Rowan appealed their convictions to the First Circuit. The government cross-appealed, arguing that the District Court erred in vacating the jury's findings on the CSA and honest services fraud predicates.

- 105. On August 26, 2021, the First Circuit affirmed all of the jury's special findings and verdicts against all defendants, thereby reversing the District Court's post-trial ruling on the predicate acts issue.
- 106. In its blistering 141-page opinion, the First Circuit excoriated Kapoor and his co-defendants for their "unalloyed greed" that squandered Subsys's potential and ruined lives.

b. Other Insys Salesforce Members and Speaker-Program Physicians Are Convicted of Federal Crimes.

- 107. In addition to the seven Insys executives convicted in the Criminal Action, a litany of other Insys employees and Subsys-prescribing doctors have been convicted of crimes for their roles in the Kapoor-Babich bribery and insurance fraud schemes. Many of these individuals recognized their own criminality by pleading guilty and then cooperating with government investigators.
- 108. Among the Insys employees to plead guilty was Gurrieri, who pleaded guilty to wire fraud conspiracy in June 2017 in connection with her role at the IRC.
- 109. Managers running Insys's salesforce also could not escape scrutiny. In addition to Burlakoff, Lee, Simon, and Rowan, who all held high-ranking sales positions at the company and were convicted in the Criminal Action, several other salesforce managers were pursued by the DOJ. For instance, Karen Hill, a former Regional Sales Manager, pleaded guilty in July 2017 to conspiring to violate the Anti-Kickback Statute. Jonathan Roper, a former District Sales Manager, pleaded

guilty in August 2017 to conspiring to violate the Anti-Kickback Statute. Jeffery Pearlman, a former district sales manager, pleaded guilty in August 2018 to conspiring to pay illegal kickbacks to doctors.

- 110. The government also pursued charges against lower-ranking salesforce members. Natalie Perhacs was the first Insys employee to plead guilty in February 2016 for her work with "pill mill" Drs. Ruan and Couch. Insys had hired Perhacs as an inducement to Dr. Ruan, who was romantically interested in her. Other salesforce members, like Natalie Levine and Fernando Serrano (who worked closely with Roper), also pleaded guilty to conspiring to pay illegal kickbacks to doctors.
- 111. The physicians and healthcare practitioners who received kickbacks have also been top targets of prosecutors. Dr. Awerbuch (arrested in 2014) and nurse practitioner Heather Alfonso (convicted in 2015), whose prosecutions are described in more detail below, marked the beginning of that campaign. To date, at least 25 doctors and healthcare practitioners have been charged or convicted under federal or state law for receiving bribes in exchange for prescribing Subsys.
- 112. In May 2015, Dr. Ruan and Dr. Couch, two of the highest-volume Subsys prescribers and speaker fee recipients, were indicted for conspiring to illegally distribute controlled substances and conspiracy to commit healthcare fraud. After a joint investigation by the FBI and DEA, they were charged with additional offenses, including racketeering conspiracy, mail and wire fraud, and conspiracy to

violate the Anti-Kickback Statute. In 2017, Dr. Ruan and Dr. Couch were convicted by a jury and sentenced to 21 and 20 years in prison, respectively.

- 113. The United States Court of Appeals for the Eleventh Circuit affirmed the convictions and sentences on all but one count.³ In describing the Speaker Program, the Court held that "[t]he evidence clearly showed that *Insys was using its program as a cover to funnel money to its top prescribers*—Couch and Ruan."⁴
- 114. Gordon Freedman, who ran a private pain management office on Manhattan's Upper East Side, received over \$300,000 in Speaker Program fees from Insys. He pleaded guilty in 2019 and was sentenced in July 2021 to more than 17 years in prison.
- 115. Jerrold Rosenberg, a Rhode Island doctor and a professor at Brown University, pleaded guilty in October 2017 to taking nearly \$188,000 in kickbacks from Insys and was sentenced to 4 years in prison and ordered to pay \$754,000 in restitution.
- 116. Christopher Clough, a New Hampshire physician's assistant who was one of the top-five prescribers of Subsys in the country, was convicted by a jury in December 2018 for accepting bribes from Insys and sentenced to four years in

³ United States v. Ruan, 966 F.3d 1101 (11th Cir. 2020), cert. granted, No. 20-1410 (U.S. Nov. 5, 2021).

⁴ *Id.* at 1146.

prison. The First Circuit affirmed Clough's conviction in October 2020.⁵ The Court credited the jury's reasonable inference that "Clough's aberrant behavior was not reminiscent of a physician assistant prescribing based on need, but rather of a *drug pusher—one who voluntarily furthered the conspiracy by knowingly and willfully enriching Insys* at the expense of the U.S. Government in exchange for kickbacks through sham speaking engagements."⁶

117. And prosecutors are apparently not finished. For example, in July 2021, the government secured two more guilty pleas from medical practitioners for taking bribes from Insys. And in September 2021, the government filed a new civil action under the Anti-Kickback Statute against a prescriber connected with Insys in Florida.

c. <u>Insys Resolves the DOJ's Criminal and Civil Claims, and</u> Collapses into Bankruptcy.

118. Due to the pervasive unlawfulness of the Kapoor-Babich scheme, Insys too became a target of federal prosecutors. On June 5, 2019, Insys entered a global resolution to settle the federal government's civil and criminal investigations for \$225 million. This global resolution involved three main components.

119. <u>First</u>, Insys resolved the government's civil False Claims Act claims by

⁵ United States v. Clough, 978 F.3d 810 (1st Cir. 2020).

⁶ *Id.* at 821.

entering into a settlement agreement, pursuant to which Insys agreed to a \$195 million payment, with \$5 million to be paid within one day of the execution of the agreement.

- agreement (the "<u>Plea Agreement</u>") in which it pleaded guilty to five counts of mail fraud and agreed to pay a \$2 million fine and \$28 million in forfeiture. In parallel, Insys entered into a deferred prosecution agreement (the "<u>DPA</u>") in which it agreed, *inter alia*, that it was jointly and severally liable for the money owed by Insys Pharma pursuant to the Plea Agreement.
- 121. Third, Insys and certain subsidiaries also entered into a corporate integrity agreement with Office of the Inspector General of the U.S. Department of Health and Human Services, in which the company agreed, *inter alia*, to establish and maintain an extensive compliance program and to cease the marketing and promotion of Subsys within 90 days, or to divest Subsys entirely.
- 122. Five days after the June 5, 2019 resolution, Insys collapsed under the weight of billions of dollars in liabilities and sought bankruptcy protection. As described in section C, *infra*, the pervasive Kapoor-Babich scheme left Insys exposed to hundreds of criminal and civil proceedings.

B. THE OUTSIDE DIRECTORS ENABLE THE CRIMINAL SCHEME WITH THEIR BAD-FAITH CONDUCT.

123. None of the pervasive criminality implemented by Kapoor and Babich,

as described above, would have been possible had it not been for the shocking bad faith of the Outside Directors in failing to carry out the fiduciary duties they owed to Insys. Rather than protect Insys and manage it in the best interest of its stakeholders, the Outside Directors—motivated by personal relationships with Kapoor—served as enablers. Despite Insys's heavily regulated and inherently risky business, the Outside Directors failed to implement compliance and monitoring initiatives to safeguard Insys from running afoul of the law. And despite learning of numerous "red flags" of potential unlawful activity, the Outside Directors wholly failed to investigate or to ensure that the few, token compliance steps they did implement were even the slightest bit effective.

1. <u>Kapoor Handpicks the Outside Directors to Give HimFree Rein with the Company.</u>

- 124. As Insys's founder and controlling stockholder, and the mastermind behind the company's criminal sales practices, Kapoor wanted free rein to market and sell Subsys as he desired, legally or not. To that end, he wielded his powers as controlling stockholder to handpick directors who would serve as rubber-stamping enablers. In appointing directors to the Insys board, Kapoor chose loyal friends and associates, with only one exception (Dr. Stanley).
- 125. Kapoor's selection of directors served his nefarious ends well, as the Outside Directors deferred to Kapoor and acted as precisely the sort of rubber-stamping enablers that he envisioned. As Babich testified in the Criminal Action:

With the [b]oard, all of these people [Kapoor] had past history with. Everyone knew he owned greater than 60 percent of the shares. So the board meetings were just to approve or disapprove of whatever thing he wanted to do with the company.

- John [Kapoor] proposed, the board would approve." Indeed, during his testimony, Babich could not recall a single instance in which the board rejected a matter or motion brought by Kapoor.
- 127. This deference to Kapoor stemmed, in large part, from the pre-existing relationships between all four of the Outside Directors and Kapoor.
- 128. <u>First</u>, Kapoor installed Fourteau as an Insys director in March 2011, in part because they have been personal friends and business associates since at least 2003. In 2003, Kapoor recruited Fourteau to join Sciele, another pharmaceutical company founded by Kapoor. Fourteau eventually became President and CEO of Sciele. Fourteau also served alongside Kapoor as one of Sciele's directors from 2003 to 2008.
- 129. In 2006, Kapoor asked Fourteau to join a predecessor to Insys as a board member. Kapoor was interested in using a sublingual spray delivery, similar to a product that Sciele produced, for fentanyl administration. Fourteau served as a director on Insys's predecessor from 2006 until 2008, and then joined the Insys board in March 2011 at Kapoor's request.

- Haven Pharmaceuticals ("New Haven"). When he joined the Insys board in 2011, Fourteau was concurrently serving as President and CEO of New Haven. Through EJ Funds (an affiliate of EJ Financial controlled by Kapoor), Kapoor made a significant investment in New Haven in 2012. New Haven's marketing materials referred to Kapoor as one of its "key shareholders."
- 131. According to Babich's testimony in the Criminal Action, Kapoor often used Fourteau as a "buffer" or intermediary if he felt that Insys management was not following Kapoor's directions.
- 132. Second, Kapoor installed Lapalme as an Insys director in March 2011, in part, because they were good friends and had known each other for roughly 35 years. Lapalme has over 40 years of operational and leadership experience in the pharmaceutical industry, including as President and CEO of North America Ethypharm Inc., CEO and Chairman of Rhone-Poulenc Pharmaceuticals, Inc. (Canada), Senior Vice President and General Manager of North America Ethicals, a division of Rhone-Poulenc Rorer, Inc. (now known as Sanofi), and chairman of the boards of several other pharmaceutical companies. Lapalme also served on the board of directors of Sciele alongside Kapoor from 2000 to 2008.
- 133. <u>Third</u>, Kapoor installed Meyer as an Insys director in 2011, in part, because of Meyer's numerous experiences managing companies in which Kapoor

had invested. In 2005, Kapoor asked Meyer to join the board of a private company called Alliant Pharmaceuticals ("Alliant"), in which Kapoor had made a significant investment. Alliant was later sold to Sciele in 2007 for over \$122 million.

- 134. Kapoor also installed Meyer on the board of directors of Akorn, Inc. ("Akorn") from 2009 to October 2020. During part of that time, Meyer served as Chairman. (Akorn initiated bankruptcy proceedings in 2020.) Kapoor was one of Akorn's principal shareholders and, through his trusts and affiliates, was entitled to nominate up to three of Akorn's directors.
- 135. Kapoor has also demonstrated trust in Meyer to manage his investments with companies outside of the pharmaceutical industry. For example, Meyer is currently the Chief Investment Officer of JMV Realty Corporation, a property investment company in which Kapoor has invested millions of dollars.
- 136. Fourth, Kapoor installed Tambi as an Insys director in November 2010, in part, because they were longtime friends and business associates. Tambi was previously associated with Lyphomed, a company that Kapoor purchased in 1981 and thereafter controlled. Like Meyer, Kapoor also tapped Tambi to serve as a director of Akorn, with Tambi serving as EJ Financial's nominee to the Akorn board.
- 137. These four friends and associates that Kapoor handpicked as Outside Directors, along with Kapoor and Babich, held six of the seven director seats on Insys's board of directors. The seventh director was Dr. Stanley (who joined the

board in March 2013, after the Subsys launch). Dr. Stanley was the only director who lacked any outside personal or professional relationship with Kapoor. Not coincidentally, Stanley was also the only Insys director who ever challenged Kapoor during his time on the board. When Stanley stood up to Kapoor, the other directors would tell Stanley in various ways to drop the topic to avoid drawing Kapoor's ire.

138. Save for Stanley, all of Insys's directors were devoted to Kapoor because he was their mentor (in Babich's case), friend, and/or the investor who continually gave them major career opportunities. The Outside Directors' individual allegiances to Kapoor lessened their willingness to tell him "no" or even to install guardrails to prevent his wrongdoing. To many, including Insys itself, their acquiescence, cowardice, and bad faith proved lethal.

2. <u>From the Launch of Subsys in March 2012, the Outside Directors</u> Fail to Implement Any Compliance or Monitoring Programs.

139. By the very nature of its business, Insys faced a number of significant legal and regulatory landmines that could destroy the company if careful steps were not taken to ensure that the company complied with applicable laws and regulations. First, Insys's main product was Subys, an inherently dangerous and heavily regulated Schedule II controlled substance with fentanyl as its active pharmaceutical ingredient (section A.1, *supra*). Second, the sale and marketing of Subys subjected the company to the risk of possible violations of the False Claim Act, Anti-Kickback Statute, and statutes and regulations concerning the off-label use of products (section

- A.2, *supra*). Accordingly, compliance with the myriad of statutes and regulations applicable to the sale and marketing of narcotics was "mission critical" for the company to succeed.
- 140. The legal compliance risks inherent to the company's business were well-known to the Outside Directors. Indeed, Insys's securities filings, which the Outsider Directors reviewed and/or signed, expressly acknowledged such risks.
- 141. For example, the Outside Directors reviewed and approved the S-1 registration statement that Insys first filed on March 30, 2011 (and the subsequent amendments thereto) in connection with its initial public offering (the "Registration Statement"). The Registration Statement acknowledged that Insys was "subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business." The Registration Statement further acknowledged that, "[i]n particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices," such as restrictions or prohibitions on "a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements."
- 142. Further, the Registration Statement acknowledged that Insys, "[a]s a pharmaceutical company," is subject to "certain federal and state healthcare laws

and regulations pertaining to fraud and abuse and patients' rights." Among those laws was the federal Anti-Kickback Statute, which constrained Insys's:

marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs.

- 143. Lastly, the Registration Statement acknowledged that "compliance programs can mitigate the risk of investigation and prosecution for violations of these laws," but that "achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly."
- 144. Insys's annual Forms 10-K included similar disclosures of the myriad compliance risks that Insys faced. The Outside Directors acknowledged these disclosures by signing them annually (along with Kapoor and Babich). For example, Insys's Form 10-K for the year ending December 31, 2013 warned that "sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices." That same Form 10-K further explained that "several [] types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years," including "anti-kickback and false claims statutes." Specifically, the Form 10-K noted that:

The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

145. The Form 10-K further acknowledged that "[t]he term 'remuneration' has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value." As well, the Form 10-K noted that:

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

146. Thus, the Outside Directors were fully aware of the legal and compliance risks that Insys faced. Yet despite the obvious risks inherent in Insys's business and the Outside Directors' extensive experience in the pharmaceutical industry (section B.1., *supra*), the Outside Directors failed to implement any compliance, audit, or monitoring functions to ensure that Insys operated lawfully

and in compliance with the statutory and regulatory regimes applicable to its business.

- 147. Indeed, Insys lacked *any* internal audit function and did not hire *any* full-time compliance personnel, or even a general counsel, until 2014, long *after* the launch of Subsys (in early 2012) and Insys's initial public offering (in early 2013). The Outside Directors (and Insys's board as a whole) failed to implement board-level monitoring of the company's mission critical compliance risks in at least six ways at the time of the Subsys launch in March 2012.
- December 2013, the Insys board had no committee tasked with direct responsibility to monitor compliance. Although Insys later formed a special/compliance committee in December 2013, that committee did not actually meet until August 2015 (as further described below). And the charters for the Insys board committees existing prior to that time indicate that none of those committee was charged with direct oversight and monitoring responsibility for the company's mission critical compliance issues.
- 149. Second, the Insys board had no regular process or protocols requiring management to apprise the board of compliance issues, instead relying only on *ad hoc* reporting from Kapoor, Babich, and their underlings.
 - 150. Third, the Insys board did not have a set schedule to address compliance

issues on a regular basis, such as quarterly or bi-annually, especially prior to mid-2015.

- 151. <u>Fourth</u>, Insys management and executives were aware of red flags that were never reported to the board (as discussed below), further establishing that there was no board-level reporting system in place.
- 152. <u>Fifth</u>, the Outside Directors did not obtain complete and accurate information regarding the company's myriad compliance issues from management.
- 153. <u>Sixth</u>, Insys's board meeting minutes reflect that there were no meaningful or regular board-level discussions of compliance issues from the Subsys launch in March 2012 until at least December 2013.
- 154. The Outside Directors' failures to implement board-level monitoring and oversight of the company's mission critical compliance risks, install proper oversight personnel and fully implement compliance procedures were especially galling given that Kapoor and Babich informed the Outside Directors of sales and marketing plans that were inherently risky from a compliance standpoint. Indeed, during 2012, the Outside Directors were made aware of at least four aspects of the sales and marketing strategy that significantly increased Insys's risk profile.
- 155. <u>First</u>, Babich informed the Outside Directors of management's hiring strategy to find inexperienced salesforce members, and specifically informed the board in an April 11, 2012, email that: "[a] number o[f] our reps have no prior

pharma experience." Hiring inexperienced salesforce personnel increased the risk of unlawful activity through mistakes made by those without prior understanding of what was appropriate behavior within the pharmaceutical sales industry and by the inability of inexperienced personnel to recognize questionable directions.

- 156. Second, during a May 22, 2012, board meeting, the Outside Directors were informed that Kapoor and Babich intended to target marketing of Susbys on the top ten percent of rapid-onset-opioid prescribers (even though such pain doctors generally did not treat cancer patients for breakthrough cancer pain). Moreover, the board presentation plainly stated that "expand[ing] efforts to oncologists & allied health" would be addressed "secondarily." Thus, the board was informed that Insys's marketing efforts would be primarily aimed at pain doctors, generally—not oncology practices, as would have been appropriate given the FDA's narrow indications for Subsys as a breakthrough pain treatment for cancer patients. Similarly, in October 2012, the board was informed by Babich of new initiatives to "target" the doctors who prescribed high-strength—i.e., 1200 and 1600 mcg—doses of Subsys.
- 157. Third, Babich informed the Outside Directors of Burlakoff's promotion to Vice President of Sales, and of Burlakoff's track record at Cephalon. Cephalon's \$425 million settlement in 2008 for its illegal sales and marketing practices was a matter of public record. Babich further informed the Outside Directors that

Burlakoff had "a passion and fire that [wa]s needed to succeed." Promoting a driven individual with a nefarious track record to Vice President of Sales created a significant risk that Cephalon's illicit practices would be implemented at Insys.

- 158. <u>Fourth</u>, in 2012, the Outside Directors were informed of Kapoor's and Babich's plan to incorporate an unusual compensation structure to the salesforce that differed from pharmaceutical industry norms and created perverse incentives.
- 159. In combination, Kapoor's and Babich's plan to hire inexperienced salesforce representatives, to target marketing efforts at high-prescribing pain doctors rather than oncologists, to promote someone with a dubious track record as Vice President of Sales, and to create a perverse incentive for salesforce personnel substantially increased the likelihood that Insys would run afoul of applicable law. In turn, the Outside Directors knew soon after the Subsys launch that Kapoor and Babich intended to pursue a particularly aggressive and risky sales and marketing strategy for an especially risky product.
- Program heightened compliance risks further still. The potential for abuse of such programs is well-known within the pharmaceutical industry. Indeed, the Pharmaceutical Research and Manufacturers of America ("PhRMA") publishes a "Code on Interactions With Health Care Professionals" that sets forth guidelines for pharmaceutical companies to follow. The PhRMA code provides:

- "Company decisions regarding the selection or retention of health care professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment."
- "Any compensation or reimbursement made to a health care professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual health care professional in connection with all speaking arrangements."
- "Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time."
- "Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines."
- "All companies that interact with health care professionals about pharmaceuticals should adopt procedures to assure adherence to this Code."

Insys did none of those things, and Insys's directors did nothing to ensure that the company would adhere to industry norms.

161. In sum, despite the many known substantial compliance risks that were mission critical to the company, Insys's directors failed to implement any board-level compliance monitoring; any regular process or protocols through which

management apprised the board of compliance issues; or any internal reporting system through which employees could bring compliance concerns to the board's attention. At best, management communicated with the board on an *ad hoc* basis. The Outsider Directors' utter failures to act in good faith to protect Insys continued even as they became aware of more and more "red flags" of potential misconduct from 2013 onwards.

- 3. From 2013 Onward, the Outside Directors Fail to Implement
 Any Meaningful Monitoring and Compliance Programs Despite
 More and More "Red Flags" of Possible Unlawful Behavior.
 - a. February 2013: The Board Learns of the IRC and Belatedly Adopts "Skeletal" Company Policies.
- 162. The Outside Directors learned of the IRC no later than a February 5, 2013 board meeting. They were told not only of the program's existence, but that the goal of the IRC was to "optimize pull through" by "aggressively mitigat[ing] p.a. [prior authorization] barriers" (supposedly "in a compliant fashion," a modifier indicating that the IRC would necessarily entail compliance risks). That stated objective screamed compliance risk.
- 163. Specifically, the steps to obtain prior authorizations should not have been perceived as "barriers," but rather as entirely appropriate protocols to follow for a potent and inherently dangerous narcotic like Subsys. In essence, the scope of Subsys's FDA approval was as a drug of last resort for cancer patients' pain management, to be prescribed only after less powerful painkillers had failed. Thus,

it was entirely consistent with Subsys's characteristics and the limited scope of its approved use for health insurance companies, before approving reimbursement requests, to insist on both typical prerequisites for a prior authorization: (a) a specific medical diagnosis; and (b) an attempted use of alternative drugs. That Babich and Kapoor nevertheless viewed the need to follow such protocols as "barriers" that needed to be "aggressively mitigate[ed]," even going so far as to set up the IRC for that purpose, should have sounded alarm bells that the IRC might facilitate improper prescribing activity and correspondingly inappropriate (or fraudulent) requests for reimbursement from insurers.

- 164. Nevertheless, the Outside Directors took no meaningful action to mitigate the obvious risks posed by the IRC's establishment, or to ensure that the IRC would operate appropriately.
- and the Speaker Program had commenced), Insys's directors made a token gesture by adopting several generic company policies—a Compliance Charter, Code of Conduct, and Compliance Program and Certification of Compliance. Those documents were so inadequate that they were described as "skeletal" even by the part-time compliance consultant that Insys had previously retained, Leslie Zacks ("Zacks"). Zacks worked full-time at Arbor Pharmaceuticals in Atlanta, Georgia

and thus had minimal time for "consulting" work for Insys. And he reported to Babich rather than to the Insys board.

166. Moreover, the circumstances surrounding the adoption of these token, "skeletal" documents reflect the cavalier disregard that the Outside Directors acted with towards compliance issues. First, the documents themselves were woefully inadequate to accomplish anything, as they did not provide for any internal audit function, board-level monitoring, line of communication between management and the board regarding compliance issues, or internal reporting mechanism for employees. Second, the documents were not adopted until almost one year after the Subsys launch, despite being circulated at least eight months earlier and after repeated nagging by Zacks for the Insys board to adopt them. Finally, the documents were not drafted until the IRC and Speaker Program were up and running, *i.e.*, the horse was out of the barn.

b. <u>July 2013: The Board Learns of Marketing Focused on "Effective Dose" and Receives Grave Warnings from the Part-Time Compliance Consultant.</u>

- 167. The Outside Directors learned about two glaring "red flags" of significant compliance risks at the board meeting held on July 11, 2013.
- 168. <u>First</u>, the Outside Directors were informed of the Kapoor-Babich plan to tie salesforce representative compensation to the strength of the prescribed dose of Subsys, one of the pillars of the effective-dose scheme. Materials presented at the

July 2013 board meeting stated: "Emphasis on effective dose: tiered % payout based on strength." The perverse incentivization of the salesforce created significant compliance risks. Yet when Stanley questioned the strategy and explained that salesforce representatives should advocate for the "right dose, not the highest dose," he was told to shut up. And none of the Outside Directors questioned the strategy, or took any steps to make sure the misaligned incentive structure for the salesforce did not result in unlawful activity that would cause trouble for Insys.

- 169. <u>Second</u>, Zacks informed the Outside Directors of the woeful shortcomings in Insys's monitoring and compliance functions, while making specific recommendations of necessary steps for improvement. Specifically, Zacks:
 - Implored the board to hire a full-time general counsel and compliance officer given the risks involved with Subsys and the promotional and reimbursement practices the company had adopted;
 - Stressed that the company's risk profile required greater compliance measures and monitoring;
 - Indicated that the company needed to "breath life into" its compliance apparatus, which remained "skeletal";
 - Highlighted that the company's risk profile required greater compliance measures and monitoring;
 - Expressly warned the board of compliance issues associated with Kapoor's salesforce promoting Subsys to providers for off-label use when the product's indication was exclusively for oncology;
 - Recommended that Insys establish an audit program for the top twenty prescribers to ensure Insys was compliant; and

• Indicated that Insys should audit the IRC with "live listens."

This shocking presentation, the first formal compliance-related presentation that Insys's board had requested or received nearly eighteen months since the Subsys launch, still did not spur the Outside Directors into meaningful action.

advice. Instead, the board took the limited and hollow gesture of retaining Compliance Implementation Services ("CIS") to conduct a limited audit of the Speaker Program and of off-label marketing practices. Even then, the Outside Directors did not monitor, design, oversee, or even seek or receive any update on the progress of the limited audit until months later in December 2013. In the interim between Zacks's presentation and December 2013, the Outside Directors failed to participate in the limited audit, raise any questions with CIS about its lack of progress on its limited audit, or follow up with CIS in any way.

- c. <u>December 2013: The Board Receives a Government Subpoena and Further Warnings from the Part-Time Compliance Consultant.</u>
- 171. In December 2013, the Outside Directors were confronted with two additional developments calling out for the implementation of effective monitoring and compliance functions at the company.
- 172. <u>First</u>, on December 10, 2013, Insys received a subpoena from the United States Department of Health and Human Services Office of Inspector

General (the "OIG Subpoena"), in connection with the federal government's investigation of the sales and marketing of Subsys. The OIG Subpoena sought 33 specific categories of documents, signaling that a whistleblower might be working with the government and that Insys likely had serious compliance issues.

173. On December 12, 2013, the Insys board met for a special telephonic meeting to discuss the OIG Subpoena, during which the board approved the engagement of Skadden, Arps, Slate, Meagher & Flom LLP ("Skadden") as counsel to the company. Kapoor specifically recommended that Insys engage Skadden due to his pre-existing connections to the firm. The Outside Directors did not question the selection of Skadden or conduct any process to consider other counsel.

174. During that meaning, the board also resolved to create a special committee comprised of Fourteau, Lapalme, and Meyer (the "Special Committee") to lead the company's response to the OIG Subpoena. In connection with the formation of the Special Committee, the full board resolved: (a) "[a]s directed by the Board, the Special Committee shall liaise with Company's employees and receive periodic updates from management in connection with the Subpoena and the Company's compliance program"; (b) "[a]s directed by the Board, the Special Committee may also review and oversee the Company's compliance program and be responsible for the oversight of matters related to compliance with federal health care program requirements, FDA requirements and with applicable US laws and

regulations"; and (c) "that the Company's compliance committee shall meet at least monthly."

- 175. As described in more detail below, however, the Special Committee was completely ineffectual. Other than some introductory calls held in late 2013, the Special Committee did not meet monthly as its founding resolution required or separately from the full board *and was entirely inactive for over 18 months* (until August 2015).
- 176. Second, during the same December 2013 board meeting in which the do-nothing Special Committee was appointed (and making its inaction far worse), the company's part-time compliance consultant, Zacks, sounded the alarm bells once again, especially related to the initial findings of CIS's limited audit of the Speaker Program. Specifically, Zacks's notes reveal that he:
 - Explained that CIS (which had been hired to conduct the limited audits approved by the board in July) had encountered "immediat[e] resistance" regarding the number of speaker programs to which they were given access;
 - Advised the board that, CIS ongoing audit revealed serious issues with the Speaker Program, including multiple programs where speakers were paid speaker fees but were the only individuals in attendance (other than Insys employees);
 - Told the board that a "high prescriber" had been flown across the country to speak to an empty restaurant (despite there being a trained speaker nearby);
 - Informed the board that Insys had an "extensive budget for 3,200 speaker programs" in 2014, a volume typical of large

- pharmaceutical companies rather than a small specialty company within only one significant product like Insys;
- Urged that it was "critical that the Company act proactively to identify any wrongdoing and to take action";
- Expressed his belief that misuse of the Speaker Program did not entail merely isolated incidents, but was likely a systemic problem;
- Advised the board that it should cease the Speaker Program until it had a better handle on the identified issues; and
- Reiterated the need for Insys to hire a full-time compliance officer, suggesting that the that person should report directly to the board, rather than within the marketing group, as the latter was akin to having the "fox in the henhouse."

More broadly, Zacks implored the board to expand upon CIS's limited review.

177. Despite the many warning signs raised by Zacks and the initial findings of the CIS limited audit, the Outside Directors abdicated responsibility and deferred to Kapoor and Babich. In particular, the Outside Directors rejected Zacks's advice to suspend the Speaker Program because Kapoor indicated that he did not want to change the company's current marketing strategy. And instead of immediately hiring a Chief Compliance Officer to clean up the mess, the Outside Directors instead handed off the task to Babich, the corrupt CEO under whose watch the concerning practices were occurring. In essence, the Outside Directors largely allowed the status quo to continue despite clear warning signs of possible unlawful activity surrounding the Speaker Program and otherwise.

d. <u>February 2014: The Board Receives a Limited Audit of the Speaker Program Identifying More Warning Signs.</u>

178. Two months after Zacks relayed concerns over CIS's initial findings, CIS completed its limited audit in February 2014, confirming that Zacks's concerns were justified. CIS's completed audit, the results of which were shared with the Outside Directors, echoed those raised by Zacks at the July 2013 and December 2013 board meetings. Moreover, CIS explained that it had selected a total of 22 programs for its limited-scope audit, but it was only able to monitor less than one-half of those programs (specifically, nine programs) due to cancellations. Yet the Outside Directors did nothing to further investigate CIS's findings or explore whether the cancellations were indicative of larger compliance issues.

e. <u>March 2014: The Board Allows Babich to Hire an Underqualified "Compliance Director"</u>

Zacks in December 2013, the Outside Directors allowed Babich to choose a "compliance director." Unsurprisingly, after months of foot-dragging, Babich hired a "compliance director" in March 2014, Danielle Davis ("Davis"), who had no pharmaceutical experience and was relatively junior. Rather than reporting to the board itself, she was directed to report to Franc Del Fosse ("Del Fosse"), who had just been hired as General Counsel in February 2014. As Babich later testified in the Criminal Action: "[W]e didn't even go out and hire someone of the stature that

you should in that situation" as "overall focus on compliance, while I was there at the company, was not evident."

180. Despite the company's extreme risk profile and many indications of possible compliance issues, the Outside Directors deferred to Babich on the selection of Davis. Tambi was the only director to question her lack of experience. Although Tambi admitted that he "ha[d] an issue with the candidate's background in Pharmaceutical Compliance," he did nothing further to pursue the matter. None of the other Outside Directors did either.

f. Spring 2014: The Board Ignores Serious Concerns Expressed by a Fellow Director, Stanley.

- 181. According to Babich's testimony in the Criminal Action, Stanley (the only director who was not a Kapoor loyalist) expressed concerns at an early 2014 board meeting based on information he had received from Napoletano regarding sales and marketing practice for Subsys. According to Babich, Stanley told his fellow directors "I think we're just turning a blind eye to a lot of these things." Following an argument back and forth, Kapoor told Stanley "that he doesn't know what he's talking about" and to "shut the F up." Stanley cowered to Kapoor's directive, and the Outside Directors likewise failed to take any additional actions.
- 182. After the meeting, Kapoor retaliated by downgrading Stanley's role at the company, and required that any future request by Stanley to travel to Insys meetings or conferences had to be personally approved by Kapoor. The Outside

Directors did nothing in response to this retaliation against Stanley or the statements that he had expressed at the early 2014 board meeting.

g. <u>May 2014: The Board Learns About Criminal Charges, a Scathing Media Report, and Additional IRC Problems.</u>

- 183. In May 2014, three developments highlighted the need for immediate action by the Outside Directors to ensure that Insys was complying with the law.
- 184. <u>First</u>, a leading prescriber of Subsys nationwide, Dr. Awerbuch was arrested. The Outside Directors received a summary of the charges on May 8, 2014. Awerbuch was charged with healthcare fraud and controlled substance distribution, and with writing prescriptions for controlled substances (including Subsys) outside the usual course of professional practice. The summary presented to the board also identified Awerbuch as the number-one prescriber of Subsys in the country, with prescriptions more than six times greater than the next-closest prescriber.
- Insys's sales and marketing practices, the Outside Directors reacted by simply downplaying the arrest and deferring to Kapoor and Babich. For example, Tambi told Babich that he believed that the issue would "dissipate" quickly, and "not to over-react." Tambi separately emailed Kapoor and Babich, urging them to quickly work past the issue so that they could "get back to tendering [sic] the business ASAP—we should not allow the Business to be side-tracked." Tambi further suggested that the Awerbuch indictment could be spun "as a normal growth

occurrence—a 'Learning/Teaching experience—here we have a start-up, young, fast growth Company/Business with a product of extraordinary Therapeutic efficacy . . . " Tambi added: "We know most of the unfortunate actions, where they occurred & how. I have no illusions that the Inspector's probe will surface the same issues and he is not inclined to cut us any slack." There is no indication that any of the other Outside Directors took the issue any more seriously than Tambi.

- 186. Second, just five days after the Outside Directors learned of and discussed Awerbuch's arrest, *The New York Times* published an article entitled "Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller" on May 13, 2014. Babich and Kapoor received the article as soon as it was published, and Babich promptly forwarded it to the entire Insys board, including the Outside Directors.
- 187. The substance of *The New York Times* article should have been troubling to the Outside Directors, especially given the many "red flags" of possible unlawful sales and marketing practices already known to them. The article noted that "questions are emerging about how [Subsys] is being sold, and to whom." It further explained that behind the company's success "is an unusual marketing machine that may have pushed Subsys far beyond the use envisioned by the Food and Drug Administration." In support, the article cited interviews with several former salesforce members, who suggested that Insys had "aggressively marketed"

Subsys, including by paying the salesforce higher commissions for selling higher doses of the drug. Finally, the article noted that "Subsys has sold surprisingly well given the drug is approved only for cancer pain, and given that only a small number of oncologists, who are typically responsible for treating their patients' pain, appear to be prescribing it."

188. Yet again, the Outside Directors responded by deferring to Kapoor and Babich about how best to put a positive PR spin on the situation, rather than ensuring that Insys was operating in accordance with the law. For example, Tambi, suggested—to the entire board—that the company should gather information that would "help[] us to prepare to explain" the practices, rather than fully investigate to ensure that Insys's sales and marketing practices were lawful. Specifically, Tambi suggested that the company should search "for other Pharmaceuticals that have had a rapid 'Market Acceptance' especially in Cancer Therapy. If so, Subsys's uptake is neither unique nor unusual. We may be in good company here." With respect to the Speaker Program, Tambi brushed aside any concern over that program, noting that "[s]peakers are necessary to educate & inform Physicians on the attributes of the drug—safety, efficacy, proper use, and other nuances of the drug—not to promote. I am sure Insys is positioning this effectively." None of the Outside Directors voiced any disagreement with Tambi's myopic views.

189. A few weeks later, Insys's directors met for a telephonic board meeting on May 23, 2014, during which they discussed Awerbuch's arrest as well as *The New York Times* article. Although Awerbuch's arrest implicated possible misconduct of Insys's salesforce representatives, Kapoor flatly informed his fellow directors that Insys was not going to terminate anyone. Kapoor did so because he believed such actions would create whistleblowers. Despite Awerbuch's alarming arrest and its implications of possible Insys salesforce wrongdoing, none of the Outside Directors objected to Kapoor's strategy. Thus, Kapoor's desire to suppress whistleblowers was allowed to take precedence over uncovering the extent of the wrongdoing and protecting Insys.

190. Third, during the same telephonic board meeting on May 23, 2014, the board (including the Outside Directors) discussed concerns of potential misconduct occurring within the IRC related to the practice of providing untrue information to insurance companies using a list of "tried-and-failed" medications that were not reflected in patients records. On the call, Kapoor admitted that Insys was "running [the] IRC w/o full understanding of requirements," was "slow in responding" to issues at the IRC, and that the company "didn't act quickly enough." Still, Kapoor advocated against shutting down the IRC prospectively, arguing that the action was "drastic," and would "blow up in their faces." At the time, none of the Outside Directors objected to Kapoor's decision to continue the IRC's operations. Nor did

the Outside Directors do anything to investigate; to install monitoring, control, or compliance mechanisms; or to take any other action to ensure that the IRC was operating lawfully.

h. <u>June 2014: The Board Hears New Concerns Raised by the Compliance Director.</u>

- 191. In June 2014, the Outside Directors received troubling new information concerning the IRC from Babich's recently installed compliance director, Davis.
- 192. During a June 9, 2014 board meeting, Davis expressed her concerns regarding the IRC's practices. Despite her lack of experience, she identified significant issues when attending the IRC's new hire training, including:
 - Davis observed IRC representatives speaking with insurance companies and "rattling off" medications a patient had tried and failed without having a chart in front of them. She discovered that the IRC personnel were quoting from the set list of "tried-and-failed" medications regardless of whether the patient had tried any of the medications on the list;
 - Davis discovered the Q&A List and the "spiel," instructing IRC personnel to respond affirmatively if asked whether a patient suffered from breakthrough cancer pain—again regardless of the patient's actual diagnosis; and
 - Davis learned that the IRC personnel were receiving bonuses tied to obtaining approvals from insurance companies. Despite her lack of experience, she immediately recognized that the company should not compensate in this manner because "it could potentially incentivize bad behavior to get the approval."

Davis reported her observations to the board, telling them: "I feel they are committing insurance fraud at the IRC." After her clear worries apparently fell on

deaf ears, Davis walked away feeling as though none of the Outside Directors was appropriately concerned. Her fears were justified; instead of responding to the warnings, the Outside Directors took no action, notwithstanding what Tambi described in an email as the "terrible tension and gloom" at the June 2014 board meeting.

- i. August 2014: The Board Hears Further Concerns from the Compliance Director, While an Internal Whistleblower Is Fired for Expressing Concerns.
- 193. In August 2014, concerns of potential illegality raised internally were yet again ignored by the Outside Directors on at least two occasions.
- 194. <u>First</u>, Davis reiterated her concerns regarding possible insurance fraud involving the IRC at the August 7, 2014 board meeting. All of the directors attended the meeting, along with Del Fosse, Burlakoff, Gurry, and other members of management. During the meeting, the board was informed about several areas of concern for the company, including the IRC's practices and issues with the Speaker Program, including paid speaker events that occurred without any attendees.
- 195. Yet despite being informed again of possible misconduct permeating the IRC and Speaker Program, the Outside Directors did nothing to follow up, investigate, or ensure that such practices were not continuing. Indeed, as Babich testified in the Criminal Action, it was clear that Davis had been "powerless" with respect to a large portion of the compliance problems that plagued the company.

Insys's board that Napoletano—who previously expressed his concerns about Insys's sales and marketing strategies to Stanley and others—had been forced out at the direction of Kapoor and Babich. The Outside Director failed to inquire about the circumstances of Napoletano's termination or his claims regarding ongoing misconduct at the company involving Babich, Burlakoff, and Kapoor.

197. Even a basic inquiry by the Outside Directors into the circumstances of Napoletano's termination would have revealed wrongdoing given that he was completely forthcoming in expressing his concerns. Just earlier that month, Napoletano repeated his concerns about multiple compliance problems occurring within the company, which were recorded in an informal memorandum (and ultimately culminated in his termination). Specifically, Napoletano stated that Babich was non-compliant, and "wanted nothing to do with compliance even after [the] subpoena [in December 2013] [was] served." Napoletano also explained that Burlakoff "[wa]s telling speakers as recent as [the prior] week that if they write he will get them over \$100k in speaker fees a year." Napoletano further described how he was "forced by [Babich] and Dr. Kapoor to do an ROI calculation on the speaker program," and that many egregious activities were taking place in the marketing and sale of Subsys. Later, in the Criminal Action, Napoletano testified that it was Kapoor's idea to track prescriptions written by Speaker Program participants

because he "wanted a positive ROI," and that it was Kapoor's plan to direct Insys salesforce representatives to urge doctors to prescribe Subsys at higher and higher doses and to "push the dose."

j. <u>September 2014: The Board Receives a Criminal Subpoena</u> <u>Directed at the Company.</u>

198. On September 8, 2014, Insys received a criminal subpoena from the United States Attorney's Office for the District of Massachusetts. On September 12, 2014, Del Fosse notified the board of the criminal subpoena.

199. In response to this subpoena, the Outside Directors took no action. They simply stood back and let Kapoor, Babich, and counsel acting largely under Kapoor's direction continue to steer the company's response.

k. May 2015: The Board Begins Meeting More Often, But Accomplishes Little and Pays Themselves for Their Do-Nothing Troubles.

200. By May 2015, with the company subject to a criminal subpoena, the Outside Directors recognized that they needed to at least give the appearance that they were paying attention to what was happening at Insys and agreed to start meeting more regularly. But even then, the Outside Directors decided to pay themselves a "special meeting" bonus of \$1,000 (in addition to their annual retainers) for each future board meeting or conference call related to the company's ongoing legal issues. This move was way too little, way too late. Even after they started meeting more regularly and paying more attention to the company's

burgeoning legal troubles, the Outside Directors continued to fail to take any effective steps to protect Insys and its stakeholders from unlawful activity.

I. <u>June 2015: The Board Learns of a Guilty Plea Arising from the Company's Illegal Kickbacks.</u>

- 201. On June 23, 2015, Heather Alfonso ("Alfonso")—a nurse practitioner in Connecticut—pleaded guilty to a single count of accepting \$83,000 in kickbacks from Insys between January 2013 and March 2015. Alfonso admitted that the money she received influenced her prescribing of Subsys. Following this event, the Outside Directors realized that the status quo could no longer continue. Alfonso's plea was an express public admission of bribery, and it would no longer be possible for the Outside Directors to completely ignore the possibility that such activity was possibly occurring at Insys.
- 202. Alfonso's guilty plea was a particularly sensitive sticking point for Insys for another reason. Natalie Levine ("Levine"), the salesforce member who sold Subsys to Alfonso, was Babich's wife. As part of Alfonso's plea, she admitted that the Speaker Program payments that Levine organized on her behalf were veiled bribes. Notably, Babich had begun dating Levine while she was engaging in the misconduct, and they married in or around March 2015, while Alfonso was being investigated by the government.
- 203. During a board meeting on June 29, 2015, Kapoor provided a summary of Alfonso's guilty plea to the Outside Directors. Following a discussion, the board

scheduled a telephonic board meeting for July 8, 2015. The board further requested that Skadden and Del Fosse provide an update at that July meeting concerning the payments to Alfonso and the procedures necessary to determine whether similar activity was happening at Insys.

m. <u>July 2015: The Board Is Informed That Insys Lacks Effective</u> Controls and Has Terminated Burlakoff.

- 204. During the ensuing board call on July 8, 2015 (in which all Defendants except Babich participated) to address Alfonso's guilty plea, Kapoor admitted that the company "did not have as much control" over sales representatives and the Speaker Program "as we should have." Kapoor added that the company was "doing a lot of work to see if [there were] other Heathers in [the] closet," (i.e., if there were other prescribers like Heather Alfonso), apparently to reassure the board that management had the situation under control.
- 205. Ultimately, in a misguided effort to help protect themselves from any fallout stemming from Alfonso's guilty plea, Insys's directors voted during the meeting to "re-constitute" the Special Committee that had purportedly been formed in December 2013—but which had entirely failed to meet or perform its designated role over the past eighteen months. But even after resurrecting this committee, Insys's directors did nothing to ensure that it would function appropriately.
- 206. After the Insys directors voted to "re-constitute" the Special Committee but before it had met, Kapoor (for self-serving reasons) terminated Burlakoff.

Kapoor made this determination not because of Burlakoff's involvement with the misconduct, but because Burlakoff spoke with a journalist about Insys's sales practices and was deemed "unstable." In other words, Kapoor feared that Burlakoff would bring unwanted attention and scrutiny to rampant ongoing illegality implemented at Kapoor's direction.

207. Del Fosse informed the board of Burlakoff's termination through an email on July 31, 2015. With no pushback from the Outside Directors and at Kapoor's direction, Burlakoff was given severance in the form of a consulting agreement, pursuant to which Burlakoff was entitled to a bonus of almost \$150,000, as well as continued vesting of his 192,500 shares of Insys stock that were subject to an option award under the company's option plan. This Kapoor directed severance package kept Burlakoff quiet until he eventually cooperated with the government after pleading guilty in November 2018.

n. <u>August 2015: The Special Committee Finally Begins to Meet</u> But Is Tainted, Ineffective, and Poorly Functioning.

- 208. In August 2015, the "re-constituted" Special Committee finally began to meet (more than eighteen months after it was first formed in December 2013). Even then, however, the Special Committee was fundamentally flawed in several respects.
- 209. <u>First</u>, the Special Committee did not act independently of Kapoor. Instead, Kapoor frequently attended Special Committee meetings, often inserted

himself into discussions, and largely took control of the investigation. He also remained intimately involved in the Special Committee's strategic decisions with respect to the regulatory investigations, employment decisions for individuals implicated by the investigation, and related matters. Indeed, even after the board finally decided to hire a Chief Compliance Officer later in 2015, the Special Committee and Outside Directors deferred to Kapoor to select the candidate, even though the Special Committee determined that Kapoor's selection was less qualified than others. In short, although Kapoor was not on the Special Committee and was directly implicated in the practices that were being investigated, he exercised a heavy hand over the Special Committee's activities.

- 210. Second, the Special Committee did not have independent or effective counsel. The Special Committee did not independently choose its own counsel, but was stuck with Skadden (at Kapoor's suggestion) and allowed Kapoor to ensure that he was made privy to any updates provided by Skadden regarding its response to the OIG Subpoena or its other investigatory work. In fact, it was Kapoor himself—not the Special Committee—who would later review and direct outside counsel's internal investigation plan in early 2016.
- 211. Moreover, Insys's general counsel, Del Fosse, kept Kapoor fully apprised of all aspects of the Special Committee's discussions and deliberations.

 Often, Del Fosse discussed issues with Kapoor in advance of Special Committee

meetings so that Del Fosse could report to the committee members and to Skadden whether proposed courses of action would be blessed or opposed by Kapoor at any upcoming Special Committee meeting. These pre-Special Committee meeting liaisons significantly curtailed terminations of Insys employees implicated in misconduct because, according to Del Fosse, Kapoor was "not a huge fan of firing people," out of fear of creating whistleblowers.

212. Third, the Special Committee was also flawed due to its composition. It was comprised of Fourteau, Meyer, and Lapalme—each of whom had significant, pre-existing business and personal relationship with Kapoor.

o. <u>September to November 2015: The Board Terminates</u> <u>Babich as a Designated "Fall Guy."</u>

- 213. At a Special Committee meeting on September 18, 2015, as it became increasingly clear that Insys faced major legal troubles, the committee members questioned whether Babich could be terminated "for cause." Under Babich's employment agreement, "[w]hether a termination is for Cause shall be decided by the Board in its sole and exclusive judgment and discretion." Among other things, "Cause" included Babich's participation in a fraud, an act of dishonesty or other act of misconduct against the company, or his violation of any statutory or fiduciary duty owed to the company.
- 214. The determination of whether Babich could be terminated for cause had a significant financial impact on Insys. If Babich were terminated "for cause," then

he would not be entitled to any severance payments. Further, all of his stock options—both vested and unvested—under the company's option plans would have been terminated immediately, and he would have been prohibited from exercising them. Thus, terminating Babich for cause would have saved tens of millions of dollars for the company.

- 215. For Kapoor, however, terminating Babich for cause was a risky maneuver because Babich, as Kapoor's main co-conspirator, could easily turn against him. Accordingly, when Kapoor finally determined that it was time for Babich to go due to the government's investigation into Babich's criminal behavior, Kapoor sought to protect himself by acting proactively, irrespective of the Special Committee's deliberations. On October 27, 2015, one day after Kapoor told Babich that he was "going to be the fall guy," Kapoor informed the Outside Directors by email that he had unilaterally determined to offer Babich a severance package as one "last favor." Kapoor insisted on this severance package even though Babich had been well compensated during his tenure as CEO, receiving \$2,899,420 in 2013, \$2,539,906 in 2014, and \$3,862,000 in 2015.
- 216. Three days later in an email on October 30, 2015, Del Fosse informed the Special Committee that Babich could receive a severance package for only a "non-Cause departure event." Del Fosse also indicated that the severance agreement was subject to Compensation Committee approval at the next Board meeting, to be

held on November 3, 2015. The minutes for that board meeting reflect no substantive discussion of whether Babich should be terminated "for cause," however, as the Outside Directors essentially rubber-stamped Kapoor's unilateral decision from a few days prior to give Babich a severance package. The Outside Directors deferred to Kapoor's decision even though at that same board meeting, an update on pending investigations indicated that there were ample grounds to terminate Babich "for cause," which would have resulted in the company not having to pay any severance to him.

- 217. Babich was thereafter given a hefty severance package worth more than \$20 million in cash and stock, including one year of salary (\$3,862,000); a pro-rated bonus for 2015 (\$443,013), accrued vacation (\$24,230), and the accelerated vesting of Babich's unvested stock options (worth over \$20 million at the time).
- 218. At bottom, the decision to pay Babich a severance was not in Insys's best interest, but rather was a decision made to protect Kapoor. As Del Fosse put it in an email to the board prior to when the decision was made, the company took "very seriously protecting [the] Board and Dr. K[apoor]," and that "any decision we make about . . . Mike [Babich] should take that into consideration," since he "could exercise self-protective behavior, go after Dr. K[apoor]." Remarkably, the Outside Directors approved Kapoor's own self-protective decision to pay a

severance to silence Babich (which worked until Babich finally pleaded guilty in January 2019).

p. November 2015: The Board Defers to Kapoor's Decision to Install Himself as CEO.

- 219. After sacrificing his primary co-conspirator in the criminal scheme (Babich), Kapoor promptly leveraged his relationships with the Outside Directors to have himself installed as CEO. When Kapoor put himself forward for the CEO role, the Outside Directors hardly blinked; they did not consider any other potential candidates for the position, nor did they discuss whether it was even appropriate for Kapoor to become CEO in light of the likelihood of misconduct at the company, Kapoor's own apparent role in that misconduct, or the status of the government's investigations into that misconduct.
- 220. The Outside Directors' loyalty and deference to Kapoor in allowing him to become CEO was particularly baffling given that they recognized and acknowledged by that time that Insys was a complete and utter mess, despite Kapoor's prior assurances. As Fourteau confessed in an August 28, 2015 email to outside counsel:

"It is clear that the whole monitoring in 2014 was very loose. The evaluation from the reps should have acted as huge red signals. The list of attendees was suspicious. We as a board were given some metrics re the Speaker's program but not these ones. Were they followed? I suspect nobody was looking at them."

Then in an October 29, 2015 email chain involving Fourteau, LaPalme, and Meyer,

those Outside Directors discussed the need for a "compliance committee" to remain in operation "until things are fully under control." In short, as Babich testified in the Criminal Action, there was "no major compliance initiative" at the company.

221. Yet the Outside Directors nevertheless allowed Kapoor to appoint himself as CEO. And they largely gave him free rein, especially over critical personnel decisions, including whether to terminate Insys employees who engaged in misconduct. As alleged above, Kapoor generally wanted to keep employees around to reduce the risk of terminated employees becoming whistleblowers. To further prevent whistleblowers and cooperation with governmental investigations, Kapoor caused Insys to advance defense costs for employees under investigation or indictment, including employees who were not directors or officers and who did not otherwise have any possible entitlement to indemnification or advancement. This behavior was ultimately self-serving, given that Kapoor directed, participated in, or knew about the misconduct of his subordinates at the company.

q. <u>December 2016 to October 2017: The Board Allows Kapoor to Remain on the Board Until He is Indicted.</u>

222. In December 2016, Insys's outside counsel spoke with the DOJ's lead investigator, Nat Yeager. Yeager informed Insys's counsel that the DOJ was particularly interested in Kapoor's involvement in the ROI Analysis. According to Yeager, the DOJ could not "move forward with a settlement with the company if the 60% owner was directly involved in the ROI analysis and speaker program."

- 223. Del Fosse forwarded a summary of the telephone call to Kapoor and the Special Committee. Although Kapoor resigned as CEO and chairman of the board in January 2017, the Special Committee members allowed Kapoor to remain a board member and to exercise continued leadership of the company's response to the government's investigation. During this time, the Special Committee still took no steps to investigate Kapoor or his prior involvement in the ROI Analysis and Speaker Program.
- 224. In October 2017, Kapoor was indicted for criminal racketeering related to the sales and marketing plan he implemented at Insys. Following his indictment, Kapoor finally resigned from the Insys board. In other words, the Outside Directors did nothing to prevent Kapoor from running the company as he saw fit, regardless of any illegality, until Kapoor was indicted more than five long and devastating years after his criminal scheme commenced.

C. THE CRIMINAL SCHEME DAMAGES AND DESTROYS INSYS.

225. The Kapoor-Babich scheme, as enabled by the Outside Directors, caused Insys to sustain substantial damages, including: (a) illegal payments to doctors through the Speaker Program; (b) awards, fines, and liabilities imposed in civil and criminal proceedings against the company; (c) fees, expenses, and costs incurred by the company in those civil and criminal proceedings; (d) fees, expenses, and costs advanced by the company in various civil and criminal proceedings against

its former directors, officers, and other employees, including Kapoor and Babich; (e) compensatory and severance payments by the company to its former directors, officers, and other employees, including Defendants, who had engaged in the misconduct; (f) fees, expenses, and costs incurred by the company in its bankruptcy case; and (g) liabilities owed to the many third-party victims of the scheme, which became creditors of the company in its bankruptcy case.

- 226. First, Insys incurred significant damages in the form of illegal payments to doctors through the Speaker Program. The company paid nearly \$24 million to doctors involved in the illicit Speaker Program, including: (a) \$2.8 million in 2013; (b) \$7.7 million in 2014; and (c) \$13.3 million in 2015. Insys never would have made these improper payments had Defendants complied with their fiduciary duties.
- 227. Second, Insys suffered enormous awards, fines, and liabilities imposed in civil and criminal proceedings. For example, in settlements with various state and federal authorities, the company incurred almost \$235 million in damages, including: (a) nearly \$10 million in settlements with various state governments, including Illinois, Oregon, Massachusetts, and New Hampshire; and (b) the \$225 million settlement with the federal government in 2019. The company never would have incurred these crippling liabilities had Defendants properly discharged their fiduciary duties.

- 228. Third, Insys incurred substantial fees, expenses, and other costs in connection with the multiple civil and criminal proceedings against the company. Indeed, Insys paid a staggering \$55 million in fees and expenses to dozens of professional firms related to those proceedings. The company never would have sustained these damages had Defendants complied with their fiduciary duties.
- 229. Fourth, Insys advanced additional fees, expenses, and other costs in connection with civil and criminal proceedings against its former directors, officers, and other employees, including Kapoor and Babich. In other words, Insys paid to defend the individuals who had destroyed the company. Specifically, the company advanced nearly \$28 million in such defense costs, including: (a) over \$12.1 million in defense costs for Kapoor; and (b) over \$6.7 million in defense costs for Babich. Insys never would have made these payments had Defendants properly discharged their fiduciary duties.
- 230. <u>Fifth</u>, Insys incurred additional damages through compensatory and severance payments to its former directors, officers, and other employees, including Defendants, who had engaged in the underlying misconduct. For instance, Kapoor collected more than \$859,000 in fees, salary, and other compensation from Insys. Babich collected nearly \$9.2 million in bonuses, salary, and other compensation from the company. He also received over \$500,000 through a severance payment. And the Outside Directors collected over \$1.6 million in fees and other

compensation from Insys, while they were simultaneously breaching their fiduciary duties to the company.

- 231. <u>Sixth</u>, after collapsing under the weight of the Kapoor-Babich scheme, Insys incurred more than \$25 million in fees, expenses, and other costs in its bankruptcy case. The company, of course, would not have commenced that case and would not have incurred those fees, expenses, and costs had Defendants complied with their fiduciary duties.
- 232. Seventh, Insys incurred billions of dollars of legal liabilities to third parties as a result of its vicarious liability for the wrongful acts perpetrated by Kapoor, Babich, and those acting under their direction (wrongful acts that were enabled by the Outside Directors and their failures). At the time of its bankruptcy filing, Insys faced:
 - Hundreds of actions (many of which were consolidated in MDL 2804) for wrongful death, negligence, product liability, insurance fraud and harm caused to governmental entities stemming from the opioid crisis;
 - Approximately 200 actions filed by governmental entities outside of MDL 2804; and
 - Over 27 personal injury lawsuits, several of which sought class action certification.

The billions of dollars of legal exposure, along with the \$225 million DOJ settlement, led to Inys's bankruptcy filing.

- 233. Although the company once had a market capitalization of more than \$2.2 billion, Insys liquidated its assets for only \$30 million in cash and \$30 million in future royalties and other payments during the bankruptcy case. In its confirmed Plan in the bankruptcy case, Insys conservatively estimated the following liabilities:

 (a) \$50 million in Class 4 claims (general unsecured claims); (b) \$258 million in Class 5 claims (insurance-related claims); (c) \$117 million in Class 6 claims (hospital and certain monitoring claims); (d) \$283 million in Class 7 claims (federal claims); and (e) \$597 million in Class 8 claims (state, municipality, and tribe claims). The company never would have incurred those liabilities had Defendants properly discharged their fiduciary duties.
- 234. Insys, therefore, incurred almost \$150 million in total out-of-pocket damages, plus billions of dollars in additional losses and liabilities, as a direct and proximate result of the misconduct by Defendants.

D. BABICH ENGAGES IN INSIDER TRADING.

235. In addition to his misconduct described above, Babich misused his position as a fiduciary of the company to trade on inside information. From January 2014 through March 2015, Babich sold \$29,610,157 worth of shares of his Insys common stock based upon his knowledge and possession of material, non-public information.

- 236. During this period, the company's quarterly revenues increased by 232% from \$39.2 million in the fourth quarter of 2013 to \$91.1 million in the third quarter of 2015. This rapid increase in revenues for Subsys was driven primarily by the improper sales and marketing practices described above, which were concealed from the market. The increase in revenue correlated with a more than 300% increase in Insys's stock price from \$13.04 on December 13, 2013 to \$40.01 on June 19, 2015. Babich took advantage of the fact that the company's revenues were rising dramatically—due to improper sales and marketing practices known to them, but not the market—to sell more than \$29.6 million worth of Insys stock before the misconduct was discovered by the public.
- 237. By early 2014, Babich knew the material non-public fact that the company's sales revenues were dependent upon improper sales activities and practices at the IRC. These improper practices—which were undoubtedly material—were not made public until years later.
- 238. Therefore, from January 2014 through well after March 2015, Babich possessed material, non-public information concerning improper activities at Insys, and were prohibited from trading the company's stock based on that information. Babich chose to misuse it for his own personal gains by selling shares of Insys common stock at a time when he could obtain significant returns due to the public's

ignorance of extensive wrongdoing at Insys, wrongdoing that Babich himself spearheaded.

- 239. Accordingly, Babich possessed material non-public information at the time that he sold his shares of Insys common stock during the period of January 2014 through March 2015. As indicated in Form 4 filings with the Securities and Exchange Commission, Babich did not effectuate any of these trades pursuant to a Rule 10b5-1 plan.
- 240. Babich, of course, played an integral role in implementing, overseeing, and executing the company's improper sales and marketing practices (section A.3, *supra*). Through the directions that he provided to subordinates, such as Burlakoff and Napoletano, Babich—along with Kapoor—was the prime orchestrater of the unlawful Speaker Program. Further, Babich had regular communications with, and provided directions to, Gurry concerning the IRC's fraudulent operations and the methods employed by the prior authorization specialists. Babich capitalized on this insider knowledge by trading shares of Insys common stock at inflated stock prices.
- 241. The following table summarizes the dates upon which Babich traded shares of Insys common stock based upon this material, non-public information, as well as the proceeds he received from those trades:

Date of Trade	Total Proceeds
March 5, 2014	\$21,512,122
October 21, 2014	\$803,404
November 3, 2014	\$279,504
November 4, 2014	\$2,813,223
March 16, 2015	\$2,814,473
March 17, 2015	\$1,387,441
Total	\$29,610,157

IV. CAUSES OF ACTION

COUNT I Breach of Fiduciary Duties (Against Kapoor)

- 242. The Trustee re-alleges the allegations set forth above.
- 243. As a director and officer of the company, Kapoor owed fiduciary duties to Insys and its stockholders. He also owed fiduciary duties as the company's controlling stockholder. By reason of his fiduciary relationships, Kapoor owed the highest obligation of due care, loyalty, and good faith to Insys and its stockholders with respect to the company's affairs, including its compliance with laws and regulations governing the sale and marketing of Subsys.
- 244. Kapoor consciously and repeatedly breached his fiduciary duties to Insys and its stockholders in multiple ways, including:
 - a. implementing and executing the company's improper sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC, thereby causing the company to violate positive law;

- b. engaging in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effectivedose scheme, Speaker Program, ROI Analysis, and IRC;
- c. failing to act in the face of a known duty to act to prevent illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC;
- d. failing to implement a reasonable oversight and compliance program on key issues of risk for the company, such as the Speaker Program and IRC;
- e. failing to actively monitor or oversee the compliance program when it finally was instituted, thus disabling the company's directors from being informed of risks or problems requiring their attention;
- f. disregarding his duty to investigate repeated red flags regarding possible illegality and other misconduct and to remedy any misconduct uncovered;
- g. acting in bad faith and putting the interests of himself and others above the interests of the company and all of its stockholders;
- h. approving or allowing severance payments to former employees (such as Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC; and
- i. approving or allowing advancement of defense costs to former directors, officers, and employees (such as Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC.

- 245. As a direct and proximate result of his breaches of fiduciary duty, Kapoor caused Insys to sustain substantial damages, including: (a) awards, fines, and penalties imposed against Insys in civil and criminal proceedings; (b) fees, expenses, and costs incurred by Insys in civil and criminal proceedings; (c) fees, expenses, and costs advanced by Insys in civil and criminal proceedings against its former directors, officers, and other employees; (d) severance payments by Insys to its former employees who had engaged in illegal conduct and other misconduct; (e) fees, expenses, and costs incurred by Insys in its bankruptcy case; and (f) liabilities incurred to victims who became creditors of Insys in its bankruptcy case.
- 246. Accordingly, Kapoor is liable to the Trustee, as successor-in-interest to Insys, for significant damages in an amount to be proven at trial. The Trustee has no adequate remedy at law.

COUNT II Breach of Fiduciary Duties (Against Babich)

- 247. The Trustee re-alleges the allegations set forth above.
- 248. As a director and officer of the company, Babich owed fiduciary duties to Insys and its stockholders. By reason of his fiduciary relationships, Babich owed the highest obligation of due care, loyalty, and good faith to Insys and its stockholders with respect to the company's affairs, including its compliance with laws and regulations governing the sale and marketing of Subsys.

- 249. Babich consciously and repeatedly breached his fiduciary duties to Insys and its stockholders in multiple ways, including:
 - a. implementing and executing the company's improper sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC, thereby causing the company to violate positive law;
 - b. engaging in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effectivedose scheme, Speaker Program, ROI Analysis, and IRC;
 - c. failing to act in the face of a known duty to act to prevent illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC;
 - d. failing to implement a reasonable oversight and compliance program on key issues of risk for the company, such as the Speaker Program and IRC;
 - e. failing to actively monitor or oversee the compliance program when it finally was instituted, thus disabling the company's directors from being informed of risks or problems requiring their attention;
 - f. disregarding his duty to investigate repeated red flags regarding possible illegality and other misconduct and to remedy any misconduct uncovered;
 - g. acting in bad faith and putting the interests of Kapoor and others above the interests of the company and all of its stockholders; and
 - h. approving or allowing severance payments to former employees (such as Burlakoff and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC.

- 250. As a direct and proximate result of his breaches of fiduciary duty, Babich caused Insys to sustain substantial damages, including: (a) awards, fines, and penalties imposed against Insys in civil and criminal proceedings; (b) fees, expenses, and costs incurred by Insys in connection with civil and criminal proceedings; (c) fees, expenses, and costs advanced by Insys in connection with civil and criminal proceedings against its former directors, officers, and other employees; (d) severance payments by Insys to its former employees who had engaged in illegal conduct and other misconduct; (e) fees, expenses, and costs incurred by Insys in its bankruptcy case; and (f) liabilities incurred to victims who became creditors of Insys in its bankruptcy case.
- 251. Accordingly, Babich is liable to the Trustee, as successor-in-interest to Insys, for significant damages in an amount to be proven at trial. The Trustee has no adequate remedy at law.

COUNT III

Breach of Fiduciary Duties (Against the Outside Directors)

- 252. The Trustee re-alleges the allegations set forth above.
- 253. As directors of the company, the Outside Directors owed fiduciary duties to Insys and its stockholders. By reason of their fiduciary relationships, the Outside Directors owed the highest obligations of good faith and loyalty to Insys and

its stockholders with respect to the company's affairs, including its compliance with laws and regulations governing the sale and marketing of Subsys.

- 254. The Outside Directors consciously and repeatedly breached their fiduciary duties to Insys and its stockholders in multiple ways, including:
 - a. failing to prevent the company from violating positive law with respect to its improper sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC;
 - b. failing to act in the face of a known duty to act to prevent illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC;
 - c. failing to implement a reasonable oversight and compliance program on key issues of risk for the company, such as the Speaker Program and IRC;
 - d. failing to actively monitor or oversee the compliance program when it finally was instituted, thus disabling the company's directors from being informed of risks or problems requiring their attention;
 - e. disregarding their duty to investigate repeated red flags regarding possible illegality and other misconduct and to remedy any misconduct uncovered;
 - f. acting in bad faith and putting the interests of Kapoor and others above the interests of the company and all of its stockholders, including by allowing Kapoor to manage the company's investigation of its sales and marketing practices;
 - g. approving or allowing severance payments to former employees (such as Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the

- company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC;
- h. approving or allowing advancement of defense costs to former directors, officers, and employees (such as Kapoor, Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC; and
- i. with respect to Fourteau, Meyer, and Lapalme, failing to satisfy their Special Committee obligations, including by not meeting at all for over 18 months after the committee's formation.
- 255. As a direct and proximate result of their breaches of fiduciary duty, the Outside Directors caused Insys to sustain substantial damages, including: (a) awards, fines, and penalties imposed against Insys in civil and criminal proceedings; (b) fees, expenses, and costs incurred by Insys in connection with civil and criminal proceedings; (c) fees, expenses, and costs advanced by Insys in connection with civil and criminal proceedings against its former directors, officers, and other employees; (d) severance payments by Insys to its former employees who had engaged in illegal conduct and other misconduct; (e) fees, expenses, and costs incurred by Insys in its bankruptcy case; and (f) liabilities incurred to victims who became creditors of Insys in its bankruptcy case.
- 256. Accordingly, the Outside Directors are liable to the Trustee, as successor-in-interest to Insys, for damages in an amount to be proven at trial. The Trustee has no adequate remedy at law.

COUNT IV Corporate Waste (Against All Defendants)

- 257. The Trustee re-alleges the allegations set forth above.
- 258. As directors and/or officers of the company, Defendants caused Insys to waste its corporate assets in several ways, including:
 - a. approving or allowing severance payments to former employees (such as Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC; and
 - b. approving or allowing advancement of defense costs to former directors, officers, and employees (such as Kapoor, Babich, Burlakoff, and others) who had engaged in illegal conduct and other misconduct with respect to the company's sales and marketing plan, including the effective-dose scheme, Speaker Program, ROI Analysis, and IRC.
- 259. These transactions were so one-sided that no business person of ordinary, sound judgment, particularly persons such as Defendants who knew about the underlying illegality and/or other misconduct, could conclude that the company received adequate consideration in exchange for these transactions. Rather, these transactions were unconscionable and constituted waste.
- 260. As a result of the waste of corporate assets, Defendants are liable to the Trustee, as successor-in-interest to Insys, for damages in an amount to be proven at trial. The Trustee has no adequate remedy at law.

COUNT V Brophy Claim (Against Babich)

- 261. The Trustee re-alleges the allegations set forth above.
- 262. As a director and officer of the company, Babich owed fiduciary duties to Insys and its stockholders, including the duty of loyalty.
- 263. Babich breached his duty of loyalty by selling his Insys common stock, while in possession of material, non-public information about the company. Babich was motivated, in whole or in part, by the substance of that information.
- 264. Specifically, from March 2014 to March 2015, Babich sold a significant amount of his Insys common stock, receiving more than \$29.6 million in proceeds. At the time that he sold his stock, Babich knew that Insys was engaging in improper sales and marketing practices, which had the effect of substantially inflating the company's revenues.
- 265. Insys's improper sales and marketing practices represented material, non-public information. This information was proprietary information belonging to Insys regarding its business and financial condition. Nonetheless, Babich used this proprietary and material, non-public information for his own benefit when he sold his Insys common stock. Indeed, Babich's sales of the stock were motivated, in whole or in part, by this information.
 - 266. Accordingly, the Trustee, as successor-in-interest to Insys, is entitled to

the imposition of a constructive trust and disgorgement of any profits obtained by Babich through his sales of the stock. The Trustee has no adequate remedy at law.

COUNT VI Unjust Enrichment (Against Babich)

- 267. The Trustee re-alleges the allegations set forth above.
- 268. To the extent that Count V fails, Babich has been unjustly enriched as a result of his sales of Insys common stock, even if he breached no cognizable duty.
- 269. Babich was involved in Insys's unlawful sales and marketing schemes, which resulted in Insys reporting inflated revenues. These inflated revenues allowed Babich to sell his stock—which he received from Insys—at a higher price.
- 270. It would be against equity and good conscience for Babich to retain the benefits of his sales of Insys stock. Accordingly, the Trustee, as successor-in-interest to Insys, is entitled to recover the amount by which Babich has been unjustly enriched, including any profits obtained by Babich through his sales of the stock. The Trustee has no adequate remedy at law.

V. PRAYER FOR RELIEF

WHEREFORE, the Trustee prays for judgment as follows:

- a. finding that Defendants breached their fiduciary duties of loyalty and good faith to Insys and its stockholders;
- b. awarding actual, compensatory, rescissory, consequential, and other damages against Defendants for breaching their fiduciary duties in an amount to be determined at trial;

- c. awarding restitution from Defendants and ordering them to disgorge (i) all benefits, salaries, and other compensation paid to them while they were breaching their fiduciary duties; (ii) all profits and proceeds received by them while they were breaching their fiduciary duties; and (iii) all advancements of defense costs and other similar payments for their benefit;
- d. awarding pre-judgment and post-judgment interest at the maximum rate permitted by law or equity;
- e. awarding reasonable attorney's fees and expenses, together with costs of court, in connection with this action; and
- f. granting such other relief as the Court deems just and proper.

Dated: April ___, 2022

REID COLLINS & TSAI LLP

Norman M. Monhait (#1040) 300 Delaware Avenue, Suite 770 Wilmington, DE 19801 (302) 467-1765 nmonhait@reidcollins.com

Counsel for William H. Henrich, as Trustee of the Insys Liquidation Trust

OF COUNSEL:

William T. Reid IV Keith Y. Cohan Ryan M. Goldstein Morgan M. Menchaca REID COLLINS & TSAI LLP 1301 S. Capital of Texas Hwy, Suite C300 Austin, TX 78746 (512) 647-6100

Eric D. Madden Michael J. Yoder REID COLLINS & TSAL LLP 1601 Elm Street, Suite 4200 Dallas, TX 75201 (214) 420-8900

Exhibit D

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United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor

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Docket 16-cr-10343-ADB

Case Status

May 2, 2019-Insys founder and former Executive Chairman John N. Kapoor, 76, of Phoenix, Ariz.; Richard M. Simon, 48, of Seal Beach, Calif., the former National Director of Sales; Sunrise Lee, 38, of Bryant City, Mich., a former Regional Sales Director; Joseph A. Rowan, 45, of Panama City, Fla., a former Regional Sales Director; and Michael J. Gurry, 55, of Scottsdale, Ariz., the former Vice President of Managed Markets, were convicted by a federal jury of RICO conspiracy.

Michael Gurry-sentenced on January 13, 2020. The defendant is sentenced on Count 1 to 33 months in the custody of the Bureau of Prisons followed by 3 years of supervised release with conditions, no fine, special assessment of \$100.00, restitution to be determined at a later date. Order of forfeiture to enter. Defendant is to self-surrender to the facility designated by the Bureau of Prisons on 2/25/2020.

Richard M. Simon-January 21, 2020. The defendant is sentenced on Count 1 to 33 month custody of the Bureau of Prisons followed by 3 years of supervised release with condition

OF

fine, special assessment in the amount of \$100.00, restitution to be determined. Order of forfeiture to issue.

Joseph Rowan-January 21, 2020. The defendant is sentenced on Count 1 to 27 months in the custody of the Bureau of Prisons followed by 3 years of supervised release with conditions, no fine, special assessment of \$100.00, restitution to be determined. Order of forfeiture to issue.

Sunrise Lee-January 22, 2020-The defendant is sentenced on Count 1 to a year and a day in the custody of the Bureau of Prisons followed by 3 years of supervised release with conditions, no fine, \$100.00 special assessment

Michael L. Babich- January 22, 2020-The defendant is sentenced on Counts 1 and 2 to 30 months in the custody of the Bureau of Prisons to be served concurrently followed by 3 years of supervised release with conditions, no fine, Special assessment of \$200.

Alec Burlakoff-January 23, 2020-The defendant is sentenced on Count 1 to 26 months in the custody of the Bureau of Prisons followed by 3 years of supervised release with conditions, no fine, special assessment of \$100.00.

John Kapoor-January 23, 2020-The defendant is sentenced on Count 1 to 66 months in the Bureau of Prisons followed by 3 years of supervised release with conditions, fine of \$250,000., special assessment of \$100.00., Restitution in the amount of \$59,755,362.45.

Case Information

On December 6, 2016, the defendants, former executives and managers of Insys Therapeutics Inc., were charged by indictment by the United States Attorney's Office for the District of Massachusetts with conspiracy to commit racketeering, mail and wire fraud, and conspiracy to violate the anti-kickback law in relation to a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain medication and defraud payers of the medication, including insurers. The indictment alleges that Michael L. Babich, 40, of Scottsdale, Ariz., the former CEO and President of the company; Alec Burlakoff, 42, of Charlotte, N.C., former Vice President of Sales; Richard M. Simon, 46, of Seal Beach, Calif., former National Director of Sales; former Regional Sales Directors, Sunrise Lee, 36, of Bryant City, Mich. and Joseph A. Rowan, 43, of Panama City, Fla.; and former Vice President of Managed Markets, Michael J. Gurry, 53, of Scottsdale, Ariz., conspired to bribe practitioners in various states, many of whom operated pain clinics, in order to get them to prescribe a fentanylbased pain medication, called Subsys. Subsys is a powerful narcotic intended to treat cancer patients suffering intense episodes of breakthrough pain. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for the patients, most of whom w **TOP** diagnosed with cancer.

The indictment also alleges that the now former corporate executives charged in the case conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up the "reimbursement unit" which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers. More information can be located by reviewing the Indictment and Press Release.

On January 5, 2017, the defendants appeared before the magistrate in federal court for their initial appearance and arraignment. The defendants have all pled not guilty and have been released on conditions approved by the court.

On October 24, 2017 a superseding indictment was filed added the defendant John N. Kapoor.

Documents

- Press Release
- Indictment
- First Superseding Indictment

Updated May 19, 2021

District of Massachusetts

Boston Office:

1 Courthouse Way, Suite 9200 Boston, MA 02210,

Email USAO-MA

Boston: 617-748-3100

Springfield: 413-785-0235 Worcester: 508-368-0100

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Exhibit E

IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re: : Chapter 11

INSYS THERAPEUTICS, INC., et al., : Case No. 19-11292 (JTD)

Liquidating Debtors.¹ : (Jointly Administered)

Elquidating Debtors. : (Jointly Administered

DECLARATION OF LAYN R. PHILLIPS IN SUPPORT OF MOTION BY LIQUIDATING TRUSTEE TO APPROVE SETTLEMENT WITH CERTAIN FORMER DIRECTORS OF THE DEBTORS PURSUANT TO 11 U.S.C. § 105(a) AND FEDERAL RULE OF BANKRUPTCY PROCEDURE 9019

I, Layn R. Phillips, hereby declare as follows, pursuant to 28 U.S.C. § 1746:

1. I submit this Declaration in my capacity as the mediator in connection with the proposed settlement described in the *Motion by Liquidating Trustee to Approve Settlement with Certain Former Directors of the Debtors Pursuant to 11 U.S.C. § 105(a) and Federal Rule of Bankruptcy Procedure 9019* (the "Rule 9019 Motion").² While the mediation process is confidential, the parties to the proposed settlement have authorized me to inform the Court of the procedural and substantive matters set forth herein in support of the Rule 9019 Motion. My statements and those of the parties during the mediation process are subject to a confidentiality agreement, mediation privileges under applicable law, and Federal Rule of Evidence 408 (as well as its state-law analogues), and there is no intention on the part of myself or the parties to waive that agreement, those privileges, or the protections of Rule 408. I make this Declaration based on personal knowledge and am competent to so testify.

¹ The Liquidating Debtors in these cases, along with the last four digits of the Debtor's federal tax identification number, are Insys Therapeutics, Inc. (7886); IC Operations, LLC (9659); Insys Development Company, Inc. (3020); Insys Manufacturing, LLC (0789); Insys Pharma, Inc. (9410); IPSC, LLC (6577); and IPT 355, LLC (0155).

² Capitalized terms not defined herein have the meanings specified in the Rule 9019 Motion.

A. Background and Qualifications

- 2. I am a former United States District Judge, a former United States Attorney, and a former litigation partner with the firm of Irell & Manella LLP. I currently serve as a mediator and arbitrator with my own alternative dispute resolution company, Phillips ADR Enterprises ("Phillips ADR"), which is based in Corona Del Mar, California. I am a member of the bars of Oklahoma, Texas, California, and the District of Columbia, as well as the United States Courts of Appeals for the Ninth and Tenth Circuits and the Federal Circuit.
- 3. I earned my Bachelor of Science in Economics as well as my J.D. from the University of Tulsa. I also completed two years of L.L.M. work at Georgetown University Law Center in the area of economic regulation of industry. After serving as an antitrust prosecutor and an Assistant United States Attorney in Los Angeles, California, I was nominated by President Reagan to serve as a United States Attorney in Oklahoma, where I served for approximately four years. Thereafter, I was nominated by President Reagan to serve as a United States District Judge for the Western District of Oklahoma. While on the bench, I presided over more than 140 federal trials and sat by designation in the United States Court of Appeals for the Tenth Circuit. I also presided over cases in Texas, New Mexico, and Colorado.
- 4. I left the federal bench in 1991 and joined Irell & Manella where, for 23 years, I specialized in alternative dispute resolution, complex civil litigation, and internal investigations.
- 5. Since my retirement from Irell & Manella in 2014, my practice has been devoted full time to alternative dispute resolution: specifically, the arbitration and mediation of high-stakes complex litigation such as this case. I have nearly thirty years of dispute resolution experience, including conducting thousands of mediations and settlement conferences in all types of complex class actions, securities fraud actions, and shareholder derivative actions.

B. The Arm's-Length Negotiations

- 6. On November 22, 2021, the parties and their counsel participated via videoconference in a full-day mediation session with me. The participants included: (a) the Trustee, his general counsel from Halperin Battaglia Benzija LLP, his special litigation counsel from Reid Collins & Tsai LLP, and his insurance counsel from Burns Bowen Bair LLP; (b) John Kapoor and his counsel from Nixon Peabody LLP; (b) Michael Babich and his counsel from Russell Piccoli PLC; (c) Patrick Fourteau and his counsel from Patterson Belknap Webb & Tyler LLP; (d) Steven Meyer and his counsel from Quinn Emanuel Urquhart & Sullivan, LLP; (e) Pierre Lapalme and his counsel from Quinn Emanuel Urquhart & Sullivan, LLP; (f) Brian Tambi; and (g) a representative from Old Republic Insurance Company and its counsel from Bailey Cavalieri LLC.
- 7. Prior to the mediation session, the parties submitted and exchanged detailed mediation statements and supporting documents addressing key factual and legal issues related to liability, causation, and damages. I found these mediation statements to be extremely valuable in helping me to understand the relative strength of the underlying claims and defenses, the risk of liability on those claims, and the amount of provable damages associated with those claims. It was apparent to me that both sides possessed strong arguments, and that neither side was assured of victory if the case were litigated to final judgment.
- 8. At the mediation session, counsel for each of the parties vigorously argued their respective positions. I also posed many questions to each side to test the strength of their positions. In addition to engaging in these merits-based discussions, the parties exchanged multiple rounds of offers and counteroffers throughout the day. While some progress was made, the parties were

³ Shortly after the mediation session, Mr. Tambi retained counsel at Winston & Strawn LLP, and he was subsequently represented by that firm in connection with this matter.

not able to reach agreement during the mediation session, which lasted more than ten (10) hours

and concluded after 9:00 p.m. Eastern Standard Time on November 22, 2021.

9. Following the mediation session, the Trustee and the Settling Defendants continued

to engage in settlement negotiations through a series of telephone calls and emails in late 2021 and

most of 2022. Their ongoing negotiations generally included myself and/or my colleague at

Phillips ADR, Michelle Yoshida. These negotiations ultimately resulted in the proposed

Settlement Agreement between the Trustee and the Settling Defendants.

C. Conclusion

10. Based on my experience as a litigator, a former United States District Judge, and a

mediator, I believe that the Settlement Agreement is the product of arm's-length, good-faith

negotiations between the parties and represents a fair and reasonable settlement with respect to the

underlying claims. As such, I strongly support the approval of the Settlement Agreement as

requested in the Rule 9019 Motion.

I declare under penalty of perjury under the laws of the United States of America that the

foregoing is true and correct.

Executed this <u>12</u> day of April, 2023, in Newport Beach, California.

LAYN R. PHILLIPS

Lelle

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