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Party Name: American Home Assurance Co., et al.	**Case Number:** **22SL-CC02974**
Address: 8001 Foryth Boulevard, Suite 1500 St. Louis, MO 63105	Case Type: Civil
	Style of Case: Opioid Master Disbursement Trust v. Ace, et
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Filing Date: November 4, 2024	
Document Filed: Reply in Support of Cross MSJ	

(Date File Stamp)

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IN THE CIRCUIT COURT FOR THE COUNTY OF ST. LOUIS
STATE OF MISSOURI

OPIOID MASTER DISBURSEMENT TRUST II, A/K/A OPIOID MDT II,	)	Case No. 22SL-CC02974
Plaintiff,	)	Division No. 2
v.	)	
ACE AMERICAN INSURANCE COMPANY, *et al.*,	)	
Defendants.	)	

NATIONAL UNION FIRE INSURANCE COMPANY OF PITTSBURGH, PA.'S AND AMERICAN HOME ASSURANCE COMPANY'S REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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The AIG Insurers,[1] by and through their undersigned counsel, respectfully submit the following Reply in Support of Cross-Motion for Summary Judgment, pursuant to Missouri Supreme Court Rule 74.04, in response to the Trust's Opposition to National Union Fire Insurance Company of Pittsburgh, Pa.'s and American Home Assurance Company's Cross-Motion for Summary Judgment, filed September 18, 2024 (the "Trust's Opposition").

INTRODUCTION

Mallinckrodt was driven into bankruptcy because it was accused in thousands of lawsuits of flooding the U.S. market with medically-unnecessary and dangerous opioids, fueling a nationwide opioid crisis, to achieve and sustain large corporate profits over many years. Among the allegations in the Opioid Lawsuits is that Mallinckrodt boosted sales of its opioid products through a misleading and knowingly deceptive marketing campaign that mischaracterized the addictive nature of opioids. The Trust that was formed in Mallinckrodt's bankruptcy proceedings—the plaintiff here—itself alleges that Mallinckrodt understood all along that its inflated opioid sales were causing dramatic societal and individual harms. Nonetheless, the Trust seeks indemnification under insurance policies that cover "accidents" for Mallinckrodt's opioid-related liability resolved through the bankruptcy. Most of that liability is to government and entity claimants for fiscal and economic losses due to the aggregate costs imposed upon them by

[1] Capitalized terms shall have the meaning set forth in National Union Fire Insurance Company of Pittsburgh, Pa.'s and American Home Assurance Company's Opposition to Plaintiff's Motion for Partial Summary Judgment and Cross-Motion for Summary Judgment, filed July 17, 2024 (the "AIG Insurers' Cross-Motion").

the opioid epidemic; a comparatively small part of that liability relates to claims by individuals who suffered addiction and addiction-related harms, sometimes including death.

The AIG Insurers' Cross-Motion, which was instigated by the Trust in the middle of fact discovery, concerns 22 insurance policies issued by the AIG Insurers ("AIG Policies"). All of the AIG Policies contain provisions that were meant to eliminate or define a limited scope of coverage for liability arising out of Mallinckrodt's products, including inherently-dangerous and addictive opioids—something that discovery provided to date demonstrates Mallinckrodt understood very well. Fourteen of those policies ("AIG Primary Policies") contain an exclusion for liability within the products-completed operations hazard ("PCOH Exclusion") that eliminates all coverage for damages because of bodily injury "arising out of" Mallinckrodt's "product" or "work." Eight of those policies ("AIG Umbrella Policies") contain endorsements limiting coverage for liability falling within the products-completed operations hazard only to liability from claims made against and reported by Mallinckrodt during the time the policy was in force, *i.e.*, the endorsements limit the PCOH coverage to "claims-made and reported" coverage ("PCOH Claims-Made Endorsement"). As the Trust concedes, there were no Opioid Lawsuits filed against or reported by Mallinckrodt during the policy periods of those eight AIG Umbrella Policies.

Although discovery is ongoing, the Trust asks this Court to rule that the PCOH Exclusion does not bar coverage for what it describes as one subset of Mallinckrodt's alleged liability for opioid-related claims. ***While the Trust's construct is a disputed***

question of fact, it argues (without proof) that the opioid-related liability Mallinckrodt resolved through its bankruptcy falls into three categories: (1) liability because of misleading and deceptive marketing that referenced its branded products and that resulted in harm caused by Mallinckrodt's own products; (2) liability because of misleading and deceptive "unbranded" marketing that resulted in harm from the use of Mallinckrodt's own products; and (3) liability because of misleading and deceptive "unbranded" marketing that resulted in harm from the use of other manufacturers' products, such as Purdue's, or illicit opioids, such as fentanyl and heroin—what Mallinckrodt calls "non-Mallinckrodt opioids." The Trust does not argue that bodily injury in connection with the first and second categories of liability are subject to the PCOH Exclusion and PCOH Claims-Made Endorsement. Instead, the Trust seeks summary judgment only on the question of whether the PCOH Exclusion and the PCOH Claims-Made Endorsement apply to claims of bodily injury in connection with the third type of liability.

The Trust seeks an impermissible advisory opinion. The issue the Trust has framed is hypothetical—in two ways. First, a necessary factual predicate to the Trust's Motion is that Mallinckrodt ***actually incurred*** liability for bodily injury arising from "non-Mallinckrodt opioids" solely because of Mallinckrodt's "unbranded marketing." But the Trust introduces no undisputed facts that would establish any such liability, nor does it identify the claimants to which such liability is owed, nor the amount owed, nor for what policy years. Second, the Trust's construct would leapfrog another critical threshold question: whether the Trust can establish that the third hypothetical category of Mallinckrodt's liability would satisfy the terms and conditions of the coverage grant in the

AIG Policies in the first place, such that any exclusion to the coverage grant would be relevant. Because the Trust understands it cannot make this showing, it argues in response that the cases do not require it. Missouri law demonstrates the Trust is flatly wrong.

However, if the Court decides to reach the merits, it should grant the AIG Insurers' Cross-Motion. The Trust cannot avoid the broad and unambiguous language of the PCOH Exclusion, which precludes coverage for all of Mallinckrodt's opioid-related liability, even accepting the Trust's hypothetical supposition that Mallinckrodt incurred liability for bodily injury resulting from "non-Mallinckrodt opioids" based purely on "unbranded marketing." The PCOH Exclusion applies to bar coverage for all "bodily injury" "***arising out of*** 'your product' or 'your work.'" (*E.g.*, Ex. M,[2] National Union Policy No. GL 509-47-72, Section V.16. at AIGINS-MNK00000826 (emphasis added); *id.* at AIGINS-MNK00000836.) And the term "your product" is defined to include representations concerning the fitness and use of the product, and the failure to warn of dangers associated with the product. (*Id.,* Section V.21. at AIGINS-MNK00000827.) Representations about the safety of opioids as a whole necessarily are representations about the subset of opioids (branded and generic) that Mallinckrodt sold, and the purpose of those (mis)representations was to sell more Mallinckrodt opioids. Unsurprisingly, multiple courts in the context of insurance claims concerning the very same Opioid Lawsuits have held that PCOH

[2] The exhibits identified by ***capitalized letters*** A, B, C, etc. refer to the ***Trust's exhibits*** submitted in connection with the Trust's Motion for Partial Summary Judgment. The exhibits identified by ***numbers*** 1, 2, 3, etc. refer to the ***AIG Insurers' exhibits*** submitted in connection with the AIG Insurers' Opposition and Cross-Motion for Summary Judgment, and Reply in Support of Cross-Motion for Summary Judgment.

exclusions preclude coverage for liability resulting from those lawsuits because they "arise out of" opioid products manufactured, distributed or sold by the insured, including misstatements and failures to warn about the dangers of opioids in general. The Trust cites no comparable contrary authority, because it cannot.

Many other courts, including Missouri and Massachusetts courts, have interpreted exclusions based on "arising out of" as requiring only a "simple causal relationship" between the excluded subject matter and the liability. Under this standard, the PCOH Exclusion quite clearly encompasses an opioid manufacturer's liability for ***its*** role in creating and sustaining the U.S. opioid epidemic over many years, based on ***its*** sales and marketing of opioids, which led to widespread addiction and death. In the teeth of this precedent, the Trust nakedly argues that "arising out of" should mean something much "narrower" because, it claims without any authority, an "ordinary person" would read it more narrowly. But the Trust never defines that "narrower" scope in its motion papers, and ***Mallinckrodt's own insurance professional*** [redacted]. Moreover, the Trust offers no response to the fact that Mallinckrodt's marketing campaigns, whether they mentioned Mallinckrodt branded products or not, were intentionally designed to sell Mallinckrodt-manufactured opioids. They were not public service announcements.

Accordingly, the AIG Insurers respectfully submit that this Court should enter an order denying Plaintiff's Motion for Partial Summary Judgment as unripe. If the Court determines that the applicability of the PCOH Exclusion is justiciable at this stage, it should deny the Trust's Motion for Partial Summary Judgment on the merits, and instead grant

the AIG Insurers' Cross-Motions for Summary Judgment on (1) the AIG Primary Policies, which contain PCOH Exclusions, and (2) the AIG Umbrella Policies, which contain PCOH Claims-Made Endorsements.

ARGUMENT

The Trust's Opposition does nothing to demonstrate that the question it has put before the Court is ripe. It offers no basis for the Court to conclude that the liability it asks the Court to decide is not barred by the PCOH Exclusion actually exists, nor in what amount—much less the undisputed evidence that would be required for the Court to issue the summary judgment ruling the Trust seeks. (*See* Trust's Opp. at 6-9.) In fact, the Trust ***concedes*** that the "non-Mallinckrodt opioids" liability is hypothetical by asking the Court to rule in its favor "***to the extent***" Mallinckrodt's liability is as the Trust asserts. (Mot. at 22-23 (emphasis added); *see, e.g.,* Trust's Opp. at 3, 5-6, 11.)

Even if the Trust could establish that it settled such hypothetical liability, the question of whether that liability is excluded from coverage under the PCOH Exclusion would remain hypothetical, unless and until the Trust first establishes that the liability for which it seeks indemnification falls within the terms and conditions of the coverage grant of the AIG Policies. Such terms and conditions include, for example, whether the liability was for damages "because of 'bodily injury,'" and for harm caused by an "accident"—two fundamental portions of the coverage grants that are very much disputed. *See, e.g., ACE Am. Ins. Co. v. Rite Aid Corp.*, 270 A.3d 239, 247 (Del. 2022) (governmental Opioid Lawsuits do not allege damages because of bodily injury and therefore are not covered under general liability insurance policies); *Acuity v. Masters Pharm., Inc.*, 205 N.E.3d 460,

473 (Ohio 2022) (same); *Heckadon v. Universal Underwriters Ins. Co.*, 586 S.W.3d 789, 801 (Mo. App. W.D. 2019) (intentionally deceptive business practice is not a covered accident); *Utica Mut. Ins. Co. v. Hamel*, 708 N.E.2d 145, 147 (Mass. App. Ct. 1999) (repeated, known wastewater spills are not a covered accident).

The Trust has not addressed at all whether the terms and conditions to coverage can be satisfied with respect to the hypothetical "non-Mallinckrodt opioids" liability as to which it seeks a ruling. (*See* AIG Insurers' Cross-Mot. at 17-21; *e.g.,* Ex. M, National Union Policy No. GL 509-47-72, Section I.1.a-b. at AIGINS-MNK00000812.) Instead, the Trust argues, incorrectly and somewhat irrelevantly, that "courts routinely rule on the applicability of exclusions at the summary judgment stage before coverage has been established[.]" (Trust's Opp. at 7.) The Trust cites four cases to support this point. (*See id.* (citing *Allen v. Cont'l W. Ins. Co*., 436 S.W.3d 548, 555 (Mo. banc 2014); *Manner v. Schiermeier*, 393 S.W.3d 58, 63 (Mo. banc 2013); *Doe Run Res. Corp. v. Am. Guarantee & Liab. Ins*., 531 S.W.3d 508, 510 (Mo. banc 2017); *Adams v. Certain Underwriters at Lloyd's of London*, 589 S.W.3d 15, 40 (Mo. App. E.D. 2019)).) None is apposite.

Three of the Trust's cases, *Allen*, *Doe Run*, and *Adams*, adjudicate an insurer's duty to defend, which is factually and legally distinct from the question of the duty to indemnify that is at issue here. *See Allen*, 436 S.W.3d at 552; *Doe Run Res. Corp.,* 531 S.W.3d at 510;[3] *Adams*, 589 S.W.3d at 40. Those duty-to-defend cases do not concern

[3] The Trust inaccurately describes *Doe Run* as "granting summary judgment for [an] insured on [a] pollution exclusion even though [the] nature of [the] underlying liability was disputed." (Trust's Opp. at 7.) In actuality, the Supreme Court of Missouri ***reversed*** the

indemnification for liability purportedly already sustained (as it is here, according to the Trust). *See Allen*, 436 S.W.3d at 552; *Doe Run,* 531 S.W.3d at 510; *Adams*, 589 S.W.3d at 40. When only the duty to defend is at issue, the question is whether there was a "potential" or "possibility" for coverage, which is solely based on the complaint's allegations. *Allen*, 436 S.W.3d at 552 ("The insurer's duty to defend … arises only when 'there is a potential or possible liability to pay[.]'"); *Adams*, 589 S.W.3d at 26 (same). In that context, the question is not hypothetical because the allegations—which must be taken as true for purposes of the duty to defend analysis—determine whether the terms and conditions of the coverage grant were otherwise satisfied, and the underlying allegations are proven simply by introducing the complaints. *See Allen*, 436 S.W.3d at 552; *Doe Run,* 531 S.W.3d at 510; *Adams*, 589 S.W.3d at 40. Not so here, where the Trust is seeking indemnification, and must prove the ***actual liability it incurred*** and for which it seeks indemnification, including the quantum of any such liability. *See Am. Economy Ins. Co. v. Jackson*, 476 F.3d 620, 624-25 (8th Cir. 2007); *Arch Ins. Co. v. Sunset Fin. Servs., Inc*., 475 S.W.3d 730, 733 (Mo. App. Ct. W.D. 2015).

The fourth case the Trust cites, *Manner v. Schiermeier*, 393 S.W.3d 58 (Mo. banc 2013), is inapplicable for a different reason. In *Manner*, the court did not overlook the coverage grant; rather, it ruled on both the terms of the coverage ***and*** the applicability of an "owned-vehicle" exclusion. *See id*. at 67. It could do so because, unlike here, the facts

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grant of summary judgment to the insured, and held that the insurer had no duty to defend. *See Doe Run,* 531 S.W.3d at 510.

it needed to make that ruling were not disputed. *See id*. at 60-61; *see also* Brief of Appellant, *Manner v. Schiermeier*, No. ED96143, 2011 WL 2143113, at *9 (Mo. App. E.D. Apr. 28, 2011). *Manner* is thus completely inapposite.

Recognizing it cannot demonstrate the specific question it has asked the Court to resolve is ripe, the Trust asserts the advisory ruling would "streamline the litigation," "promote settlement," and "conserve party and judicial resources," including those for "injured claimants." (Trust's Opp. at 7-8.) But a ruling that is not grounded in established facts, and especially a ruling that could have no impact at all on the possibility of insurance coverage, will do nothing to streamline the case or promote settlement. As the AIG Insurers demonstrated, were the Court to rule as the Trust asks, there would be no further clarity on whether there is coverage for any claim than if the Court had not ruled at all. (*See* AIG Insurers' Cross-Mot. at 21.)

It is the Trust's Motion that threatens to "needlessly complicate and delay this case" (Trust's Opp. at 8), not the AIG Insurers' commonsense opposition. If the Trust were truly concerned "about conserving its limited resources to compensate injured claimants and pay for opioid abatement" as it professes (Trust's Opp. at 8), it never would have brought its motion. Nonetheless, if the Court decides to reach the merits, it should grant summary judgment to the AIG Insurers on the application of the PCOH Exclusion (Part I, below), and the related PCOH Claims-Made Endorsement (Part II, below).

I. IF THE COURT REACHES THE MERITS, THE AIG INSURERS' CROSS-MOTION SHOULD BE GRANTED BECAUSE THE PCOH EXCLUSION BARS COVERAGE FOR ALL OPIOID-RELATED LIABILITY.

Nothing in the Trust's Opposition alters the conclusion that the Court must conclude that the PCOH Exclusion bars coverage under the AIG Primary Policies. The Insuring Agreement in the AIG Primary Policies provides:

> We will pay those sums that the insured becomes legally obligated to pay as damages because of "bodily injury" or "property damage" to which this insurance applies. … This insurance applies to "bodily injury" and "property damage" only if: (1) The "bodily injury" or "property damage" is caused by an "occurrence" [defined as "an accident"] that takes place in the "coverage territory"; (2) The "bodily injury" or "property damage" occurs during the policy period; and (3) Prior to the policy period, no insured [identified in the policy] knew that the "bodily injury" or "property damage" had occurred, in whole or in part.

(*E.g.*, Ex. M, National Union Policy No. GL 509-47-72, Section I.1.a-b. at AIGINS-MNK00000812; *id.*, Section V.13. at AIGINS-MNK00000826.) The AIG Primary Policies contain an identical Products-Completed Operations Hazard Exclusion that takes back or excludes a portion of that coverage, and:

> This insurance does not apply to "bodily injury" or "property damage" included within the "products-completed operations hazard."

(*Id*. at AIGINS-MNK00000836.) The term "products-competed operations hazard"

> [i]ncludes all "bodily injury" and "property damage" occurring away from premises you own or rent and ***arising out of "your product" or "your work***[.]"

(*Id.*, Section V.16.a. at AIGINS-MNK00000826 (emphasis added).) "Your Product," in turn, is broadly defined as follows:

> (1) ***Any goods or products***, other than real property, manufactured, sold, handled, distributed or disposed of by (a) You; (b) Others trading under your name; or (c) A person or organization whose business or assets you have acquired; and (2) Containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products. . . . [And] [i]ncludes: (1) ***Warranties or***

> ***representations*** made at any time with respect to the fitness, quality, durability, performance or use of "your product"; and (2) The providing of or ***failure to provide warnings*** or instructions.

(*Id*., Section V.21. at AIGINS-MNK00000827 (emphasis added).) "Your Work" is defined as:

> (1) ***Work*** or operations performed by you or on your behalf; and (2) Materials, parts or equipment furnished in connection with such work or operations. . . . [And] [i]ncludes (1) ***Warranties or representations*** made at any time with respect to the fitness, quality, durability, performance or use of "your work"; and (2) The providing of or ***failure to provide warnings*** or instructions.

(*Id*., Section V.22. at AIGINS-MNK00000827 (emphasis added).)

The operative language of the PCOH Exclusion—"'bodily injury . . . arising out of 'your product' or 'your work,'" which includes "representations" and "the failure to provide warnings" about "your product"—is clear and unambiguous, and it applies to exclude any opioid-related liability Mallinckrodt has incurred.

As a starting point, the Trust ***does not dispute*** that the following liability for bodily injury is "included within the 'products-completed operations hazard'" and thus ***excluded*** from coverage: (1) bodily injury liability resulting from marketing and sales activities that referenced Mallinckrodt's products, which resulted in harm caused by Mallinckrodt's products; and (2) liability for "unbranded" marketing that referenced opioids, such as oxycodone, but did not specifically mention the brand name (i.e., Roxicodone) of oxycodone sold by Mallinckrodt, which in turn resulted in harm caused by an opioid product manufactured by Mallinckrodt. (*See* AIG Insurers' Cross-Mot. at 26-27; *see also* Mot. at 1-4, 14-15, 17, 26, 29.) That is, Mallinckrodt does not dispute that it bought policies

that did not provide coverage for the overwhelming amount of liability it faced in the Opioid Lawsuits.

Instead, according to the Trust, the applicability of the PCOH Exclusion is in dispute ***only*** with respect to what it characterizes as liability Mallinckrodt purportedly faced from "non-Mallinckrodt opioids," which it describes as liability resulting from "unbranded" marketing—again, marketing that referenced opioids, such as oxycodone, but did not specifically mention the brand name (i.e., Roxicodone) of oxycodone sold by Mallinckrodt—and that led to harm from the use of an opioid that was not manufactured by Mallinckrodt, such as oxycodone sold by Purdue and called OxyContin. (*See* Trust's Opp. at 2-3.) In the Trust's own words:

> Mallinckrodt's liability for bodily injury due to non-Mallinckrodt products resulted from its central role in creating and fueling the nationwide opioid crisis through an unbranded promotional campaign that was not about Mallinckrodt products in particular, but rather promoted opioids as a class of drug. The campaign . . . was designed to, and did, change the medical consensus regarding the dangers and proper uses of opioids, leading in particular to massive overprescribing of all brands of opioids, including non-Mallinckrodt opioids, for long-term chronic pain, a concomitant explosion in addiction, and a dramatic increase in the use of illicit opioids.

(*Id*.)

The Trust's Motion is based on assertions about what gave rise to Mallinckrodt's liability that are false, or at the very least disputed. If, however, the Court is willing to accept the Trust's hypothetical, it can nonetheless easily conclude that all of Mallinckrodt's opioid-related liability, including the Trust's hypothetical subset of liability, is excluded from coverage under the PCOH Exclusion.

The Trust makes three arguments in opposition to the AIG Insurers' motion. First, it argues that the PCOH Exclusion is ambiguous as applied to "non-Mallinckrodt products." Second, the Trust argues that even the PCOH Exclusion bars their claims it should not be read to do so, because it would render coverage illusory. Third, the Trust argues that even if the PCOH Exclusion would bar coverage, the concurrent cause rule saves their hypothetical "non-Mallinckrodt opioids" claims. None of the Trust's arguments in opposition has merit.

A. The PCOH Exclusion Is Unambiguous And Bars Coverage, As Multiple Courts Have Held.

The Trust's position on interpreting the PCOH Exclusion can be summed up simply as "heads I win, tails you lose." According to the Trust, if the Court agrees that the PCOH Exclusion does not encompass what it calls liability from "non-Mallinckrodt opioids," as the Trust urges, then the Trust wins. But if the Court agrees with the AIG Insurers that the PCOH Exclusion bars coverage for all of Mallinckrodt's opioid-related liability as arising out of Mallinckrodt's opioid products, then the Trust still wins, because the Trust's contrary position is "reasonable," and gives rise to an ambiguity that must be construed in favor of the Trust. However, an insurance policy is "not ambiguous merely because the parties disagree over its meaning." *Trainwreck West Inc. v. Burlington Ins. Co.,* 235 S.W.3d 33, 40 (Mo. App. E.D. 2007). Many courts have applied the PCOH exclusion, including to these very Opioid Lawsuits, finding they unambiguously barred even the possibility of coverage for those lawsuits. Many other courts have interpreted the operative phrase, "arising out of," without difficulty concluding it could be interpreted and applied in a way

that would clearly encompass the Trust's claims. Moreover, the Trust does not provide any defined, alternative reading of the PCOH Exclusion, opting instead to argue that it must be read more narrowly in generalities and hypothetical scenarios that fall flat.

As the AIG Insurers established in their Cross-Motion, ***multiple courts*** have held that PCOH exclusions substantially identical to the PCOH Exclusion in the AIG Primary Policies unambiguously bar coverage for the Opioid Lawsuits, including some of the same Opioid Lawsuits naming Mallinckrodt. (AIG Insurers' Cross-Mot. at 28-32.) In *Traveler's Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026, 1040-41 (2017), the California Court of Appeals held that the PCOH exclusion applied as a matter of law to all of the alleged liability, because "'[a]ll of the harm that is asserted in the [Opioid] [L]awsuits—narcotics addiction, the public nuisance in the California action and the public health costs, etc. highlighted in the Chicago [Opioid Lawsuit]—stem from [Actavis affiliate] Watson's products and what Watson said and did not say about the products." *Id.* at 1044; *see also Zogenix, Inc. v. Fed. Ins. Co.*, 4:20-cv-06578-YGR, 2022 WL 3908529, at *9 (N.D. Cal. May 26, 2022) (following *Actavis* and holding that the PCOH exclusion precluded coverage for claims in the Opioid Lawsuits of intentional misrepresentation by an opioids manufacturer); *Sentynl Therapeutics*, *Inc. v. U.S. Specialty Ins. Co.*, 527 F. Supp. 3d 1203, 1209 (S.D. Cal. 2021), *aff'd* No. 21-55370, 2022 WL 706941 (9th Cir. Mar. 9, 2022); *Travelers Prop. Cas. Co. of Am. v. Anda, Inc.*, 658 F. App'x 955, 958-59 (11th Cir. 2016).

The Trust makes two extremely weak arguments to try to distinguish *Actavis*. First, the Trust argues that because the *Actavis* court held there was no coverage under liability

policies for an additional reason—that the Opioid Lawsuits do not allege an accident—this Court can discount the additional holding that the PCOH exclusion applies. (Trust's Opp. at 19.) This argument is illogical, because the issues are not related in any way that would suggest a reason to link them. Second, the Trust argues that *Actavis* is distinguishable because it "failed to address … that the unbranded promotional campaign promoted the use of all opioids generally and never mentioned the insured or its products[.]" (Trust's Opp. at 21.) This is simply false. The *Actavis* court described in detail the marketing campaign involving Watson, the insured there, and the "other defendants," among which were Mallinckrodt, to "persuade[] doctors and patients" that opioids as a class of drugs were safe to use for chronic pain and not as addictive as the drug companies knew it was—exactly the unbranded marketing at issue here. 16 Cal. App. 5th at 1033-34. That is, the unbranded marketing campaign that the Trust alleges is outside the "products-completed operations hazard" is the same unbranded marketing campaign at issue in *Actavis*. *Actavis* is directly on point.

So too are several other opinions reaching the same conclusion. *See Anda, Inc.*, 658 F. App'x at 956-59; *Zogenix*, 2022 WL 3908529, at *9; *Sentynl Therapeutics*, *Inc.*, 527 F. Supp. 3d at 1209. In *Anda*, the Eleventh Circuit held that the PCOH exclusion precluded coverage for claims concerning the insured distributor's overdistribution of opioids that "flooded the market" and led to an "opioid epidemic." 658 F. App'x at 956-59. In *Zogenix*, the Northern District of California held that the PCOH exclusion precluded coverage for Opioid Lawsuits (at least one of which named Mallinckrodt as a co-defendant) asserting that the insured opioid manufacturer's intentional misrepresentations in its marketing of

opioids, including unbranded marketing activities, led to an "opioid epidemic" in the United States. 2022 WL 3908529, at *9. (*See* Ex. 21, Plaintiff's Original Petition and Jury Trial Demand (Excerpted) ¶¶ 1, 19, 115, 141-180, *County of Walker v. Abbott Labs., et al.,* No. 4:19-cv-01767 (S.D. Tex. May 14, 2019), *transferred to MDL In Re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio).) In *Sentynl*, the Southern District of California held, and the Ninth Circuit affirmed, that the PCOH exclusion precluded coverage for liability relating to a government investigation into the insured's "marketing practices tied to the known dangers of opioids." 527 F. Supp. 3d at 1209.

Further, numerous courts, including Missouri and Massachusetts[4] courts, have held that "arising out of"—the operative phrase in the PCOH Exclusion—is "'a very broad, general and comprehensive phrase' meaning 'originating from' or 'having its origins in' or 'growing out of' or 'flowing from.'" *Capitol Indem. Corp. v. 1405 Assocs., Inc.,* 340 F.3d 547, 550 (8th Cir. 2003) (applying Missouri law). (*See* AIG Insurers' Cross-Mot. at 23-26 (citing cases).) These courts have easily applied the phrase in exclusions to bar coverage where appropriate. *See Capitol Indem. Corp. v. Callis*, 963 S.W.2d 247, 248-50 (Mo. App. W.D. 1997) (exclusion for injury "arising out of assault, battery or assault and battery" barred coverage); *1405 Assocs., Inc*., 340 F.3d at 550 (exclusion for injury "arising out of" "termination" barred coverage); *Columbia Mut. Ins. Co. v. Schauf*, 967 S.W.2d 74, 78-81 (Mo. Banc 1998) (exclusion for property damage "arising out of" insured's "operations"

[4] The Trust does not dispute that certain policies at issue were issued to Massachusetts-based insured, Tyco Healthcare Group LP, or that Massachusetts law governs such policies. (*See* AIG Insurers' Cross-Mot. at 24 n.9.) Accordingly, the AIG Insurers continue to cite both Missouri and Massachusetts law.

barred coverage); *Cincinnati Ins. Co. v. Intek Corp*., No, 4:08cv1440 JCH, 2010 WL 716197, at *4 (E.D. Mo. Feb. 24, 2010) (PCOH exclusion precluded coverage for liability arising out of malfunctioning warming plate); *Scottsdale Ins. Co. v. Aqueous Vapor, LLC*, No. 4:20-00328-CV-RK, 2021 WL 123401 (W.D. Mo. Jan. 12, 2021) (PCOH exclusion precluded coverage for injuries arising out of exploding e-cigarette); *Finn v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pa.*, 896 N.E.2d 1272, 1278 (Mass. 2008) (exclusion for "any claim arising out of any misappropriation of trade secret" barred coverage); *Kinsella v. Wyman Charter Corp*., 417 F. Supp. 2d 159, 164 (D. Mass. 2006) (exclusion for "'bodily injury' . . . arising out of the ownership, maintenance, use or entrustment to others of any . . . watercraft" barred coverage); *Brazas Sporting Arms, Inc. v. Am. Empire Surplus Lines Ins. Co*., 59 F. Supp. 2d 223 (D. Mass. 1999), *aff'd* 220 F.3d 1 (1st Cir. 2000) (PCOH exclusion barred coverage for gun manufacturers' liability concerning the overproduction of firearms); *Cytosol Labs., Inc. v. Fed. Ins. Co*., 536 F. Supp. 2d 80 (D. Mass. 2008) (PCOH exclusion barred coverage for pharmaceutical manufacturer's liability concerning toxins in ophthalmic solution).

None of these courts suggested that the phrase "arising out of" swept so broadly as to make the exclusion ambiguous. Notably, the Trust's responses to these "arising out of" cases, which unpersuasively seek to distinguish their facts, are buried in footnotes (Trust's Opp. at 18 n.7, 20 n.10, 23 n.11.), a telltale sign that, in fact, the cases cannot be reconciled with the Trust's arguments.

Despite the settled law and clear terms of the PCOH Exclusion, the Trust argues that the phrase "arising out of" must be read more narrowly than the plain language or case

law would otherwise dictate. (*See* Trust's Opp. at 16-17.) However, the Trust never offers an alternative, narrower definition, and does not present any case law that contradicts the plethora of cases holding that the phrase should be interpreted broadly.

The only case the Trust cites in support of its proposed "narrow construction" of the PCOH exclusion, *Schauf*, 967 S.W.2d at 78-81, holds exactly the opposite. In *Schauf*, the Missouri Supreme Court considered an appeal of the grant of summary judgment to the insurer on the duty to indemnify. The underlying claim concerned damages to real property resulting from a fire that began when the insured was cleaning paint sprayer equipment. *Id*. at 76. The exclusion provided: "This insurance does not apply to 'property damage' to that particular part of real property on which you or any contractor or subcontractor working directly or indirectly on your behalf is performing operations, ***if the 'property damage' arises out of those operations***." *Id*. at 76-77 (emphasis added). The insured argued that the exclusion did not apply because he was cleaning his equipment at the time of the damages, not "performing operations," so they did not "arise out of" "operations." The court disagreed and held that the exclusion applied, as the "narrow construction" of the exclusion urged by the insured "disregards the fact that the object of his cleaning was to advance his work of painting the . . . house." *Id*. at 79. The court thus took an expansive view of the phrase "arises out of" and ruled that the damages resulting from cleaning equipment still arose out of the operations within the meaning of the exclusion. *Id*.

Nonetheless, the Trust argues that an "ordinary person of average understanding" would understand that the PCOH exclusion does not apply here, because, "[a] person whose son or daughter died of a heroin overdose would say that they died of heroin, not a

Mallinckrodt product." (Trust's Opp. at 3; *see also id.* at 4, 10, 13, 15.) This is a misdirection—and one shamelessly deployed at the expense of victims of Mallinckrodt's wrongful conduct. First of all, Mallinckrodt's bankruptcy plan is clear that a claim made by or on behalf of an individual will only lead to a recovery from the Trust if it can be shown that ***the individual actually used a Mallinckrodt product***. (*See* Ex. 22, Twentieth Plan Supplement (Excerpted), Mallinckrodt Opioid Personal Injury Trust Distribution Procedures for Non-NAS PI Claims, Art. 4.2, 5.2 at 5, 10-13, *In re Mallinckrodt plc, et al.*, No. 20-12522 (Bankr. D. Del. June 22, 2022) ECF No. 7684 (requiring personal injury claimants to "[d]emonstrate usage of one of the qualifying prescribed opioids listed in section 5.2(a)," which lists certain of Mallinckrodt's opioid products).) Even the Trust concedes such a claim would be barred by the PCOH Exclusion. (*See* Mot. at 1-3, 14-15, 17, 26, 29.)

Moreover, if Mallinckrodt otherwise incurred legal liability for heroin overdoses, that is because Mallinckrodt's "product" was a contributing factor to those deaths. For example, as many plaintiffs allege, and as has been widely reported, the rise in heroin use is a direct result of—that is, arises out of—addiction that begins with the use of prescription opioids, like Mallinckrodt's. (*E.g.*, Ex. D, Georgia Compl. ¶ 238 (alleging that there is a "well-established relationship between the use of prescription opiates and the use of non-prescription opioids – like heroin and illicit … fentanyl[.]"); Ex. C, St. Charles Compl. ¶ 615 ("Individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high.").)

Equally fatal to the Trust's argument is that the record demonstrates that an "ordinary person"—in fact, people whose job was to protect Mallinckrodt by buying insurance—concluded quite readily that [redacted]. Correspondence between Mark Huddleston, Mallinckrodt's Risk Manager, and Kenneth Boland, Senior Vice President of Claims at Marsh, the broker that helped Mallinckrodt purchase the policies at issue, agreed that [redacted]. (*See* Ex. 19, Email Correspondence, at MNK_INS_011072711-14.) They discussed that the [redacted] and agreed it would make sense to [redacted]. (*See id*.) Mallinckrodt's response to this devastating evidence is to backtrack on its "ordinary person" approach and argue (in a footnote) that "the Court must determine the scope of coverage based on the terms of the policies themselves." (Trust's Opp. at 12 n.6.)

The bankruptcy proceedings further demonstrate that Mallinckrodt's opioid-related liability was for harms arising out of its products. Mallinckrodt represented that it was "dragged into an all-consuming tidal wave of litigation ***concerning the production and sales of its opioid products***." (Ex. A, Welch Dec. ¶ 76 (emphasis added).) Mallinckrodt also represented that it was "named in over 3,000 lawsuits ***stemming from the Debtors' production and sale of opioid medications***." (*Id*. ¶ 12 (emphasis added).) Relying on that sworn testimony, the bankruptcy court likewise found that, "[i]n the years leading up to the commencement of these bankruptcy cases, Debtors faced an onslaught of litigation ***arising***

out of their production of certain drugs." (Ex. 13, Confirmation Opinion (Excerpted) at 2 (emphasis added).) The Trust's response to this record is to ignore it.

Finally, recognizing that the phrase "arising out of" would encompass its hypothetical liability from "non-Mallinckrodt opioids," the Trust attempts to read the phrase out of the exclusion. The policies provide: "This insurance does not apply to 'bodily injury' or 'property damage' included within the 'products-completed operations hazard,'" and then define that hazard as "'bodily injury' and 'property damage' occurring away from premises you own or rent and arising out of 'your product' or 'your work[.]'" In what can only be described as hopelessly tortured logic, the Trust argues that the phrase "included within" narrows the scope of the phrase "arising out of," even though the liability that is "included within" the products-completed operations hazard is broadly "bodily injury . . . arising out of 'your product' or 'your work.'" (*See* Trust's Opp. at 3, 5, 11, 18.) The language is crystal clear that the liability that is "included within" is as broad as bodily injury that "aris[es] out of" Mallinckrodt's products and work.

B. Applying The PCOH Exclusion Here Does Not Mean Coverage Is "Illusory."

The Trust also asks the Court to ignore the PCOH Exclusion under the theory that it would render coverage illusory. The Trust asserts that the AIG Insurers' view of the PCOH Exclusion "would encompass any act by Mallinckrodt, as everything Mallinckrodt did was in service of its business manufacturing and selling products and would not have been done 'but for' that business." (Trust's Opp. at 12.) The Trust argues that the AIG Insurers' interpretation of the PCOH Exclusion would sweep in "pollution claims" and

sales force car accidents. (*Id.* at 14.) Thus, according to the Trust, "AIG's reading of [the PCOH Exclusion] is so broad that it would render coverage under the policy illusory, because any liability of a product manufacturer like Mallinckrodt would not exist 'but for' its business manufacturing and selling products." (Trust's Opp. at 4; *see also id.* at 12-14.)

As an initial matter, the Trust cannot seriously contend that the AIG Insurers' view of the PCOH Exclusion means coverage is illusory when the Trust itself has conceded that the vast majority of its opioid-related liability is subject to the PCOH Exclusion. The parties agree that the AIG Policies do not cover liability concerning Mallinckrodt's "branded" marketing activities, regardless of the opioid ultimately consumed in any given instance. (*See* Mot. at 1-4.) They also agree that the AIG Insurers' policies do not cover liability concerning "unbranded" marketing activities that led to harms from the use of Mallinckrodt's opioids. (*See id*. at 7, 14-15, 17, 26, 29.) What remains in dispute is only the third theory of liability concerning unbranded marketing and non-Mallinckrodt products. In other words, the parties' disagreement is at the margins.

The Trust's argument also rests on a blatant mischaracterization of the AIG Insurers' position. The AIG Insurers have never argued that "but for" causation, however remote the causal connection, satisfies the "arising out of" standard. (*See* AIG Insurers' Cross-Mot. at 23-26.) Rather, "'arising out of' may be established by a 'simple causal relationship . . . between the accident or injury and the activity of the insured.'" *1405 Assocs., Inc.,* 340 F.3d at 550; *see also Hunt v. Capitol Indem. Corp*., 26 S.W.3d 341, 345 (Mo. App. E.D. 2000); *Brazas*, 220 F.3d at 7. To be sure, the Trust's construct of hypothetical liability for "unbranded" marketing that somehow also had no connection to

Mallinckrodt's business as a seller of opioids is entirely fanciful. (*See* Trust's Opp. at 14-15 (citing AIG Insurers' Cross-Mot. at 12, 27).) Regardless, the AIG Insurers have been crystal clear that if that liability exists, it is encompassed within the PCOH Exclusion because "arising out of" Mallinckrodt's product means "'originating from' or 'having its origins in' or 'growing out of' or 'flowing from'" its opioid products. *1405 Assocs., Inc.,* 340 F.3d at 550.

Critically, this is not a case that requires the Court to draw a fine line between what does and what does not fall within the ambit of the PCOH Exclusion. The liability Mallinckrodt incurred as a result of the Opioid Lawsuits, and that drove it into bankruptcy, unquestionably arose out of its conduct in flooding the market with its own opioids over more than two decades, which oversupply Mallinckrodt knew—because it was apparent to every American—was fueling an opioid epidemic of addiction and death. And one way Mallinckrodt was able to sell so many opioids over such a long period of time was by misleading physicians and the public about the dangers of its opioid products, including through marketing that sometimes hid the fact that Mallinckrodt and other drug manufacturers were funding it (the Trust's "unbranded marketing"). Mallinckrodt was not driven out of business because its opioid sales people got into automobile accidents.

C. The "Concurrent Cause" Rule Has No Application Here.

As a last-ditch effort, the Trust asserts that Mallinckrodt was liable "because of bodily injury arising out of both covered (non-Mallinckrodt products) and excluded (Mallinckrodt products) causes," and thus the AIG Insurers' Policies must respond to the liability at issue under the "concurrent cause rule." (Trust's Opp. at 23-24.) This is a red

herring, because, assuming Mallinckrodt's liability is because of bodily injury as the Trust hypothesizes, it is because of bodily injury "arising from" Mallinckrodt's products and misrepresentations about its products.

As the Supreme Court of Missouri articulated in *Taylor*, a case the Trust cites, "'the concurrent proximate cause' rule … states that 'an insurance policy will be construed to provide coverage where an injury was proximately caused by two events—even if one of these events was subject to an exclusion clause—if the differing allegations of causation are independent and distinct." *Taylor v. Bar Plan Mut. Ins. Co*., 457 S.W.3d 340, 347 (Mo. banc 2015). For an insured to get the benefit of the rule, it must "point to a cause, such as negligent supervision or hiring, that is covered under the policy and is wholly separate from the excluded cause." *Id*. at 347-48. Where there is no "readily identifiable independent cause of the injury"—as was the case the only time the Supreme Court of Missouri has had occasion to consider this rule in a coverage case—the rule does not apply. *Id*. (exclusion in professional liability policy precluded coverage for malpractice lawsuit concerning self-interested transactions). In short, there must be an excluded risk and a risk not subject to an exclusion, which constitute concurrent proximate causes for the insured's liability, for the rule to have any applicability. *Braxton v. U.S. Fire Ins. Co*., 651 S.W.2d 616, 619 (Mo. App. E.D. 1983).

Here, ***all*** of the insured's liability-causing activities—misconduct concerning the marketing and sale of Mallinckrodt's opioids—are clearly encompassed within the exclusion, and there is no separate, intervening risk. (*See supra* at Section I.A.) Mallinckrodt's marketing of opioids, whether branded or unbranded, can in no way be

labeled "independent and distinct" from its opioid products. The concurrent cause rule does not apply.

D. The Liability At Issue Also "Arises Out Of" Mallinckrodt's "Work."

The PCOH Exclusion separately precludes coverage for injuries "arising out of" "***your work***," meaning "work or operations performed by [Mallinckrodt]" as well as "[w]arranties or representations made at any time with respect to the fitness, quality, durability, performance or use of 'your work" and the "providing of or failure to provide warnings or instructions." (Ex. M, National Union Policy No. GL 509-47-72, Section V.16, V.22 at AIGINS-MNK00000826-27 (emphasis added).) This provision also bars coverage for Mallinckrodt's opioid-related liability.

The Trust asserts, and the AIG Insurers do not disagree, that "your work" means "'(1) Work or operations performed by you or on your behalf; and (2) Materials, parts or equipment furnished in connection with such work or operations." (Trust's Opp. at 25; Ex. M, National Union Policy No. GL 509-47-72, Section V.22. at AIGINS-MNK00000827).) Essentially, "your work" is defined as "work" or several other items. "Work" is not further defined. In such cases, the "plain meaning" of the word applies, and the plain meaning of "work," as its commonly understood, would include a business's marketing activities. *See Hawkeye-Security Ins. Co. v. Davis*, 6 S.W.3d 419, 424 (Mo. App. S.D. 1999) (affirming summary judgment for the insurer on duties to defend and indemnify).

The Trust responds that the "your work" portion of the PCOH Exclusion does not apply because "'your work' applies only to services Mallinckrodt has sold." (Trust's Opp. at 25-26.) But that is not what the PCOH Exclusion says, and the cases the Trust cites in

support adjudicate entirely unrelated issues. *See City of Park Ridge v. Clarendon Am. Ins. Co*., 90 N.E.3d 479, 484 (Ill. App. Ct. 2017) (failure of paramedics to treat unresponsive child was not within "products-completed operations hazard" under Illinois law); *Liberty Mut. Ins. Co. v. Triangle Indus., Inc*., 957 F.2d 1153, 1158 (4th Cir. 1992) (environmental damages from "toxic sludge" were not a "product hazard" or "completed operations hazard" under New Jersey law); *Visteon Corp. v. National Union Fire Ins. Co. of Pittsburgh, Pa*., 777 F.3d 415 (7th Cir. 2015) (environmental damages from leakage of toxic solvent into soil was not "completed operations hazard" under Michigan law); *Baker v. Nat'l Interstate Ins. Co*., 180 Cal. App. 4th 1319, 1340 (2009) (negligent inspection of a bus was "work" within meaning of "products-completed operations hazard exclusion").

Missouri courts have not had occasion to consider whether a business's marketing activities are a part of the undefined policy term "work." Based on its plain meaning, the Court should conclude that liability concerning marketing misconduct "originat[es] from," "ha[s] its origins in," "grow[s] out of," or "flow[s] from" Mallinckrodt's "work." *1405 Assocs., Inc.,* 340 F.3d at 550; *Colony Ins. Co. v. Pinewoods Enters., Inc.*, 29 F. Supp. 2d 1079, 1083 (E.D. Mo. 1998); *Brazas*, 220 F.3d at 6. Accordingly, Mallinckrodt's opioid-related liability, including the Trust's hypothetical theory of liability for bodily injury arising out on "non-Mallinckrodt opioids" as a result of "unbranded marketing," also "arises out of" Mallinckrodt's "work"—its marketing.

II. THE AIG INSURERS' CROSS-MOTION ON THE PCOH CLAIMS-MADE ENDORSEMENT SHOULD BE GRANTED FOR THE SAME REASONS.

The AIG Insurers also are entitled to summary judgment on the eight AIG Umbrella Policies that contain a PCOH Claims-Made Endorsement. By virtue of the endorsement, the policies ***provide coverage*** for claims within the definition of the products-completed operations hazard, ***but only on a claims-made and reported basis***—that is, only if ***during the policy period***, (1) a claim was first made against Mallinckrodt, and (2) written notice of the claim was provided by Mallinckrodt to National Union or American Home.

The AIG Insurers have established that the liability at issue here falls within the scope of the products-completed operations hazard, which is defined the same way as in the AIG Primary Policies, and that none of the underlying claims were made against Mallinckrodt during the policy periods, nor did Mallinckrodt provide notice of any such claims during the policy periods. (*See* AIG Insurers' Cross-Mot. at 35-36 (citing Amended Petition, ¶ 3; Ex. 9, National Union Policy No. 15972632; Ex. 20, Affidavit of Lowell J. Chase; Ex. 10, Email Correspondence regarding Notice, at AIGINS-MNK00003257 – 3258).)

The Trust does not dispute—and in fact agrees—that the PCOH Claims-Made Endorsement provides only claims-made coverage for liability falling within the scope of the products-completed operations hazard. (Trust's Opp. at 27.) The Trust also does not dispute that no such claims were made during the policy periods of the AIG Umbrella Policies. (*See id*.)

The Trust takes issue only with the applicability of the PCOH Claims-Made Endorsement in the first place, contending that "the bodily injury at issue is not within the products hazard for the reasons detailed above, and so the claims-made requirements" of the endorsement are "irrelevant." (*Id*.) For the reasons discussed herein, the Trust is incorrect. All of the liability concerning injuries originating from "unbranded marketing" —including those following the use of "non-Mallinckrodt products"—falls within the products-completed operations hazard, and thus is subject to the PCOH Claims-Made Endorsements under the AIG Umbrella Policies.

CONCLUSION

For the foregoing reasons, the AIG Insurers respectfully request that this Court enter an order denying Plaintiff's Motion as unripe; alternatively, the AIG Insurers respectfully request that the Court enter an order denying Plaintiff's Motion and granting the AIG Insurers' Cross-Motion on the AIG Primary Policies. Separately, the AIG Insurers respectfully request that this Court enter an order granting the AIG Insurers' Cross-Motion on the AIG Umbrella Policies.

Dated: November 4, 2024
St. Louis, MO

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2024, the foregoing was electronically filed with the Clerk of the St. Louis County Circuit Court by operation of the Court's electronic filing system with copies served upon all counsel of record and sent via email to the following:

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EXHIBIT 21

1929076

Cause No._____

County of Walker Plaintiff,	§	In the District Court
v.	§	of Walker County, Texas
	§	Walker County - 12th District Court
Abbott Laboratories; Abbott Laboratories, Inc.; Abbvie Inc.; Actavis LLC; Actavis, Inc. f/k/a Watson; Actavis Elizabeth LLC; Actavis Pharma, Inc.; Advanced Pharma, Inc., d/b/a/ Avella of Houston; Allergan Finance LLC f/k/a Actavis, Inc. a/k/a Watson Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLC; Alpharma Pharmaceuticals Inc; Alpharma Pharmacecuticals LLC; AmerisourceBergen Drug Corporation; Apotex Inc., Aveva Drug Delivery Systems, Inc.; Apotex Inc.; Cardinal Health, Inc.; Caremark Rx, L.L.C.; CaremarkPCS Health, LLC; Caremark LLC; Caremark PCS LLC; Cephalon, Inc.; CuraScript SV Specialty Distribution, LLC; CuraScript, Inc; CVS Caremark Corporation; CVS Health Corporation; CVS Pharmacy, Inc.; Depomed, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Express Scripts Holding Company; Express Scripts, Inc.; Fresenius USA Manufacturing, Inc.; Fresenius Kabi USA; HD Smith Drug Co.; ICU Medical Sales Inc.; ICU Medical Inc.; Impax Laboratories, Inc.; Insys Therapeutics, Inc.; Insys Manufacturing, LLC; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc.; JM Smith Corporation; Johnson & Johnson;	§	_____ Judicial District

Filed: 1/11/2019 4:59 PM
Robyn M. Flowers
District Clerk
Walker County, Texas

Brandy Roberson

Knoll Pharmaceutical Company;	§
Mallinckrodt PLC; Mallinckrodt	§
LLC; Mallinckrodt Pharmaceuticals;	§
Mallinckrodt Inc.; Mckesson	§
Corporation; McKesson	§
Medical-Surgical, Inc.; Medco	§
Health Solutions of Texas, LLC;	§
Mission Pharmacal Company;	§
Mylan, Inc.; Mylan Specialty, LP;	§
Mylan Pharms Inc.; Mylan	§
Pharmaceuticals, Inc.; Mylan	§
Technologies Inc.; Navitus	§
Management, LLC; Navitus	§
Holdings, LLC; Navitus Health	§
Solutions, LLC; Neos Therapeutics	§
Inc.; Nesher Pharmaceuticals USA	§
LLC; NexGen Pharma, Inc.; Noven	§
Pharmaceuticals, Inc.; OptumRx,	§
Inc.; OptumRX Administrative	§
Services, LLC; Optum, Inc.;	§
Ortho-Mcneil-Janssen	§
Pharmaceuticals, Inc. n/k/a Janssen	§
Pharmaceuticals, Inc.;	§
Paddock Laboratories, LLC;	§
Par Pharmaceuticals, Inc.;	§
Perrigo Company; Prime	§
Therapeutics LLC; Purdue	§
Pharma, Inc.; Purdue Pharma, L.P.;	§
Purdue Pharmaceuticals, L.P.;	§
QS/1Data Systems of JM Smith	§
Corporation; Teva Pharmaceutical	§
Industries, Ltd.; Teva	§
Pharmaceuticals USA, Inc.; The	§
Purdue Frederick Company;	§
UnitedHealthcare of Texas, Inc.;	§
UnitedHealth Group Incorporated;	§
Watson Laboratories, Inc.; Zogenix,	§
Inc.; and Zydus Pharmaceuticals	§
USA Inc.,	§
Defendants.	§

Contents

Plaintiff's Original Petition and Jury Trial Demand

Plaintiff, the County of Walker, Texas, ("Walker County" or "County"), by and through the undersigned attorneys and against Defendants, alleges as follows:

Introduction

The Staggering Impact of the Opioid Epidemic

1. The United States is in the midst of an opioid epidemic caused by Defendants' fraudulent marketing, distribution, and sales of prescription opioids ("opioids"). This epidemic has resulted in: rampant addiction rates and the tragic loss of hundreds of thousands of lives; soaring costs for medical care, including huge burdens on the Medicare system; increased criminal activity leading to an exponential increase in the costs of policing; increasing rates of incarceration; and an increase in unemployment resulting in tax revenue losses.

2. The rampant distribution and use of opioids is killing tens of thousands of Americans every year. According to the US Department of Health and Human Services, drug overdose is now the leading cause of death among people under 50 years of age. Per the Centers for Disease Control and Prevention (the "CDC"), more than 90 Americans die each day from opioid overdose. Indeed, for the year 2016 alone, Americans suffered more than 600,000 drug overdoses and more than 63,000 drug-related deaths, with more than 66 percent of them—42,249 deaths—involving opioids. This 2016 opioid-related death rate represents a 27.9% increase over 2015. Furthermore, deaths from the opioid drug fentanyl doubled for that same period.

3. In addition to killing many thousands of people, Defendants' marketing, distribution, and sales of opioids is causing additional public health crises. For example,

hepatitis C virus ("HCV") rates have increased almost 300 percent (including in infants exposed to hepatitis C), and there have been similar increases in the hepatitis B virus ("HBV"), HIV, endocarditis, septic arthritis, epidural abscess, and osteomyelitis. Additionally, more than two newborns per hour in the U.S. are diagnosed with opioid withdrawal, known as neonatal abstinence syndrome (NAS).

4. The financial impact of the opioid crisis has been no less staggering: from 2001 to 2017, the cost of the opioid crisis in the United States exceeded $1 trillion, and it is estimated to cost an additional $500 billion by 2020.

5. President Donald Trump, on October 26, 2017, declared the opioid crisis a "nationwide public health emergency."

6. Unlike many other public health epidemics, the opioid crisis was entirely avoidable. The opioid crisis is not like influenza, HIV-AIDS, or a natural disaster like a hurricane or earthquake. Instead, the opioid epidemic is a public health crisis caused by corporate greed: the makers, distributors, and sellers of opioids caused America to become awash in these highly-addictive pills so that these corporations could make billions of dollars in profits.

The Cause of the Opioid Epidemic

7. Beginning in the late 20th century and continuing to the present, Defendants flooded the market with prescription opioids, causing massive harm to public health. As described in more detail below, Defendants accomplished this expansion in three primary ways. First, pharmaceutical manufacturers ("Manufacturing Defendants," as defined below) misled the public (including prescribing physicians) into believing that opioids were safer, more effective, and less likely to form an addiction than they really were. Second, the pharmacy benefit managers ("PBM Defendants," as defined below) accepted

payments from the Manufacturing Defendants and ensured that opioids were widely available, regularly prescribed, and quickly reimbursed. Third, the Manufacturing Defendants, pharmaceutical distributors ("Distributor Defendants," as defined below), and pharmacies ("Pharmacy Defendants," as defined below) each failed to take action in response to clear evidence that opioids were being distributed and used in an unlawful manner.

8. What makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. In other words, Defendants deceptively and unfairly targeted a vulnerable patient base that—physically and psychologically—could not turn away from their drugs.

9. Defendants' marketing efforts were both ubiquitous and persuasive. Their deceptive messages tainted virtually every source of information that doctors could rely on to make informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess Defendants' misleading statements. Among other things, Defendants literally wrote the book on how to prescribe opioids by controlling the treatment guidelines for these drugs. Defendants callously manipulated what doctors wanted to believe—namely, that opioids represented a compassionate means of relieving their patients' real suffering. And to further enhance this emotional plea, Defendants marketed similar deceptive messages directly to patients so that they would go to physicians demanding these "miracle" drugs.

10. This nefarious conduct resulted in a sharp increase in the number of prescriptions for opioids. More than 250 million opioid prescriptions were issued in 2012 alone, almost enough prescriptions for every adult in the United States to be prescribed a bottle of pills. From 1999 to 2008, sales of prescription opioids increased by 400 percent nationally. During that same time, overdose deaths caused by prescription opioids and hospital admissions for opioid abuse also increased 400 percent. Even heroin abuse during this same time period was largely driven by prescription opioid sales, with 4 out of 5 heroin users reporting that their heroin addiction began with the abuse of prescription painkillers.

11. Children have not escaped the scourge of prescription opioid and heroin addiction. By 2015, 122,000 people under the age of 18 were addicted to prescription opioids, with an additional 21,000 driven to heroin use.

The Impact of the Opioid Epidemic on Walker County

12. Walker County has suffered considerable damages from the opioid epidemic in the past and will continue to suffer damages in the future. Data from the CDC shows that for the year 2015, Walker County residents received far more opioids per person (601 morphine mg equivalents "MME") than the Texas statewide average (420.63 MME). Furthermore, Walker County also had higher than the Texas and national averages for the number of opioid pills prescribed per month per Medicare Part D enrollee. Each Medicare Part D enrollee in Walker County was prescribed 2.09 months-worth of opioids for every 30-day period (in short, two times the number of pills that would have been reasonable for even a legitimate patient). The same CDC data showed that for the year 2016, the number of opioid drug deaths per 100,000 persons in Walker County's Congressional District 8 was 0.7% higher than an already grossly inflated state average. Indeed, there were 583

opioid drug-related deaths in District 8 in 2016, representing more than one-fifth of the total number of opioid drug-related deaths for all of Texas.

13. The CDC reports that the Walker County opioid mortality rate more than quadrupled from 2000 to 2016. These drug-related deaths grew steadily from 2–3.9 per 1,000 people in 1999 to 8–9.9 per 1,000 people in 2016.

14. Every Walker County purchaser of private health insurance paid higher premiums, co-payments, and deductibles because of Defendants' actions. Insurance companies pass onto their insureds the expected cost of future care—including opioid-related coverage. Accordingly, insurance companies factored in the unwarranted and exorbitant healthcare costs of opioid-related coverage caused by Defendants and charged that back to insureds in the form of higher premiums, deductibles, and co-payments.

Rule 47 Statement of Monetary Relief Sought

15. Pursuant to Texas Rule of Civil Procedure No. 47, Plaintiff states that it seeks monetary relief over $1,000,000.

Venue and Jurisdiction

16. This Court has personal jurisdiction over these Defendants because they carry on a continuous and systematic part of their business within Texas, have transacted substantial business with Texas entities and residents, and have caused harm in Texas as a result. Each of the non-resident Defendants has done business in the state, has purposefully availed itself of the privileges of conducting business within Texas, and/or has sufficient minimum contacts with the State of Texas generally and Walker County specifically to render it subject to the Court's jurisdiction.

17. Plaintiff specifically alleges that the claims and causes of action set forth in this petition are entirely based on the provisions of Texas law. Plaintiff specifically disclaims any cause of action based on federal law and does not seek any relief on the basis of federal law or any violation thereof. There is no claim of fraud on the federal Food and Drug Administration. One or more of the Defendants named herein is a resident of the State of Texas, so there is not complete diversity among the parties.

Discovery Control Plan

18. Plaintiff, Walker County, designates this case as a Level 3 case requiring a discovery control plan tailored to the circumstances of this specific suit.

Parties

a. Plaintiff

19. This action is brought for and on behalf of Walker County, Texas, which provides a wide range of services on behalf of its residents, including services for families and children, public health, emergency care, public assistance, law enforcement, and social services, as well as medical and prescription benefits that the County provides to its employees and retirees.

b. Defendants

20. Each of the parties named below manufactures, promotes, sells, and/or distributes opioids in Texas and in Walker County.

Manufacturing Defendants

21. The Defendants identified in paragraphs 22 to 48 shall be referred to herein as "Manufacturing Defendants."

22. Abbott Laboratories is a corporation organized under the laws of Illinois with its principle place of business in Abbott Park, Illinois. Abbott Laboratories, Inc. is an Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively "Abbott"). Both Abbott Laboratories and Abbott Laboratories, Inc. may be served through their registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

23. Abbvie Inc. ("Abbvie") is a Delaware corporation with its principal place of business in North Chicago, Illinois, and may be served through its registered agent for service of process, CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604. Knoll Pharmaceutical Company ("Knoll") has been a wholly-owned subsidiary of Abbvie from January 1, 2013. Knoll Pharmaceutical Company is a New Jersey corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 208 S. LaSalle Street, Suite 814, Chicago, IL 60604.

24. Knoll irresponsibly marketed narcotics, such as Vicodin, through whimsical toys and souvenirs and did so to boost the sales of opioids. Taking advantage of the fact that Vicodin was not regulated as a Schedule II controlled substance for many years, and the fact that physicians and consumers did not fully appreciate the highly addictive nature of Vicodin, Knoll advertised Vicodin with tag lines such as "The Highest Potency Pain Relief You Can Still Phone In." This tag line came as part and parcel of souvenirs like a "Vicodin" fanny pack and water bottle, both bearing the name of Vicodin, the opioid Knoll

was promoting. This irresponsible marketing of a narcotic drug caused doctors and patients to believe Vicodin was safer than it really was, to the detriment of people in Walker County.

25. Abbvie began manufacturing, developing, promoting, marketing, and selling the opioid drug, Vicodin, in the U.S. and in Walker County beginning January 1, 2013. On information and belief, it continues to do so at the time of filing this pleading.

26. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 20I2, and the combined company changed its name to Allergan Finance, LLC as of October 2013. Allergan Finance, LLC is a Nevada Corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, The Corporation Trust Company of Nevada, 701 S. Carson St., Suite 200, Carson City, NV 89701. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), and may be served through its registered agent for service of process, Corporate Creations Network, Inc., 8275 South Eastern Ave., #200, Las Vegas, NV 89123. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc., and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process,

Corporate Creations Network, Inc., 3411 Silverside Rd., Tatnall Building, Suite 104, Wilmington, DE 19810. On information and belief, Actavis Elizabeth LLC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Allergan Finance, LLC, Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis"). Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009. Actavis manufactures, promotes, sells, and distributes opioids in nationally, including in Texas and Walker County.

27. Alpharma Pharmaceuticals Inc. is a Delaware corporation with its principal place of business located in New Jersey. Alpharma operates as a subsidiary of Defendant King Pharmaceuticals, Inc, which is itself a wholly owned subsidiary of Defendant Pfizer, Inc. On information and belief, Alpharma Pharmaceuticals LLC is a Tennessee corporation, with its principal place of business located in New York (collectively "Alpharma").

28. Cephalon, Inc. ("Cephalon") is a corporation organized under the laws of Delaware and has its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. As

of October 2011, Cephalon, Inc. operates as a subsidiary of Defendant Teva Pharmaceuticals Industries, Ltd.

29. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Endo Health Solutions Inc. is a wholly-owned subsidiary of Endo Pharmaceuticals, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. are referred to as "Endo").

30. Endo develops, markets, and sells opioid drugs nationally, including in Texas and Walker County. Endo also manufactures and sells generic opioids nationally, including in Texas and Walker County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

31. Fresenius USA Manufacturing, Inc. is a corporation organized under the laws of Delaware and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. Fresenius Kabi USA is a related entity associated with Fresenius USA Manufacturing Inc. through which Fresenius USA Manufacturing Inc. is operating and conducting business in this State (collectively, "Fresenius").

32. Insys Therapeutics, Inc. is a corporation organized under the laws of Delaware and may be served through its registered agent for service of process, CT Corporation System,

1999 Bryan Street, Suite 900, Dallas, Texas 75201. Insys manufactures, promotes, sells, and/or distributes opioids nationally and in Walker County, including the opioid drug Subsys (fentanyl sublingual spray). Insys Manufacturing LLC, a Texas resident, is a related entity associated with Insys Therapeutics, Inc. through which Insys Therapeutics Inc. is operating and conducting business in this state, with its principle place of business at 2700 Oakmont Drive, Round Rock, Texas 78665 (collectively, "Insys").

33. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, TX 75201. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and may be served through its registered agent for service of process, Attention: Legal Department, One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutical Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen").

34. Janssen manufactures, promotes, sells, and distributes opioids nationally, including in Texas and Walker County.

35. King Pharmaceuticals, LLC ("King") is a wholly owned subsidiary of Pfizer, Inc., which acquired the Tennessee drug maker in October 2010. The corporation is organized and existing under the laws of the state of Delaware and has a principal place of business at 235 E. 42nd Street, New York, New York 10017. King may be served through its registered agent for service of process, CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919. Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, NY 10017. Pfizer may be served through its registered agent for service of process, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

36. Mylan, Inc. is organized as a corporation under the laws of Pennsylvania with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan conducts its pharmaceutical business operations through various entities, including Mylan Specialty, LP, Mylan Pharms Inc., and in Texas through Mylan Pharmaceuticals, Inc., which may be served through its registered agent Corporation Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701. Mylan Technologies Inc. is a West Virginia corporation, having its principal place of business at 110 Lake Street, Saint Albans, Vermont 05478 (collectively, "Mylan").

37. Nesher Pharmaceuticals USA LLC, a generic pharmaceutical manufacturer located in St. Louis, MO, is a subsidiary of privately held Zydus Pharmaceuticals USA Inc. Zydus Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of New

Jersey, with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

38. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808. Purdue Pharma L.P. is, through its ownership structure, a Texas resident. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and may be served through its registered agent for service of process, Corporation Service Company, 80 State Street, Albany, NY 12207. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut, and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808 (collectively, "Purdue").

39. Teva Pharmaceuticals Industries, Ltd., is an Israeli company with its principal place of business in Petah Tikva, Israel, and US headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc., an American subsidiary of Teva Pharmaceuticals, Ltd., is a corporation organized under the laws of Delaware, with headquarters at 19 Hughes, Irvine, California 92618 (collectively, "Teva").

40. ICU Medical Sales Inc. is a drug manufacturer and corporation organized under the laws of Delaware with its principal place of business in San Clemente, California, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. ICU Medical Inc. is a related entity associated with ICU Medical Sales Inc. through which ICU Medical Sales Inc. is operating

and conducting business in this State (collectively, "ICU"). ICU is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including Meperidine hydrochloride (ANDA # 088432) and morphine sulfate (NDA # 019916 and NDA # 019917).

41. Impax Laboratories, Inc. is a drug manufacturer and a corporation organized under the laws of the State of Delaware with its principal place of business located at 30831 Huntwood Avenue, Hayward, California 94544. Impax is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including oxymorphone hydrochloride (ANDA # 079087).

42. Mission Pharmacal Company ("Mission") is a drug manufacturer and organized as a corporation under the laws of Texas with a principal place of business at 10999 IH-10 West, Suite 1000, City View Building, San Antonio, Texas 78230. Mission may be served through its registered agent for service of process, Neill B. Walsdorf, 10999 IH-10 West, Suite 1000, City View Building, San Antonio, Texas 78230. Mission is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hycofenix (guaifenesin, hydrocodone bitartrate, pseudoephedrine hydrochloride) (NDA # 022279.

43. Neos Therapeutics, Inc. is a drug manufacturer and a limited partnership organized under the laws of Texas with its principle place of business at 2940 North Highway 360, Suite 400, Grand Prairie, Texas 75050. Neos conducts its pharmaceutical business through various entities, including Neos Therapeutics Brands LLC, Neos Therapeutics, LP, and may be served through its registered agent for service of process, CT Corporation System,

1999 Bryan Street, Suite 900, Dallas, Texas 75201. Neos is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hydrocodone polistirex and chlorpheniramne (ANDA # 091671).

44. NexGen Pharma, Inc. ("NexGen") is a drug manufacturer and corporation organized under the laws of Texas with its principal place of business at 1000 Cole Avenue, Rosenberg, Texas 77471. NexGen may be served through its registered agent for service of process, Business Filings Incorporated, 701 Brazos Street, Suite 720, Austin, Texas 78701. NexGen is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including butalbital, acetaminophen, caffeine, and codeine phosphate (ANDA # 076560).

45. Noven Pharmaceuticals, Inc. is a drug manufacturer and a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186. Noven is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including fentanyl transdermal system (ANDA # 077775).

46. Paddock Laboratories, LLC ("Paddock") is a drug manufacturer and a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 3940 Quebec Avenue N, Minneapolis, MN 55427. Upon information and belief, Paddock is a wholly owned subsidiary of Defendant Perrigo Company ("Perrigo"). Upon information and belief, Defendant Perrigo Company is a corporation organized and existing under the laws of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Paddock is identified by the FDA as the

sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including hydromorphone hydrochloride extended-release (ANDA # 204278).

47. Par Pharmaceuticals, Inc. ("Par") is a drug manufacturer and a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including morphine sulfate extended release (ANDA # 200812), oxymorphone hydrochloride (ANDA # 200792), and fentanyl transdermal system (ANDA # 077062).

48. Zogenix, Inc. is a drug manufacturer and a Delaware corporation with its principal place of business at 12400 High Bluff Drive, Suite 650, San Diego, California, 92130. Zogenix is identified by the FDA as the sponsor of one or more opioid-containing medications that are distributed and/or sold or available for sale in Walker County, Texas, including Zohydro ER (NDA # 202880).

Pharmacy Defendants

49. The Defendants identified in paragraph 49 shall be referred to herein as "Pharmacy Defendants."

50. Advanced Pharma, Inc. is a corporation organized under the laws of Texas and has its principal place of business at 9265 Kirby Dr., Houston, Texas 77054. Advanced Pharma, Inc. was purchased by Avella Specialty Pharmacy in 2016, and does business as Avella Specialty Pharmacy or Avella of Houston. Advanced Pharma, Inc., Avella Specialty Pharmacy, and Avella of Houston are referred to here as "Advanced Pharma".

Distributor Defendants

51. The Defendants identified in paragraphs 52 to 63 shall be referred to herein as "Distributor Defendants."

52. AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Amerisource does substantial business in Texas and, upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in Texas. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

53. Defendant Aveva Drug Delivery Systems, Inc. ("Aveva") is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 3250 Commerce Parkway, Miramar, Florida 33025. Aveva was purchased by Defendant drug manufacturer Apotex Inc. in 2012. Apotex Inc. ("Apotex") is a corporation organized and existing under the laws of Canada, with its principal place of business in Ontario, Canada. Apotex manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

54. Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio, and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons, Suite 125, Columbus, OH 43219. Cardinal does substantial business in Texas and, upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Texas. Cardinal

distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

55. CuraScript, Inc. ("CuraScript") is a pharmaceutical distributor with its principal place of business in Dover, Delaware and may be served through it's the Secretary of State for service of process, One Express Way, St. Louis, Missouri 63121. CuraScript SV Specialty Distribution LLC is a pharmaceutical distributor with its principal place of business in Dallas, Texas and may be served through its registered agent, Diahvion Burks for service of process at 9737 Forest Lane, Apt. 227, Dallas, Texas 75243.

56. CuraScript does substantial business in Texas and, upon information and belief, CuraScript is a pharmaceutical distributor licensed to do business in Texas. CuraScript distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

57. HD Smith Drug Co. ("HD Smith") is a corporation organized under the laws of Delaware with its principal place of business located at 3063 Fiat Avenue, Springfield, Illinois 62703. HD Smith does substantial business in Texas and, upon information and belief, HD Smith is a pharmaceutical distributor licensed to do business in Texas. HD Smith distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County. In November 2017, Defendant AmerisourceBergen announced its intention to acquire HD Smith.

58. JM Smith Corporation d/b/a QS/1Data Systems of JM Smith Corporation ("JM Smith"). JM Smith is a South Carolina corporation with its principal place of business in Spartanburg, South Carolina, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. JM

Smith does substantial business in Texas and, upon information and belief, JM Smith is a pharmaceutical distributor licensed to do business in Texas. JM Smith distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

59. Mallinckrodt PLC ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-Upon-Thames, Surrey, United Kingdom and maintains a U.S. headquarters at 675 McDonnell Boulevard, St. Louis, Missouri 63042. Mallinckrodt distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Walker County. Mallinckrodt sells powerful, addictive opioids in Texas, such as oxycodone and hydrocodone and other opioids through third party drug distributors, such as Defendants Advanced Pharma, Inc. and Avella of Houston.

60. Mallinckrodt LLC, is a wholly owned subsidiary of Mallinckrodt PLC and is a Delaware limited liability company with its principal place of business in St. Louis, Missouri. Mallinckrodt LLC is registered to do business in Texas and has been since 1989. Mallinckrodt LLC may be served in Texas through its registered agent: The CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

61. Mallinckrodt Pharmaceuticals ("Mallinckrodt Pharma") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Hazelwood, Missouri.

62. Mallinckrodt Inc. is a Delaware corporation having its principal place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042. Mallinckrodt PLC, Mallinckrodt LLC, Mallinckrodt Pharmaceuticals, and Mallinckrodt Inc. are collectively referred to as "Mallinckrodt".

63. McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California, and may be served through its registered agent for service of process, CSC - Lawyers Incorporating Service, 211 E. 7th Street, Suite 620, Austin, TX 78701. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Texas. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including in Texas and Walker County. McKesson Corporation also does business in Texas under the entity names McKesson Corporation at 3301 Pollock Drive, Conroe, Texas 77303, and McKesson Medical-Surgical Inc. at 20710 Hempstead Road, Houston, Texas 77065 (collectively, "McKesson").

PBM Defendants

64. The Defendants identified in paragraphs 65 to 93 shall be referred to herein as "PBM Defendants."

65. CVS Health Corporation ("CVS Health"), formerly known as CVS Caremark Corporation ("CVS Caremark") is the sole shareholder of CVS Pharmacy, Inc. ("CVS Pharmacy"), which is the sole member of Caremark Rx, L.L.C. ("Caremark Rx"), which is the sole member of Caremark, L.L.C. ("Caremark"). CVS Health is a pharmacy benefit manager ("PBM") with its principal place of business at Woonsocket, Rhode Island, and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Caremark, L.L.C. may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

66. On information and belief, CVS Health is the direct or indirect parent company of CaremarkPCS Health, L.L.C., which is registered to do business in Texas (since at least 2009) and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

67. Caremark PCS, L.L.C., is a Delaware limited liability company formerly known as AdvancePCS Inc., which was founded in 1996 and is based in Irving, Texas. Caremark PCS, L.L.C. is registered to do business in Texas and may be served by their registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

68. CVS Health does substantial business in Texas and, upon information and belief, it is a pharmaceutical distributor licensed to do business in Texas. CVS Health provides pharmacy benefit management services to various health insurance entities on behalf of 90 million plan participants, including in Texas and Walker County.

69. According to the Pharmacy Benefit Management Institute, CVS Health (Caremark) was the second highest ranking PBM in 2015 with twenty-five percent (25%) of the industry market share.

70. At all times relevant hereto, CVS Health and Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas.

71. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits in Texas through several different means including, but not limited to, providing services and formulary to the Teacher Retirement System of Texas. At all times relevant hereto, Caremark has served as the PBM for the Texas

Association of Counties Health and Employees Benefits Pool and has reimbursed for opioids throughout Texas, including in Walker County.

72. Express Scripts Holding Company ("Express Scripts") is a pharmacy benefit manager ("PBM"), with its principal place of business in Jefferson City, Missouri, and may be served through its registered agent for service of process, CSC-Lawyers Incorporating Service Co., at 221 Bolivar Street, Jefferson City, Missouri 65101.

73. Express Scripts, Inc. is a pharmacy benefit manager ("PMB), with its principal place of business in Jefferson City, Missouri, and may be served through its registered agent for service of process, CSC-Lawyers Incorporating Service Co., at 221 Bolivar Street, Jefferson City, Missouri 65101.

74. Express Scripts Holding Company and Express Scripts, Inc. are collectively referred to as "Express Scripts." On November 15, 2011, Express Scripts and Medco Health Solutions, Inc. ("Medco") merged and formed a new holding company Aristotle Holding, Inc. ("Aristotle"). On April 2, 2012, the Federal Trade Commission ("FTC") approved the merger. Express Scripts and Medco each became a wholly-owned subsidiary of Aristotle Holding, Inc., which was renamed Express Scripts Holding Company.

75. In 2015, Express Scripts was the top ranking PBM nationwide with twenty-six percent (26%) of the industry market share.

76. Express Scripts derives substantial revenue managing pharmacy benefits in Texas through several different means. During much of the relevant period of this complaint, ESI provided services and formulary to the Teacher Retirement System of Texas.

77. Current and former employees of the Huntsville Independent School District and New Waverly Independent School District are members of the Teacher Retirement System

of Texas which means they receive their pharmacy benefits from Express Scripts and pursuant to an Express Scripts formulary. Upon information and belief, this is only one of the many ways in which Express Scripts reimburses for claims in Walker County, including opioids.

78. At all times relevant hereto, Express Scripts has operated offices throughout Texas, including in Austin and Irving, Texas. ESI publishes employment vacancies related to its Texas PBM business activities on its website.

79. Medco Health Solutions of Texas, L.L.C. is incorporated in Texas, and through its ownership structure is a Texas resident. It may be served through its registered agent for service of process, Corporation Service Company d/b/a CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, TX 78701. Medco Health Solutions of Texas, L.L.C. provides pharmacy benefit management services to various health insurance entities on behalf of 83 million plan participants, including in Texas and Walker County.

80. Navitus Health Solutions, L.L.C. ("Navitus") is a pharmacy benefit manager ("PBM"), with its principal place of business in Madison, Wisconsin, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. Navitus does substantial business in Texas and, upon information and belief, Navitus is a PBM licensed to do business in Texas. Navitus provides pharmacy benefit management services to health insurance entities on behalf of Texas plan participants, including in Walker County.

81. Navitus Holdings, LLC, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison Wisconsin. Navitus Holdings, LLC may be served through its registered agent: CT Corporation System, 301

South Bedford Street, Suite 1, Madison, Wisconsin 53703. Navitus Health Solutions, LLC, a pharmacy benefit manager, is a limited liability company organized under the law of Wisconsin with its principal place of business located in Madison, Wisconsin and is a wholly owned subsidiary of Navitus Holdings, LLC. Navitus Health Solutions, LLC is registered to do business in Texas (since at least 2008) and may be served in Texas through it registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

82. Navitus derives substantial revenue managing pharmacy benefits in Texas through the services it provides and the formulary it maintains in its relationships with health plans including, but not limited to, Community First Health Plans, Community Health Choice, El Paso First Health Plans, FirstCare Health Plans, Parkland Community Health Plan, and Senders Health Plans.

83. According to the Texas Medical Association "of the roughly 20 Medicaid plans operating in the state, more than half say they collectively use the same PBMs — Navitus or CVS."

84. The Navitus pharmacy directory denotes numerous pharmacies located in Walker County.

85. OptumRx, Inc. ("OptumRx") is a pharmacy benefit manager ("PBM") with its principal place in Minnetonka, Minnesota, and may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. OptumRx does substantial business in Texas and, upon information and belief, OptumRx is a PBM licensed to do business in Texas. OptumRx provides pharmacy benefit

management services to various health insurance entities on behalf of 28 million plan participants, including in Walker County.

86. OptumRx Administrative Services, LLC, is wholly owned by OptumRx, Inc., with its principal place of business in Minnetonka, Minnesota, and may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. OptumRx Administrative Services LLC is a Texas resident. OptumRx provides pharmacy benefit management services to various health insurance entities on behalf plan participants, including in Walker County.

87. Optum, Inc., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRx, Inc. On information and belief, Optum, Inc. is a subsidiary of UnitedHealth.

88. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits in Texas through several different means, including, but not limited to, providing services and formulary through the HealthSelect Prescription Drug Program for the Employee Retirement System of Texas and, for at least the years 2015-17, the Public Employee Benefits Alliance (PEBA) of Texas.

89. Prime Therapeutics LLC, ("Prime") is a pharmacy benefit manager ("PBM"), with its principal place of business in Eagan, Minnesota, and may be served through its registered agent for service of process, Corporation Service Company DBA CSC–Lawyers Incorporated, 211 E. 7th Street, Suite 620, Austin, Texas 78701. Prime is owned by seventeen Blue Cross and Blue Shield health insurance entities. Prime provides pharmacy benefit management services to those seventeen Blue Cross and Blue Shield health

insurance entities on behalf of more than 20 million plan participants, including in Texas and Walker County.

90. UnitedHealth Group, Inc. ("United") is a managed health care organization ("MCO") and pharmacy benefit manager ("PBM") with its principal place of business in Minnetonka, Minnesota and may be served through its registered agent for service of process, The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801. United operates in four segments:

a. UnitedHealthcare, which includes UnitedHealthcare Employer & Individual, UnitedHealthcare Medicare & Retirement, UnitedHealthcare Community & State, and UnitedHealthcare Global, manages networks that include 1.2 million physicians and approximately 6,500 hospitals and other facilities.

b. OptumHealth provides health management services though programs offered by employers, payers, and government entities and directly with health care delivery systems comprising more than 30,000 physicians. Optum Financial Services, through Optum Bank, a wholly-owned subsidiary, manages 4.8 million health savings accounts with over $8 billion in assets.

c. OputmInsight provides technology services and software to hospital systems, physicians, health plans, governments, and other health care entities, including to more than 100,000 physicians and 300 health plans. As of December 31, 2017, these services expected to yield $15 billion.

d. OptumRx, Inc. provides pharmacy services to more than 65 million people in the United States through a network of more than 67,000 retail pharmacies, multiple home delivery and specialty pharmacies, and home infusions service centers. In 2017 alone, OptumRx managed approximately $85 billion in pharmaceutical spending, including $35 billion in specialty pharmaceutical spending.

91. UnitedHealthcare of Texas, Inc. is a wholly-owned subsidiary of United and is a Texas resident that may be served through its registered agent for service of process, CT Corporation, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

92. United does substantial business in Texas and, upon information and belief, United is a pharmaceutical distributor licensed to do business in Texas. United distributes pharmaceuticals to retail pharmacies and institutional providers to customers nationally, including in Texas and Walker County.

93. OptumRx (UnitedHealth) was the third highest ranking PBM in 2015 with twenty-two (22%) of the industry market share.

94. Defendants are regularly engaged in the business of manufacturing, distributing, dispensing and reimbursing prescription opioids in Texas and, specifically, in Walker County. Defendants' activities in Walker County in connection with the manufacture, distribution, dispensation and reimbursement of prescription opioids was, and is, continuous and systematic, and gave rise to the causes of action alleged herein.

Preliminary Statement and Nature of the Action

95. This suit seeks recovery of damages caused by Defendants' deliberate and negligent flooding of Walker County with opioids, which resulted in Walker County residents

bearing the pain and costs of opioid addiction. To expand and maintain market shares and profits, Manufacturing Defendants deliberately misinformed doctors about the approved indications of their opioid drugs, trained doctors to misstate diagnoses so that payment would be approved for unapproved uses for these drugs, and gave kickbacks to doctors in exchange for prescribing various opioid drugs. PBM Defendants took payments from Manufacturing Defendants and ensured that opioids were widely available, even at the expense of treatments that were less addictive and more effective. Distributor Defendants and Pharmacy Defendants failed to carry out their obligations to flag and report suspicious drug sales, and otherwise failed to implement any controls over the sale and distribution of opioids. Defendants' schemes are described in more detail below.

Defendants' Fraudulent Schemes

Background

A. Opioids Are Dangerous and Ineffective

96. Due to concerns about their addictive properties, opioids have been regulated as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" that can result from an excessive dose.

97. In fact, opioids are so addictive that most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued, commonly referred to as "dependence". Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Symptoms of opioid withdrawal include: severe

anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and others, which may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

98. Compounding the severe health issues caused by their addictive nature, when under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction he or she has become accustomed to. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction.

99. The FDA has acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. For example, patients receiving high doses of opioids as part of long-term therapy are three to nine times more likely to suffer overdose than those on low doses. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death." The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." The FDA required that—going forward—makers of long-acting opioid formulations clearly communicate these risks in their labels (defined to include promotional materials disseminated by or on behalf of the manufacturer of the drug). Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain—that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."

100. Similarly, studies have shown that between 30 percent and 40 percent of long-term users of opioids experience problems with opioid use disorders.

101. In addition to these staggering rates of addiction, it must be noted that there are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and showed only short-term efficacy for a minority of patients. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data were insufficient to establish long-term effectiveness. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain). Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

102. In short, despite the fact that opioids now are routinely prescribed, there never has been evidence of their safety and efficacy for long-term use. Worse, Defendants have always been aware of these gaps in knowledge and exploited them for their financial gain, including promoting opioids to treat chronic pain while both failing to disclose the lack of evidence to support their use long-term and failing to disclose the contradictory evidence that chronic opioid therapy can actually make patients worse.

B. Manufacturing Defendants Negligently and Illegally Distorted the Marketplace to Sell More Drugs

a. Off-label Marketing and Misbranding

103. Pharmaceutical drugs cannot be distributed in interstate commerce unless the manufacturer of the drug demonstrates that the drug is safe and effective for each of its intended uses. Once a drug is approved for a particular use, however, nothing prevents doctors from prescribing the drug for uses that are different than those approved. Though physicians may prescribe drugs for off-label usage, drug manufacturers are prohibited from marketing or promoting a drug for a use that is not approved, a practice known as "off-label marketing."

104. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses. If the manufacturer intends to promote the drug for new uses, in addition to those already approved, the materials on off-label uses must meet stringent requirements, and the manufacturer must resubmit the drug for testing and approval.

105. Manufacturing Defendants achieved larger market size, market share, and profit by promoting opioids for off-label uses. They systematically made false statements about opioid effectiveness and medical research, and designed opioid educational programs to push these false narratives.

106. For example, in 2007, Defendant Purdue and three of its executives pled guilty to misbranding in their promotion of OxyContin and agreed to pay a $634.5 million-dollar settlement to resolve a Department of Justice investigation.

107. Purdue manufactures, promotes, sells, and distributes opioids nationally, including in Texas and Walker County. Purdue's opioid drug, OxyContin, is among the most

addictive and abused prescription drugs in the history of America. Purdue promotes sales of its opioids throughout the United States, including in Texas and Walker County.

108. OxyContin is Purdue's largest-selling opioid, in both Walker County and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

109. Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids nationally and in Walker County, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[1] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate

[1] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and

naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

110. Manufacturing Defendants produce opioid drugs that are misbranded in violation of Texas law.[2] Manufacturing Defendants also introduced into Texas commerce drugs that are misbranded in violation of Texas law.[3] The following table contains a list of opioids and the associated Manufacturing Defendant:

Product name	Application number	Application holder
morphine sulfate extended-release	ANDA 203849	Actavis Elizabeth LLC
hydromorphone hydrochloride	ANDA 202144	Actavis Elizabeth, LLC
oxymorphone hydrochloride	ANDA 079046	Actavis Elizabeth, LLC
morphine sulfate extended-release	ANDA 079040	Actavis Elizabeth, LLC
Embeda	NDA 022321	Alpharma Pharmaceuticals LLC
fentanyl transdermal system	ANDA 077449	Aveva Drug Delivery Systems, Inc. (An Apotex Company)
Opana ER	NDA 201655	Endo Pharmaceuticals INC
Opana ER	NDA 021610	Endo Pharmaceuticals Inc
oxymorphone hydrochloride	ANDA 079087	Impax Laboratories, Inc.
Nucynta ER	NDA 200533	Janssen Pharmaceuticals INC
Duragesic	NDA 019813	Janssen Pharmaceuticals INC
Avinza	NDA 021260	King Pharmaceuticals LLC
Exalgo	NDA 021217	Mallinckrodt INC The Pharmaceuticals Business of Covidien
oxymorphone hydrochloride	ANDA 202946	Mallinckrodt Pharmaceuticals
fentanyl transdermal system	ANDA 077154	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076438	Mallinckrodt Pharmaceuticals
morphine sulfate extended-release	ANDA 076412	Mallinckrodt Pharmaceuticals
methadone hydrochloride	ANDA 040517	Mallinckrodt Pharmaceuticals
Methadose	ANDA 040050	Mallinckrodt Pharmaceuticals

[2] "[T]he manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(h).

[3] "[T]he introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(a).

Product name	Application number	Application holder
morphine sulfate	ANDA 200824	Mylan Pharmaceuticals Inc.
fentanyl transdermal system	ANDA 076258	Mylan Technologies Inc.
morphine sulfate extended-release	ANDA 77855	Nesher Pharms
morphine sulfate extended-release	ANDA 76733	Nesher Pharms
morphine sulfate extended-release	ANDA 76720	Nesher Pharms
fentanyl transdermal system	ANDA 077775	Noven Pharmaceuticals, Inc.
hydromorphone hydrochloride extended-release	ANDA 204278	Paddock Laboratories, LLC
morphine sulfate extended-release	ANDA 200812	Par Pharmaceuticals, Inc.
oxymorphone hydrochloride	ANDA 200792	Par Pharmaceuticals, Inc.
fentanyl transdermal system	ANDA 077062	Par Pharmaceuticals, Inc.
Hysingla ER	NDA 206627	Purdue Pharma LP
Targiniq ER	NDA 205777	Purdue Pharma LP
Oxycontin	NDA 022272	Purdue Pharma LP
methadone hydrochloride	ANDA 090707	Watson Laboratories, Inc.
fentanyl transdermal system	ANDA 076709	Watson Laboratories, Inc.
Zohydro ER	NDA 202880	Zogenix INC

111. Defendant wholesalers also receive drugs that are misbranded in violation of Texas law. "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." TEX. FOOD, DRUG, & COSMETICS ACT § 431.021(jj).

112. The Medicaid drug rebate program is a system involving various entities such as manufacturers, wholesalers, PBMs, pharmacies, the Centers for Medicaid and Medicare Services ("CMS"), and the state Medicaid agencies. However, the system mainly relies upon a two-way interaction between manufacturers and CMS.

113. Drug manufacturers pay rebates to the states to ensure that the Medicaid program is receiving the lowest price on covered drugs. But the system has put the entire process, practically unmonitored, into the hands of the very people who abuse the system.

114. The manufacturer calculates its Medicaid rebate per unit using its lowest price ("best price"), and its average price (average manufacturer's price, or "AMP"). The manufacturer then pays the state that calculated rebate amount for each unit paid for by Medicaid. Manufacturers have exploited this rebate system by falsely reporting the correct best price and/or the correct AMP. Manufacturers have been caught reporting that false number in order to reduce their rebate liability.

b. Defendants Promoted Their Products Through Direct Marketing to Prescribers and Consumers

115. Manufacturing Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, Manufacturing Defendants used branded and unbranded marketing tactics to build confidence in long-term opioid use by overstating their benefits and downplaying their risks, and thereby expand the chronic pain market. In addition, Manufacturing Defendants used sales representatives, physician speakers recruited by the sales representatives, and medical journal advertising to claim a larger share of that expanded market. Manufacturing Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

116. Manufacturing Defendants engaged in widespread advertising campaigns touting the benefits of their drugs. Manufacturing Defendants purchased print advertisements in a broad array of medical journals that ranged from those aimed at specialists (such as the *Journal of Pain* and *Clinical Journal of Pain*), to journals with wider medical audiences (such as the *Journal of the American Medical Association*). Manufacturing Defendants' advertising budgets nearly tripled from 2001 to 2011, at which time they collectively spent

more than $14 million on medical journal advertising of opioids. The 2011 total included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

117. A number of these advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in the medical literature.

118. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturing Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Manufacturing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

119. In addition to advertising in medical journals, Manufacturing Defendants devoted massive resources to direct sales contacts with prescribers. In 2014 alone, Manufacturing Defendants collectively spent $168 million on selling opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Manufacturing Defendants' collective spending on selling in 2000.

120. Manufacturing Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that sales representatives' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face selling has the highest influence on prescribing. Manufacturing Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for selling and who responded by prescribing more of Defendants' drugs.

121. Manufacturing Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Manufacturing Defendants' opioids.

122. Manufacturing Defendants target individual health care providers by a combination of zip code, facility, type of practice, specialty, ease of in-person access, and the potential for persuading the provider to prescribe. Manufacturing Defendants start this process with external IQVIA prescribing data and internal wholesaler chargeback data. Manufacturing Defendants then further refine their targets with input from sales representatives, which includes ease of in-person access, potential to be persuaded, the provider's desire for healthcare data, and any information on payments and inducements that the provider has accepted. There is no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

123. Collectively, Manufacturing Defendants' marketing plans reveal dual strategies, which often operated parallel to one another. In the beginning, Manufacturing Defendants'

sales representatives continued to focus their selling efforts on pain specialists and anesthesiologists, who are the highest-volume prescribers of opioids but are also, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop market share and expand sales, however, Manufacturing Defendants also targeted increasing numbers and types of prescribers for marketing.

124. This expanded market of prescribers was, as a group, less informed about opioids and, market research concluded, more susceptible to Manufacturing Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants. The expanded market also included internists, general practitioners, and family doctors who were low- to mid-volume prescribers.

125. Manufacturing Defendants knew that physicians were more likely to prescribe their medications when patients asked for those medications. Manufacturing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives to, as Endo put it, "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss."

126. Manufacturing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (home office clinical specialists); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising.

127. Each Manufacturing Defendant promoted the use of opioids for chronic pain through sales representatives who visited individual physicians and their staff in their offices and facilities. Manufacturing Defendants also promoted the use of opioids for chronic pain through small group speaker programs. By establishing close relationships with doctors, Manufacturing Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

128. Manufacturing Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing volume. Manufacturing Defendants purchase and closely analyze prescription sales data from a healthcare data company called IQVIA (previously known as "IMS Health"). This data allows them to precisely track the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their sales efforts. Manufacturing Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their sales representatives.

129. Manufacturing Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to Walker County prescribers, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

130. Each Manufacturing Defendant carefully trained its sales representatives to deliver messages that the companies designed to generate prescriptions of that company's drugs in particular and opioids in general. Manufacturing Defendants direct and monitor their sales representatives—through detailed action plans, training, tests, scripts, role-plays, supervisor tag-alongs, and other means. These tactics were employed to ensure that individual sales representatives actually delivered the desired messages and did not veer off-script. Manufacturing Defendants require their sales representatives to deploy sales aids that were reviewed, approved, and supplied by the company. The companies forbade the sales representatives from using "homemade bread"—*i.e.*, promotional materials from any source other than the company's marketing and compliance departments. Sales representatives' adherence to their corporate training is a required component of employment. Departing from their company's approved messaging can and does lead to severe consequences, including termination of employment.

131. Besides carefully training their sales representatives, Manufacturing Defendants also used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers. These "verbatim" recollections of sales representatives' messages are an integral tool in ensuring consistent delivery of approved messages. They also help Manufacturing Defendants gauge physicians' perceptions of, and willingness to prescribe, a particular Defendant's drugs.

132. In addition to making sales calls, Manufacturing Defendants' sales representatives also identified doctors to become paid speakers, who presented the company's sales pitch to other physicians during meals at high-priced restaurants. Manufacturing Defendants almost always select physicians who are "product loyalists." Endo, for instance, sought to

use high prescribers of its drugs as local thought leaders to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, and even speaker training typically is compensated at $500 per hour.

133. These speaker programs and associated speaker training serve three purposes: 1) they provide a financial incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) they provide a forum in which to further market to the speaker; and 3) they provide an opportunity to market to the speaker's peers. Manufacturing Defendants grade their speakers, and future opportunities are based on speaking performance and product usage. Manufacturing Defendants also track the prescribing of event attendees. It would make little sense for Manufacturing Defendants to devote significant resources to programs that did not increase their sales, which is often referred to in the industry as "return on investment" or "ROI".

134. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. This is important because the FDA regards promotional talks as part of product labeling and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Manufacturing Defendants' marketing departments. These presentations conveyed misleading information, omitted material information, and failed to correct Manufacturing Defendants' prior misrepresentations about the risks and benefits of opioids. Although these meal-based speaker events are more expensive to host and typically have lower attendance than continuing medical education events ("CMEs"), they

are subject to less professional scrutiny and thus afford Manufacturing Defendants greater freedom in the messages they present.

135. For example, numerous executives with Defendant pharmaceutical manufacturer Insys have been indicted since 2016 for devising and fostering a scheme to bribe practitioners to write large numbers of Fentanyl Spray prescriptions, most often for patients who did not have cancer, for which the drug was indicated. The indictment states that because insurers were reluctant or unwilling to pay for the drug for patients without cancer, employees of the company were directed to call insurers directly and defraud them by lying about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication. By bribing practitioners to write prescriptions for Fentanyl Spray and then defrauding insurers, Insys dramatically increased the volume of prescriptions written and the rate at which insurers approved payment for the drug, generating substantial profits.

136. In the Insys case, the company admitted that its payments to doctors for speaking fees or "honoraria" were for the purpose of increasing prescriptions and served as a bribe. In fact, Insys targeted prescribing physicians who were going through divorce or other financial difficulties, knowing that these doctors would be more likely to engage in the qui pro quo that Insys sought.

137. Once Insys made a connection with a prescribing physician, Insys would often provide an Insys-paid staffer to work in the physician's office with responsibility for persuading insurance companies to pay for Insys drugs, including causing insurers to believe that patients had cancer when they did not.

138. In addition to these in-person visits and speaker programs, Manufacturing Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called "e-detailing." Manufacturing Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed Manufacturing Defendants to use this seemingly credible vehicle to market to hard-to-reach audiences such as prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person sales calls.

139. As they did nationwide, Manufacturing Defendants extensively tracked the prescribing behavior of Walker County-area health care providers and used that data to target their sales calls and speaker recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

140. Manufacturing Defendants employed the same marketing plans, strategies, and messages in and around Walker County, Texas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturing Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Manufacturing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

c. Defendants Used "Unbranded" Marketing, Manipulated Doctor Groups, and Planted Research to Increase Opioid Use.

141. In addition to their direct marketing efforts, Manufacturing Defendants used third-party marketing of opioid drugs in general ("unbranded marketing"), which they deployed as part of their national marketing strategies for their drugs. Each Manufacturing Defendant marketed their drugs by (a) employing a network of key opinion leaders ("KOLs"), doctors who were influential leaders, (b) funding and controlling third-party groups ("Front Groups") that were nominally independent but in fact served Manufacturing Defendants, and (c) planting research in medical journals that was not factually true.

142. Manufacturing Defendants' unbranded marketing created and relied upon an appearance of independence and credibility that was false and undeserved but central to its effectiveness.

143. Unlike their direct promotional activities, Manufacturing Defendants' unbranded marketing allowed them to evade the oversight of regulators and gave them greater freedom to expand their deceptive messages.

144. For example, unbranded advertising avoided regulatory scrutiny because Defendants did not have to submit it to the FDA. The results were predictable. Manufacturing Defendants' deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

a. Opana ER Advertisement (Branded): "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

b. Pain: Opioid Therapy (Unbranded): "People who take opioids **as prescribed usually do not become addicted**."

145. All of this unbranded marketing violated Texas and federal law. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. Under Federal law, a drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.4 Under Texas law, drug manufacturers that introduce into Texas commerce drugs that are misbranded are in violation of Texas law.

> "[T]he introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Tex. Food, Drug, & Cosmetics Act § 431.021(a).
>
> "[T]he manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded." Tex. Food, Drug, & Cosmetics Act § 431.021(h).

146. Defendant wholesalers who received drugs that are misbranded are also in violation of Texas law:

> "[T]he receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise." Tex. Food, Drug, & Cosmetics Act § 431.021(jj).

147. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand

the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

148.

149. Thus, Manufacturing Defendants' promotional materials (including unbranded marketing) are part of their drugs' labels and required to be accurate, balanced, and not misleading.

150. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included." Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

151. The Texas False Claims Act (Tx. Hum. Res. Code Ann. §§ 36) and the Texas Deceptive Trade Practices Act (Tx. Bus. & Com. §§ 17) reflect the same judgment that drug companies, just like other businesses, have a duty to deal honestly with consumers, government, and other payors who purchase and use their products.

152. While Texas statutes, regulations, and common law (like federal law) require that Defendant Manufacturers engage in honest marketing, in fact Defendant Manufacturers engaged in widespread schemes to promulgate false and misleading information about opioids.

153. For example, Manufacturing Defendants market through Front Groups—third parties such as organizations of scientists, physician organizations, or patient or professional organizations—that appear to be independent and therefore more credible. In the case of opioids, Manufacturing Defendants marketed through Front Groups such as the non-profit American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. The FDA has made clear that its promotional requirements apply to both direct marketing and Front Group marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf. . .. . Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.

154. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework.

155. Manufacturing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These were important elements of Manufacturing Defendants' marketing plans. These plans specifically contemplated the use of KOLs and Front Groups, because they seemed independent and therefore outside of FDA oversight. Through unbranded materials, Manufacturing Defendants presented information and instructions concerning opioids that were contrary or inconsistent with information on FDA

approved marketing materials; drug labels; and Manufacturing Defendants' own knowledge of opioid risks and benefits. Manufacturing Defendants did so knowing that unbranded materials typically are not submitted to the FDA for review.

156. Once Defendant Manufacturers' unbranded messages were channeled through Front Groups, other Defendants adopted these messages as their own. Manufacturing Defendants cited to them, edited them, approved them, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. Sales representatives distributed deceptive Front Group marketing materials to Manufacturing Defendants' target audiences. Manufacturing Defendants are responsible for these materials.

157. Moreover, Manufacturing Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these Front Groups, ensuring that Manufacturing Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Manufacturing Defendants exercised control over their deceptive messages and acted in concert[5] with these Front Groups to fraudulently promote the use of opioids for the treatment of chronic pain.

158. For example, on September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . .

[5] As used in this Petition, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The letter details a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness and that "imply that patients will experience improved social or physical functioning or improved work productivity", including:

a. "'Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"

b. "'All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.'"

c. "'Significantly reduced nighttime awakenings.'"

d. "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"

e. "'Significant improvement in physical functioning summary score.'"

f. "'Significant improvement in social functioning.'"

g. "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'"

159. The Front Group publications that Manufacturing Defendants assisted in creating and distributing did not include the warnings and instructions consistent with the risks and benefits known to Manufacturing Defendants. For example, these publications either did

not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

160. By acting through Front Groups, Manufacturing Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Manufacturing Defendants would cite to these sources as "independent" corroboration of their own statements. Front Group documents not only had greater credibility, but broader distribution, as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation ("APF") on display in their offices, as they might with first-party, drug company pieces.

161. Nevertheless, the independence of these materials was a ruse—Manufacturing Defendants were in close contact with these Front Groups. Manufacturing Defendants paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

162. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

163. The most prominent of Manufacturing Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

164. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of

addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Walker County.

165. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Dr. Russell Portenoy (whose deep connections to Manufacturing Defendants is discussed below), explained, the lack of funding diversity was one of the biggest problems at APF.

166. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Manufacturing Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Manufacturing Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's

desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

167. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

168. APF assisted in other marketing projects for drug companies. One project funded by Defendant drug company Alpharma—*APF Reporter's Guide: Covering Pain and Its Management* (2009)—recycled text that was originally created as part of the company's training document.

169. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

170. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturing Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Manufacturing Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

171. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Manufacturing Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

172. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturing Defendants, issued treatment guidelines, and sponsored and hosted medical education programs essential to Manufacturing Defendants' deceptive marketing of chronic opioid therapy.

173. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its amual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

174. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Perry Fine, Dr. Russell Portenoy, and Dr. Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."

175. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturing Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

176. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturing Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic pain.

177. Manufacturing Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Manufacturing Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and

misleading, these misstatements were nevertheless disseminated to Walker County prescribers and patients.

178. One vehicle for their collaboration was the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Dr. Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

179. PCF comprises representatives of opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other likeminded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Manufacturing Defendants.

180. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[6] This Control of the REMS process was critical because a REMS that went too far in narrowing the uses or benefits of chronic opioid therapy, or highlighting its risks, would deflate Defendants' marketing efforts. The recommendations—drafted by Dr. Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS

[6] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

"should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[7] Manufacturing Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

181. In addition to using Front Groups, Manufacturing Defendants cultivated a group of doctors who, upon information and belief, were selected and sponsored by Manufacturing Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Manufacturing Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Manufacturing Defendants by touting the benefits of opioids to treat chronic pain.

182. Pro-opioid doctors have been at the hub of Manufacturing Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, even while acknowledging the lack of evidence in support of that position. They have also served on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturing Defendants were able to exert control of each of these modalities through their KOLs.

[7] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

EXHIBIT 22

MALLINCKRODT OPIOID PERSONAL INJURY TRUST DISTRIBUTION PROCEDURES FOR NON-NAS PI CLAIMS

These Mallinckrodt Opioid Personal Injury Non-NAS Trust Distribution Procedures ("**PI TDP**") provide for resolving all PI Opioid Claims ("**PI Claims**"),[1] as defined in the *Fourth Amended Joint Plan Of Reorganization (With Technical Modifications) Of Mallinckrodt Plc And Its Debtor Affiliates Under Chapter 11 Of The Bankruptcy Code*, dated as of February 18, 2022 and confirmed by the Bankruptcy Court on March 2, 2022 [Docket No. 6660] (as such plan may be amended, modified or supplemented, the "**Plan**"), as provided in and required by the Plan and the Mallinckrodt Opioid Personal Injury Trust Agreement ("**Trust Agreement**"). The Plan and the Trust Agreement establish the Mallinckrodt Opioid Personal Injury Trust ("**PI Trust**"). The trustee of the PI Trust ("**Trustee**") shall implement and administer these PI TDP in accordance with the Trust Agreement. Holders of PI Claims are referred to herein as "**PI Claimants**."[2]

ARTICLE 1

INTRODUCTION

1.1 Purpose of the PI TDP. The goal of the PI Trust is to treat all present and future claims equitably and in accordance with the requirements of the Plan and the Bankruptcy Code. These PI TDP further that goal by setting forth objective, efficient, and fair procedures for processing and paying the Debtors' several shares of the unpaid portion of the liquidated value of PI Claims.

1.2 Funding of the Trust. The PI Trust shall be funded in accordance with the Plan. As set forth in the Trust Agreement, the PI Trust will maintain a separate fund (the "**PI Trust Non-NAS Fund**") among the PI Trust's assets to be used to pay the administrative costs and expenses of the PI Trust on a pro rata basis until the PI Trust NAS Fund is exhausted (after which the PI Trust Non-NAS Fund will pay all administrative costs and expenses of the PI Trust, and pay Awards to holders of Allowed PI Claims in accordance with these PI TDP).

1.3 Interpretation. Except as may otherwise be provided below, nothing in these PI TDP shall be deemed to create a substantive right for any claimant. The rights and benefits provided herein, if any, to holders of PI Claims shall vest in such holders as of the Effective Date.

ARTICLE 2

PI TDP ADMINISTRATION

2.1 Claims Processor and Other Agents. Nothing in these PI TDP shall preclude the PI Trust from contracting with a third party to provide claims-processing, claims-audit, or other services to the PI Trust so long as decisions about the resolution of PI Claims are based on the relevant

[1] Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Plan or the PI Trust Agreement.

[2] The term "**PI Claimant**" includes each person holding a PI Claim arising from his/her own opioid use and each person holding a PI Claim arising from the opioid use of a decedent (such deceased person, a "**Decedent**").

provisions of these PI TDP, including the evidentiary criteria set forth herein. In accordance with the Trust Agreement, the Trustee may retain additional professionals, agents, and consultants to assist in carrying out the duties of the Trust.

2.2 PI Trust Advisory Committee and Future Claimants' Representative. Pursuant to the Plan and the Trust Agreement, the Trustee shall administer the PI Trust and these PI TDP in consultation with the PI Trust Advisory Committee ("**Committee**"), which represents the interests of holders of present PI Claims, and the Future Claimants' Representative ("**FCR**"), who represents the interests of holders of PI Claims that will be asserted in the future. The duties of the Committee and FCR with respect to the PI Trust are set forth in the Trust Agreement. The Trustee shall obtain the consent of the Committee and the FCR on any amendments to these PI TDP and on such other matters as are otherwise required below and in the PI Trust Agreement. The initial Trustee, the initial members of the Committee, and the initial FCR are identified in the PI Trust Agreement.

2.3 Consent and Consultation Procedures. In those circumstances in which consultation or consent is required, the Trustee shall provide written notice, which may be provided via email, to the Committee and the FCR of the specific amendment or other action that is proposed. The Trustee shall not implement such amendment nor take such action unless and until the parties have engaged in the Consultation Process or the Consent Process described in the PI Trust Agreement.

ARTICLE 3

OVERVIEW OF CLAIMS LIQUIDATION PROCEDURES

3.1 PI Trust Claims Liquidation Procedures.

(a) Claims Materials. Within 14 days after the Effective Date or as soon as practicable thereafter, the PI Trust will publish claims materials for all PI Claims.[3] The claims materials will include a proof of claim form substantially in the form of **Exhibit A** ("**Claim Form**"), which shall require a certification by the claimant under penalty of perjury, and instructions for submitting the information and evidence required to establish an Allowed PI Claim eligible to receive payment from the Trust. Additionally, the claims materials shall include (i) a HIPAA release form ("**HIPAA Release**"), substantially in the form of **Exhibit B**, that a PI Claimant must provide if requested by the PI Trust, (ii) an heirship declaration(s) ("**Heirship Declaration**"), substantially in the form of **Exhibit C**,[4] which must be provided by any person seeking a Distribution from the PI Trust in the capacity of an heir when an Executor, Administrator, or Personal Representative of the Deceased Person's Estate has not been appointed by a Court, or, if an Executor, Administrator, or Personal Representative has been appointed by a Court, then the Court Order appointing such person including with respect to a claim for which liquidation in

[3] The PI Trust will seek to have the claims materials for PI Claims mailed with the notice of Plan confirmation. Additionally, the PI Trust will make the claims materials available on the Trust Website.

[4] Exhibit C contains two declaration forms: one applies if the Decedent named the PI Claimant as executor in his/her will; the other applies if the Decedent had no will.

the tort system is elected, and (iii) a form of release ("**PI Claim Release**"), substantially in the form of **Exhibit D**, which will be issued individually to each PI Claimant when the Trust issues an offer for an Award. The claims materials may be amended by the Trustee with the consent of the Committee and the FCR, so long as any such amendment is consistent with the terms of these PI TDP and the Plan, and does not effect a change to the evidentiary criteria or the point awards for base payments and level awards set forth in section 5.1 below.

(b) Determination of Compensability. The PI Trust will receive, process, and resolve PI Claims in accordance with these PI TDP and determine whether they are Allowed and therefore eligible to receive payment from the Trust, or Disallowed and therefore not eligible for payment from the Trust. An "**Allowed PI Claim**" is a claim that provides credible evidence that satisfies (as determined by the PI Trust) the evidentiary criteria set forth below and is otherwise eligible for an offer of payment in accordance with these PI TDP.

(c) Treatment of Disallowed Claims. The PI Trust will not pay Awards to Disallowed Claims.

(i) Because the PI Trust will have limited funds, economic damages are not compensable. These PI TDP compensate only general pain and suffering. Nonetheless, all claims for personal injury damages from use of Qualifying Opioids are being channeled to the PI Trust and released, including both economic and non-economic or general damages. In no circumstance shall the PI Trust assign any claim value for any punitive damages, exemplary damages, statutory enhanced damages, or attorneys' fees or costs (including statutory attorneys' fees and costs). Claims that involve no use of opioid products made or sold by the Debtors are not compensable under these TDP, regardless of the theory of liability.

(ii) The adjudication of a PI Claim, whether under the liquidation procedures of these PI TDP or in the tort system for PI Claimants who opt to liquidate their PI Claims in the tort system, shall be deemed to be an adjudication of that PI Claim and any associated PI Claims of the PI Claimant regarding the same injuries that are the subject of its PI Claim. Any Distribution from the PI Trust on an Award (under the liquidation procedures of these PI TDP) or a Final Judgment (for a PI Claimant who elects to liquidate a claim in the tort system) in respect of such PI Claim, if any, shall be deemed to be a Distribution in satisfaction and conclusive resolution of such PI Claim and such associated PI Claims.

(iii) No Claim submitted by a co-defendant of the Debtors will be deemed compensable unless and until (1) the co-defendant establishes to the Trust's satisfaction that the co-defendant has paid in full and has obtained a release from a PI Claimant for liability of the Debtors that would be an Allowed PI Claim under these PI TDP, (2) the Trust confirms that it has not previously issued payment to the PI Claimant, and (3) the co-defendant has obtained a release from the PI Claimant in favor of the Trust.

(d) Determination of Awards and Deductions. The PI Trust will liquidate and determine the gross amounts receivable on account of Allowed PI Claims (an "**Award**") in accordance with these PI TDP. Awards will be a gross number before deduction of any allowed deductions or holdbacks (the "**PI Trust Deductions and Holdbacks**").

3.2 Election to Liquidate Claim in the Tort System.

(a) A PI Claimant who (i) submits a Claim Form to the PI Trust and (ii) elects expressly in the Claim Form to liquidate his/her PI Claim in the tort system rather than pursuant to the streamlined procedures set forth in these PI TDP (each, an "**Opt-Out Claimant**"), may assert and liquidate such PI Claim in the tort system at his/her own expense, as set forth in more detail article 7 below, and shall forfeit all rights to liquidate such PI Claim (and any associated PI Claims regarding the same injuries that are the same subject of its PI Claim) under the streamlined procedures set forth in sections 4-5 of these PI TDP. The right to litigate in the tort system is available only with respect to Claims that meet the definition of "PI Opioid Claim" set forth in the Plan.

(b) OPTING OUT REQUIRES THE CLAIMANT TO TAKE THE AFFIRMATIVE ACTION OF CHECKING THE "OPT OUT" BOX ON THE CLAIM FORM AND TO SUBMIT THE CLAIM FORM TO THE PI TRUST. FAILURE TO CHECK THE "OPT OUT" BOX WILL CONSTITUTE A WAIVER OF THE RIGHT TO OPT OUT OF HAVING THE PI CLAIM PROCESSED AND LIQUIDATED PURSUANT TO THE PROVISIONS OF THESE PI TDP.

(c) ONCE A PI CLAIMANT HAS SUBMITTED A CLAIM FORM INDICATING EITHER AN ELECTION TO "OPT OUT" TO PURSUE THE PI CLAIM THROUGH LITIGATION OR AN ELECTION TO HAVE THE PI CLAIM RESOLVED UNDER THE LIQUIDATION PROVISISION OF THE PI TDP, THE PI CLAIMANT CANNOT LATER CHANGE THE ELECTION. IF A CLAIM FORM IS SUBMITTED WITHOUT AN ELECTION TO "OPT OUT", THE PI CLAIMANT WILL BE BOUND TO HAVING THE PI CLAIM LIQUIDATED UNDER THE TDP AND HAS WAIVED THE OPTION TO PURSUE THE PI CLAIM IN THE TORT SYSTEM.

ARTICLE 4

PROCESSING AND RESOLUTION OF PI CLAIMS BY THE PI TRUST

4.1 Processing of PI Claims.

(a) As soon as possible after the establishment of the PI Trust, the Trustee, shall proceed to have the PI Trust receive, review, and liquidate all PI Claims. PI Claims shall be processed based on their place in the FIFO Processing Queue (as defined below) and paid based on their place in the FIFO Payment Queue (as defined below). The Trust shall make every reasonable effort to resolve each year at least that number of PI Claims required to exhaust the applicable Maximum Annual Payment (as that term is defined below).

(b) To process PI Claims under these PI TDP, the PI Trust has the discretion to request additional documentation beyond that required by these PI TDP that is believed to be in the possession of the PI Claimant or his or her authorized agent or lawyer.

(c) The PI Trust will use appropriate technology and strategies to prevent the payment of fraudulent or otherwise invalid claims, while making the claims-submission process as simple as possible. Reasonable steps will be taken to mitigate fraud so as to ensure a fair and secure claims review and payment process, while not falsely flagging legitimate PI Claims.

(d) The PI Trust may investigate any claim and may request information from any PI Claimant to ensure compliance with the terms outlined in these PI TDP. The PI Trust may request a PI Claimant to execute a HIPAA Release to enable the PI Trust to directly obtain the PI Claimant's or Decedent's medical records for evaluation in accordance with these PI TDP.

(e) The Trustee has the sole discretion, subject to the appeal process set forth herein, to determine a PI Claim is Disallowed or to reduce or eliminate Awards on PI Claims being liquidated hereunder where the Trustee concludes that there has been a pattern or practice to circumvent full or truthful disclosure of information requested under these PI TDP or by the PI Trust to resolve a PI Claim.

4.2 General Criteria for Allowed PI Claims. To establish an Allowed PI Claim in accordance with these PI TDP, a PI Claimant must satisfy the following criteria:

(a) Demonstrate in the Claim Form that the PI Claimant holds a PI Claim against one or more Debtors;

(b) Complete the Claim Form, checking at least one injury box (other than jail)[5], sign and submit the Claim Form.

(c) Demonstrate usage of one of the qualifying prescribed opioids listed in section 5.2(a) below (a "**Qualifying Opioid**");

(d) If requested by the Trust, complete, sign and submit the HIPAA release form(s) substantially in the form attached as Exhibit B; and

(e) If the PI Claim concerns the injuries of a Decedent, execute and submit a Heirship Declaration substantially in the form attached hereto as Exhibit C.

[5] In the event a PI Claimant does not check any injury box (other than jail) from use of opioids on the Claim Form, the PI Claim shall be deemed Disallowed. The Claim Form shall include clear language notifying a PI Claimant that if he or she fails to check any injury box (other than jail) from use of opioids, she/he will receive no recovery on the PI Claim.

(f) As a condition to receiving any payment from the PI Trust, a claimant shall be required to execute and submit the PI Claim Release, which will be provided to the PI Claimant when the PI Trust issues an offer for an Award.

4.3 Base Payment and Level Award Process. The Base Payment and Level Award process is designed to provide an opportunity for a PI Claim to be reviewed and evaluated for a "Base Payment" with the possible addition (for a Tier 1 PI Claim) of a "Level Award" that can enhance the amount of the total payment offered to the PI Claimant. "Base Payments" and "Level Awards" are determined based upon a Point Value at the time of payment. The Point Value will be determined initially, and may be periodically adjusted by the Trustee, with the consent of the FCR (the "**Point Value**"). The valuation of and evidentiary requirements for Base Payment and Level Awards are discussed in article 5.

4.4 Order of Payments.

(a) Establishment of Initial Point Value. With the consent of the PI Committee and the FCR, the Trustee will establish the Point Value and, if appropriate, the protocol for staggering payments, making payments in installments, and the timing of payments for Allowed PI Claims as soon as possible following 90 days after the Effective Date. Payments will be issued on a rolling basis to Allowed PI Claims on a first in, first out ("**FIFO**") basis based upon the date the PI Trust determines each PI Claim is Allowed. All payments will be subject to the Maximum Annual Payment (as defined herein). PI Claims with earlier positions in the FIFO queue are more likely to receive payment up to the Point Value sooner than PI Claims assigned later positions in the FIFO queue.

(b) Establishment of the FIFO Processing and Payment Queues.

(i) The PI Trust shall order claims that are sufficiently complete to be reviewed for processing purposes on a FIFO basis except as otherwise provided herein (the "**FIFO Processing Queue**").

(ii) The claimant's position in the FIFO Processing Queue shall be determined by the date the claim is filed with the PI Trust. If any claims are filed on the same date, the claimant's position in the FIFO Processing Queue shall be determined by the date of the diagnosis of the Opioid Use Disorder, addiction, or death for which the claim was filed. If any claims are filed and diagnosed on the same date, the claimant's position in the FIFO Processing Queue shall be determined by the claimant's date of birth, with older claimants given priority over younger claimants.

(iii) Allowed PI Claims shall be paid in FIFO order based on the date an executed PI Claim Release is received by the PI Trust (the "**FIFO Payment Queue**"). The Trust may issue payments in installments.

(iv) Unless otherwise ordered by the Bankruptcy Court, where the PI Claimant is deceased or incompetent, and the settlement and payment of his or her claim must be approved by a court of competent jurisdiction or through a probate process prior to acceptance of the claim by the claimant's representative, an offer

made by the PI Trust on the claim shall remain open so long as proceedings before that court or in that probate process remain pending, provided that the PI Trust has been furnished with evidence that the settlement offer has been submitted to such court or in the probate process for approval. If the offer is ultimately approved by the court or through the probate process and accepted by the claimant's representative, the PI Trust shall pay the claim in the amount so offered, based upon the Point Value in effect at the time the offer was first made.

(v) Where the PI Claimant is not deceased or incompetent, the Trust shall pay the PI Claimant based on the Point Value at the time of payment(s), including any installment payment.

(vi) If executed PI Claim Releases are received by the PI Trust on the same date, the PI Claimant's position in the FIFO Payment Queue shall be determined by the date of the diagnosis of the addiction or injury for which the claim was filed. For such claims, if the respective holders' addiction or injury was diagnosed on the same date, the position of those claims in the FIFO Payment Queue shall be determined by the PI Trust based on the dates of the claimants' birth, with older claimants given priority over younger claimants.

(c) While the PI Trust may enter into a lien resolution program, each PI Claimant remains responsible for satisfying any liens that third parties may claim against an Award to such PI Claimant.

(d) Pursuant to Article IV.X.8 of the Plan, 5% of each Distribution made by the PI Trust will be paid to the Common Benefit Escrow and then, upon its establishment, directly to the Common Benefit Fund, on a periodic schedule. To the extent a Holder of a PI Claim has retained, or is a member of a group of Holders that has retained, separate counsel through an individual contingency fee arrangement, the amount payable from such Holder's Distributions under this § 4.4(d) shall be deducted from any contingency fees and/or costs, in accordance with the Common Benefit Fund, owed to such separate counsel. If the order establishing the Common Benefit Fund provides for the reimbursement of attorneys' costs, a portion of the Common Benefit Fund assessment (up to but not exceeding 40% of the amount payable under Article IV.X.8 of the Plan) may be applied to the reimbursement of such counsel's actual costs and expenses, in which case such agreed cost-reimbursement amount shall not reduce the contingency fee amounts payable to such counsel. Except as expressly set forth in Article IV.X.8 of the Plan, nothing in the Plan shall impair or otherwise affect any contingency fee contract between any Holder of a PI Claim (or any group of Holders of PI Claims) and such Holder's (or group's) counsel.

4.5 Process for Adjustment of the Point Value and Setting the Maximum Annual Payment.

(a) Uncertainty of Debtors' PI Claim Liabilities. There is inherent uncertainty regarding the Debtors' total PI Claim liabilities, which means there is inherent uncertainty regarding the amounts that holders of PI Claims will receive. Accordingly,

the Trustee must periodically evaluate and adjust the Point Value, with the consent of the FCR. The Trustee shall undertake such evaluation upon the request of the Trustee, the PI Committee, or the FCR. Unless the Trustee provides persuasive evidence to convince the FCR otherwise, the Point Value will change to the proposed level of the party who requested the evaluation, pending completion of the evaluation.

(b) Determination and Adjustment of the Point Value.

(i) The Trustee must base his or her determination of the Point Value on current estimates of the number, types, and values of present and future PI Claims, the value of the assets then available to the PI Trust for their payment, all anticipated administrative and legal expenses, and any other material matters that are reasonably likely to affect the sufficiency of funds to treat all Holders of PI Claims in a substantially similar manner. When making these determinations, the Trustee may rely on the advice of experts and shall exercise common sense and flexibly evaluate all relevant factors.

(ii) If a redetermination of the Point Value has been proposed in writing by either the Trustee, the PI Committee, or the FCR but has not yet been adopted, then Awards offered to PI Claimants shall be based upon the lower of the current Point Value or the proposed Point Value. However, if the proposed Point Value was the lower amount but was not subsequently adopted, then Awards offered to PI Claimants shall thereafter receive the difference between the lower proposed Point Value and the higher current Point Value. Conversely, if the proposed Point Value was the higher amount and was subsequently adopted, then Awards offered to PI Claimants shall thereafter receive the difference between the lower current Point Value and the higher adopted Point Value.

(iii) If the Trustee, with the consent of the FCR, makes a determination to increase the Point Value, the Trustee shall make supplemental payments to all PI Claimants, who previously liquidated their claims against the Trust and received payments based on a lower Point Value. The Trustee's obligation to make a supplemental payment to a PI Claimant shall be suspended in the event the payment in question would be less than $100, and the amount of the suspended payment shall be added to the amount of any prior supplemental payment/payments that was/were also suspended because it/they would have been less than $100. However, the Trustee's obligation shall resume and the Trustee shall pay any such aggregate supplemental payments due the PI Claimant at such time that the total exceeds $100.

(c) Determination of the Maximum Annual Payment. The PI Trust shall create a model of cash flow, expenses, principal, and income year-by-year to be paid over the term of the PI Trust. In each year, the PI Trust shall be empowered to pay out to claimants the portion of its funds payable for that year according to the model (the "**Maximum Annual Payment**"). The Point Value and the Maximum Annual Payments are based on projections over the lifetime of the PI Trust. If such long-term projections are revised, the Point Value may be adjusted accordingly, which will result in a new

model of the PI Trust's anticipated cash flow and a new calculation of the Maximum Annual Payment. If the PI Trust determines at any time that the present value of the PI Trust's assets is less than the projected present value of its assets for such date, then it will remodel the cash flow year-by-year to be paid over the life of the PI Trust.

ARTICLE 5

VALUATION OF AND EVIDENTIARY REQUIREMENTS FOR ALLOWED CLAIMS

5.1 Base Payments and Level Awards for Base Payment and Level Awards. The PI Trust will value Allowed PI Claims using the Base Payments and Level Awards set forth in this matrix. In the event a PI Claimant may qualify only for the Base Payment and not for a Level Award, then no additional amount above the Base Payment will be offered.

	Tier 1: Use of MNK Opioids ≥ 6 months	**Tier 2:** Use of MNK Opioids <6 months
Base Payment:[6]	5,000 points	3,000 points
Level A:	Death from an Opioid 10,000 points	n/a

[6] If a PI Claimant does not qualify for an additional Level Award, the PI Claim is not entitled to receive additional money above the Base Payment.

5.2 Evidentiary Requirements for Opioid Product Identification.

(a) List of Qualifying Opioid Products. The following list sets forth the Qualifying Opioids as required to establish an Allowed PI Claim pursuant to section 4.2(c):

MLNK Qualifying Branded opioids:
Roxicodone, Exalgo, Methadose, Anexsia

MLNK Qualifying Generic Opioids:

Compound	NDC (Labeler Prefix and Drug Code)
Hydrocodone Bitartrate And Acetaminophen	0406-0123
Hydrocodone Bitartrate And Acetaminophen	0406-0124
Hydrocodone Bitartrate And Acetaminophen	0406-0125
Hydrocodone Bitartrate And Acetaminophen	0406-0376
Hydrocodone Bitartrate And Acetaminophen	0406-0377
Hydrocodone Bitartrate And Acetaminophen	0406-0378
Acetaminophen And Codeine Phosphate	0406-0483
Acetaminophen And Codeine Phosphate	0406-0484
Acetaminophen And Codeine Phosphate	0406-0485
Oxycodone and Acetaminophen	0406-0512
Oxycodone and Acetaminophen	0406-0522
Oxycodone and Acetaminophen	0406-0523
Methadone Hydrochloride (Methadose)	0406-0527
Methadone Hydrochloride (Methadose)	0406-0540
Oxycodone Hydrochloride	0406-0552
Oxycodone Hydrochloride	0406-0595
Oxymorphone Hydrochloride	0406-1009
Oxymorphone Hydrochloride	0406-1010
Methadone Hydrochloride	0406-1510
Methadone Hydrochloride	0406-2540
Methadone Hydrochloride	0406-5755
Methadone Hydrochloride	0406-5771
Buprenorphine and Naloxone	0406-1923
Buprenorphine and Naloxone	0406-1924
Buprenorphine and Naloxone	0406-8020
Hydromorphone Hydrochloride	0406-3243
Hydromorphone Hydrochloride	0406-3244
Hydromorphone Hydrochloride	0406-3249
Hydromorphone Hydrochloride	0406-3308
Hydromorphone Hydrochloride	0406-3312
Hydromorphone Hydrochloride	0406-3316

Compound	NDC (Labeler Prefix and Drug Code)
Hydromorphone Hydrochloride	0406-3332
Morphine Sulfate	0406-8003
Morphine Sulfate	0406-8315
Morphine Sulfate	0406-8320
Morphine Sulfate	0406-8330
Morphine Sulfate	0406-8380
Morphine Sulfate	0406-8390
Oxycodone Hydrochloride	0406-8515
Oxycodone Hydrochloride	0406-8530
Oxycodone Hydrochloride	0406-8556
Oxycodone Hydrochloride	0406-8557
Methadose (sugar free)	0406-8725
Fentanyl (transdermal patch)	0406-9000
Fentanyl (transdermal patch)	0406-9012
Fentanyl (transdermal patch)	0406-9025
Fentanyl (transdermal patch)	0406-9037
Fentanyl (transdermal patch)	0406-9050
Fentanyl (transdermal patch)	0406-9062
Fentanyl (transdermal patch)	0406-9075
Fentanyl (transdermal patch)	0406-9100
Fentanyl (transdermal patch)	0406-9112
Fentanyl (transdermal patch)	0406-9125
Fentanyl (transdermal patch)	0406-9150
Fentanyl (transdermal patch)	0406-9175
Fentanyl Citrate	0406-9202
Fentanyl Citrate	0406-9204
Fentanyl Citrate	0406-9206
Fentanyl Citrate	0406-9208
Fentanyl Citrate	0406-9212
Fentanyl Citrate	0406-9216

(b) Evidence of Qualifying Opioid Products. One of the following is required to demonstrate a Qualifying Opioid as listed in section (a):

(i) A PI Claimant who provides evidence of a prescription for brand name opioids Roxicodone, Exalgo, Methadose, or Anexsia, may rely on the name alone without the necessity of a corresponding NDC number.

(ii) To qualify based on the use of one of the generic products listed in section (a) above, a PI Claimant must present either:

(A) The corresponding NDC number, which is set forth in the list in section (a) above;[7] or

(B) A notation in the record that the product is manufactured or sold by Mallinckrodt or SpecGx.

(c) Evidence Required for Qualifying Opioid Products. All PI Claimants must demonstrate a prescription (which contains the name of the PI Claimant or Decedent, as applicable) and a Qualifying Opioid by submitting one of the following pieces of evidence:

(i) Pharmacy prescription records;

(ii) Prescription records, including without limitation:

(A) A visit note in which the prescribing physician lists a prescription for one of the Qualifying Opioids, or

(B) A signed prescription from a doctor for one of the Qualifying Opioids;

(iii) A historical reference[8] to one of the Qualifying Opioids, including but not limited to:

(A) A reference in contemporaneous medical records to historical use of one of the Qualifying Opioids,

(B) A reference in contemporaneous substance abuse, rehabilitation, or mental health records to historical use of one of the Qualifying Opioids,

(C) A reference in contemporaneous law enforcement records to historical use of one of the Qualifying Opioids, or

(D) A reference in contemporaneous family law or other legal proceedings records to historical use of one of the Qualifying Opioids;

(iv) A photograph of the prescription bottle or packaging of one of the Qualifying Opioids with the name of the PI Claimant (or Decedent, as applicable) as the patient listed on the prescription label; or

(v) A certification supplied by a Debtor, any of its successors (including the Trust), or a third party at a Debtor's or one of its successors' request, indicating the customer loyalty programs, patient assistance programs ("**PAPs**") copay

[7] The list of NDC numbers may be supplemented as additional information becomes available.

[8] For Voting Claims, the record must have been created prior to Petition Date only if the historical reference is self-reported by the PI Claimant.

assistance programs, or any other data otherwise available to the certifying entity reflects that the PI Claimant (or Decedent, as applicable) had at least one prescription for one of the Qualifying Opioids.

(vi) The PI Claimant must submit evidence that establishes that the PI Claimant holds a PI Claim based upon exposure to any opioid product or substance based on conduct of the Debtors occurring or existing on or before the Effective Date. The PI Trust shall have discretion to determine whether this requirements has been met so as to provide sufficient indicia of reliability that the PI Claimant or Decedent (as applicable) was prescribed and used Qualifying Opioids.

(vii) Whether the PI Claimant qualifies for Tier 1 or Tier 2 will be based on the length of use stated in the declaration.

(viii) Any PI Claimant who does not meet the requirements of sections 4.2, 5.2(a), 5.2(b), and 5.2(c)(i-vi), is not entitled to any payment from the Trust.

5.3 Award Determination. Allowed PI Claims held by PI Claimants who meet the Qualifying Opioid requirement shall be categorized[9] as follows:

(a) Tier 1:

(i) PI Claimants must demonstrate use of a Qualifying Opioid for 6 or more months; however, the usage does not have to be consecutive.

(ii) Tier 1 Level A Payment: To qualify for an Award under Tier 1 Level A, a PI Claimant must meet the criteria of the Tier 1 Base Payment and demonstrate death caused by an opioid. If making a claim for a Tier 1 Level Award based on death, the death certificate of the Decedent as well as any toxicology reports or autopsy reports must be provided. The records do not have to coincide in time with the provided Qualifying Opioid use. No affidavits may be used to meet this requirement.

(b) Tier 2:

(i) Use of a Qualifying Opioid less than 6 months or otherwise not meeting the criteria of Tier 1 are entitled to no additional payments other than the Base Payment.

(ii) In the event a PI Claimant does not qualify for Tier 1, such PI Claimant will be eligible to receive the Tier 2 Base Payment and only the Tier 2 Base Payment.

[9] PI Claimants who assert or allege Qualifying Opioid usage in their Claim Form for which they cannot produce corresponding evidence will not recover on account of such alleged opioid usage.

5.4 Deficiencies and Opportunity to Cure.

(a) The Trust will develop policies and procedures to notify PI Claimants when a claim submitted for liquidation pursuant to these PI TDP is incomplete or otherwise deficient, and the timing by which such deficiency must be cured in order to establish an Allowed PI Claim.

(b) If the deficiency is timely cured to the satisfaction of the Trust, no deduction or penalty will be assessed to an otherwise qualifying Claim.

5.5 [Reserved]

5.6 Appeals to Special Master.

(a) With the consent of the FCR the Trustee may appoint one or more neutral persons to serve as an Appeals Special Master pursuant to this provision. Each Appeals Special Master shall be paid a flat rate of $1,000 to review and issue a determination on each appeal referred to the Appeals Special Master for resolution.

(b) A PI Claimant who disagrees with the ruling of the PI Trust may appeal to the Appeals Special Master within fourteen (14) days of notice of such ruling by submitting a written statement outlining the PI Claimant's position and why the PI Claimant believes the PI Trust has erred.

(c) An appeal fee of $1,000 shall be assessed against the PI Claimant's recovery from the PI Trust. If the PI Claimant's appeal to the Appeals Special Master results in a decision in favor of the PI Claimant, the appeal fee will be refunded to the PI Claimant.

(d) The Appeals Special Master shall review only the appeal record and claim file in deciding the appeal. The Appeals Special Master shall apply the guidelines and procedures established in these PI TDP, and the appeals process shall not result in any modification of substantive eligibility criteria.

(e) The Appeals Special Master shall issue a determination on the appeal in writing, which shall be served on the PI Claimant (and the PI Claimant's counsel, where applicable) and the Trust.

(f) Decisions of the Appeals Special Master are final and binding, and PI Claimants have no further appeal rights beyond those set forth in these PI TDP.

5.7 Claims Audit Program.

(a) In General. Within 60 days of the Effective Date, the Trustee, with the consent of the FCR, shall develop methods for auditing the reliability of the evidence and statements made in claims submitted to the PI Trust and approved for an offer of payment (a claims audit program). The PI Trust may retain an independent third-party to implement the audit program. In the event that the PI Trust reasonably determines that any individual or entity has engaged in a pattern or practice of providing unreliable evidence to the Trust, it

may decline to accept additional evidence from such provider in the future.

(b) Assessment of Additional Information. To the extent that the PI Trust or the entity overseeing the claims audit program believe that it is relevant, nothing herein shall preclude the PI Trust or the entity overseeing the claims audit program, in the Trust's sole discretion, from reviewing or taking into consideration other claims filed in state or federal court complaints or against other trusts. Any PI Claimant subject to the claims audit program shall cooperate and, if requested, provide the PI Trust or the entity overseeing the claims audit program with a HIPAA Release that authorizes the PI Trust to obtain medical and other records to verify the claim.

(c) Actions Based on Audit Results. In the event that an audit reveals that fraudulent information has been provided to the Trust, the PI Trust may penalize any PI Claimant or PI Claimant's attorney by rejecting the PI Claim or by other means including, but not limited to, requiring the source of the fraudulent information to pay the costs associated with the audit and any future audit or audits, raising the level of scrutiny of additional information submitted from the same source or sources, refusing to accept additional evidence from the same source or sources, seeking the prosecution of the claimant or claimant's attorney for presenting a fraudulent claim in violation of 18 U.S.C. § 152, and seeking sanctions from the Bankruptcy Court.

5.8 Costs Considered. Notwithstanding any provision of these PI TDP to the contrary, the Trustee shall give appropriate consideration to the cost of investigating and uncovering invalid PI Claims so that the payment of Allowed PI Claims is not further impaired by such processes with respect to issues related to the validity of the evidence supporting a claim. The Trustee shall have the latitude to make judgments regarding the amount of transaction costs to be expended by the PI Trust so that Allowed PI Claims are not unduly further impaired by the costs of additional investigation. Nothing herein shall prevent the Trustee, in appropriate circumstances, from contesting the validity of any claim against the PI Trust whatever the costs, or declining to accept medical evidence from sources that the Trustee has determined to be unreliable pursuant to the claims audit program described herein or otherwise.

ARTICLE 6

CONFIDENTIALITY

6.1 Confidentiality of Claimants' Submissions.

(a) In General. All submissions to the PI Trust by a holder of a PI Claim, including the Claim Form and materials related thereto, shall be treated as made in the course of settlement discussions between the holder and the Trust, and intended by the parties to be confidential and to be protected by all applicable state and federal privileges and protections, including but not limited to those directly applicable to settlement discussions.

(b) Authorized Disclosures.

(i) Claimant Consent and Subpoenas. The PI Trust will preserve the confidentiality of PI Claimant submissions, and shall disclose the contents thereof only to such other persons as authorized by the holder or in response to a valid subpoena of such materials issued by the Bankruptcy Court, a Delaware state court, or the United States District Court for the District of Delaware. The PI Trust shall provide the PI Claimant or counsel for the PI Claimant a copy of any such subpoena immediately upon being served; provided, however, that if a subpoena seeks records or information pertaining to more than fifty (50) PI Claimants, the PI Trust may instead first provide a copy of the subpoena to counsel for the Committee and the FCR and delay providing a copy of the subpoena to counsel for individual holders of PI Claims until, in the Trustee's judgment, it appears likely that information or records relating to the holders may have to be produced in response to the subpoena. In such a case, the PI Trust shall ensure that the notice that is provided to counsel for the holders allows such counsel sufficient time to object to the production. The PI Trust shall on its own initiative or upon request of the PI Claimant in question take all necessary and appropriate steps to preserve said privileges before the Bankruptcy Court, a Delaware state court, or the United States District Court for the District of Delaware and before those courts having appellate jurisdiction related thereto.

(ii) Other Required Disclosures. Notwithstanding anything in the foregoing to the contrary, with the consent of the Committee and the FCR, the PI Trust may, in specific limited circumstances, disclose information, documents or other materials reasonably necessary in the Trust's judgment to preserve, litigate, resolve, or settle coverage, or to comply with an applicable obligation under an insurance policy or settlement agreement, or as required in connection with a lien-resolution program or lien-resolution laws (including those relating to Medicare liens); provided, however, that the PI Trust shall take any and all steps reasonably feasible in its judgment to preserve the further confidentiality of such information, documents and materials, and prior to the disclosure of such information, documents or materials to a third party, the PI Trust shall receive from such third party a written agreement of confidentiality that (a) ensures that the information, documents and materials provided by the PI Trust shall be used solely by the receiving party for the purpose stated in the agreement and (b) prohibits any other use or further dissemination of the information, documents and materials by the third party except as set forth in the written agreement of confidentiality.

(c) Claimant Discovery Obligations. Nothing in this PI TDP, the Plan or the Trust Agreement expands, limits or impairs the obligation under applicable law of a PI Claimant to respond fully to lawful discovery in any underlying civil action regarding his or her submission of factual information to the PI Trust for the purpose of obtaining compensation for opioid-related injuries from the Trust.

(d) Secure Destruction Upon Termination. As part of the process by which the PI Trust's activities are wound-down in connection with termination of the PI Trust, and once the Trustee has been determined that there is no legitimate reason to retain PI Claims records submitted by PI Claimants, the PI Trust shall securely destroy all records

containing personal information about PI Claimants or other individuals identified in the claims records. The destruction of the records shall comply with Delaware law and any applicable federal laws that may apply to the information contained within the records, such that any personal or individual-identifying information is rendered unreadable, undecipherable, and inaccessible. Following such destruction, the Trustee shall file a certification with the Bankruptcy Court attesting to the PI Trust's compliance with this provision.

ARTICLE 7

PROCEDURES FOR PI CLAIMANTS WHO OPT TO LIQUIDATE THEIR PI CLAIMS IN THE TORT SYSTEM

7.1 Option to Elect to Liquidate a PI Claim in the Tort System.

(a) A PI Claimant may elect to liquidate his or her PI Claim by commencing a lawsuit against the Trust in the tort system subject to the following terms.

(b) By electing to liquidate a PI Claim in the tort system, a PI Claimant forfeits any right to have its PI Claim liquidated under sections 4 through 5 of these PI TDP, and instead shall have the right to liquidate the PI Claim exclusively in the tort system. This option is available only for claims that meet the definition of "PI Claim" under the Plan.

(c) A PI Claimant who opts to pursue a PI Claim in the tort system may recover (i) no amount greater than a PI Claimant can recover for a similar PI Claim under the liquidation procedures of these PI TDP, and (ii) compensatory damages only for direct injuries (no punitive damages will be paid by the PI Trust). A PI Claimant may not pursue an indirect claim in the tort system.

7.2 Process to File Suit in the Tort System.

(a) A PI Claimant may elect to liquidate a PI Claim in the tort system rather than under these PI TDP by checking the box so indicating on the Claim Form, which must be filed with the PI Trust in accordance with section 4.2(b) above.[10]

(b) If the PI Claimant makes such election, then the PI Claimant may file a lawsuit regarding only its PI Claim (and no other claims) against only the PI Trust (and including no other parties as defendants) solely in the United States District Court for the District of Delaware ("**Delaware District Court**"),[11] unless such court shall order pursuant to 28

[10] The filing of a Claim Form indicating that a PI Claimant has elected to liquidated his or her PI Claim in the tort system shall have no effect on any federal or state statute of limitations or repose applicable to the claims asserted by such PI Claimant's action.

[11] The Debtors shall seek an order from the Delaware District Court requiring that lawsuits filed by Holders of PI Claims who elect, subject to the terms hereof, to liquidate their PI Claims by commencing separate lawsuits in the tort system be filed and tried solely in the Delaware District Court pursuant to 28 U.S.C. § 157(b)(5).

U.S.C. § 157(b)(5) that such suit may be tried in the United States District Court (other than the Delaware District Court) for the district in which the PI Claim arose.

(c) Any such lawsuit must be filed by the PI Claimant in an individual capacity and not as a member or representative of a class, and no such lawsuit may be consolidated with the lawsuit of any other plaintiff by, or on the motion of, any plaintiff.[12]

(d) All defenses (including, with respect to the PI Trust, all defenses which could have been asserted by the Debtors, including whether the lawsuit was timely filed) shall be available to both sides at trial.[13]

(e) If a PI Claimant obtains a judgment on his/her PI Claim in the tort system and such judgment becomes a final order (each, a "**Final Judgment**"), such Final Judgment shall be deemed Allowed for purposes under the Plan and shall be payable by the Trust, subject to the below provisions on limitation on damages, the Recovery Percentage, the Maximum Value, deductions as set forth below, and the resolution of healthcare liens.

7.3 Limitation on Damages and Attorneys' Fees. Notwithstanding their availability in the tort system, and except as provided below for claims asserted under the law of a Foreclosed Jurisdiction, no multiple, exemplary, statutory enhanced and/or punitive damages (i.e., damages other than compensatory damages), and no interest, attorneys' fees or costs (including statutory attorneys' fees and costs) shall be payable, with respect to any PI Claim litigated against the PI Trust in the tort system. For purposes of these TDP, a "**Foreclosed Jurisdiction**" shall mean a jurisdiction that describes a claim for compensatory damages under these TDP as a claim for "exemplary" or "punitive" damages, thereby foreclosing a claimant from a remedy or compensation under these TDP if the law for that jurisdiction were to be applied hereunder. In the event a PI Claim is made under these TDP for compensatory damages that would otherwise satisfy the criteria for payment under these TDP, but Claimant's Jurisdiction is a Foreclosed Jurisdiction, the claimant may elect the Commonwealth of Pennsylvania as the PI Claimant's jurisdiction, and such PI Claimant's damages shall be determined pursuant to the statutory and common laws of the Commonwealth of Pennsylvania without regard to its choice of law principles. The choice of law provision in this Section 7.3 applicable to any PI Claim with respect to which, but for this choice of law provision, the applicable law of the PI Claimant's jurisdiction is determined to be the law of a Foreclosed Jurisdiction, shall only govern the rights between the PI Trust and the PI Claimant including, but not limited to, suits in the tort system pursuant to this Article 7.

7.4 Maximum Point Value.

[12] The Trustee shall be empowered (i) to bring one or more consolidated actions against multiple Holders of PI Claims who elect, subject to the terms hereof, to liquidate their PI Claims by commencing separate lawsuits in the tort system and (ii) to seek to consolidate multiple lawsuits commenced by individual Holders of PI Claims who elect, subject to the terms hereof, to liquidate their PI Claims by commencing separate lawsuits in the tort system.

[13] Among other things, the PI Trust shall be empowered to assert that the claim that is the subject of a PI Claimant's lawsuit is not a "PI Claim" within the meaning of the Plan.

(a) Payment on a Final Judgment for a PI Claim shall not exceed the dollar-equivalent of 45,000 points (the "**Maximum Value**"), which is three times the maximum Point Value attributed under the liquidation provisions of the PI TDP to eligible claims for death. The Maximum Value shall be determined based upon the Point Value at the time of payment.

(b) Points will be converted to dollars consistent with the conversion set forth in section 4.5 of these PI TDP. As set forth in these PI TDP, the dollar amount ultimately awarded per point will be determined with reference to the funds remaining in the PI Trust and to the pool of claims remaining against the PI Trust. It will vary depending on how many people choose to opt out their claims and how expensive it is for the PI Trust to defend those claims in the tort system. It will also depend on the payment elections made by those who are liquidating their claims under sections 4 through 5 of these PI TDP.

(c) Any payments on a Final Judgment are subject to the Maximum Annual Payment.

7.5 Recovery Percentage.

(a) A Final Judgment on a PI Claim, minus any multiple, exemplary, statutory enhanced and/or punitive damages (i.e., damages other than compensatory damages), interest, attorneys' fees or costs (including statutory attorneys' fees and costs) that have been awarded as part of such Final Judgment, shall be subject to reduction by the same percentage that PI Claims liquidated under these PI TDP are reduced prior to payment. In other words, a PI Claimant who elects to liquidate his or her PI Claim in the tort system shall not be entitled to receive more than his or her pro-rata share of the value available for distribution to all PI Claims entitled to a recovery pursuant to these PI TDP.

(b) Based upon the statistical sampling and modeling performed by financial analysts and subject-matter experts, review of judgments obtained in lawsuits, settlement history, and collaborative discussions with stakeholders, the Base Payments and Level Awards described in these PI TDP represent an estimated pro-rata percentage recovery by PI Claimants holding Allowed PI Claims of approximately ½% (such pro-rata percentage recovery as may be altered over time, the "**Recovery Percentage**"). Accordingly, the initial Recovery Percentage is 1/2%.

(c) No holder of a PI Claim who elects to liquidate his or her PI Claim in the tort system shall receive a payment that exceeds the liquidated value of his or her PI Claim multiplied by the Recovery Percentage in effect at the time of payment (such value so reduced, the "**Percentage-Reduced Claim**"); provided, however, that if there is a reduction in the Recovery Percentage, the Trustee, in his or her sole discretion, may cause the PI Trust to pay a PI Claim based on the Recovery Percentage that was in effect prior to the reduction if the judgment in respect of such PI Claim became a Final Judgment prior to the date the Trustee proposes the new Recovery Percentage to the Committee and the FCR, and the processing of such PI Claim was unreasonably delayed due to circumstances beyond the control of the PI Claimant or the PI Claimant's counsel (as applicable).

7.6 Adjustment of the Recovery Percentage.

(a) The Recovery Percentage shall be subject to change if the Trustee, with the consent of the FCR, determines that an adjustment is required. At any time when the Trustee reviews the Point Value, the Trustee shall also review the then-applicable Recovery Percentage to assure that it is based on accurate, current information and may, after such reconsideration, change the Recovery Percentage if necessary with the consent of the FCR. Adjustment of the Recovery Percentage requires the consent of the FCR.

(b) The Trustee shall base his or her determination of the Recovery Percentage on current estimates of the number, types, and values of current and future PI Claims, the value of the assets of the PI Trust available for the payment of Allowed PI Claims pursuant to these PI TDP and amounts due and estimated to become due pursuant to these PI TDP in respect of Final Judgments obtained by PI Claimants who elect to liquidate their PI Claims in the tort system, all anticipated administrative and legal expenses, and any other material matters that are reasonably likely to affect the sufficiency of funds to pay a comparable percentage of (i) full value to all Holders of Allowed PI Claims and (ii) the Maximum Value to PI Claimants who elect to liquidate their PI Claims in the tort system. When making these determinations, the Trustee shall exercise common sense and flexibly evaluate all relevant factors.

(c) If a redetermination of the Recovery Percentage has been proposed in writing by the Trustee, but such redetermination of the Recovery Percentage has not yet been adopted, a PI Claimant that has obtained a Final Judgment shall receive the lower of the then-current Recovery Percentage and the proposed Recovery Percentage. However, if the proposed Recovery Percentage is the lower amount but is not subsequently adopted, the PI Claimant shall thereafter receive the difference between the lower proposed amount and the higher current amount. Conversely, if the proposed Recovery Percentage is the higher amount and subsequent adopted, the PI Claimant who has obtained a Final Judgment shall thereafter receive the difference between the over current amount and the higher adopted amount.

(d) At least thirty (30) days prior to proposing in writing a change in the Recovery Percentage, the Trustee shall post to the Trust's website a notice indicating the Trustee is reconsidering the Recovery Percentage.

(e) If the Trustee, with the consent of the FCR, makes a determination to increase the Recovery Percentage due to a material change in estimates of the future assets and/or liabilities of the Trust, the PI Trust shall make supplemental payments to all PI Claimants who obtained previously a Final Judgment and received payments based on a lower Recovery Percentage. The amount of any such supplemental payment shall be the liquidated value of the PI Claim in question multiplied by the newly-adjusted Recovery Percentage, less all amounts paid previously to the PI Claimant with respect to such PI Claim.

(f) The Trust's obligation to make a supplemental payment to a PI Claimant shall be suspended in the event the payment in question would be less than $100.00, and the

amount of the suspended payment shall be added to the amount of any prior supplemental payment/payments that was/were also suspended because it/they would have been less than $100.00. However, the Trust's obligation shall resume, and the PI Trust shall pay any such aggregate supplemental payments due to the PI Claimant that obtained a Final Judgment at such time that the total exceeds $100.00.

7.7 Payment of Judgments for Money Damages.

(a) A PI Claimant who obtains a Final Judgment shall be entitled to receive from the PI Trust in full and final satisfaction of that Final Judgment, a gross amount (subject to deductions set forth next) equal to the *lesser* of (i) the Percentage-Reduced Claim and (ii) the Maximum Value, in each case as then in effect, as described next (such lesser amount, the "**Gross Amount**").

(b) A PI Claimant's Gross Amount shall be subject to allowable deductions and holdbacks.

(c) The resulting net amount shall be paid to the PI Claimant in the form of six equal installments, each not to exceed an amount to be set by the Trustee with the consent of the Committee and the FCR at the time of the first installment. The first installment will be placed in the FIFO Payment Queue based on the date on which the judgment became final. Additional equal installments will be paid in years six (6) through ten (10) following the year of the initial payment. All installment payments will be subject to the Maximum Annual Payment and prior satisfaction of any outstanding liens in accordance with section 7.8. In no event shall interest be paid in respect of any judgment obtained in the tort system.

(d) None of the Percentage-Reduced Claim, the Maximum Value, the Gross Amount, the deductions therefrom, or the payment schedule is subject to any appeal or reconsideration.

7.8 Resolution of Liens. The PI Trust shall not issue any payment in respect of a Final Judgment until the PI Trust has received proof that any private or governmental health care liens or similar claims against such Final Judgment have been satisfied or will be satisfied out of the recovery.

7.9 Special Procedures for Minors and Heirs. The special procedures set forth in article 8 of these PI TDP shall apply to PI Claimants who are minors under applicable law and elect, subject to the terms hereof, to liquidate their PI Claims by commencing a lawsuit in the tort system. Any person seeking a Distribution from the PI Trust in the capacity of an heir must provide the Heirship Declaration.

ARTICLE 8

DISTRIBUTIONS FOR THE BENEFIT OF MINORS

8.1 Procedures Regarding Distributions to or for the Benefit of Minor Claimants. The following procedures apply to any PI Claimant who is a minor under applicable law (a "**Minor**

Claimant") for so long as the PI Claimant remains a minor under applicable law. These procedures apply regardless of whether the Minor Claimant's Proxy (as defined below) elects to have the PI Claim liquidated under these PI TDP or to pursue the claim in the tort system.

8.2 Actions by Proxy of Minor Claimant.

(a) A Minor Claimant's custodial parent, his/her legal guardian under applicable law (a "**Guardian**"), or an adult providing custody and care to the minor (any of the foregoing acting on behalf of the Minor Claimant, the "**Proxy**" is authorized to make submissions on behalf of the Minor Claimant under the PI TDP, subject to section 8.2(b) below.

(b) The Proxy shall be responsible for submitting, on behalf of such Minor Claimant, all required forms under the PI TDP, including the proof of claim form, as well as any evidence required by the PI Trust to support the proof of claim form, and any other documentation required or requested pursuant to the PI TDP.

(c) The Proxy is authorized to take, on behalf of a Minor Claimant, all actions under the PI TDP that the Minor Claimant would be authorized to take if such Minor Claimant were an adult, other than receiving distributions from the PI Trust (unless so authorized by section 8.6 below). These actions include, where permitted, making an opt-out or, if the Minor Claimant is a PI Claimant, making a payment election or requesting an appeal pursuant to the PI TDP.

8.3 Establishing Proxy of a Minor Claimant.

(a) Any purported Proxy making a submission to the PI Trust on behalf of a Minor Claimant shall include along with such submission documentation of his/her authority to act on behalf of the Minor Claimant, consisting of the following:

(i) If the purported Proxy is the Guardian of the Minor Claimant, then the court order appointing that Proxy as Guardian, or other documents reasonably acceptable to the PI Trust as sufficient under applicable law to evidence the guardianship.

(ii) If the purported Proxy is the custodial parent of the Minor Claimant, then a statement under penalty of perjury that such Proxy is the custodial parent of the Minor Claimant.

(iii) If the purported Proxy is neither the Guardian nor custodial parent of the Minor Claimant, then a statement under penalty of perjury by the purported Proxy that he/she is providing custody and care to the Minor Claimant, stating for how long he/she has been providing such care and custody, explaining his/her relationship to the Minor Claimant and the circumstances around the provision of care and custody, as well as a statement and/or records from one or more of the following in support of his/her statement under penalty of perjury:

(A) Minor Claimant's school;

(B) Purported Proxy's landlord or property manager;

(C) Minor Claimant's health provider;

(D) Minor Claimant's child care provider;

(E) Purported Proxy's placement agency;

(F) Governmental social services agency;

(G) Indian tribe officials; or

(H) Purported Proxy's Employer.

(iv) Whether the purported Proxy is a Guardian, custodial parent, or neither, the PI Trust may require additional corroborating evidence at his discretion, including in the event that instructions are received from more than one purported Proxy for the same Minor Claimant.

8.4 Distributions to Minor Claimants.

(a) When the PI Trust has determined the final distributable amount on a Minor Claimant's claim, it will send notice of such final amount to the Minor Claimant's Proxy and counsel (if known). Such notice will include a letter inviting the Proxy to discuss how the distributable amount was determined, and the PI Trust will take reasonable steps to ensure that the Proxy understands how such amount was determined.

(b) Any distributions owing to a Minor Claimant that are ready for issuance by the PI Trust at a time when the Minor Claimant is still a minor under applicable law shall be (i) used to pay the individual attorneys' fees of the Minor Claimant pursuant to section 8.5 below and (ii) with respect to the remainder, paid into an interest-bearing sub-fund of the PI Trust (the "**Minor Claimants Account**"), held there for the sole benefit of the Minor Claimant, and invested in a U.S. governmental money-market fund until such funds are distributed pursuant to section 8.6 below or until the Minor Claimant becomes an adult under applicable law (the "**Adult Distribution Date**"), at which time the amount then held in such account (including interest earned) shall be paid directly to such PI Claimant.

(c) Pending distributions for all Minor Claimants may be held in the same sub-fund.

8.5 Payments of attorneys' fees.

(a) Within a reasonable period following receipt of notice of the final distributable amount on Minor Claimant's PI Claim, and using forms to be provided by the Trust, the Minor Claimant's counsel shall submit to the Trust, with a copy to the Proxy, a request for payment of legal fees and expenses from the Minor's recovery.

(b) It is the Minor Claimant's attorney's duty to comply with all ethical and legal rules respecting such legal fees and expenses, and the PI Trust is permitted to rely upon such representation in issuing payments in respect of such fees and expenses.

(c) Absent objection from the Proxy with respect to such asserted fees and expenses, the PI Trust shall remit payment to the Minor Claimant's attorney in accordance with the latter's request.

8.6 Early Distributions.

(a) Funds held in the Minor Claimants Account for a Minor Claimant may be released prior to the Adult Distribution Date only pursuant to (a) an order of a U.S. court of general jurisdiction in the Minor Claimant's state of residence, or (b) an order entered by the U.S Bankruptcy Court for the District of Delaware.

MNK PI TDP EXHIBIT A

SAMPLE CLAIM FORM FOR
NON-NAS PI TRUST DISTRIBUTION PROCEDURES

This proof of claim form ("**Claim Form**") must be completed by each PI Claimant seeking an Award from the Mallinckrodt Opioid Personal Injury Trust (the "**PI Trust**") on a Non-NAS PI Claim.[14]

FAILURE TO SUBMIT THIS CLAIM FORM AS PROVIDED IN THE PI TDP MAY CAUSE THE PI CLAIM TO BE DEEMED NON-COMPENSABLE UNDER THE PI TDP.

Instructions:
If you hold multiple PI Claims against the Debtors on account of injuries to more than one opioid user, then fill out one Claim Form for each of those PI Claims. If you hold multiple PI Claims on account of multiple injuries to the same opioid user, then fill out only one Claim Form. One Claim Form submitted for a PI Claim shall be deemed to be a Claim Form in respect of that PI Claim and also any PI Claims against a Released Person or Shareholder Released Person that are associated with that PI Claim.

Follow the instructions of each section carefully to ensure that your Claim Form is submitted correctly. If any section does not pertain to your claim, leave it blank. Except as otherwise indicated, all words shall be given their ordinary, dictionary meaning. Submitting this Claim Form does not guarantee that you will receive payment from the PI Trust. Whether you will receive payment depends on whether you provide the required submissions, as set forth in the PI TDP and whether your claim meets the eligibility requirements set forth in the PI TDP.

This Claim Form allows you to choose to "opt out" of the streamlined, expedited PI TDP liquidation process with respect to any PI Claim against one or more of the Debtors, and instead pursue that PI Claim in the tort system by filing a lawsuit against the PI Trust at your own expense. You may litigate in court only with respect to a PI Claim held against one or more Debtors, and may not litigate other PI Claims. **If you select the "opt out" option, you will not be eligible to receive an award based on the liquidation provisions of the TDP. Furthermore, you will not be allowed to opt back in to the PI TDP if your lawsuit is unsuccessful in the tort system.** Any final judgment you obtain in the tort system against the PI Trust will be subject to reduction pursuant to the "opt out" procedures set forth in the PI TDP.

A CLAIMANT MAY OPT OUT ONLY BY CHECKING THE "OPT OUT" BOX AND SUBMITTING THIS CLAIM FORM. FAILURE TO SUBMIT THIS CLAIM FORM TO THE PI TRUST DOES NOT CONSTITUTE OPTING OUT OF HAVING A PI CLAIM LIQUIDATED UNDER THE PI TDP. If you choose to "Opt Out" and litigate your claim in the

[14] Capitalized terms used but not defined herein have the meanings ascribed to them in the Mallinckrodt Opioid Personal Injury Non-NAS Trust Distribution Procedures ("**PI TDP**") or, if not defined therein, then the meanings ascribed to them in the Plan.

tort system, the PI Trust will be able to raise any available defenses to your claim, including any defenses based on whether your claim was timely filed under the applicable statute of limitations.

Each PI Claimant is responsible for satisfying any liens that health insurance companies, government entities (including Medicare and Medicaid), or any other third party may have against any Award that may be issued by the PI Trust. By submitting this Claim Form and choosing to liquidate your Claim under the PI TDP, you understand that the PI Trust may enter into a lien resolution program ("**LRP**") and, if the PI TDP does enter into a LRP, you are deemed to consent to the LRP and the PI Trust's release of information provided in connection with your PI Claim as required under the LRP to identify any liens that may be asserted against an Award based on the PI. If any liens are identified against your Award, the PI Trust may reduce your Award by the amount required to satisfy the lien(s).

Claim Form Submission: You may submit this completed Claim Form online at mnkpitrust.com or by mailing it to MNK PI Trust, 501 Riverchase Parkway East, Suite 100, Hoover, Alabama, 35244.

PART ONE: PERSONAL INFORMATION OF PI CLAIMANT
(All Claimants must complete this Part)
Please fill out only **one** of the following sections (Section 1.A or 1.B).

- If you hold a PI Claim arising from your own use of opioids (or if such holder is alive and you are completing this form as his/her representative), fill out Section 1A.

- If you hold a PI Claim due to use of opioids by a deceased person (or you are completing this form on behalf of such a holder as his/her representative), fill out Section 1.B.

Section 1.A: If you hold a PI Claim arising from your own use of opioids (or if such holder is alive and you are completing this form as his/her representative), then the term "Claimant" in this Claim Form refers to the person who used opioids, whether that is you or the person you represent. Please fill out the information below:

Claimant's Name:

Claimant's Date of Birth:

Claimant's Address:

Claimant's Social Security Number (or Taxpayer ID or Social Insurance Number (Canada)):

Representative Name (if applicable):

Legal Authority for Representative (if applicable):
(e.g., POA, Legal Guardian, Conservator):

Section 1.B: If you are filing a PI Claim for a deceased person with a claim due to the deceased person's use of opioids, or you are completing this form as the representative of an individual with a claim for a deceased person's use of opioids, please fill out the information below:

Name of Deceased Person Who Used Opioids:

Date of Birth of Deceased Person Who Used Opioids:

Date of Death:

Cause of Death:

Social Security Number (or Taxpayer ID or Social Insurance Number (Canada)) of Person Who Used Opioids:

Name of Claimant Filing Claim on behalf of the Person Who Used Opioids:

Claimant's Address:

Claimant's Relationship to Person Who Used Opioids:
(i.e., parent, sibling, child, spouse, etc.)

Representative Name (if applicable):

Legal Authority for Representative (if applicable):
(e.g., POA, Legal Guardian, Conservator):

If a Court has appointed you as Executor, Administrator or Personal Representative of the Deceased Person's Estate, then submit the Court Order so appointing you along with your Claim Form. If a Court has not appointed you as Executor, Administrator, or Personal Representative of the Deceased Person's Estate, then also execute and submit the appropriate Heirship Declaration attached.

PART TWO: "OPT OUT" OF THE PI TDP LIQUIDATION PROCEDURES
(Complete this part only if you elect to "Opt Out" of the PI TDP liquidation procedures and file a lawsuit to liquidate your claim in the tort system. If you choose to have your claim evaluated under the PI TDP liquidation procedures, skip this Part Two).

If you would like to forfeit all rights to have your PI Claims liquidated under the PI TDP and instead to pursue your PI Claim by filing a lawsuit against the PI Trust in court at your own expense, check the following box. **If you "opt out," you will not be eligible to receive an Award from the PI Trust based upon the TDP liquidation procedures.**

Mark the following box **only if** you **elect to "opt out" of the PI TDP liquidation procedures and instead pursue your PI Claim in civil court through the tort system by filing a lawsuit in court at your own expense:**

_____ I elect to Opt-Out of the PI TDP liquidation procedures and pursue my PI Claim by filing a lawsuit against the PI Trust.

Holders of PI Claims who elect to "Opt Out" of the PI TDP must complete only Parts 1, 2 and 10 of this Claim Form.

PART THREE: PRESCRIBED MEDICATIONS
(If you selected "Opt Out," skip this Part Three).

Section 3: Identify the Qualifying Opioids that the opioid user who is the subject of this PI Claim was prescribed. *Include evidence of the prescriptions when submitting this Claim Form.*

		Date of First Prescription:	Date of Last Prescription:	Length of Use (in months):
Roxicodone	☐			
Exalgo	☐			
Methadose	☐			
Anexsia	☐			
Mallinckrodt / SpecGx Generic (name) _____ _____	☐			

PART FOUR: OPIOID USER AND OPIOID CLAIMANT INJURIES
(If you selected "Opt Out," skip this Part Four).

WARNING: IF YOU DO NOT CHECK ANY INJURIES ON THIS LIST OTHER THAN JAIL, THEN YOUR PI CLAIMS WILL BE DISALLOWED AND YOU WILL RECEIVE NO RECOVERY

Section 4:

Please mark all that are applicable to your claim.

___ ADDICTION

___ OPIOID USE DISORDER

___ WITHDRAWALS

___ OVERDOSE

___ JAIL

___ REHAB

Please enter the earliest date of injury for any injuries checked above: _____

PART FIVE: TIERING AND LEVEL DESIGNATION
(If you selected "Opt Out", skip this Part Five).

Section 5.A: In this section, please check the tier that applies to your PI Claim. Please refer to the PI TDP for full definitions and qualifying criteria.

_____ **Tier 1:** You can demonstrate use of a Qualifying Opioid for 6 months or more (does not have to be consecutive use).

____ **Tier 2** You can demonstrate use of a Qualifying Opioid for less than 6 months and otherwise do not meet the criteria of Tier 1.

Section 5.B: If you selected **Tier 1** above, please mark the designation that applies to your PI Claim. IF BOTH BASE PAYMENT AND LEVEL A APPLY TO YOU, CHOOSE LEVEL A. Please refer to the PI TDP for full definitions and qualifying criteria.

_____ Level A: You can demonstrate death caused by an opioid (e.g., death caused by overdose or withdrawal).

_____Base Payment: You can demonstrate use of a Qualifying Opioid for 6 months or more.

PART SIX: MEDICAL LIENS
(If you selected "Opt Out," skip this Part Six).

Section 6.A: Did any insurance company pay for medical treatment for the opioid-related injuries that gave rise to your PI Claim?

Yes: No:

Section 6.B: In the last 20 years, was the opioid user who is the subject of your claim eligible for coverage by any of the following, or did any of the following actually pay for his/her opioid-related health costs?
Respond by writing "Yes" or "No" next to each insurance provider name, and provide the requested information as to each. If any insurance carrier who provided coverage to the opioid user is not identified, please fill in that carrier's information at the bottom of the chart.

Type of Insurance:	**Yes/No**	**Street Address:**	**Phone Number**	**Policy Number (if any)**	**Policy Holder**	**Dates of Coverage**
Medicare						
Medicaid						
Tricare						
VA						

Champus						
Private (name below:						

PART SEVEN: SIGNATURE (You must complete this Part Seven regardless of your elections above)

This Claim form must be signed by the Injured Party or the Injured Party's Personal Representative.

Name of person who is signing this form: _____
E-mail address of person who is signing this form: _____
Phone Number of person who is signing this form: _____

I am including the evidence requested above in my submission of this form: ☐

I declare under penalty of perjury that the representations made and the information provided on this Claim Form are true, correct and complete to the best of my knowledge.

Signature of Non-NAS PI Claimant (or signature of Representative Completing this Form for a Non-NAS PI Claimant)

This page intentionally left blank.

MNK PI TDP EXHIBIT B

[SAMPLE]
HIPAA RELEASE FORM FOR
NON-NAS PI TRUST DISTRIBUTION PROCEDURES

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Claimant Name: **Date:**

Date of Birth: **Soc. Sec. No.**

1. The following individuals or organizations are authorized to disclose my health records to the parties specified below in section #4:

_____
_____
_____
_____
_____
_____
_____

(Note: Please list the names of your medical care providers and your health insurance providers that may have records relevant to the resolution of your PI Claim. If you are unsure of the exact legal name of your medical providers and health insurance providers, you can leave this blank, and we will complete it for you with the understanding that you authorize all relevant parties):

2. The type and amount of information to be used or discloses is as follows:

The entire record, including but not limited to: any and all medical records, mental health records, psychological records, psychiatric records, problem lists, medication lists, lists of allergies, immunization records, history and physicals, discharge summaries, laboratory results, x-ray and imaging reports, medical images of any kind, video tapes, photographs, consultation reports, correspondence, itemized invoices and billing information, and information pertaining to Medicaid or Medicare eligibility and all payments made by those agencies, for the following dates:

Dates of Services - From:_____ To: _____

(Note: List the date range for which the medical providers and insurance companies above may have records relevant to the resolution of your PI Claim. If you are unsure of the exact dates, then leave this blank, and we will complete this section for you with the understanding that you authorize all relevant date ranges).

3. I understand that the information in my health records may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human

immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, as well as treatment for alcohol and drug abuse.

4. The health information may be disclosed to and used by the following individual and/or organization:

[fill in name of entity]

5. I understand I have the right to revoke this authorization at any time. I understand if I revoke this authorization, I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire 10 years after the date that I sign it.

6. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization and forego a recovery under the Mallinckrodt Opioid Non-NAS Personal Injury Trust Distribution Procedures. I understand that no organization may condition treatment, payment, enrollment, or eligibility for benefits on my signing of this authorization. I understand I may inspect or copy the information to be used or disclosed, as provided in CFR 1634.524. I understand any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules or HIPAA. If I have questions about disclosure of my health information, I can contact the parties listed above in section #4.

_____ _____

Patient or Legal Representative Date

_____

Relationship to Patient (If signed by Legal Representative)

MNK PI TDP EXHIBIT C

[SAMPLE]
HEIRSHIP DECLARATIONS FOR
MALLINCKRODT OPIOID NON-NAS PI TRUST DISTRIBUTION PROCEDURES

SD-1	**SWORN DECLARATION: SIGNATORY IS EXECUTOR UNDER DECEDENT'S LAST WILL AND TESTAMENT**
You are required to complete this declaration if you hold a PI Claim[15] (and thus are a "**PI Claimant**") regarding the opioid-related death of another person (the "**Decedent**"), and you have not been appointed with the authority to act on behalf of the Decedent because no probate or estate proceeding has been commenced, but you have been named as executor or executrix (or comparable position under applicable state law) under the Last will and Testament of the Decedent.	

I. Decedent Information			
Name:	First Name	Middle Initial	Last Name
Social Security Number:		Date of Death:	
Residence/Legal Domicile Address at Time of Death	Street		
	City	State	Zip Code

II. PI Claimant Information			
Your Name	First Name	Middle Initial	Last Name
Your Social Security Number			
Your Address	Street		
	City	State	Zip Code
Your Relationship to Decedent			
Basis of Your Authority to Act for the Decedent			
List here and attach copies of all document(s) evidencing the basis for your authority	1. Last Will and Testament of _____, dated _____. 2.		

[15] Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Plan.

III. Heirs and Beneficiaries of Decedent (Attach additional sheets if needed)			
Use the space below to identify the name and address of all persons who may have a legal right to share in any settlement payment on behalf of the claim of the Decedent. Also state if and how you notified these persons of the settlement, or the reason they cannot be notified.			
	Name:	**Information:**	
1.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
2.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
3.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
4.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
5.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:

IV. PI CLAIMANT CERTIFICATION

This Sworn Declaration is an official document for submission to the PI Trust. By signing this Sworn Declaration, I certify and declare under penalty of perjury pursuant to 28 U.S.C. §1746 that:

(a) I am seeking authority to act on behalf of the Decedent and his or her estate, heirs, and beneficiaries in connection with the PI TDP, including with respect to the submission of forms and supporting evidence and the receipt of payment for any such awards.

(b) I will abide by all substantive laws of the Decedent's last state of domicile concerning the compromise and distribution of any monetary award to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments.

(c) No one else has been appointed the personal representative, executor, administrator, or other position with the authority to act on behalf of the Decedent and his or her estate.

(d) The copy of the Last Will and Testament provided by me is the Last Will and Testament of the Decedent.

(e) No application or proceeding has been filed in state or other court to administer the estate of the Decedent or to appoint an executor or administrator because state law does not require it.

(f) I will notify the PI Trust immediately if my authority to act is curtailed, surrendered, withdrawn, or terminated.

(g) I am not aware of any objections to my appointment and service as the PI Claimant on behalf of the Decedent and his or her estate, heirs, and beneficiaries.

(h) No person notified under Section III objects to my serving as the PI Claimant and taking such steps as required by the PI TDP to resolve all claims related to the Decedent's prescription and/or use of Mallinckrodt opioids. The persons named in Section III are all of the persons who may have a legal right to share in any settlement payment issued in respect of the injuries of the Decedent.

(g) I will comply with any and all provisions of the state law regarding the compromise and distribution of the proceeds of the settlement of a survival or wrongful death claim to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments.

(h) I will indemnify and hold harmless the PI Trust and its agents and representatives, from any and all claims, demands, or expenses of any kind arising out distributions from the PI Trust on account of injuries of the Decedent.

The information I have provided in this Declaration is true and correct. I understand that the PI Trust and Court will rely on this Declaration, and false statements or claims made in connection with this Declaration may result in fines, imprisonment, and/or any other remedy available by law.

V. PI Claimant Signature			
Signature:		**Date**:	

SD-2	SWORN DECLARATION: DECEDENT DID NOT LEAVE A LAST WILL AND TESTAMENT
You are required to complete this declaration if you hold a PI Claim[16] (and thus are a "**PI Claimant**") regarding the opioid-related death of another person (the "**Decedent**"), and you have not been appointed with the authority to act on behalf of the Decedent because the Decedent Claimant died without a Will and no probate or estate proceeding has been opened.	

I. Decedent Information			
Name:	First Name	Middle Initial	Last Name
Social Security Number:		Date of Death:	
Residence/Legal Domicile Address at Time of Death	Street		
	City	State	Zip Code

II. PI Claimant Information			
Your Name	First Name	Middle Initial	Last Name
Your Social Security Number			
Your Address	Street		
	City	State	Zip Code
Your Relationship to Decedent			
Basis of Your Authority to Act for the Decedent			
List here and attach copies of all document(s) evidencing the basis for your authority	1. A copy of the intestate statute of the state or domicile of the Deceased Claimant at the time of his or her death. 2.		

[16] Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Plan.

III. Heirs and Beneficiaries of Decedent (Attach additional sheets if needed)			
Use the space below to identify the name and address of all persons who may have a legal right to share in any settlement payment on behalf of the claim of the Decedent. Also state if and how you notified these persons of the settlement, or the reason they cannot be notified.			
	Name:	**Information:**	
1.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
2.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
3.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
4.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:
5.		Address	
		Relationship to Decedent	
		Notified of Settlement?	__Yes. How notified: __ No. Why not notified:

IV. PI CLAIMANT CERTIFICATION
This Sworn Declaration is an official document for submission to the PI Trust. By signing this Sworn Declaration, I certify and declare under penalty of perjury pursuant to 28 U.S.C. §1746 that:

(a) I am seeking authority to act on behalf of the Decedent and his or her estate, heirs, and beneficiaries in connection with the PI TDP, including with respect to the submission of forms and supporting evidence and the receipt of payment for any such awards.

(b) I will abide by all substantive laws of the Decedent's last state of domicile concerning the compromise and distribution of any monetary award to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments.

(c) No one else has been appointed the personal representative, executor, administrator, or other position with the authority to act on behalf of the Decedent and his or her estate.

(d) There is no known last will and testament of the Decedent and no application or proceeding has been filed in state or other court to administer the estate of the Decedent or to appoint an executor or administrator.

(e) I will notify the PI Trust immediately if my authority to act is curtailed, surrendered, withdrawn, or terminated.

(f) I am not aware of any objections to my appointment and service as the PI Claimant on behalf of the Decedent and his or her estate, heirs, and beneficiaries.

(g) No person notified under Section III objects to my serving as the PI Claimant and taking such steps as required by the PI TDP to resolve all claims related to the Decedent's prescription and/or use of Mallinckrodt opioids. The persons named in Section III are all of the persons who may have a legal right to share in any settlement payment issued in respect of the injuries of the Decedent.

(h) I will comply with any and all provisions of the state law regarding the compromise and distribution of the proceeds of the settlement of a survival or wrongful death claim to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments.

(i) I will indemnify and hold harmless the PI Trust and its agents and representatives, from any and all claims, demands, or expenses of any kind arising out distributions from the PI trust on account of injuries of the Decedent.

The information I have provided in this Declaration is true and correct. I understand that the PI Trust and Court will rely on this Declaration, and false statements or claims made in connection with this Declaration may result in fines, imprisonment, and/or any other remedy available by law.

V. PI Claimant Signature			
Signature:		**Date**:	

MNK TDP EXHIBIT D

MALLINCKRODT OPIOID PERSONAL INJURY TRUST
NON-NAS PI CLAIM RELEASE

NOTICE: THIS IS A BINDING DOCUMENT THAT AFFECTS YOUR LEGAL RIGHTS. PLEASE CONSULT YOUR ATTORNEY IN CONNECTION WITH EXECUTING THIS DOCUMENT. IF YOU DO NOT PRESENTLY HAVE AN ATTORNEY, YOU MAY WISH TO CONSIDER CONSULTING ONE.

PI Claimant's Name: _____

PI Claimant's Social Security Number: _____

Law Firm (if represented by counsel): _____

If the PI Claimant or personal representative filed a lawsuit against Mallinckrodt for opioid-related injuries and PI Claimant's spouse is a party to the lawsuit, please provide the following additional information:

Name of PI Claimant's Spouse: _____

Liquidated Value of Claim: $ _____(subject to deductions set forth in the PI TDP)

The Mallinckrodt Opioid Personal Injury Trust (the "**Trust**"), and the undersigned PI Claimant or "**Personal Representative**"[17] (either being referred to herein as "**Releasor**"), agree as follows:

1. Capitalized terms used but not defined herein shall have the meanings assigned to them in the *Fourth Amended Joint Plan Of Reorganization (With Technical Modifications) Of Mallinckrodt Plc And Its Debtor Affiliates Under Chapter 11 Of The Bankruptcy Code*, dated as of February 18, 2022 (as it may be amended or modified, the "**Plan**"), confirmed by order of the United States Bankruptcy Court for the District of Delaware entered on March 2, 2022 [Docket No. 6660], or the Mallinckrodt Opioid Personal Injury Non-NAS Trust Distribution Procedures (as may be amended from time to time, the "**PI TDP**"), which are incorporated into this Non-NAS PI Claim Release ("**Release**") by reference.

2. Releasor has filed a claim against the Trust (the "**Claim**"). The Trust has reviewed the Claim to determine whether it is compensable under the terms of the TDP. The Trust has offered an Award to the PI Claimant for the Claim in the liquidated value set forth above. The Award shall be paid subject to any deductions required as set forth in the PI TDP. Releasor has decided to accept the offer and enter into this Release.

3. The amount of the Award to Releasor under this Release (the "**Payment Amount**") has been calculated in accordance with the PI TDP. The Point Value may be adjusted from time to time as provided in the TDP. Releasor acknowledges that the Trust cannot provide any assurance of the level of the Point Value that will apply to the liquidated value of the Claim. Releasor acknowledges that the Point Value are based on estimates that change over time, and that other claimants may have in the past received, or may in the future receive, a smaller or larger valuation of their claims than the Releasor. Releasor further

[17] The "Personal Representative" is the person who under applicable state law or legal documentation has the authority to represent the PI Claimant, the PI Claimant's estate or the PI Claimant's heirs.

acknowledges that, other than as specifically set forth in the PI TDP, the fact that claimants have in the past been paid, or may in the future be paid, a smaller or larger valuation of their claims shall not entitle the Releasor to any additional compensation from the Trust. Should the Point Value be increased subsequent to the payment of the Payment Amount under this Release, Releasor shall be entitled to supplemental payments as provided in section 4.5 of the PI TDP. Subject to the payment provisions set forth in the PI TDP, the Trust will mail or electronically transfer to Releasor (or Releasor's counsel) the Payment Amount. This Release shall be effective upon receipt by Releasor (or Releasor's counsel) of the Payment Amount.

4. In consideration for the agreements described herein and other good and valuable consideration, Releasor hereby fully releases (i) the Trust, (ii) the current and former Trustee and the Delaware Trustee of the Trust, (iii) the Trust Advisory Committee of the Trust, (iv) the Future Claimants' Representative of the Trust, (v) each of the current and former directors, members, officers, agents, consultants, advisors, employees, attorneys, predecessors, successors and assigns of any of the parties set forth in items (i) through (iv), and (vi) any and all persons or organizations who are entitled to benefit from the injunctions entered pursuant to the Plan (the parties set forth in (i) through (vi) each, a "**Releasee**" and collectively, "**Releasees**") from any and all PI Claims, whether such claims are known or unknown, suspected or unsuspected, concealed or hidden, accrued or not accrued. This Release provides a release only with respect to PI Claims (as such term is defined in the Plan) released hereunder, and no other claims Releasor may have against any Releasee are released hereby.

5. Releasor expressly covenants and agrees forever to refrain from bringing any suit or proceeding, at law or in equity, against Releasees with respect to any Opioid Claim released hereby.

6. In the event of a verdict against others, any judgment entered on the verdict that takes into account the status of the Trust as a party legally responsible for a joint tortfeasor who is legally responsible for the PI Claimant's injuries shall be reduced by no more than the total and actual amount paid as consideration under this Release or such lesser amount as allowed by law.

7. The Releasor (1) represents that no judgment debtor has satisfied in full the Releasees' liability with respect to the PI Claimant's PI Claim as the result of a judgment entered in the tort system and (2) upon information and belief, represents that the Releasor has not entered into a release (other than this Release) that discharges or releases the Releasees' liability to the Releasor with respect to the PI Claimant's PI Claim.

8. Releasor agrees that this Release is to be effective not only on behalf of the PI Claimant but also for the PI Claimant's estate, spouse, children, heirs, administrators, executors, personal representatives, beneficiaries, successors and assigns and for any other person or entity asserting any PI Claim based in whole or in part on any opioid–related injury allegedly suffered by the PI Claimant; provided, however, that this Release does not release claims (including PI Claims) for opioid-related injuries suffered by the PI Claimant's spouse, children, heirs, administrators, executors, personal representatives, beneficiaries, successors or assigns, or any other person, because of such person's personal use of opioids.

9. Releasor agrees that this is a compromise of disputed claims and that the payment of the consideration for this Release is not to be considered an admission of liability on the part of any person or entity released hereby. It is further understood that this Release is not intended to relinquish any claim Releasees may have against any party or Releasor has against any party that is not a Releasee. The parties further agree that this Release shall not be admissible in any suit or proceeding whatsoever as evidence, except to enforce this Release, nor shall it be an admission of any liability.

10. Releasor, on behalf of the PI Claimant and the PI Claimant's spouse, children, heirs, administrators, executors, personal representatives, beneficiaries, successors and assigns, agrees to indemnify and hold

harmless Releasees from any further payment of liabilities, debts, liens, charges, costs and/or expenses of any character (including reasonable attorneys' fees and costs) arising out of any and all opioid-related claims by or on behalf of the PI Claimant and the PI Claimant's spouse, children, heirs, administrators, executors, personal representatives, beneficiaries, successors and assigns up to the full extent of the compensation paid or to be paid by the Trust to Releasor on account of the Claim (excluding attorneys' fees and costs); provided, however, that this indemnification and hold harmless obligation shall not apply to claims for (i) subsequently arising claim based on death to the extent such claims are not released pursuant to paragraph 4 of this Release and (ii) opioid-related injuries suffered directly by PI Claimant's spouse, children, heirs, administrators, executors, personal representatives, beneficiaries, successors or assigns, or any other person, because of such person's (as opposed to PI Claimant's) personal exposure to opioids to the extent such claims are not released pursuant to paragraph 8 of this Release.

11. Releasor represents and warrants that all Valid Liens[18], subrogation and reimbursement claims, including any obligations owing or potentially owing under MMSEA[19], relating to benefits paid to or on account of the PI Claimant in connection with, or relating to, the Claim have been resolved or will be resolved from the net proceeds of the settlement payment to the Releasor under this Release or from other funds or proceeds to the extent permitted under applicable lien settlement agreements or under applicable law. Upon request by the Trust, Releasor shall promptly provide the Trust with documentation evidencing Releasor's compliance with the certification in the foregoing sentence. It is further agreed and understood that no Releasee shall have any liability to the Releasor or any other person or entity in connection with such liens or reimbursement claims and that the Releasor will indemnify and hold the Releasees harmless from any and all such alleged liability as provided in the following sentence. The Releasor will indemnify and hold the Releasees harmless, to the extent of the amount of payment hereunder, excluding attorney's fees and costs, from any and all liability arising from subrogation, indemnity or contribution claims related to the PI Claim released herein and from any and all compensation or medical payments due, or claimed to be due, under any applicable law, regulation or contract related to the PI Claim released herein.

12. Releasor acknowledges that the Trust and the Protected Parties are the beneficiaries of the Claimant's certification pursuant to paragraph 11. In addition, the Releasor consents to the Trust's disclosure of information concerning the Claim as necessary for the Trust to comply with any lien resolution program or other obligation of the Trust with respect to liens that may be asserted against an Award based on an Allowed PI Claim. Such disclosure may include providing information about the Claim and payment of the Claim, including (1) the names, contact information, and Social Security numbers or Tax Identification numbers of the Releasor and the PI Claimant; (2) the PI Claimant's opioid-related injuries, date of birth, date of death, and dates regarding use of opioid products, diagnoses of an Opioid Use Disorder, and treatment regarding such opioid use; and (3) any other information needed to satisfy any obligations concerning such liens to the entity or agent charged with responsibility for monitoring, assessing, or receiving reports or payments in connection with such lien, (b) any third party retained by the Trust to assist the Trust in complying with any lien resolution program or reporting obligations, and (c) any person designated as a Protected Party under the Plan and for which the Trust is obligated to act as a reporting agent pursuant to any lien resolution or reporting obligations.

13. It is further agreed and understood that if the Releasor has filed a civil action against the Trust or the Debtor related to an opioid personal injury claim, the Releasor shall dismiss such civil action and obtain

[18] A "Valid Lien" is a lien that is permitted by applicable law and with respect to which the lien holder has taken all steps necessary under the terms of the document creating the lien and under applicable law to perfect the lien.
[19] "MMSEA" means 42 U.S.C. §1395y *et seq.* and related statutes, rules, regulations, or guidance in connection therewith, or relating thereto, including the Medicare, Medicaid, and SCHIP Extension Act of 2007 (P. L. 110-173), or any other similar statute or regulation, and any related rules, regulations, or guidance issued in connection therewith or relating thereto.

the entry of an order of dismissal with prejudice with respect to any PI Claim released herein no later than 30 days after the date hereof.

14. This Release contains the entire agreement between the parties and supersedes all prior or contemporaneous, oral or written agreements or understandings relating to the subject matter hereof except, if applicable, for the provisions of the TDP.

15. Releasor agrees that the law of the State of Delaware shall govern the construction of this Release notwithstanding any application of choice of law analysis. Releasor expressly authorizes the Trust to make payment under the terms of this Release to Releasor's counsel (if any) as agent for the Releasor.

16. Releasor further states that he or she is of legal age, with no mental disability of any kind, and is fully and completely competent to execute this Release on his or her own behalf and/or in his or her capacities as specified herein. Releasor further states that he or she knows the contents, as well as the effect, of this Release. Releasor further acknowledges that he or she executed this instrument after consultation with his or her attorney or the opportunity to consult with an attorney of his or her choice.

17. TO ENSURE THE ENFORCEMENT OF THIS RELEASE FULLY IN ACCORDANCE WITH THE TERMS HEREOF, INCLUDING BUT NOT LIMITED TO PARAGRAPH 4 HEREOF, RELEASOR HEREBY WAIVES ALL RIGHTS UNDER CALIFORNIA CIVIL CODE SECTION 1542 AND UNDER ANY OTHER FEDERAL OR STATE LAW OF SIMILAR EFFECT. CALIFORNIA CIVIL CODE SECTION 1542 PROVIDES THAT "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR." IF REPRESENTED BY AN ATTORNEY, RELEASOR ACKNOWLEDGES THAT HE OR SHE HAS BEEN ADVISED BY HIS OR HER ATTORNEY(S) CONCERNING, AND IS FAMILIAR WITH, THE EFFECT OF THIS WAIVER. RELEASOR UNDERSTANDS AND ACKNOWLEDGES THAT THIS WAIVER PREVENTS RELEASOR FROM MAKING ANY CLAIM AGAINST RELEASEES FOR ADDITIONAL DAMAGES EXCEPT AS SPECIFICALLY PROVIDED HEREIN. RELEASOR ACKNOWLEDGES THAT HE OR SHE INTENDS THESE CONSEQUENCES.

18. If any provision or part of any provision of this Release is determined to be void and unenforceable by a court of competent jurisdiction, the remainder of this Release shall remain valid and enforceable to the extent that Releasees' purpose for obtaining this Release can be realized.

19. Releasor acknowledges that the Trust's obligation to pay the Releasor is not triggered until the Trust receives the executed Release from Releasor.

20. Releasor acknowledges that pursuant to Article IV.X.8 of the TDP, 5% of each Distribution made by the Trust will be paid to the Common Benefit Escrow and then, upon its establishment, directly to the Common Benefit Fund, on a periodic schedule. To the extent a Holder of a PI Claim has retained, or is a member of a group of Holders that has retained, separate counsel through an individual contingency fee arrangement, the amount payable from such Holder's Distributions under this § 5.3(g)(iv) shall be deducted from any contingency fees and/or costs, in accordance with the Common Benefit Fund, owed to such separate counsel. If the order establishing the Common Benefit Fund provides for the reimbursement of attorneys' costs, a portion of the Common Benefit Fund assessment (up to 40% of the amount payable under Article IV.X.8 of the Plan may be applied to the reimbursement of actual costs and expenses incurred by such Holder's counsel, in which case such agreed cost-reimbursement amount shall not reduce the contingency fee amounts payable to such counsel.

MEDICARE SECONDARY PAYER CERTIFICATION

Pursuant to paragraph 12 of the Release, Releasor hereby represents and certifies to the Trust that, in respect of the Claim, the Releasor has paid or will provide for the payment and/or resolution of any obligations owing or potentially owing under MMSEA in connection with, or relating to, the Claim.

CERTIFICATION

The undersigned hereby (i) agrees to the terms of this Release, (ii) unconditionally and expressly warrants that the person executing this Release on behalf of any other person has full authority to do so on such person's behalf in all respects, (iii) certifies that the information that has been provided to support the Claim, is accurate according to my knowledge, information and belief, formed after an inquiry reasonable under the circumstances, and (iv) declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed on this ___ day of _____, 20___

_____
Signature of PI Claimant or Personal Representative

Name of Personal Representative (if applicable):_____