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.	)	

DEFENDANT NATIONAL UNION FIRE INSURANCE COMPANY OF PITTSBURGH, PA. AND AMERICAN HOME ASSURANCE COMPANY'S RESPONSE TO PLAINTIFF'S STATEMENT OF UNCONTROVERTED FACTS AND STATEMENT OF ADDITIONAL UNCONTROVERTED FACTS IN OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

Defendants National Union Fire Insurance Company of Pittsburgh, Pa. and American Home Assurance Company (together, the "AIG Insurers"), by and through their undersigned counsel, pursuant to Missouri Supreme Court Rule 74.04(c)(2), submit the following Response to Plaintiff's Statement of Uncontroverted Facts in Support of Plaintiff's Motion for Partial Summary Judgment (the "Motion") and Statement of Additional Facts in Support of the AIG Insurers' Opposition to Plaintiff's Motion for Partial Summary Judgment and Cross-Motion for Summary Judgment (together with Plaintiff's Motion, the "Motions") (altogether, the "Response").

In its Statement of Uncontroverted Facts, Plaintiff Opioid Master Disbursement Trust II ("Trust") has not posited "facts" at all, much less uncontroverted material facts. Instead, the Trust has largely presented cherry-picked allegations from a select set of "exemplar" complaints that it believes support its theory that the Opioid Lawsuits allege

injuries arising out of something other than Mallinckrodt's products. In so doing, the Trust did not include in its "facts"—essentially skipping over—the many allegations in the complaints that compromise its argument. Included in the AIG Insurers' Response are many examples of the allegations that the Trust failed to present to this Court, which show that the underlying plaintiffs sought to hold Mallinckrodt liable for its role as a ***producer and seller of opioid products***.

The following Response to Plaintiff's Statement of Uncontroverted Facts responds to each paragraph therein and is supplemented by the AIG Insurers' Statement of Additional Facts that follows.

THE AIG INSURERS' RESPONSE TO PLAINTIFF'S STATEMENT OF UNCONTROVERTED FACTS

1. The term "Mallinckrodt" as used herein refers to the following entities: Mallinckrodt LLC, Mallinckrodt APAP LLC, Mallinckrodt Enterprises LLC, SpecGx LLC, and SpecGx Holdings LLC.

RESPONSE: The AIG Insurers object to Paragraph 1 and state that no response is warranted, because Paragraph 1 is not material. To the extent a response is required, Paragraph 1 is uncontroverted for purposes of the Motions.

2. Mallinckrodt faced more than 3,000 pending opioid-related civil actions when it filed for bankruptcy on October 12, 2020 (the "Bankruptcy"). Declaration of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Petitions and First Day Motions Ex. A ¶ 12, In re Mallinckrodt plc, Case No. 20-12522 (JTD) (Bankr. D. Del. Oct. 12, 2020), ECF No. 128 ("Welch Decl. Ex. A").[1]

RESPONSE: The AIG Insurers object to Paragraph 2 and state that no response is warranted, because Paragraph 2 is not material. To the extent a response is required, Paragraph 2 is uncontroverted for purposes of the Motions.

[1] 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.

3. These underlying lawsuits were asserted by a wide variety of individuals and entities, including personal injury victims, governmental entities (consisting of states, counties, municipalities and tribal governments), hospitals, and third-party payors, such as treatment centers and insurance companies. *See* Welch Decl. Ex. A ¶ 15.

RESPONSE: The AIG Insurers object to Paragraph 3 and state that no response is warranted, because Paragraph 3 is not material. To the extent a response is required, Paragraph 3 is uncontroverted for purposes of the Motions.

4. These underlying lawsuits included allegations that, "[Mallinckrodt] Debtors, along with other opioid manufacturers, engaged in misleading marketing that overstated the benefits of opioid products and understated their risks." Welch Decl. Ex. A ¶ 77.

RESPONSE: The AIG Insurers object to Paragraph 4 and state that no response is warranted, because Paragraph 4 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuits to which Paragraph 4 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 4 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 4. Paragraph 4 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

5. The underlying lawsuits alleged that, as a result of this conduct, "manufacturers, distributors, and pharmacies flooded the market with opioids, increasing diversion of opioid products and thus increasing addiction, misuse, and abuse." Welch Decl. Ex. A ¶ 77.

RESPONSE: The AIG Insurers object to Paragraph 5 and state that no response is warranted, because Paragraph 5 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuits to which Paragraph 5 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a response is required, Paragraph 5 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 5.

Paragraph 5 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

A. Exemplar Allegations Asserted by State Governmental Entities

6. Included among the pre-petition claims asserted against Mallinckrodt were lawsuits commenced by state governmental entities.

RESPONSE: The AIG Insurers object to Paragraph 6 and state that no response is warranted, because Paragraph 6 is not material. To the extent a response is required, Paragraph 6 is uncontroverted for purposes of the Motions.

7. The State of Mississippi filed an amended complaint against Mallinckrodt (and other entities) in the Chancery Court of the First Judicial District of Hinds County, Mississippi in November 2019. *See* Amended Complaint Ex. B, Mississippi v. Purdue Pharma L.P. et al., No. 25CH1:15-cv-01814 (Miss. Chancery Ct. Nov. 12, 2019), No. 292 ("Ex. B").

RESPONSE: The AIG Insurers object to Paragraph 7 and state that no response is warranted, because Paragraph 7 is not material. To the extent a response is required, Paragraph 7 is uncontroverted for purposes of the Motions.

8. Mallinckrodt is included within the definition of "Defendants" as used by Mississippi in its amended complaint. Ex. B ¶ 48.

RESPONSE: The AIG Insurers object to Paragraph 8 and state that no response is warranted, because Paragraph 8 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 8 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 8 is uncontroverted for purposes of the Motions.

9. Mississippi alleged the following in its amended complaint:

a. "In a "marketing blitz" designed to ensure that every piece of information regarding chronic opioid therapy assured physicians and consumers that the benefits of using their opioids outweighed the risks, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly

truthful scientific and educational materials that misrepresented the risks, benefits, and superiority of opioids used long-term to treat chronic pain as described in Section IV.B.2 and IV.C.2; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids, as described in Section IV.B.2; (c) recruiting prescribing physicians as paid speakers, as means of both securing those physicians' future "brand loyalty" and extending their research to the physicians' peers, as described in Section IV.B.2; (d) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" (KOLs), not only to deliver scripted talks, but to draft misleading studies, conduct continuing medical education programs (CMEs) that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy as described in Section IV.C.2; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as Front Groups) that developed educational materials and treatment guidelines urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain as described in Section IV.C.2.f." Ex. B ¶ 7 (internal footnotes omitted).

b. "Indeed, opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on State agencies that address heroin use and addiction. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10–$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction." Ex. B ¶ 17.

c. "[D]rug 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, described in Section IV.C.1, governing branded communications." Ex. B ¶ 131.

d. "Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid while doing so—through KOLs and Front Groups. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside of FDA oversight. Through these unbranded materials, Defendants presented information and instructions concerning opioids that were generally contrary to, or at best, inconsistent with, information and instructions listed on Defendants' branded marketing materials and drug labels and with Defendants' own knowledge of the risks, benefits and advantages of opioids. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA." Ex. B ¶ 132.

e. "Through their well-funded, comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change prescriber perceptions, despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants' own labels—compelled disclosure." Ex. B ¶ 234.

f. "The fact that Mississippi would pay for these ineligible prescriptions is both the foreseeable and intended consequence of Defendants' fraudulent

marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy *so that* doctors would prescribe and government payors, such as the State, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids." Ex. B ¶ 599.

g. "In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Thus, prescription drug abuse is fueling the rise of heroin usage in Mississippi. According to Mississippi Bureau of Narcotics Director Marshall Fisher, '[w]hat is happening, the addicts are figuring out they can get heroin on the street, cheaper, and with much less risk than prescription drugs.' As a result, self-reported heroin use nearly doubled in the U.S. between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal Drug Enforcement Agency official, 'Who would have ever thought in this country it would be cheaper to buy heroin than pills and obtain them more easily. That is the reality we're facing.'" Ex. B ¶ 622 (internal footnotes omitted).

h. "The toll on patients who abuse or become addicted to opioids does not lend itself to quantification, or even easy descriptions. Many of them will lose their jobs and some of them will lose their homes and their families. Some of them will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. As noted above, some will become so desperate for drugs that they will switch to

heroin—moving from taking prescription drugs to buying and even injecting illegal drugs. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falls, traffic accidents, assaults, or from premature heart or neurological disease that hastens their death by 10 or 20 years." Ex. B ¶ 623.

i. "The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused harm to the community that includes, but is not limited to . . . f. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them . . . g. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process." Ex. B ¶ 662(f–g).

RESPONSE: The AIG Insurers object to Paragraph 9 and state that no response is warranted, because Paragraph 9 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 9 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a response is required, Paragraph 9 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 9. Paragraph 9 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. B, Amended Complaint, *Mississippi v. Purdue Pharma L.P. et al.*, No. 25CH1:15-cv-01814 (Miss. Chancery Ct. Nov. 12, 2019), No. 292 ("Mississippi Compl."):

- **"Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States based on prescriptions." (Ex. B, Mississippi Compl. ¶ 48.)**

- **"Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths." (Ex. B, Mississippi Compl. ¶ 49.)**

- **"While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated, based on IMS Health data for 2015, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications." (Ex. B, Mississippi Compl. ¶ 50.)**

- **"In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a profound transformation in medical and public perception that would permit the use of opioids not only for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches." (Ex. B, Mississippi Compl. ¶ 5.)**

- **"Defendants would not spend billions of dollars on marketing to physicians if they did not believe that such efforts were successful in generating prescriptions. For that reason, they devote substantial resources to marketing their drugs to prescribers and patients and then meticulously tracking their return on that investment." (Ex. B, Mississippi Compl. ¶ 93.)**

- **"Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance it created and led." (Ex. B, Mississippi Compl. ¶ 581.)**

10. Through its amended complaint, Mississippi sought: "a judgment requiring Defendants to pay damages, restitution, civil penalties, and attorneys' fees, costs, and expenses." Ex. B ¶ 22.

RESPONSE: The AIG Insurers object to Paragraph 10 and state that no response is warranted, because Paragraph 10 is not material and is not a "fact" at all but instead references relief sought. To the extent a response is required, Paragraph 10 is uncontroverted for purposes of the Motions.

11. Mississippi also requested "that the Court issue an order requiring Defendants to cease their unlawful promotion of opioids, to correct their misrepresentations, and to abate the public nuisance they have created, in addition to granting any other equitable relief authorized by law." *Id*.

RESPONSE: The AIG Insurers object to Paragraph 11 and state that no response is warranted, because Paragraph 11 is not material and is not a "fact" at all but instead references relief sought. To the extent a response is required, Paragraph 11 is uncontroverted for purposes of the Motions.

12. The State of Georgia filed a complaint against Mallinckrodt (and other entities) in the Superior Court of Gwinnett County, Georgia in January 2019. *See, e.g.*, Complaint Ex. D ¶¶ 3, 232, Georgia v. Purdue Pharma L.P. et al., No. 19-A-00060-8 (Ga. Super. Ct. Jan. 3, 2019) ("Ex. D").

RESPONSE: The AIG Insurers object to Paragraph 12 and state that no response is warranted, because Paragraph 12 is not material. To the extent a response is required, Paragraph 12 is uncontroverted for purposes of the Motions.

13. Mallinckrodt is included within the definition of "Defendants" as used by Georgia in its Complaint. Ex. D, at 2. Mallinckrodt is also included within the definition of "Manufacturer Defendants" as used by Georgia in its complaint. Ex. D ¶¶ 24–29.

RESPONSE: The AIG Insurers object to Paragraph 13 and state that no response is warranted, because Paragraph 13 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 13 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 13 is uncontroverted for purposes of the Motions.

14. Georgia alleged the following in its complaint:

a. "The opioid crisis does not exist as a matter of coincidence. Instead, it has been, and is still being, fueled by the unlawful actions of Defendants, who have generated billions of dollars in drug sales through their deceptive and illegal marketing of opioids, and who have failed to prevent the diversion of opioids in the State of Georgia. Defendants' actions have not only created short-term losses to the State, but long-term, costly problems that Georgia must grapple with for generations to come." Ex. D ¶ 3.

b. "Heroin overdose deaths have skyrocketed too, as those addicted to prescription opioids often switch to a cheaper alternative to meet their addiction demands. Consequently, the heroin and fentanyl death rates correspond with the increase in opioid-related deaths." Ex. D ¶ 76.

c. "As Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products. Distributor Defendants' continued indifference to their legal duties led to the unlawful shipment of massive quantities of opioids into the state, fueling the epidemic to levels never seen before. Consequently, the rates of opioid-related substance abuse, hospitalization, death, costs to the State of Georgia, and billions in profits to Defendants all track the rates of prescription, sale, and distribution of opioid products—all fostered by Defendants' efforts." Ex. D ¶ 232.

d. "Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids—like heroin and illicit (i.e., illegally manufactured) fentanyl—the massive distribution of opioids caused the opioid epidemic to become an opioid, heroin, and fentanyl crisis." Ex. D ¶ 238.

RESPONSE: The AIG Insurers object to Paragraph 14 and state that no response is warranted, because Paragraph 14 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in

the underlying lawsuit to which Paragraph 14 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a response is required, Paragraph 14 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 14. Paragraph 14 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. D, Complaint, *Georgia v. Purdue Pharma L.P. et al.*, No. 19-A-00060-8 (Ga. Super. Ct. Jan. 3, 2019) ("Georgia Compl."):

- **"Mallinckrodt plc, Mallinckrodt LLC, SpecGx LLC, and their DEA registrant subsidiaries and affiliates (collectively, 'Mallinckrodt') are or have been in the business of manufacturing, marketing, selling and distributing opioids throughout the United States, including the State of Georgia, including generic formulations of morphine sulfate, extended release, morphine sulfate, fentanyl transdermal, oral transmucosal fentanyl citrate, oxycodone with acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, naltrexone hydrochloride, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, buprenorphine, and naloxone." (Ex. D, Georgia Compl. ¶ 27.)**

- **"Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. D, Georgia Compl. ¶ 28.)**

- **"Manufacturer Defendants employed the same marketing plans and strategies and deployed the same message in Georgia as they did nationwide. They spread their false and deceptive statements throughout the State, both by marketing their branded opioids directly to doctors and patients and through seemingly unbiased and independent third parties that they controlled." (Ex. D, Georgia Compl. ¶ 108.)**

- **"Manufacturer Defendants' direct marketing of opioids proceeded on numerous tracks. First, each Manufacturer Defendant conducted advertising campaigns touting the purported benefits of their branded drugs, including through adve1iising in medical journals. Upon information and belief, Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. Many of these branded ads deceptively**

portrayed the benefits of opioids for chronic pain." (Ex. D, Georgia Compl. ¶ 109.)

- **"Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through detailers - sales representatives who visited individual doctors and medical staff in their offices - and small-group speaker programs. Each Manufacturer Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Manufacturer Defendants spent more than $133 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. Sales representatives visited hundreds of thousands of doctors and disseminated Manufacturer Defendants' misleading marketing messages. In accordance with common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health Holdings, Inc. (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to precisely track the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above." (Ex. D, Georgia Compl. ¶ 110.)**

- **"Third, Manufacturer Defendants marketed their opioids using unbranded advertising, paid speakers and key opinion leaders ('KOLs'), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as 'Front Groups'). By funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to promote opioids falsely and misleadingly for the treatment of chronic pain through scientific publications, treatment guidelines, Continuing Medical Education ('CME') programs, and medical conferences and seminars." (Ex. D, Georgia Compl. ¶ 111.)**

- **"The goal of Manufacturer and Distributor Defendants was the same: to create a large and excessive market for opioids, to bolster their revenue, to increase their profits, and to grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold." (Ex. D, Georgia Compl. ¶ 202.)**

15. The State of Florida filed an amended complaint against Mallinckrodt (and other entities) in the Circuit Court of the Sixth Judicial Circuit in and for Pasco County, West Pasco Division, New Port Richey, Florida in November 2018. *See* Amended Complaint Ex. E, Florida v. Purdue Pharma L.P. et al., No. 2018-CA-001438 (Fla. Cir. Ct. Nov. 16, 2018) ("Ex. E").

RESPONSE: The AIG Insurers object to Paragraph 15 and state that no response is warranted, because Paragraph 15 is not material. To the extent a response is required, Paragraph 15 is uncontroverted for purposes of the Motions.

16. Mallinckrodt is included within the definition of "Defendants" as used by Florida in its amended complaint. Ex. E, at 1. Mallinckrodt is also included within the definition of "Manufacturer Defendants" as used by Florida in its amended complaint. Ex. E ¶ 23.

RESPONSE: The AIG Insurers object to Paragraph 16 and state that no response is warranted, because Paragraph 16 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 16 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 16 is uncontroverted for purposes of the Motions.

17. Florida alleged the following in its amended complaint:

a. "As their tolerance grows and addiction deepens, many opioid users seek prescriptions from multiple doctors, buy black-market prescription opioids on the street, or turn to opium-derived street drugs like heroin and illicitly-produced fentanyl. Nearly 80% of heroin users reported using a prescription opioid prior to using heroin. Fentanyl and heroin carry extremely high risks of fatal overdose, and deaths caused by fentanyl and fentanyl analogs have skyrocketed in recent years, including in Florida, where deaths involving fentanyl increased by 80% between 2015 and 2016, and deaths involving heroin increased by more than 30%." Ex. E ¶ 69.

b. "The Defendants, led by the Manufacturer Defendants, spread misinformation through front groups that were created to appear to be neutral, third-party patient advocacy groups and professional associations, but that were in fact funded and influenced by Defendants, including, in some cases, the Distributor Defendants. The Defendants used these organizations to perpetuate the messages that chronic pain is undertreated and that opioids are as safe, effective, and extremely low-risk for most patients with chronic or "breakthrough" pain. The front organizations published "educational" literature for patients on pain management and pain treatment, as well as for doctors and other prescribers. The Defendants funded, influenced, and/or controlled the content of these ostensibly-neutral publications. Defendants then used these publications as supposedly independent support for their marketing claims. These front organizations purposely appeared as though they were acting independently of Defendants. Defendants funded and used these front organizations as mouthpieces to promote the widespread use of opioids for chronic pain, which increased the sales of the Manufacturer Defendants' branded and generic opioid products." Ex. E ¶ 109.

c. "**The U.S. Pain Foundation** describes itself as an educational and advocacy organization for people with chronic pain. The U.S. Pain Foundation has engaged in advocacy efforts nationwide, including through its participation in 62 advocacy coalitions and active engagement on 80 legislative bills. The U.S. Pain Foundation has close financial connections with the Manufacturer Defendants. For example, between 2012 and 2017, Insys contributed $2.5 million; Purdue contributed over $350,000; and Janssen contributed over $40,000. Teva is still listed as a sponsor on the U.S. Pain Foundation's website, as are other front groups like AAPM and APS." Ex. E ¶ 120.

d. "As described further below, the Manufacturer Defendants sponsored and participated in developing a large number of front group publications and marketing materials that spread the campaign of misinformation about

opioids and supported Defendants' efforts to sell both branded and generic opioids. These publications include *Treatment Options: A Guide for People Living with Pain*, which was sponsored by Purdue, Cephalon, and others and published by APF; *Finding Relief: Pain Management for Older Adults* (2009), which was sponsored by Janssen, with AGS and AAPM as "partners"; *Exit Wounds*, which was sponsored by Purdue and others and published by APF; and others described herein. The marketing materials that appeared to be neutral resources about chronic pain or responsible opioid use include websites such as www.PainKnowledge.com; and www.LetsTalkPain.org, which contain the misrepresentations described herein." Ex. E ¶ 121.

e. "The Manufacturer Defendants also spread misinformation through medical experts whom the Manufacturer Defendants paid to deliver deceptive messages because of their ability to influence their peer prescribers, known as KOLs. The Manufacturer Defendants intentionally positioned KOLs to appear to be independent, neutral actors in order to lend legitimacy to their opinions, making doctors and their patients more likely to accept their claims. However, the Manufacturer Defendants paid KOLs to present misrepresentations about opioids by paying them to speak at conferences, paying them consulting fees, hiring them to create promotional videos for opioids, paying them travel and lodging expenses, and paying them food and beverage expenses. The Manufacturer Defendants funded KOLs to create studies to support Defendants' claims. Defendants also trained KOLs and selected them for their ability to stay on message." Ex. E ¶ 124.

f. "The KOLs furthered Defendants' scheme to increase the number of opioid prescriptions and opioid use by consumers in Florida and elsewhere." Ex. E ¶ 129.

g. "The C.A.R.E.S. Alliance worked closely with other front groups. For example, the Alliance offered to send doctors (for free) *Clinical Guidelines*

for the Use of Opioid Therapy in Chronic Noncancerous Pain, written by APS and the AAPM. In addition, a portion of the sales of *Defeat Chronic Pain Now!* were donated to the American Pain Foundation." Ex. E ¶ 194.

h. "Mallinckrodt also had direct relationships with front groups. For example, Mallinckrodt was a member of the U.S. Pain Foundation." Ex. E ¶ 195.

i. "Mallinckrodt had close relationships with numerous KOLs. For example, Dr. Lynn Webster served on the company's Advisory Board and performed a study about the anti-deterrent effects of Mallinckrodt's drugs that the company relied on in its marketing materials. Dr. Scott Fishman's book, *Responsible Opioid Prescribing*, was given away for free by Mallinckrodt's C.A.R.E.S. Alliance. The book argues in favor of opioid-use for non-cancer pain, and its distribution was funded by opioid manufacturers such as Endo and Purdue. Dr. Fishman served as president of both APF and the AAPM and received funding from Manufacturer Defendants including Janssen, Endo, Cephalon, and Purdue. Dr. Fishman published a glowing review of *Defeat Chronic Pain Now!*" Ex. E ¶ 196.

j. "Mallinckrodt and its representatives made, and continue to make, these and other misrepresentations in order to increase opioid prescriptions." Ex. E ¶ 198.

k. "Mallinckrodt delivered its false and misleading misrepresentations to Florida doctors." Ex. E ¶ 199.

l. "Mallinckrodt's deceptive, unfair, and unconscionable actions led Florida prescribers to prescribe and consumers to consume opioid products. The opioid crisis described herein is a direct and foreseeable result of Mallinckrodt's actions. The State of Florida was damaged by Mallinckrodt's actions." Ex. E ¶ 206.

m. "Each Manufacturer Defendant promoted its own branded and generic products, and also, individually and jointly, including through front organizations, promoted unfounded and mutually reinforcing

misrepresentations about the safety and efficacy of opioids in general. The Distributor Defendants promoted opioids directly, and promoted unfounded representations about opioids through studies and through their trade organization. These misrepresentations collectively caused the dramatic increase in branded and generic opioid prescribing and use. At the same time, the Distributor Defendants greatly increased the supply of opioids beyond safe levels through a deliberate campaign to ignore their obligations to prevent diversion." Ex. E ¶ 417.

n. "As a result of Defendants' actions to inflate the demand for and supply of opioids, between 1999 and 2014, sales of opioids nearly quadrupled, according to the CDC. Nearly 259 million opioid prescriptions were written in the United States in 2012 alone. This equates to more than one opioid prescription for every American adult. At the same time, diagnoses of opioid addiction increased nearly 500% from 2010 to 2016. Many tens of thousands of Floridians are currently addicted to opioids. Defendants' relentless campaign of deceptive, unfair, and unconscionable marketing, along with their concerted effort to overcome every safeguard intended to prevent abuse and diversion, caused this spike in opioid usage rates—and opioid abuse rates—in Florida and in the United States." Ex. E ¶ 418.

o. "Opioid users frequently turn to other opioids when they are suffering the symptoms of withdrawal, because opioids work the same way and have many similar properties and effects on those who are addicted. For example, a person who becomes addicted to an opioid prescribed by a doctor may turn to whatever opioids he or she can buy on the street if the doctor refuses to provide the opioids he or she craves. If the user cannot afford black market prescription opioids, he or she may turn to heroin. According to the National Survey on Drug Use and Health, four out of five current heroin users report that their drug use began with an opioid pain reliever." Ex. E ¶ 419.

p. "Each Defendant created or assisted in the creation of the epidemic of opioid use and injury, and each Defendant is jointly and severally liable for abating it. Left unabated, the opioid epidemic will continue to threaten the health and safety of Florida residents. The State of Florida, acting on its own behalf and on behalf of its residents, therefore seeks monetary and injunctive relief to abate the public nuisance and halt the threat of future harm." Ex. E ¶ 473.

RESPONSE: The AIG Insurers object to Paragraph 17 and state that no response is warranted, because Paragraph 17 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 17 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 17 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 17. Paragraph 17 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. In particular, the Trust has not established that Mallinckrodt was actually held jointly and severally liable. The following are additional examples of allegations in Ex. E, Amended Complaint, *Florida v. Purdue Pharma L.P. et al.*, No. 2018-CA-001438 (Fla. Cir. Ct. Nov. 16, 2018) ("Florida Compl."):

- **"Mallinckrodt manufactures four branded opioids: Exalgo (extended-release hydromorphone), Roxicodone (oxycodone), Xartemis XR (extended-release oxycodone and acetaminophen), and Methadose (methadone hydrochloride). Mallinckrodt is also one of the largest manufacturers of generic opioids, manufacturing extended-release morphine sulfate, oral solution of morphine sulfate, fentanyl transdermal system, oral transmucosal fentanyl citrate, a combination of oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride and an extended-release version of the same, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, and buprenorphine and naloxone." (Ex. E, Florida Compl. ¶ 26.)**

- **"Mallinckrodt promoted, advertised, and sold branded and generic opioids in Florida." (Ex. E, Florida Compl. ¶ 27.)**

- **"As described further below, the Manufacturer Defendants sponsored and participated in developing a large number of front group publications and marketing materials that spread the campaign of**

misinformation about opioids and supported Defendants' efforts to sell both branded and generic opioids." (Ex. E, Florida Compl. ¶ 121.)

- **"Mallinckrodt promulgated and spread misinformation about opioids to prescribers and consumers, nationwide and in Florida, to convince doctors to prescribe and consumers to purchase and consume branded and generic opioid products." (Ex. E, Florida Compl. ¶ 184.)**
- **"Mallinckrodt is one of the largest manufacturers of opioids in the world." (Ex. E, Florida Compl. ¶ 185.)**
- **"Mallinckrodt's 30 mg oxycodone pills were so widely abused in Florida that they were called 'M's' by drug users, in reference to the Mallinckrodt logo engraved into the pills. Interstate 75, from Florida to Appalachia, was known as the Blue Highway, a reference to the blue coating on Mallinckrodt's 30 mg pills." (Ex. E, Florida Compl. ¶ 186.)**
- **"Mallinckrodt advertised Exalgo and Xartemis XR as abuse-resistant. For example, one Mallinckrodt press release stated that 'the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.'" (Ex. E, Florida Compl. ¶ 187.)**
- **"Mallinckrodt's sales team marketed its generic opioids as well as its branded opioids." (Ex. E, Florida Compl. ¶ 197.)**
- **"Mallinckrodt and its representatives made, and continue to make, these and other misrepresentations in order to increase opioid prescriptions. (Ex. E, Florida Compl. ¶ 198.)**
- **"Mallinckrodt also actively marketed its own opioid products." (Ex. E, Florida Compl. ¶ 200.)**

B. Exemplar Allegations by Local Governmental Entities

18. Local governmental entities (consisting of counties and municipalities) also asserted pre-petition claims against Mallinckrodt.

RESPONSE: The AIG Insurers object to Paragraph 18 and state that no response is warranted, because Paragraph 18 is not material. To the extent a response is required, Paragraph 18 is uncontroverted for purposes of the Motions.

19. St. Charles County, Missouri filed a complaint against Mallinckrodt and other opioid-related entities in a lawsuit it filed in August 2018 in the United States District Court for the Eastern District of Missouri, Eastern Division. *See* Complaint Ex. C, St. Charles County, Missouri v. Purdue Pharma L.P. et al., No. 4:18-cv-01376-NCC (E.D. Mo. Aug. 20, 2018), ECF No. 1 ("Ex. C").

RESPONSE: The AIG Insurers object to Paragraph 19 and state that no response is warranted, because Paragraph 19 is not material. To the extent a response is required, Paragraph 19 is uncontroverted for purposes of the Motions.

20. Mallinckrodt is included within the definition of "Defendants" as used by St. Charles County in its complaint. Ex. C ¶ 2. Mallinckrodt is also included within the definition of "Marketing Defendants" as used by St. Charles County in its complaint. Ex. C ¶¶ 37, 79.

RESPONSE: The AIG Insurers object to Paragraph 20 and state that no response is warranted, because Paragraph 20 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 20 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 20 is uncontroverted for purposes of the Motions.

21. St. Charles County alleged the following in its complaint:

a. "On the demand side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers ("Marketing Defendants"). Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids." Ex. C ¶ 11.

b. "The Marketing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded." Ex. C ¶ 12.

c. "The Marketing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month." Ex. C ¶ 13.

d. "As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment." Ex. C ¶ 17.

e. "Defendants' conduct in promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns

in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others." Ex. C ¶ 21.

f. "The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant." Ex. C ¶ 145.

g. "As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the 'C.A.R.E.S. Alliance' it created and led." Ex. C ¶ 179.

h. "Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as 'a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.' The 'C.A.R.E.S. Alliance' itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.)

copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt." Ex. C ¶ 180.

i. "By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book," Ex. C ¶ 181, include the following:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line**: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

Ex. C ¶ 181.

j. "The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs." Ex. C ¶ 292.

k. "Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies." Ex. C ¶ 293 (internal footnote omitted).

l. "Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as 'a national network of physicians dedicated to ensuring patient

access to approved therapies and appropriate clinical care.' It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 'Associate Members and Financial Supporters.' The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon." Ex. C ¶ 324 (internal footnotes omitted).

m. "Among its activities, APA issued a 'white paper' titled 'Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.' Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

> We cannot merely assume that these programs will reduce prescription pain medication use and abuse."

Ex. C ¶ 326 (internal footnote omitted).

n. "The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.

Ex. C ¶ 327 (internal footnote omitted).

o. "In addition, in an echo of earlier industry efforts to push back against what they termed 'opiophobia,' the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications."

Ex. C ¶ 328 (internal footnote omitted).

p. "In conclusion, the white paper states that '[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.'" Ex. C ¶ 329.

q. "The USPF was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. . . . The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e., Janssen), and Mallinckrodt as 'Platinum,' 'Gold,' and 'Basic' corporate members. Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF." Ex. C ¶ 332 (internal footnotes omitted).

r. "The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA

Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising." Ex. C ¶ 385.

s. "Each Defendant's conduct damaged, and continues to damage Plaintiff in an amount to be determined at trial." Ex. C ¶ 858.

RESPONSE: The AIG Insurers object to Paragraph 21 and state that no response is warranted, because Paragraph 21 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 21 refers speak for themselves, and AIG respectfully refers the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 21 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 21. Paragraph 21 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are additional examples of allegations in Ex. C, Complaint, *St. Charles County, Missouri v. Purdue Pharma L.P. et al.*, No. 4:18-cv-01376-NCC (E.D. Mo. Aug. 20, 2018), ECF No. 1 ("St. Charles Compl."):

- **"Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and in St. Charles County. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. C, St. Charles Compl. ¶ 73.)**

- **"Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March**

2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force." (Ex. C, St. Charles Compl. ¶ 74.)

- **"While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ('DEA') entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications." (Ex. C, St. Charles Compl. ¶ 75.)**

- **"Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups." (Ex. C, St. Charles Compl. ¶ 76.)**

- **"Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids." (Ex. C, St. Charles Compl. ¶ 253.)**

- **"Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that 'the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.' One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has 'a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion.'" (Ex. C, St. Charles Compl. ¶ 287.)**

- **"With respect to Xartemis XR, Mallinckrodt's promotional materials stated that 'XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.' In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales**

representatives to promote it, and CEO Mark Trudeau said the drug could generate 'hundreds of millions in revenue.'" (Ex. C, St. Charles Compl. ¶ 288.)

- **"The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. They knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse." (Ex. C, St. Charles Compl. ¶ 426.)**

C. Exemplar Allegations Asserted by Personal Injury and Neonatal Abstinence Syndrome Claimants

22. Pre-petition claims were asserted by Personal Injury ("PI") and Neonatal Abstinence Syndrome ("NAS") claimants.

RESPONSE: The AIG Insurers object to Paragraph 22 and state that no response is warranted, because Paragraph 22 is not material. To the extent a response is required, Paragraph 22 is uncontroverted for purposes of the Motions.

1. Exemplar Allegations by Personal Injury Claimants

23. The Estate of Bruce Brockel filed a third amended complaint against Mallinckrodt (and other entities) on December 5, 2018. *See* Third Amended Complaint Ex. F, Estate of Brockel v. Couch, et al., No. 2017-CV-902787 (Al. Cir. Ct. Dec. 5, 2018) ("Ex. F").

RESPONSE: The AIG Insurers object to Paragraph 23 and state that no response is warranted, because Paragraph 23 is not material. To the extent a response is required, Paragraph 23 is uncontroverted for purposes of the Motions.

24. Mallinckrodt was included within the definition of "Defendants" as used by Brockel in his complaint. Ex. F ¶ 17. Mallinckrodt was also included within the definition of "Brand-Name Manufacturer Defendants" as used by Brockel in his complaint. Ex. F ¶ 26.

RESPONSE: The AIG Insurers object to Paragraph 24 and state that no response is warranted, because Paragraph 24 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the

underlying lawsuit to which Paragraph 24 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 24 is uncontroverted for purposes of the Motions.

25. Brockel alleged the following in his third amended complaint:

a. "**BROCKEL** was prescribed numerous opioids during the 2004 through 2017 time period. These opioids were manufactured by numerous pharmaceutical companies many of which are named Defendants herein. Copies of **BROCKEL**'s records from CVS Pharmacy and Walgreens Pharmacy for the 2010 through 2017 time period are attached hereto as cumulative Exhibit 2. These records show the types of opioids, the manufacturers of the opioids (either by name and/or NDC Number), the prescriber's names, the dates when the prescriptions were filled, and the quantity of opioids. These are not the complete pharmacy records for the 2010 through 2017 time period. For example, **PLAINTIFF** does not have the records from **C&R** and is still trying to obtain same." Ex. F ¶ 9 (emphasis in original).

b. "In 2004, **BROCKEL** was involved in a serious motor vehicle accident in Atlanta, Georgia resulting in a broken back, neck and arm. For the next 14 years, **BROCKEL** was prescribed thousands of Schedule II opioids that were manufactured, promoted, marketed, sold, distributed and/or prescribed by the Brand-Name Manufacturer Defendants, Generic Manufacturer Defendants and Provider Defendants." Ex. F ¶ 45 (emphasis in original).

c. Brockel used opioids manufactured by Mallinckrodt as well as other opioid manufacturers. Ex. F ¶¶ 9–24, 45; *see also* Exs. 2–7 to Ex. F.

d. "To take advantage of the lucrative market for chronic pain patients, the Brand-Name and Generic Manufacturer Defendants developed a well-funded marketing scheme based on deception. The Brand-Name and Generic Manufacturer Defendants used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread

false and deceptive statements about the risks and benefits of long term opioid use. Such statements benefitted not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other opioid manufacturers. These statements were not only unsupported by, or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations." Ex. F ¶ 79.

e. "The Brand-Name and Generic Manufacturer Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers (including **COUCH & TARABEIN**) and patients (including **BROCKEL**) nationwide and in Alabama. These promotional messages were intended to and did encourage patients (including **BROCKEL**) to ask for and doctors (including **COUCH & TARABEIN**) to prescribe chronic opioid therapy." Ex. F ¶ 80 (emphasis in original).

f. "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 evade the extensive regulatory framework governing branded communications." Ex. F ¶ 87.

g. "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." Ex. F ¶ 88.

h. "The Brand-Name and Generic Manufacturer Defendants generally avoided using branded advertisements to spread their deceptive messages and claims

regarding opioids. The Brand-Name and Generic Manufacturer Defendants did so in order to evade regulatory review." Ex. F ¶ 90.

i. "Instead, the Brand-Name and Generic Manufacturer Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, the Brand-Name and Generic Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading." Ex. F ¶ 91.

j. "The Brand-Name and Generic Manufacturer Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, the Brand-Name and Generic Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading." Ex. F ¶ 94.

k. "Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, the Brand-Name and Generic Manufacturer 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 opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain." Ex. F ¶ 98.

l. "The Brand-Name and Generic Manufacturer Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, the Brand-Name and Generic Manufacturer Defendants succeeded in changing the perceptions of many physicians (including **COUCH** and **TARABEIN**), patients (including **BROCKEL**), and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn,

directly led to the expected, intended, and foreseeable result that doctors (including **COUCH** and **TARABEIN**) prescribed more opioids to more patients (including **BROCKEL**)—thereby enriching Defendants." Ex. F ¶ 99 (emphasis in original).

RESPONSE: The AIG Insurers object to Paragraph 25 and state that no response is warranted, because Paragraph 25 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 25 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 25 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 25. Paragraph 25 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. F, Third Amended Complaint, *Estate of Brockel v. Couch, et al.*, No. 2017-CV-902787 (Al. Cir. Ct. Dec. 5, 2018) ("Brockel Compl."):

- **"MALLINCKRODT manufactures, promotes, markets, sells and/or distributes Schedule II controlled substances such as Oxycodone/Acetaminophen, Morphine Sulfate ER, Oxycodone Hydrochloride, Roxicodone and Methadone HCL. On information and belief, these drugs were prescribed to BROCKEL during the 2010 through 2017 time period. See Exhibits 2 and 6. Xanodyne Pharmaceuticals, Inc. formerly manufactured Roxicodone. In 2012, MALLINCKRODT purchased Roxicodone from Xanodyne Pharmaceuticals, Inc." (Ex. F, Brockel Compl. ¶ 17.)**

- **"Defendants PURDUE PHARMA, PFIZER, ENDO, MALLINCKRODT and CEPHALON are collectively referred to as 'Brand-Name Manufacturer Defendants' herein." (Ex. F, Brockel Compl. ¶ 26.)**

- **"[T]he Brand-Name and Generic Manufacturer Defendants have manufactured, promoted, marketed, sold and/or distributed opioids for the management of pain by misleading consumers (including BROCKEL) and medical providers (including COUCH and TARABEIN) through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids, and by flooding Alabama with highly addictive prescription medications without regard for the**

adverse consequences to the State and its residents like BROCKEL." (Ex. F, Brockel Compl. ¶ 55.)

- **"The Brand-Name and Generic Manufacturer Defendants spent millions of dollars to market their drugs to prescribers (including COUCH & TARABEIN) and patients (including BROCKEL) and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Brand-Name and Generic Manufacturer Defendants' fraudulent marketing campaign." (Ex. F, Brockel Compl. ¶ 83.)**
- **"The Brand-Name and Generic Manufacturer Defendants' misrepresentations were aimed at doctors (including COUCH & TARABEIN) and patients (including BROCKEL)." (Ex. F, Brockel Compl. ¶ 85.)**
- **"By acting through third parties, the Brand-Name and Generic Manufacturer Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, the Brand-Name and Generic Manufacturer Defendants would cite to these sources as 'independent' corroboration of their own statements. Further, as one physician adviser to the Brand-Name and Generic Manufacturer Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not 'push back' at having materials, for example, from the non-profit American Pain Foundation ('APF') on display in their offices, as they would with drug company pieces." (Ex. F, Brockel Compl. ¶ 92.)**
- **"Even where such unbranded messages were disseminated through third-party vehicles, the Brand-Name and Generic Manufacturer Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. As described herein, the Brand-Name and Generic Manufacturer Defendants' sales representatives distributed third-party marketing material to Defendants' target audience that was deceptive." (Ex. F, Brockel Compl. ¶ 95.)**

- **"The Brand-Name and Generic Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors (including COUCH & TARABEIN) and patients (including BROCKEL) throughout the country and in Alabama. The Brand-Name and Generic Manufacturer Defendants deployed throughout the state seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain." (Ex. F, Brockel Compl. ¶ 100.)**

- **"[T]he Brand-Name and Generic Manufacturer Defendants promoted the use of opioids for chronic pain through 'detailers' - sales representatives who visited individual doctors (including COUCH & TARABEIN) and medical staff in their offices and small group speaker programs. The Brand-Name and Generic Manufacturer Defendants have not corrected this misinformation. Instead, the Brand-Name and Generic Manufacturer Defendants have devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, the Brand-Name and Generic Manufacturer Defendants spent $168 million on detailing branded opioids to doctors (including COUCH & TARABEIN)." (Ex. F, Brockel Compl. ¶ 103.)**

26. The Estate of James P. Koechley filed a complaint against Mallinckrodt (and other entities) on September 17, 2018. *See* Complaint Ex. G, Koechley v. Purdue Pharma, et al., No. G-4801-CI-0201803741-000 (Ohio Ct. Comm. Pl. Sept. 17, 2018) ("Ex. G").

RESPONSE: The AIG Insurers object to Paragraph 26 and state that no response is warranted, because Paragraph 26 is not material. To the extent a response is required, Paragraph 26 is uncontroverted for purposes of the Motions.

27. Mallinckrodt was included within the definition of "Defendants" as used by Koechley in his complaint. Ex. G at 5. Mallinckrodt was also included within the definition of "Manufacturers" as used by Koechley in his complaint. *Id.*

RESPONSE: The AIG Insurers object to Paragraph 27 and state that no response is warranted, because Paragraph 27 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 27 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 27 is uncontroverted for purposes of the Motions.

28. Koechley alleged the following in his complaint:

a. "This is a wrongful death and survival action based up on the tragic, but avoidable death of Jimmy Koechley, a remarkable young man whose life ended at the age of 30 as a direct and proximate result of the Defendants' joint and/or several negligence and/or misrepresentations in connection with the development, design, research, manufacture, promotion, marketing, advertisement, distribution, and/or sale of prescription opioid drugs." Ex. G ¶ 14.

b. "On September 15, 2016, Jimmy Koechley died. The cause of his death was identified as Fentanyl (an opioid) toxicity." Ex. G ¶ 16.

c. "To establish and exploit the lucrative market of chronic pain patients, Manufacturer Defendants developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use—statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in Ohio." Ex. G ¶ 71.

d. "Moreover, at all times relevant to this complaint, the Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third

parties like front groups and KOLs. These Defendants purposely hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain." Ex. G ¶ 117.

e. "The Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public." Ex. G ¶ 118.

f. "Jimmy was prescribed opioids from each Manufacturer Defendant, including but not limited to morphine, fentanyl, hydrocodone, OxyContin, oxycodone, and Percocet." Ex. G ¶ 240.

g. "Despite valiant efforts to battle his addiction, on September 15, 2016, Jimmy died from an unintentional overdose of fentanyl." Ex. G ¶ 248.

RESPONSE: The AIG Insurers object to Paragraph 28 and state that no response is warranted, because Paragraph 28 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 28 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 28 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 28. Paragraph 28 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. G, Complaint, *Koechley v. Purdue Pharma, et al.*, No. G-4801-CI-0201803741-000 (Ohio Ct. Comm. Pl. Sept. 17, 2018) ("Koechley Compl."):

- **"At all relevant times, the Manufacturer Defendants, identified herein, have researched, developed, manufactured, labeled, distributed, supplied, sold, placed into the stream of commerce, marketed, and/or advertised opioid drugs." (Ex. G, Koechley Compl. ¶ 17.)**

- **"Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances." (Ex. G, Koechley Compl. ¶ 43.)**

- **"The Manufacturer Defendants spread their false and negligent statements by marketing their branded opioids directly to doctors and patients in Ohio. (Ex. G, Koechley Compl. ¶ 72.)**

- **"Manufacturer Defendants' direct and branded ads negligently portrayed the benefits of opioids for chronic pain." (Ex. G, Koechley Compl. ¶ 74.)**

- **"The Defendants promoted the use of opioids for chronic pain through 'detailers'-sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on detailing branded opioids to doctors." (Ex. G, Koechley Compl. ¶ 75.)**

- **"The Manufacturer Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing." (Ex. G, Koechley Compl. ¶ 77.)**

- **"Defendants' marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse." (Ex. G, Koechley Compl. ¶ 99.)**

- **"The Defendants' negligent marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their negligent marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million." (Ex. G, Koechley Compl. ¶ 123.)**

- **"The escalating number of opioid prescriptions written by doctors who were deceived by the Defendants' negligent marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Ohio." (Ex. G, Koechley Compl. ¶ 124.)**

- **"Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse." (Ex. G, Koechley Compl. ¶ 125.)**

- **"Contrary to the Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful." (Ex. G, Koechley Compl. ¶ 126.)**

29. Through his complaint, Koechley "prays that this Court grant judgment against Defendants, jointly and severally . . ." Ex. G, at 65.

RESPONSE: The AIG Insurers object to Paragraph 29 and state that no response is warranted, because Paragraph 29 is not material and is not a "fact" at all but instead references relief sought. Further, the allegations in the underlying lawsuit to which Paragraph 29 refers speak for themselves, and AIG respectfully refers the court to the allegations for their true, accurate, and complete contents. To the extent a response is required, Paragraph 29 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 29. Paragraph 29 is controverted in part, insofar as it is an incomplete recitation of the relief sought and is unsupported by admissible evidence. In particular, the Trust has not established that Mallinckrodt was actually held jointly and severally liable.

2. Exemplar Allegations by NAS Claimants

30. Andrew G. Riling and Beverly Riling, the guardians of A.P. Riling, filed an amended complaint in May 2019 against Mallinckrodt (and other entities) in the United States District Court for the Northern District of Ohio, Eastern Division. *See* Complaint Ex. H, Riling v. Purdue Pharma L.P. et al., No. 1:19-op-45056 (N.D. Ohio May 10, 2019) ("Ex. H").

RESPONSE: The AIG Insurers object to Paragraph 30 and state that no response is warranted, because Paragraph 30 is not material. To the extent a response is required, Paragraph 30 is uncontroverted for purposes of the Motions.

31. A.P. Riling was diagnosed with NAS, which is "a condition suffered by babies of mothers addicted to opioids." Ex. H ¶ 2. "NAS is a clinical diagnosis, and 'a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.'" *Id.*

RESPONSE: The AIG Insurers object to Paragraph 31 and state that no response is warranted, because Paragraph 31 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 31 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 31 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 31. Paragraph 31 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

32. Mallinckrodt was included within the definition of "Pharmaceutical Defendants" as used by the Rilings in their complaint. Ex. H ¶ 34.

RESPONSE: The AIG Insurers object to Paragraph 32 and state that no response is warranted, because Paragraph 32 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 32 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 32 is uncontroverted for purposes of the Motions.

33. The Rilings alleged the following in their complaint:

a. "Upon information and belief, during her pregnancy in 2006 and 2007, A.P. Riling's mother consumed opioids manufactured or distributed by the named defendants including: a. Purdue's products, including Oxycontin, which is sold as extended release oxycodone tablets; b. Endo's products, including Percocet, which is sold as oxycodone tablets mixed with acetaminophen; c. Mallinckrodt's products, including Roxicodone, which is sold as immediate release oxycodone tablets, and generic pills for OxyContin, Roxicodone, and Percocet." Ex. H ¶ 5.

b. "The Pharmaceutical Defendants negligently marketed opioids in West Virginia through unbranded advertising that promoted opioid use generally, but were silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents." Ex H ¶ 51.

c. "The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source." Ex. H ¶ 52.

d. "The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacturer to distribution to retail." Ex. H ¶ 54.

RESPONSE: The AIG Insurers object to Paragraph 33 and state that no response is warranted, because Paragraph 33 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 33 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 33 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 33. Paragraph 33 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. H, Complaint, *Riling v. Purdue Pharma L.P. et al.*, No. 1:19-op-45056 (N.D. Ohio May 10, 2019) ("Riling Compl."):

- **"Mallinckrodt's core business revolves around the manufacture, marketing, and sale of controlled substances in the United States market, and its special expertise is in navigating United States controlled substance laws and regulations, as well as the regulatory agencies that implement them. Mallinckrodt's opioid portfolio includes both brand name drugs—including the current rights to Roxicodone, the name brand for immediate release oxycodone tablets sold in pills containing up to 30 mg of oxycodone—and an extensive portfolio of current and former generic opioids, which fall under what Mallinckrodt euphemistically refers to as its 'Specialty Generics' business. Included within Mallinckrodt's generic opioids portfolio are generics of Roxicodone itself—immediate release oxycodone tablets sold in pills containing as much as 30 mg of oxycodone per pill, which, along with pre-abuse deterrent OxyContin formulations in 40 mg and 80 mg tablets, was and remains the opioid prescription and pill of choice for drug abusers and drug diverters throughout the United States. Mallinckrodt was purchased by Tyco International plc (nka Johnson Controls International plc) in 2000, spun off from Tyco into Covidien plc in 2007, and then spun off from Covidien as Mallinckrodt plc in 2013. Upon information and belief, through its predecessor in interest, Tyco International, Mallinckrodt also manufactured, marketed, and sold a generic extended release oxycodone tablet—a generic for OxyContin—during the time period in question (2006 and 2007). Upon information and belief, Defendant Mallinckrodt is the clear United States market leader in generic oxycodone tablets generally and of generic 30 mg immediate release oxycodone tablets specifically, and was the market leader in those categories in 2006 and 2007 as well." (Ex. H, Riling Compl. ¶ 31.)**

- **"As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in West Virginia. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations." (Ex. H, Riling Compl. ¶ 92.)**

- **"The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent." (Ex. H, Riling Compl. ¶ 93.)**

- **"[T]he CDC data also shows that the OxyContin Action Plan had no impact on the overall upward trend in prescriptions written for oxycodone. Prescribers—upon information and belief, especially pill mill prescribers and others anxious to avoid the attention of the DEA—simply switched a portion of their patients to immediate release formulations of oxycodone. The name brand most commonly associated with immediate release oxycodone tablets is [Mallinckrodt's] Roxicodone, but immediate release oxycodone tablets were already widely available as generics." (Ex. H, Riling Compl. ¶ 115.)**

- **"Enter St. Louis based Defendant Mallinckrodt (and its subsidiary SpecGX), which was then a division of Tyco International. Mallinckrodt, upon information and belief, specializes in the manufacture and sale of controlled substances. Mallinckrodt owns some significant brand-name controlled substances (including, now, Roxicodone, but not in 2006 and 2007), but really specializes in what it refers to as 'Specialty Generics'—generics for controlled substances. While this aspect of Mallinckrodt's business was less open to public view when it was only one (relatively smaller) part of Tyco's larger portfolio in 2006, since being spun off Mallinckrodt proudly announces to investors that it has special expertise in the manufacture and sale of controlled substances and that it views this business as an essential cash cow, where it enjoys market power and other competitive advantages. In 2006 and 2007, SpecGX, a subsidiary of Mallinckrodt, was the principal arm through which Mallinckrodt distributed generic OxyCodone in Wyoming County, West Virginia." (Ex. H, Riling Compl. ¶ 116.)**

- **"Upon information and belief, Mallinckrodt's true specialty is in using financial incentives—called 'chargebacks'—to its distributors in order to obtain data from which it can quickly and efficiently identify rising pill mills and geographical clusters of controlled substance abuse and diversion so it can direct its efforts to capturing the lion's share of those lucrative markets. In other words, Mallinckrodt specializes in beating other generic manufacturers of controlled substances to the large and profitable, less competitive (at least as far as generics go), but somewhat risky market for the drugs that end up being abused and diverted." (Ex. H, Riling Compl. ¶ 117.)**

- **"Upon information and belief, in 2006 and 2007, and most likely for years preceding that, Mallinckrodt (and its subsidiary SpecGX) used financial incentives, called chargebacks, to obtain data from distributors**

about the end use markets for generic oxycodone tablets, such as the pharmacies and geographical centers associated with oxycodone sales in large volumes (relative to population) and other factors that indicated they were likely to be associated with abuse and diversion, rather than legitimate medical use, and therefore most likely to continue to grow at high rates with the growing problem of addiction and abuse started by OxyContin." (Ex. H, Riling Comp. ¶ 121.)

- **"Upon information and belief, in 2006 and 2007, and probably for years before that Mallinckrodt, SpecGX, Actavis, and Par were aware of pharmacies in southern West Virginia and pharmacies and clinics in Florida (which by this time were fueling the national epidemic) that were placing suspicious orders of its products. Upon information and belief, these Defendants negligently and recklessly declined to report or control the activities of these pharmacies and clinics, and recklessly encouraged those activities." (Ex. H, Riling Compl. ¶ 124.)**

34. Count II of the Rilings' amended complaint asserted a claim of "Negligence, Gross Negligence, and Recklessness" against Mallinckrodt (and other entities). Ex. H, at 50–53.

RESPONSE: The AIG Insurers object to Paragraph 34 and state that no response is warranted, because Paragraph 34 is not material and is not a "fact" at all but instead references a count. To the extent a response is required, Paragraph 34 is uncontroverted for purposes of the Motions.

35. Brandi Brumbarger, the guardian of Baby J.B.B., filed a class action complaint in June 2019 against Mallinckrodt (and other entities) in the United States District Court for the Northern District of Ohio, Eastern Division. *See* Complaint Ex. I, Brumbarger v. Purdue Pharma L.P. et al., No. 1:19-op-45469-DAP (N.D. Ohio June 14, 2019) ("Ex. I").

RESPONSE: The AIG Insurers object to Paragraph 35 and state that no response is warranted, because Paragraph 35 is not material. To the extent a response is required, Paragraph 35 is uncontroverted for purposes of the Motions.

36. Baby J.B.B. was diagnosed with NAS, which is "a condition suffered by babies of mothers addicted to opioids." Ex. I ¶ 2. "NAS is a clinical diagnosis, and 'a

consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.'" *Id.*

RESPONSE: The AIG Insurers object to Paragraph 36 and state that no response is warranted, because Paragraph 36 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 36 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 36 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 36. Paragraph 36 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

37. Mallinckrodt was included within the definition of "Pharmaceutical Defendants" and "Marketing and Manufacturing Defendants" as used by Brumbarger in her complaint. Ex. I ¶ 75.

RESPONSE: The AIG Insurers object to Paragraph 37 and state that no response is warranted, because Paragraph 37 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 37 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 37 is uncontroverted for purposes of the Motions.

38. Brumbarger alleged the following in her complaint:

a. "Like thousands of children born every year, Baby J.B.B. was born addicted to opioids. Prenatal exposure to opioids cause (sic) severe withdrawal symptoms and lasting developmental impacts. The first days of Baby J.B.B.'s life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby J.B.B. will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby J.B.B. and their mother are victims of the opioid crisis that has ravaged Indiana, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath." Ex. I ¶ 1.

b. "Upon information and belief, J.B.B.'s mother consumed opioids manufactured and distributed by all named defendants including: a. Purdue's products Oxycontin, Dilaudid, and MS Contin; b. Cephalon's products Actiq and Fentora; c. Janssen's product Duragesic; d. Endo's products Perodan, Percoset, Opana, Opana ER, Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and e. Activis' product Norco and Kadian." Ex. I ¶ 4.

c. "Defendants have foreseeably caused damages to Baby J.B.B. and Class Members including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff Baby J.B.B. and the Class." Ex. I ¶ 27.

d. "The Pharmaceutical Defendants negligently marketed opioids in Indiana through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents." Ex. I ¶ 92.

e. "The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source." Ex. I ¶ 93.

f. "The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail." Ex. I ¶ 95.

g. "The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is 'less likely if you have never had an addiction problem;' (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that '[p]eople who take opioids as prescribed usually do not become addicted;' (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: 'most people do not develop an addiction problem;' (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as 'myth' the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are 'overestimated;' (g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management—that negligently claims that pain is undertreated due to 'misconceptions about opioid addiction.'" Ex. I ¶ 100.

h. "Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain." Ex. I ¶ 133.

i. "Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as 'a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.'" Ex. I ¶ 169.

j. "Mallinckrodt's aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction." Ex. I ¶ 172.

RESPONSE: The AIG Insurers object to Paragraph 38 and state that no response is warranted, because Paragraph 38 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 38 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 38 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 38. Paragraph 38 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. I, Complaint,

***Brumbarger v. Purdue Pharma L.P. et al.*, No. 1:19-op-45469-DAP (N.D. Ohio June 14, 2019) ("Brumbarger Compl."):**

- **"Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals ('MPMO'), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, 'Mallinckrodt') manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. I, Brumbarger Compl. ¶ 53.)**

- **"To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the 'new' market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers." (Ex. I, Brumbarger Compl. ¶ 84.)**

- **"As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in Indiana. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations." (Ex. I, Brumbarger Compl. ¶ 131.)**

- **"The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent." (Ex. I, Brumbarger Compl. ¶ 132.)**

- **"Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion." (Ex. I, Brumbarger Compl. ¶ 167.)**

39. Chloe Paul, the guardian of Baby A.R.P., filed a class action complaint in June 2019 against Mallinckrodt (and other entities) in the United States District Court for the Northern District of Ohio, Eastern Division. *See* Complaint Ex. J, Paul v. Purdue Pharma, L.P. et al., No. 1:19-op-45467 (N.D. Ohio June 14, 2019) ("Ex. J").

RESPONSE: The AIG Insurers object to Paragraph 39 and state that no response is warranted, because Paragraph 39 is not material. To the extent a response is required, Paragraph 39 is uncontroverted for purposes of the Motions.

40. Baby A.R.P. was diagnosed with NAS, which is "a condition suffered by babies of mothers addicted to opioids." Ex. J ¶ 2. "NAS is a clinical diagnosis, and 'a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.'" *Id*.

RESPONSE: The AIG Insurers object to Paragraph 40 and state that no response is warranted, because Paragraph 40 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 40 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 40 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 40. Paragraph 40 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

41. Mallinckrodt was included within the definition of "Pharmaceutical Defendants" and "Marketing and Manufacturing Defendants" as used by Paul in her complaint. Ex. J ¶ 75.

RESPONSE: The AIG Insurers object to Paragraph 41 and state that no response is warranted, because Paragraph 41 is not material and is not a "fact"

at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 41 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 41 is uncontroverted for purposes of the Motions.

42. Paul alleged the following in her complaint:

a. "Like thousands of children born every year, Baby A.R.P. was born addicted to opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby A.R.P.'s life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby A.R.P. will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby A.R.P. and their mother are victims of the opioid crisis that has ravaged South Carolina, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath." Ex. J ¶ 1.

b. "Upon information and belief, A.R.P.'s mother consumed opioids manufactured and distributed by all named defendants including: a. Purdue's products Oxycontin, Dilaudid, and MS Contin; b. Cephalon's products Actiq and Fentora; c. Janssen's product Duragesic; d. Endo's products Perodan, Percoset, Opana, Opana ER, Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and e. Activis' product Norco and Kadian." Ex. J ¶ 4.

c. "Defendants have foreseeably caused damages to Baby A.R.P. and Class Members including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently

have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff Baby A.R.P. and the Class." Ex. J ¶ 27.

d. "The Pharmaceutical Defendants negligently marketed opioids in South Carolina through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents." Ex. J ¶ 92.

e. "The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source." Ex. J ¶ 93.

f. "The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail." Ex. J ¶ 95.

g. "The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is 'less likely if you have never had an addiction problem;'

(b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that '[p]eople who take opioids as prescribed usually do not become addicted;' (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: 'most people do not develop an addiction problem;' (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as 'myth' the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are 'overestimated;' (g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management—that negligently claims that pain is undertreated due to 'misconceptions about opioid addiction.'" Ex. J ¶ 100.

h. "Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain." Ex. J ¶ 133.

i. "Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as 'a noncommercial resource for HCPs, providing open access to clinical news,

information, research, and education for a better understanding of evidence-based pain-management practices.'" Ex. J ¶ 169.

j. "Mallinckrodt's aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction." Ex. J ¶ 172.

RESPONSE: The AIG Insurers object to Paragraph 42 and state that no response is warranted, because Paragraph 42 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 42 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 42 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 42. Paragraph 42 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. J, Complaint, *Paul v. Purdue Pharma, L.P. et al.*, No. 1:19-op-45467 (N.D. Ohio June 14, 2019) ("Paul Compl."):

- **"Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals ('MPMO'), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, 'Mallinckrodt') manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. J, Paul Compl. ¶ 53.)**

- **"To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to**

spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers." (Ex. J, Paul Compl. ¶ 84.)

- **"As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in South Carolina. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations." (Ex. J, Paul Compl. ¶ 131.)**

- **"The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent." (Ex. J, Paul Compl. ¶ 132.)**

- **"Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion." (Ex. J, Paul Compl. ¶ 167.)**

43. April Berzinski, the guardian of Baby A.Z., filed a class action complaint in June 2019 against Mallinckrodt (and other entities) in the United States District Court for the Northern District of Ohio, Eastern Division. *See* Complaint Ex. K, Berzinski v. Purdue Pharma, L.P. et al., No. 1:19-op-45503 (N.D. Ohio June 17, 2019) ("Ex. K").

RESPONSE: The AIG Insurers object to Paragraph 43 and state that no response is warranted, because Paragraph 43 is not material. To the extent a response is required, Paragraph 43 is uncontroverted for purposes of the Motions.

44. Baby A.Z. was diagnosed with NAS, which is "a condition suffered by babies of mothers addicted to opioids." Ex. K ¶ 2. "NAS is a clinical diagnosis, and 'a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.'" *Id.*

RESPONSE: The AIG Insurers object to Paragraph 44 and state that no response is warranted, because Paragraph 44 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 44 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 44 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 44. Paragraph 44 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

45. Mallinckrodt was included within the definition of "Pharmaceutical Defendants" and "Marketing and Manufacturing Defendants" as used by Berzinski in her complaint. Ex. K ¶ 75.

RESPONSE: The AIG Insurers object to Paragraph 45 and state that no response is warranted, because Paragraph 45 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 45 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 45 is uncontroverted for purposes of the Motions.

46. Berzinski alleged the following in her complaint:

a. "Like thousands of children born every year, Baby A.Z. was born addicted to opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby A.Z.'s life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby A.Z. will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby A.Z. and their mother are victims of the opioid crisis that has ravaged Wisconsin, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath." Ex. K ¶ 1.

b. "Upon information and belief, A.Z.'s mother consumed opioids manufactured and distributed by all named defendants including: a. Purdue's products Oxycontin, Dilaudid, and MS Contin; b. Cephalon's products Actiq

and Fentora; c. Janssen's product Duragesic; d. Endo's products Perodan, Percoset, Opana, Opana ER, Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and e. Activis' product Norco and Kadian." Ex. K ¶ 4.

c. "Defendants have foreseeably caused damages to Baby A.Z. including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff Baby A.Z." Ex. K ¶ 27.

d. "The Pharmaceutical Defendants negligently marketed opioids in Wisconsin through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents." Ex. K ¶ 93.

e. "The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source." Ex. K ¶ 94.

f. "The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion

leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail." Ex. K ¶ 96.

g. "These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG")." Ex. K. ¶ 97.

h. "The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is 'less likely if you have never had an addiction problem;' (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that '[p]eople who take opioids as prescribed usually do not become addicted;' (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: 'most people do not develop an addiction problem;' (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as 'myth' the claim that opioids are addictive; (f) a Janssen website negligently claimed

that concerns about opioid addiction are 'overestimated;' (g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management—that negligently claims that pain is undertreated due to 'misconceptions about opioid addiction.'" Ex. K ¶ 101.

i. "Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain." Ex. K ¶ 134.

j. "Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as 'a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.'" Ex. K ¶ 170.

k. "Mallinckrodt's aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction." Ex. K ¶ 173.

RESPONSE: The AIG Insurers object to Paragraph 46 and state that no response is warranted, because Paragraph 46 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 46 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true,

accurate, and complete contents. To the extent a further response is required, Paragraph 46 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 46. Paragraph 46 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. K, Complaint, *Berzinski v. Purdue Pharma, L.P. et al.*, No. 1:19-op-45503 (N.D. Ohio June 17, 2019) ("Berzinski Compl."):

- **"Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals ('MPMO'), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, 'Mallinckrodt') manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. K, Berzinski Compl. ¶ 53.)**

- **"To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the 'new' market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers." (Ex. K, Berzinski Compl. ¶ 85.)**

- **"As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in Wisconsin. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations." (Ex. K, Berzinski Compl. ¶ 132.)**

- **"The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent." (Ex. K, Berzinski Compl. ¶ 133.)**
- **"Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion." (Ex. K, Berzinski Compl. ¶ 168.)**

47. Brittany Alsup, the guardian of Baby BSN, filed a class action complaint in March 2020 against Mallinckrodt (and other entities) in the United States District Court for the Northern District of Ohio, Eastern Division. *See* Complaint Ex. L, Alsup v. Purdue Pharma, L.P. et al., No. 1:20-op-45083 (N.D. Ohio Mar. 3, 2020) ("Ex. L").

RESPONSE: The AIG Insurers object to Paragraph 47 and state that no response is warranted, because Paragraph 47 is not material. To the extent a response is required, Paragraph 47 is uncontroverted for purposes of the Motions.

48. Baby BSN was diagnosed with NAS, which is "a condition suffered by babies of mothers addicted to opioids." Ex. L ¶ 2. "NAS is a clinical diagnosis, and 'a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.'" *Id.*

RESPONSE: The AIG Insurers object to Paragraph 48 and state that no response is warranted, because Paragraph 48 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 48 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 48 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 48. Paragraph 48 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence.

49. Mallinckrodt was included within the definition of "Pharmaceutical Defendants" and "Marketing and Manufacturing Defendants" as used by Alsup in her complaint. Ex. L ¶ 57.

RESPONSE: The AIG Insurers object to Paragraph 49 and state that no response is warranted, because Paragraph 49 is not material and is not a "fact" at all but instead references allegations. Further, the allegations in the underlying lawsuit to which Paragraph 49 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 49 is uncontroverted for purposes of the Motions.

50. Alsup alleged the following in her complaint:

a. "Like thousands of children born every year, Baby BSN was born addicted to opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby BSN's life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby BSN will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby BSN and their mother are victims of the opioid crisis that has ravaged ALABAMA, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath." Ex. L ¶ 1.

b. "Upon information and belief, BSN's mother consumed opioids manufactured and distributed by all named defendants including: a. Cephalon's products Actiq and Fentora; b. Janssen's product Duragesic; c. Endo's products Perodan, Percoset, Opana, Opana ER, Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and d. Activis' product Norco and Kadian." Ex. L ¶ 4.

c. "Defendants have foreseeably caused damages to Baby BSN including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this

civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff Baby BSN." Ex. L ¶ 27.

d. "The Pharmaceutical Defendants negligently marketed opioids in ALABAMA through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents." Ex. L ¶ 75.

e. "The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source." Ex. L ¶ 76.

f. "The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail." Ex. L ¶ 78.

g. "These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American

Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG")." Ex. L. ¶ 79.

h. "The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is 'less likely if you have never had an addiction problem;' (b) Cephalon co-sponsored APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that '[p]eople who take opioids as prescribed usually do not become addicted;' (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: 'most people do not develop an addiction problem;' (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as 'myth' the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are 'overestimated.'" Ex. L ¶ 83.

i. "Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and

organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain." Ex. L ¶ 112.

j. "Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as 'a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.'" Ex. L ¶ 148.

k. "Mallinckrodt's aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction." Ex. L ¶ 151.

RESPONSE: The AIG Insurers object to Paragraph 50 and state that no response is warranted, because Paragraph 50 is not material and is not a "fact" at all but instead references a series of allegations. Further, the allegations in the underlying lawsuit to which Paragraph 50 refers speak for themselves, and the AIG Insurers respectfully refer the court to the allegations for their true, accurate, and complete contents. To the extent a further response is required, Paragraph 50 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 50. Paragraph 50 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations and is unsupported by admissible evidence. The following are examples of additional allegations in Ex. L, Complaint, *Alsup v. Purdue Pharma, L.P. et al.*, No. 1:20-op-45083 (N.D. Ohio Mar. 3, 2020) ("Alsup Compl."):

- **"Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals ('MPMO'), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA**

registrant subsidiaries and affiliates (together, 'Mallinckrodt') manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions." (Ex. L, Alsup Compl. ¶ 53.)

- **"To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers." (Ex. L, Alsup Compl. ¶ 67.)**
- **"As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in ALABAMA. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations." (Ex. L, Alsup Compl. ¶ 110.)**
- **"The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent." (Ex. L, Alsup Compl. ¶ 111.)**
- **"Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion." (Ex. L, Alsup Compl. ¶ 146.)**

D. The Relevant Policy Language

51. The National Union policies[2] are standard-form policies drafted by the insurance industry and promulgated by National Union that provide coverage for "those sums that the insured becomes legally obligated to pay as damages because of 'bodily injury' . . . ." *See, e.g.*, National Union policy No. GL 509-47-72, Ex. M, at 13.

RESPONSE: The AIG Insurers object to Paragraph 51 in part as it includes purported facts that are not material, including that the policies "are standard-form policies drafted by the insurance industry." Paragraph 51 is controverted insofar as it is an incomplete recitation of the policy language, which includes various terms and conditions to coverage, and is unsupported by the cited policy except for the quoted excerpted language. The AIG Insurers further respond that that Mallinckrodt was represented by a sophisticated insurance broker, Marsh. (*See* Ex. 19, Email Correspondence, at MNK_INS_011072711-14.) The full provision is as follows:

> **"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*. We will have the right and duty to defend the insured against any 'suit' seeking those damages. *However, we will have no duty to defend the insured against any 'suit' seeking damages for 'bodily injury' or 'property damage' to which this insurance does not apply.*" (Ex. M, National Union policy No. GL 509-47-72, at 13 (emphasis added).)**

52. The National Union policy forms and the "products hazard" exclusions specify that they were drafted by the Insurance Services Office, Inc., commonly known as ISO. *See* Ex. M.

RESPONSE: The AIG Insurers object to Paragraph 52 and state that no response is warranted, because Paragraph 52 is not material or relevant. To the extent a response is required, Paragraph 52 is controverted insofar as Paragraph 52 misstates the exclusion and is unsupported by the cited policy. The National Union policies contain a "Products-Completed Operations Hazard" Exclusion. (*See, e.g.*, Ex. M., National Union Policy No. 509-47-72 at AIGINS-MNK00000836.)

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[2] The National Union policies that are at issue in this motion are attached to Plaintiff's Memorandum in Support of Its Motion for Partial Summary Judgement as Appendix A.

53. ISO is an insurance industry organization established more than 50 years ago and comprised of approximately 1,400 domestic property and casualty insurers that promulgates various standard insurance policies that are utilized by insurers throughout the country, including National Union. *See, e.g.*, *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 772 (1993) ("Insurance Services Office, Inc. (ISO), an association of approximately 1,400 domestic property and casualty insurers . . ., is the almost exclusive source of support services in this country for CGL insurance. ISO develops standard policy forms and files or lodges them with each State's insurance regulators; most CGL insurance written in the United States is written on these forms.").

RESPONSE: The AIG Insurers object to Paragraph 53 and state that no response is warranted, because Paragraph 53 is not material or relevant. To the extent a response is required, Paragraph 53 is controverted, because it is unsupported by admissible evidence.

54. The National Union policies contain insurer-drafted exclusions for coverage for "'bodily injury' . . . included within" the "products-completed operations hazard" as defined in the policies. *See* National Union Policy No. GL 509-47-72 Ex. M, at 37 ("Exclusion-Products-Completed Operations Hazard") (the "products-completed operations hazard" is referred to in this Statement as the "products hazard"). Similar to the base policy forms, the "products hazard" exclusions are also standard-form language drafted by ISO. *Id*.

RESPONSE: The AIG Insurers object to Paragraph 54 in part, because Paragraph 54 includes purported facts that are not material or relevant, including that the policies are "insurer-drafted" and "standard-form language drafted by the ISO." To the extent a response is required, Paragraph 54 is controverted, insofar as it is an incomplete recitation of the policy language and unsupported by the cited policy except for the quoted excerpted language. The AIG Insurers further respond that that Mallinckrodt was represented by a sophisticated insurance broker, Marsh. (*See* Ex. 19, Email Correspondence, at MNK_INS_011072711-14.) The full provision is:

> **"This insurance does not apply to 'bodily injury' or 'property damage' included within the 'products-completed operations hazard.'" (Ex. M, National Union Policy No. GL 509-47-72 at AIGINS-MNK00000836.)**

55. The National Union policies define the "products hazard", in relevant part, as "'bodily injury' . . . arising out of 'your product.'" *See id*. at 27.

RESPONSE: Paragraph 55 is controverted insofar as it is an incomplete recitation of the policy language. The full provision is:

> **The term "products-competed operations hazard" is defined to "Include[] all 'bodily injury' and 'property damage' occurring away from premises you own or rent and arising out of 'your product' or 'your work.'" (Ex. M, National Union Policy No. GL 509-47-72, Section V.16.a. at AIGINS-MNK00000836.)**

56. The policies, in insurer-drafted language, define "[y]our product" as "[a]ny goods or products . . . 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 . . . " *See id.* at 28.

RESPONSE: The AIG Insurers object to Paragraph 56 in part, because Paragraph 56 includes purported facts that are not material or relevant, including that the policies are "insurer-drafted." Paragraph 56 is controverted, insofar as it is an incomplete recitation of the policy language and unsupported by the cited policy except for the quoted excerpted language. "Your Product" is 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." (Ex. M, National Union Policy No. GL 509-47-72, Section V.21. at AIGINS-MNK00000827.)**

57. The National Union policies do not contain any exclusions for bodily injury arising out of products manufactured, sold, handled, distributed, or disposed of by entities or persons other than Mallinckrodt, such as bodily injuries arising from other manufacturers' opioid products or illicit opioids alleged to have resulted from Mallinckrodt's unbranded promotional campaign.

RESPONSE: The AIG Insurers object to Paragraph 57 and state that no response is warranted, because 57 is not a "fact" at all but instead includes a conclusion of law. National Union respectfully directs the Court to its Answer and the applicable exclusions discussed in Ex. O, Letter from AIG Claims, Inc. to Mallinckrodt, dated December 10, 2020. To the extent a further response is required, Paragraph 57 is controverted and is unsupported by admissible evidence, and the Products-Completed Operations Hazard Exclusion contained in the AIG Primary Policies does exclude coverage for bodily injuries arising out products manufactured, sold, handled, distributed or disposed of by entities or persons other than Mallinckrodt where, as here, Mallinckrodt's liability arises out of Mallinckrodt's products, Mallinckrodt's warranties, representations or failures to warn about its products, or its work, as explained in the AIG Insurers' Opposition and Cross-Motion.

E. National Union's Denial of Coverage

58. National Union has denied coverage for the Opioid Mass Tort Claims on numerous grounds. *See generally* Defendants AIG Insurance Company – Puerto Rico, AIG Specialty Insurance Company, American Home Assurance Company, and National Union Fire Insurance Company of Pittsburgh, Pa.'s Answer to the First Amended Petition, ("Ex. N").

RESPONSE: Paragraph 58 is uncontroverted for purposes of the Motions.

59. In its First Amended Petition in this litigation, the Trust asserted that: "[c]ertain of the Insurance Policies contain exclusions for bodily injuries that are within the products-completed operations hazard, which generally is defined to apply to products of the Debtors. Defendants bear the burden of establishing that such exclusions bar coverage here. They cannot meet that burden because, without limitation, the Opioid Mass Tort Claims seek to hold the Debtors liable for more than harm allegedly caused by the Debtors' products. The Opioid Mass Tort Claims also seek to hold the Debtors liable for bodily injuries allegedly caused by the Debtors' conduct in creating and fueling the nationwide opioid crisis and by the opioid products of other manufacturers and illicit narcotics. In addition, in many instances, the Debtors are alleged to be jointly and severally liable with other manufacturers and distributors for injuries caused by opioids that are not Debtors' products. These injuries do not arise out of the Debtors' own products, but instead

are alleged to arise out of the Debtors' extensive use of unbranded promotional activities to change the way the medical community and the public perceived, prescribed, and used opioids in general, and their concomitant or resulting use of other manufacturers' opioid products and illicit opioids. These injuries are therefore not within the products-completed operations hazard exclusions." *Id.* ¶ 134.

RESPONSE: The AIG Insurers object to Paragraph 59 and state that no response is warranted, because Paragraph 59 is not a "fact" at all but instead references a series of allegations from the Trust's petition and includes conclusions of law. The AIG Insurers further object because this purported "fact" hypothetically assumes that the terms and conditions to coverage have been established, when the Trust has not established any. To the extent a further response is required, Paragraph 59 is controverted, because it is unsupported by admissible evidence. In particular, the Trust has not established that Mallinckrodt was actually held jointly and severally liable.

60. In its Answer to the First Amended Petition, in responding to ¶ 134 of the First Amended Petition, National Union stated: "To the extent this paragraph of the Petition states legal conclusions, no response is required. To the extent this paragraph of the Petition relates to the AIG Insurers, the AIG Insurers deny the allegations contained in this paragraph. To the extent this paragraph relates to policies issued by Defendants other than the AIG Insurers, the AIG Insurers lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in this paragraph of the Petition." *Id.*, Resp. to ¶ 134.

RESPONSE: The AIG Insurers object to Paragraph 60 and state that no response is warranted, because Paragraph 60 is not a "fact" at all but instead references allegations in National Union's Answer to the First Amended Petition. The AIG Insurers respectfully refer the Court to National Union's Answer to the First Amended Petition for its true, accurate, and complete contents. To the extent a further response is required, Paragraph 60 is controverted insofar as it is an incomplete recitation of the allegations.

61. Prior to filing its answer to the petition, in a letter sent in response to Mallinckrodt's notice of certain Opioid Mass Tort Claims, AIG, National Union's parent, denied coverage and stated that, "[c]overage does not exist under the Policies for the Lawsuits pursuant to the 'Exclusion-Products-Completed Operations Hazard'

Endorsement." Letter from AIG to Mallinckrodt Pharmaceuticals (Dec. 10, 2020), Ex. O, at 3.

RESPONSE: Paragraph 61 is uncontroverted in part, insofar as AIG Claims, Inc. sent a coverage position letter to Mallinckrodt in response to purported notice of opioid-related liability. Paragraph 61 is controverted in part, insofar as it is an incomplete recitation of the letter. The AIG Insurers respectfully refer the Court to Ex. O, Letter from AIG Claims, Inc. to Mallinckrodt, dated December 10, 2020.

THE AIG INSURERS' STATEMENT OF ADDITIONAL UNCONTROVERTED FACTS IN OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

The AIG Insurers' Response to Plaintiff's Statement of Uncontroverted Facts is hereby incorporated by reference.

62. All of the AIG Primary Policies[3] include the following in their Insuring Agreements:

> 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. … The 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., at AIGINS-MNK00000812 (emphasis added); *id.,* Section V.13. at AIGINS-MNK00000826.)

[3] The complete list of AIG Primary Policies, which contain the PCOH exclusion and are the subject of this Cross-Motion, is as follows: National Union Policy Nos. GL 187-21-21, GL 650-64-83, GL 436-10-60, GL 270-49-92, GL 964-51-88, GL 509-47-72, GL 726-71-72, GL 333-31-10, GL 379-66-74, GL 693-89-45 (covering 2017 – 2018), GL 693-89-45 (covering 2018 – 2019), GL 686-23-54, GL 1728939 (*see* Mot., Appendix A), and Ex. 1, American Home Policy No. GL 159-53-88.

63. All of the AIG Primary Policies contain an identical "Products-Completed Operations Hazard" Exclusion. The PCOH Exclusion is set forth in an endorsement included in each of the policies. It provides in full: "This insurance does not apply to 'bodily injury' or 'property damage' included within the 'products-completed operations hazard.'" (*E.g.*, Ex. M, National Union Policy No. GL 509-47-72 at AIGINS-MNK00000836.)

64. All of the AIG Umbrella Policies[4] contain an identical endorsement, the "Products-Completed Operations Hazard Claims-Made Retained Limit Endorsement":

> The provisions of this endorsement are limited to Claims and Suits seeking damages included within the Products-Completed Operations Hazard for all healthcare products, medications, medical devices and pharmaceuticals[.] …
>
> We will pay on behalf of the Insured those sums in excess of the Retained limit that the Insured becomes legally obligated to pay as damages by reason of liability imposed by law or assumed by the Insured under an Insured Contract because of Bodily Injury or Property Damage to which this insurance applies.
>
> This Policy applies, only if: (1) the Bodily Injury or Property Damage is caused by an Occurrence that takes place anywhere in the world, and the Bodily Injury or Property Damage occurs on or after the Retroactive Date and prior to the end of the Policy Period, and (2)(a) a Claim for damages because of Bodily Injury or Property Damage is first made in writing against any Insured in accordance with Paragraph C. below during the Policy Period or any Extended Reporting Period we provide and written notice is received by us during the Policy Period or Extended Reporting Period (if applicable), or (2)(b) written notice of the Occurrence is received by us during the Policy Period[.]

[4] The complete list of AIG Umbrella Policies, which contain the PCOH Claims-Made Endorsement and are the subject of this Cross-Motion, is as follows: Ex. 2, National Union Policy No. BE2977855; Ex. 3, National Union Policy No. BE2978239; Ex. 4, National Union Policy No. BE2979931; Ex. 5, American Home Policy No. BE4485682; Ex. 6, American Home Policy No. BE9835077; Ex. 7, National Union Policy No. BE2227062; Ex. 8, National Union Policy No. 27471560; Ex. 9, National Union Policy No. 15972632.

(Ex. _, National Union Policy No. BE 2227062, ENDORSEMENT NO.23, at AIGINS-MNK00000409-410.)

65. In all of the AIG Primary Policies and AIG Umbrella Policies, "products-competed operations hazard" is defined to "Include[] all 'bodily injury' and 'property damage' occurring away from premises you own or rent and arising out of 'your product' or 'your work.'" (*E.g.,* Ex. M, National Union Policy No. GL 509-47-72, Section V.16.a. at AIGINS-MNK00000836; *e.g.,* Ex. 2, National Union Policy No. BE2977855 at AIGINS-MNK00018095.)

66. In all of the AIG Primary Policies and AIG Umbrella Policies, "Your Product" is 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."

(*E.g.,* Ex. M, National Union Policy No. GL 509-47-72, Section V.21. at AIGINS-MNK00000827; *e.g.*, Ex. 2, National Union Policy No. BE2977855 at AIGINS-MNK00018095 – 18096.)

67. In all of the AIG Primary Policies and AIG Umbrella Policies, "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.

(*E.g.*, Ex. M, National Union Policy No. GL 509-47-72, Section V.22. at AIGINS-MNK00000827; Ex. 2, National Union Policy No. BE2977855 at AIGINS-MNK00018096.)

68. The policy periods of the AIG Umbrella Policies cover annual periods from 2003 until 2011. (*See* Ex. 2, National Union Policy No. BE2977855; Ex. 3, National Union Policy No. BE2978239; Ex. 4, National Union Policy No. BE2979931; Ex. 5, American Home Policy No. BE4485682; Ex. 6, American Home Policy No. BE9835077; Ex. 7, National Union Policy No. BE2227062; Ex. 8, National Union Policy No. 27471560; Ex. 9, National Union Policy No. 15972632; Ex. 20, Affidavit of Lowell J. Chase.)

69. The AIG Insurers did not receive notice on behalf of Mallinckrodt plc or any affiliated entity concerning opioid-related liability during the policy periods of the AIG Umbrella Policies. (Ex. 20, Affidavit of Lowell J. Chase; *see* Ex. 10, Email Correspondence regarding Notice, at AIGINS-MNK00003257 – 3258.)

70. Mallinckrodt plc and its affiliates ("Mallinckrodt") comprise a pharmaceutical company that develops, manufactures, and sells opioid products. (Amended Petition at ¶¶ 2, 80; *see* Ex. A, Welch Dec. ¶¶ 31, 40.)

Dated: July 17, 2024
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and accurate Word-Version copy of the foregoing document was e-mailed pursuant to Missouri Rules of Civil Procedure Rule 74.04(c)(1) on July 17, 2024 to:

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