

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

OPIOID MASTER DISBURSEMENT TRUST II,  
A/K/A OPIOID MDT II,

Plaintiff,

v.

ACE AMERICAN INSURANCE COMPANY, *et al.*

Defendants.

Case No. 22SL-CC02974

Division No. 2

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**PLAINTIFF’S RESPONSE TO ASPEN’S & ACE’S STATEMENT OF  
UNCONTROVERTED FACTS IN SUPPORT OF JOINT MOTION FOR  
SUMMARY JUDGMENT ON THE TRUST’S 11 EXEMPLAR OPIOID LAWSUITS**

Plaintiff, the Opioid Master Disbursement Trust II, also known as the Opioid MDT II (the “Trust”), pursuant to Missouri Supreme Court Rule 74.04(c)(2), respectfully submits this Response to Aspen Insurance UK Ltd. (“Aspen”) and ACE American Insurance Company’s (“ACE”) Statement of Uncontroverted Facts in Support of Their Joint Motion for Summary Judgment on the Trust’s 11 Exemplar Opioid Lawsuits (the “Motions”).

In their Statement of Uncontroverted Facts, Aspen and ACE do not raise any genuine disputes at to any material facts. Instead, they focus their attention on immaterial facts related to the bodily injuries that were allegedly caused by Mallinckrodt’s own opioids—in other words, the bodily injuries that are not at issue in the Motions. They improperly draw legal conclusions to recast the allegations of the “exemplar” complaints and Mallinckrodt’s statements within the bankruptcy as pertaining only to those immaterial facts, and rely on inadmissible, non-expert, hearsay statements to prop up their legal conclusions. For purposes of the Motions only, however, and without prejudice to the Trust’s rights to dispute facts and legal claims to the extent they are

material to other issues in this case, the Trust does not controvert any material fact set forth by Aspen and ACE.

The following Response to Aspen and ACE's Statement of Uncontroverted Facts ("Response") responds to each paragraph therein.

**I. Since 2006, Mallinckrodt Was a National Leader in Selling and Marketing Opioid Products.**<sup>1</sup>

1. Plaintiff Opioid Master Disbursement Trust II's (the "Trust") bankruptcy debtors, namely Mallinckrodt plc, Mallinckrodt LLC, Mallinckrodt APAP LLC, Mallinckrodt Enterprises LLC, SpecGx LLC, and SpecGx Holdings LLC (collectively "Mallinckrodt"), as well as their former parents, Covidien plc and Covidien Ltd. (collectively Covidien), manufactured, marketed, and distributed opioid products. *See* Ex. 1 hereto (Trust's First Amended Petition in this case) at ¶¶ 2, 80.

**RESPONSE: The Trust objects to Paragraph 1 and states that no response is warranted, because Paragraph 1 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 1 is uncontroverted for purposes of the Motions.**

2. "Mallinckrodt, while under Covidien's domination and control, became the most significant manufacturer, marketer, and producer of opioid products in the United States as measured by market share[,] producing 28.9 billion opioid pills from 2006 to 2012, according to the Drug Enforcement Administration ("DEA"). *See* Ex. 2 hereto (Trust's First Amended Complaint in the adversary proceeding styled *Opioid Master Disbursement Trust II v. Covidien Unlimited Co., f/k/a Covidien Ltd. and Covidien plc, et al.*, case no. 22-50433-JTD, pending in the

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<sup>1</sup> The headings used throughout this Response are those used by Aspen and Ace in their Statement of Uncontroverted Facts and are restated verbatim here for purpose of maintaining the same organization used in the insurers' filing. The Trust does not agree with any characterization or assertions made in these headings and does not believe any response to the headings is required under the Missouri Rules of Civil Procedure.

bankruptcy matter styled *In re Mallinckrodt PLC*, case no. 20-12522-JTD (D. Del.), henceforth the “Trust’s Fraud Complaint”) at ¶ 33.

**RESPONSE: The Trust objects to Paragraph 2 and states that no response is warranted, because Paragraph 2 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 2 is uncontroverted for purposes of the Motions.**

3. Mallinckrodt’s opioid products included five “branded” opioids (*i.e.*, products sold under a trade name): (a) Exalgo (hydromorphone hydrochloride); (b) Xartemis (oxycodone hydrochloride with acetaminophen); (c) Roxicodone (oxycodone hydrochloride), which it purchased in 2012; (d) Magnacet (oxycodone with acetaminophen); and (e) Methadose (methadone hydrochloride). *See* Ex. 1 at ¶ 83. Mallinckrodt also sold generic oxycodone. *See id.*

**RESPONSE: The Trust objects to Paragraph 3 and states that no response is warranted, because Paragraph 3 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 3 is uncontroverted for purposes of the Motions.**

4. According to internal Mallinckrodt documents produced by the Trust in discovery, Mallinckrodt engaged in both “branded” and “unbranded” marketing (*i.e.*, marketing without reference to a specific brand) to increase the demand for, and sales of, its branded opioid products as well as its generic opioid products. *See, e.g.*, Group Ex. 3 hereto (assorted documents obtained in discovery) at PCOH-MSJ-000055 (MNK795 Executive Committee Update dated July 3, 2013).<sup>2</sup>

**RESPONSE: The Trust objects to Paragraph 4 and states that no response is warranted, because Paragraph 4 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 4 is uncontroverted for purposes of the Motions.**

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<sup>2</sup> For the sake of clarity, documents in Group Exhibit 3 have been assigned these new Bates numbers for this motion.

5. “Unbranded advertising” or “unbranded marketing” has been recognized as “a strategy where businesses promote their products or services without directly associating them with a specific brand name.” See Adogy Media Distribution, *Unbranded Marketing*, ADOGY.COM, <https://www.adogy.com/terms/unbranded-marketing/> (last visited July 16, 2024).

**RESPONSE: The Trust objects to Paragraph 5 and states that no response is warranted, because Paragraph 5 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 5 is uncontroverted insofar as the cited article includes the quoted language.**

6. “Companies use this type of advertising to draw consumer attention to problems and issues that the company product can potentially resolve[.]” See Tyler Lacoma, *Branded vs. Unbranded Advertising*, CHRON.COM, <https://smallbusiness.chron.com/branded-vs-unbranded-advertising-10226.html> (last visited July 16, 2024).

**RESPONSE: The Trust objects to Paragraph 6 and states that no response is warranted, because Paragraph 6 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 6 is uncontroverted insofar as the cited article includes the quoted language.**

7. “[S]uch campaigns can increase product awareness and increase physician visits, prescribing and sales.” See Teresa Leonardo Alves *et al.*, *Unbranded Advertising of Prescription Medicines to the Public by Pharmaceutical Companies*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483488/pdf/CD012699.pdf>, at 2.

**RESPONSE: The Trust objects to Paragraph 7 and states that no response is warranted, because Paragraph 7 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 7 is uncontroverted insofar as the cited article includes the quoted language.**

8. “Pharmaceutical companies, or third parties acting on their behalf, have an underlying commercial intent to drive the choice for a particular treatment[.]” and “[t]his

unbranded advertising is part of a broader and integrated marketing campaign that aims to increase sales of prescription-only medicines.” *See id.* at 3.

**RESPONSE: The Trust objects to Paragraph 8 and states that no response is warranted, because Paragraph 8 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 8 is uncontroverted insofar as the cited article includes the quoted language.**

9. For example, in an effort to ultimately increase sales of Mallinckrodt’s branded opioid product Exalgo, Mallinckrodt’s launch plan for Exalgo included a “Medical Communication Plan” relating to “Disease State/Unbranded Message Development.” *See* Group Ex. 3 at PCOH-MSJ-000077 (Exalgo Business Plan Presentation dated July 8, 2009), PCOH-MSJ-000125 (Exalgo Field Sales Trainer Presentation dated August 26, 2009), PCOH-MSJ-000147 (Sept. 1, 2009 Meeting Invite Entitled “Exalgo- Unbranded/Branded – Pub & PR Strategy).

**RESPONSE: The Trust objects to Paragraph 9 and states that no response is warranted, because Paragraph 9 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 9 is uncontroverted insofar as the cited document includes the quoted language.**

10. In an effort to ultimately increase sales of Mallinckrodt’s product Exalgo, the Exalgo unbranded strategy plan included “partner[ing] with pain societies to potentially leverage for unbranded scientific communications pertinent to the brand.” *See id.* at PCOH-MSJ-000148 (Sept. 1, 2009 Meeting Invite Entitled “Exalgo-Unbranded/Branded – Pub & PR Strategy).

**RESPONSE: The Trust objects to Paragraph 10 and states that no response is warranted, because Paragraph 10 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 10 is uncontroverted insofar as the cited document includes the quoted language.**

11. In an effort to ultimately increase sales of Mallinckrodt’s product Exalgo, Mallinckrodt utilized unbranded disease state awareness campaigns to “create demand for

[Exalgo] on approval.” *See id.* at PCOH-MSJ-000149 (Sept. 24, 2009 Advertising Agency Memorandum re: “Exalgo prelaunch and launch proposal”).

**RESPONSE: The Trust objects to Paragraph 11 and states that no response is warranted, because Paragraph 11 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 11 is uncontroverted insofar as the cited document includes the quoted language.**

12. In an effort to ultimately increase sales of Mallinckrodt’s product Exalgo, Mallinckrodt created an “Exalgo Executive Advisory Board” to “access national thought leaders to provide input and guidance to Covidien on specific issues related to Exalgo’s brand development, including...branded and unbranded medical communications.” *See id.* at PCOH-MSJ-000153 (Exalgo Executive Advisory Board Proposal).

**RESPONSE: The Trust objects to Paragraph 12 and states that no response is warranted, because Paragraph 12 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 12 is uncontroverted insofar as the cited document includes the quoted description.**

13. In an effort to ultimately increase sales of Mallinckrodt’s product Exalgo, Mallinckrodt hired a public relations (“PR”) firm to minimize negative press regarding Exalgo and to “appropriately communicate messages relating to Covidien’s commitment to safe use of all dosing form of Exalgo through Covidien’s unbranded initiatives.” *See id.* at PCOH-MSJ-000155 (Exalgo 32 mg Framing Project Statement of Work).

**RESPONSE: The Trust objects to Paragraph 13 and states that no response is warranted, because Paragraph 13 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 13 is uncontroverted insofar as the cited document includes the quoted language.**

14. In an effort to ultimately increase sales of Mallinckrodt’s product Exalgo, Covidien’s “Specialty Brands Commercial Team,” its “Medical Affairs,” and its PR firm “moved forward with development of a work plan for FY2012 unbranded activities to position Covidien’s

leadership in the pain space and branded initiatives in support new positioning and messaging for Exalgo that is being finalized before the end of the calendar year.” *See id.* at PCOH-MSJ-000160 (Communications Monthly Report – September 2011).

**RESPONSE: The Trust objects to Paragraph 14 and states that no response is warranted, because Paragraph 14 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 14 is uncontroverted insofar as the cited document includes the quoted language.**

15. In addition to branded and generic opioid products, Mallinckrodt has long “developed, manufactured, marketed, promoted, and sold active pharmaceutical ingredients (‘APIs’)[,]” which were “used by [Mallinckrodt] and other manufacturers to create finished dosage opioid products[.]” *See* Ex. 1 at ¶¶ 2, 80. *See also id.* at ¶ 83 (listing generic opioids).

**RESPONSE: The Trust objects to Paragraph 15 and states that no response is warranted, because Paragraph 15 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 15 is uncontroverted insofar as the cited document includes the quoted language.**

16. For example, Mallinckrodt’s Chief Transformation Officer, Stephen Welch, explained in the Mallinckrodt bankruptcy that within its “Specialty Generics” division, Mallinckrodt “manufacture[d] both (a) finished dosage products, meaning the product (whether in the form of a tablet, capsule, or liquid) that the patient ultimately receives, and (b) APIs, which are then used to create finished products[.]” whether “by the [Mallinckrodt] Debtors themselves to manufacture their finished products or” instead “sold to other manufacturers for use in a variety of therapeutic areas.” *See* Declaration of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Petitions and First Day Motions, attached as Exhibit A to the Trust’s Motion for Partial Summary Judgment against Defendant National Union Fire Insurance Company of Pittsburgh, PA (“Welch Decl.”) at ¶ 40.

**RESPONSE: The Trust objects to Paragraph 16 and states that no response is warranted, because Paragraph 16 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 16 is uncontroverted insofar as the cited document includes the quoted language.**

17. According to Mr. Welch, at the time of Mallinckrodt’s bankruptcy, “Specialty Generics’ revenues [were] well-diversified, with *roughly half of its revenue coming from APIs*, and the other half from finished dosage pharmaceutical products[.]” *See id.* at ¶ 41 (emphasis added).

**RESPONSE: The Trust objects to Paragraph 17 and states that no response is warranted, because Paragraph 17 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 17 is uncontroverted insofar as the cited document includes the quoted language.**

18. According to Mr. Welch, Mallinckrodt’s APIs were sold to other opioid manufacturers, who used Mallinckrodt’s products to make other opioid products:

Similar to other pharmaceutical manufacturers, the Debtors’ direct customers for their Products are primarily Distributors that sell the Products directly to pharmacies, hospitals, and other healthcare providers and organizations, some of which are subject to governmental contracts. Certain Specialty Generics Products are also sold to Addiction Treatment Clinics that dispense them to patients. The Debtors also contract directly with Payers and Pharmacy Benefit Managers to ensure coverage and reimbursement for certain Specialty Brands Products to patients that are prescribed these products by their physicians. As for the APIs, in addition to using the APIs themselves, the Debtors also sell APIs to third-party customers, including (a) Pharmaceutical Companies, (b) Contract Manufacturers, (c) Other Industrial Customers, and (d) API Distributors.

For the fiscal year ending December 27, 2019, the Debtors generated net sales of approximately (a) \$2,423.8 million from the Specialty Brands Products, (b) \$364.9 million from Specialty Generics Products, and (c) \$337.1 million from APIs.

*See id.* at ¶¶ 286–87.

**RESPONSE: The Trust objects to Paragraph 18 and states that no response is warranted, because Paragraph 18 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 18 is uncontroverted insofar as the cited document includes the quoted language.**



19. According to the Trust, Mallinckrodt engaged in unbranded marketing as a means to increase sales of Mallinckrodt's own API products to other opioid manufacturers:

In addition to sales and marketing efforts for Mallinckrodt's products, Covidien and Mallinckrodt sought to 'change the culture' around opioid prescribing more generally to position opioids as a safe, effective solution for all types of everyday chronic pain. Covidien was incentivized to increase the overall opioid market because that would increase its API sales to other opioid manufacturers.

See Ex. 2 at ¶ 92.

**RESPONSE: The Trust objects to Paragraph 19 and states that no response is warranted, because Paragraph 19 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the lawsuit to which Paragraph 19 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 19 is uncontroverted insofar as the cited document includes the quoted language.**

**II. From 2017 to 2020, Mallinckrodt Was Sued in over 3,000 Lawsuits Alleging Liability Arising Out of Its Activities in Manufacturing, Marketing, and Distributing Opioid Products.**

20. From 2017 to 2020, Mallinckrodt was named in over 3,000 underlying lawsuits brought by government entities, third-party payors, and individuals, which generally asserted that Mallinckrodt was liable for harms sustained by the underlying plaintiffs as the result of the national opioid epidemic. See Ex. 1 at ¶ 3.

**RESPONSE: The Trust objects to Paragraph 20 and states that no response is warranted, because Paragraph 20 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 20 is uncontroverted for purposes of the Motions.**

21. As a sample of the three categories of underlying lawsuits, the Trust has submitted to this Court complaints filed in eleven "exemplar lawsuits," namely: (1) *Mississippi v. Purdue Pharma, L.P.*, No. 25CH1:15-cv-1814 (Hinds Cnty., Miss. Cir. Ct); (2) *St. Charles County v. Purdue Pharma, L.P.*, No. 4:18-cv-01376 (E.D. Mo.); (3) *Georgia v. Purdue Pharma, L.P.*,

No. 19-A-00060-8 (Gwinnett Cnty, Ga. Super. Ct.); (4) *Florida v. Purdue Pharma, L.P.*, No. 2018-CA-001438 (Pasco Cnty., Fla. Cir. Ct.); (5) *Estate of Bruce Brockel v. John Patrick Couch*, No. 2017-CV-902787 (Mobile Cnty., Ala. Cir. Ct.); (6) *Koechley v. Purdue Pharma, Inc.*, No. 18-op-46165 (N.D. Ohio); (7) *Riling v. Purdue Pharma L.P, et al.*, No. 19-op-45056 (N.D. Ohio); (8) *Brumbarger v. Purdue Pharma, L.P.*, No. 19-op-45469 (N.D. Ohio); (9) *Paul v. Purdue Pharma, L.P.*, No. 19-op-45467 (N.D. Ohio); (10) *Berzinski v. Purdue Pharma, L.P.*, No. 19-op-45503 (N.D. Ohio); and (11) *Alsup v. McKesson Corp.*, No. 20-op-45083 (N.D. Ohio). *See* complaints (collectively, the “exemplar complaints”) attached as Exhibits B through L to the Trust’s Statement of Uncontroverted Facts in Support of its Motion for Partial Summary Judgment against National Union (the “Trust’s SOF”), which are incorporated herein by reference.

**RESPONSE: Paragraph 21 is uncontroverted for purposes of the Motions.**

22. Generally, the exemplar complaints describe the national opioid epidemic as one involving unprecedented levels of opioid misuse, addiction, and death. *See* Ex. B to the Trust’s SOF at ¶ 14; Ex. C to the Trust’s SOF at ¶ 3; Ex. D to the Trust’s SOF at ¶¶ 70–71; Ex. E to the Trust’s SOF at ¶ 2; Ex. F to the Trust’s SOF at 29; Ex. G to the Trust’s SOF at ¶ 12; Ex. H to the Trust’s SOF at ¶ 12; Ex. I to the Trust’s SOF at ¶ 5; Ex. J to the Trust’s SOF at ¶ 5; Ex. K to the Trust’s SOF at ¶ 5; and Ex. L to the Trust’s SOF at ¶ 5.

**RESPONSE: Paragraph 22 is uncontroverted for purposes of the Motions.**

23. The exemplar complaints generally allege that the opioid epidemic was caused by opioid manufacturers’ and distributors’ (1) deceptive promotion (by both “branded” and “unbranded” marketing) of prescription opioid products as safe and effective for chronic pain, thus leading to overuse; and (2) shipping suspicious orders of prescription opioid products instead of halting them and reporting them to regulatory authorities, leading to widespread oversupply and product diversion to illicit uses. *See* Ex. B to the Trust’s SOF at ¶¶ 272, 591; Ex. C to the Trust’s

SOF at ¶¶ 37, 129; Ex. D to the Trust's SOF at ¶¶ 68, 89; Ex. E to the Trust's SOF at ¶¶ 62, 75; Ex. F to the Trust's SOF at ¶¶ 55, 304; Ex. G to the Trust's SOF at ¶¶ 43, 71; Ex. H to the Trust's SOF at ¶¶ 19, 44; Ex. I to the Trust's SOF at ¶¶ 16, 25; Ex. J to the Trust's SOF at ¶¶ 16, 25; Ex. K to the Trust's SOF at ¶¶ 16, 25; and Ex. L to the Trust's SOF at ¶¶ 16, 25.

**RESPONSE: Paragraph 23 is uncontroverted for purposes of the Motions.**

24. The exemplar complaints assert that the defendants' conduct in selling and marketing their own opioid products caused a downstream increase not only in the use of legal prescription opioids, but also the use of illegal opiates and opioids like heroin and fentanyl. According to the complaints, opioid users became addicted to opioids after first using prescription opioid products made and marketed by the defendants like Mallinckrodt, and then moved to illegal drugs when they were no longer able to obtain the opioids legally, often because they were too expensive. *See, e.g.*, Ex. B to the Trust's SOF at ¶ 622; Ex. C to the Trust's SOF at ¶ 615; Ex. D to the Trust's SOF at ¶ 76; Ex. E to the Trust's SOF at ¶ 69; Ex. F to the Trust's SOF at 72; Ex. G to the Trust's SOF at ¶ 136; Ex. I to the Trust's SOF at ¶ 283; Ex. J to the Trust's SOF at ¶ 283; Ex. K to the Trust's SOF at ¶ 284; and Ex. L to the Trust's SOF at ¶ 163.

**RESPONSE: The Trust objects to Paragraph 24 and states that no response is warranted, because Paragraph 24 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 24 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 24 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 24. Paragraph 24 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include allegations that Mallinckrodt marketed opioids, generally, through the unbranded promotional campaign. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.**

25. The exemplar complaints identify Mallinckrodt as a defendant based on its manufacture, marketing, and distribution of both branded and generic prescription opioid products.

See Ex. B to the Trust's SOF at ¶ 48; Ex. C to the Trust's SOF at ¶ 73; Ex. D to the Trust's SOF at ¶ 27; Ex. E to the Trust's SOF at ¶¶ 25–27; Ex. F to the Trust's SOF at 17; Ex. G to the Trust's SOF at ¶ 43; Ex. H to the Trust's SOF at ¶ 31; Ex. I to the Trust's SOF at ¶ 53; Ex. J to the Trust's SOF at ¶ 53; Ex. K to the Trust's SOF at ¶ 53; and Ex. L to the Trust's SOF at ¶ 53.

**RESPONSE: The Trust objects to Paragraph 25 and states that no response is warranted, because Paragraph 25 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 25 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a 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, which also include allegations identifying Mallinckrodt as a defendant based on its role in creating the opioid crisis through the unbranded promotional campaign, and insofar as it is unsupported by admissible evidence. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.**

26. The *Mississippi* complaint (Ex. B to the Trust's SOF) alleges liability arising out of Mallinckrodt's manufacture, marketing, and distribution of its opioid products:

In addition to their direct marketing efforts, Defendants [including Mallinckrodt] used ***unbranded, third-party marketing***, which they deployed as part of their national marketing strategies for their ***branded drugs***. Each Defendant executed these strategies through a network of third-party KOLs [*i.e.*, “key opinion leaders”] and Front Groups, with which it acted in concert by funding, assisting, encouraging and directing their efforts, while at the same time exercising substantial control over the content of the messages these third parties generated and disseminated, and distributing certain of those materials themselves. As with their other marketing strategies, Defendants' unbranded marketing created and relied upon an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

\* \* \*

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

unbranded communications, drug companies can sidestep the extensive regulatory framework, described in Section IV.C.1, governing branded communications.

\* \* \*

For example, Defendants [including Mallinckrodt] knew the FDA had admonished drug companies for making claims in *branded* materials that opioids allow patients to sleep, return to work, or walk more easily as lacking any scientific basis. Yet Defendants created and disseminated these same unsupported claims through *unbranded* marketing materials.

See Ex. B to the Trust's SOF at ¶¶ 124, 131, 135 (bold emphasis added).

**RESPONSE: The Trust objects to Paragraph 26 and states that no response is warranted, because Paragraph 26 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 26 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 26 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 26 is uncontroverted in part, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 26. Paragraph 26 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.**

27. The *St. Charles County* complaint (Ex. C to the Trust's SOF) alleges liability arising out of Mallinckrodt's manufacture, marketing, and distribution of its opioid products:

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.

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.

\* \* \*

The Marketing Defendants [defined to include Mallinckrodt] 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.

See Ex. C to the Trust’s SOF at ¶¶ 179–80, 385 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 27 and states that no response is warranted, because Paragraph 27 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 27 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 27 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 27 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 27. Paragraph 27 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

28. The *Georgia* complaint (Ex. D to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

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...

\* \* \*

Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

\* \* \*

The opioid epidemic did not happen by accident.

Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

In an effort to *reverse* this common medical understanding, each Manufacturer Defendant conducted, and continues to conduct, a *marketing scheme designed to mislead doctors and patients* about the safety and efficacy of opioids for the treatment of chronic pain. *The result of this scheme has been the use of opioids by a far broader group of patients* who are more likely to become addicted and suffer other adverse effects from the long-term use of opioids. Each Manufacturer Defendant spent, and continues to spend, *millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids* while overstating the benefits of using them for chronic pain.

\* \* \*

The *goal* of Manufacturer [defined to include Mallinckrodt] 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.

See Ex. D to the Trust's SOF at ¶¶ 3, 28, 101–03, 202 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 28 and states that no response is warranted, because Paragraph 28 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 28 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 28 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 28 is uncontroverted in part for purposes of the Motions, 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, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

29. The *Florida* complaint (Ex. E to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

The crisis has a cause: Defendants [including Mallinckrodt] cooperated to sell and ship ever-increasing quantities of opioids into Florida. *To create newfound demand for opioids*, Defendants used unfair and misleading *marketing*—including the use of *front groups*, *“paid opinion leaders,”* and *Continuing Medical Education courses (“CMEs”)*—to convince both doctors and patients that opioids could *safely be prescribed* for common ailments that cause chronic pain. To meet the artificially inflated demand, Defendants sold, shipped, and dispensed opioids in quantities that could not possibly have been medically justified and in the face of clear evidence that opioids were being diverted for illegitimate uses. Defendants’ *plan succeeded*, and they recorded *multibillion-dollar profits as a result*.

\* \* \*

The Defendants, led by the Manufacturer Defendants [defined to include Mallinckrodt], 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.

\* \* \*

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.” But Mallinckrodt knew, and has known for years, that its opioids were at high risk



of being abused, and that abuse-resistant formulas did not make opioids less addictive. It also knew that its opioids were sought after by drug abusers, and that even its abuse-resistant opioid formulations could deliver a fatal dose if crushed and consumed.

*Mallinckrodt designed its marketing scripts to overcome doctors' concerns of abuse so they would prescribe more of Mallinckrodt's opioids.*

See Ex. E to the Trust's SOF at ¶¶ 1, 109, 187–88 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 29 and states that no response is warranted, because Paragraph 29 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 29 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 29 refers speak for themselves, and the Trust 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 for purposes of the Motions, 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 underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.

30. The *Brockel* complaint (Ex. F to the Trust's SOF) alleges liability arising out of Mallinckrodt's manufacture, marketing, and distribution of its opioid products:

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...

The Brand-Name [defined to include Mallinckrodt] and Generic Manufacturer Defendants also marketed through *third-party, unbranded advertising to avoid regulatory scrutiny* because that advertising is not submitted to and typically is not reviewed by the FDA. The Brand-Name and Generic Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source.

See Ex. F to the Trust's SOF at ¶¶ 17, 133 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 30 and states that no response is warranted, because Paragraph 30 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 30 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 30 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 30 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 30. Paragraph 30 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

31. The *Koechley* complaint (Ex. G to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

[The underlying plaintiff’s decedent] was *prescribed opioids from each Manufacturer Defendant* [defined to include Mallinckrodt], including but not limited to morphine, fentanyl, hydrocodone, OxyContin, oxycodone, and Percocet.

\* \* \*

The Manufacturer Defendants’ negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

See Ex. G to the Trust’s SOF at ¶¶ 78, 240 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 31 and states that no response is warranted, because Paragraph 31 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 31 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 31 refers speak for themselves, and the Trust respectfully refers 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 for purposes of the Motions, 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, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

32. The *Riling* complaint (Ex. H to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

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...Mallinckrodt’s products*, including Roxicodone, which is sold as immediate release oxycodone tablets, and generic pills for OxyContin, Roxicodone, and Percocet.

\* \* \*

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.

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.

The Pharmaceutical Defendants’ negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

See Ex. H to the Trust’s SOF at ¶¶ 5, 51–53 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 32 and states that no response is warranted, because Paragraph 32 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 32 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 32 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 32 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 32. Paragraph 32 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

33. The *Brumbarger* complaint (Ex. I to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

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...[The Mallinckrodt Entities] 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.

\* \* \*

To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant [defined to include Mallinckrodt] 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 Indiana.

\* \* \*

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.*

The Pharmaceutical Defendants' negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

See Ex. I to the Trust's SOF at ¶¶ 53, 84, 93–94 (emphasis added). Ex. H to the Trust's SOF at ¶¶ 5, 51–53 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 33 and states that no response is warranted, because Paragraph 33 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 33 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 33 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 33 is uncontroverted in part for purposes of the Motions, 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, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.

34. The *Paul* complaint (Ex. J to the Trust's SOF) alleges liability arising out of Mallinckrodt's manufacture, marketing, and distribution of its opioid products:

To *establish and exploit the lucrative market* of chronic pain patients, each Pharmaceutical Defendant [defined to include Mallinckrodt] 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 South Carolina.

\* \* \*

The Pharmaceutical Defendants [defined to include Mallinckrodt] spread their false and negligent statements by *marketing their branded opioids directly to doctors and patients* in South Carolina. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of South Carolina.

\* \* \*

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.

\* \* \*

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.

See Ex. J to the Trust's SOF at ¶¶ 84–85, 167, 172 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 34 and states that no response is warranted, because Paragraph 34 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 34 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 34 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 34 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 34. Paragraph 34 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust's Statement of Uncontroverted Facts is hereby incorporated by reference.

35. The *Berzinski* complaint (Ex. K to the Trust's SOF) alleges liability arising out of Mallinckrodt's manufacture, marketing, and distribution of its opioid products:

To *establish and exploit the lucrative market* of chronic pain patients, each Pharmaceutical Defendant [defined to include Mallinckrodt] 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 Wisconsin.

\* \* \*

The Pharmaceutical Defendants [defined to include Mallinckrodt] spread their false and negligent statements by *marketing their branded opioids directly to doctors and patients* in Wisconsin. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of Wisconsin.

\* \* \*

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.

\* \* \*

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.

See Ex. K to the Trust’s SOF at ¶¶ 85–86, 168, 173 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 35 and states that no response is warranted, because Paragraph 35 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 35 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 35 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 35 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 35. Paragraph 35 is controverted in part, insofar as it is an incomplete recitation of the underlying allegations, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

36. The *Alsup* complaint (Ex. L to the Trust’s SOF) alleges liability arising out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

Upon information and belief, BSN’s mother consumed opioids manufactured and distributed by *all named defendants*...

\* \* \*

The Pharmaceutical Defendants [defined to include Mallinckrodt] 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.

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.

The Pharmaceutical Defendants’ negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

*See* Ex. K to the Trust’s SOF at ¶ 4, 75–755 (emphasis added).



**RESPONSE:** The Trust objects to Paragraph 36 and states that no response is warranted, because Paragraph 36 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from underlying allegations. To the extent that Paragraph 36 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the underlying lawsuit to which Paragraph 36 refers speak for themselves, and the Trust respectfully refers 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 for purposes of the Motions, 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, which also include bodily injuries allegedly caused by non-Mallinckrodt opioids, and insofar as it is unsupported by admissible evidence. The Trust’s Statement of Uncontroverted Facts is hereby incorporated by reference.

**III. From 2009 to 2011, Mallinckrodt’s Parent, Covidien, Purchased Insurance from Aspen and ACE That Only Insured Claims Arising Out of Mallinckrodt’s Opioid Products If Those Claims Were First Made Against Mallinckrodt and First Reported to Aspen During the Corresponding Policy Period.**

37. In this action, the Trust has sued Aspen under two policies issued to Mallinckrodt’s now-former parent, Covidien: (1) policy no. K0A0DKT09A0E, effective for the period November 15, 2009 to November 15, 2010; and (2) policy no. K0A0DKT10A0E, effective for the period November 15, 2010 to November 15, 2011.<sup>34</sup> See Group Ex. 4 hereto (collectively, the “Aspen policies”).

**RESPONSE:** The Trust objects to Paragraph 37 and states that no response is warranted, because Paragraph 37 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 37 is uncontroverted for purposes of the Motions.

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<sup>3</sup> In addition to the 2009–11 Aspen policies, the Trust sued Aspen under reinsurance contract no. K0A0DKT08A0E, effective for the period November 15, 2008 to November 15, 2009. The 2008–09 Aspen reinsurance contract does not provide direct insurance to Covidien or Mallinckrodt. Instead, it reinsures a separate insurance policy issued by Defendant Old Colony State Insurance Company. Neither Mallinckrodt nor Covidien was ever a party to, or third-party beneficiary of, the Aspen reinsurance contract. Because the 2008–09 Aspen reinsurance contract is not properly before this Court, this briefing does not address the 2008–09 reinsurance contract. Aspen reserves all rights to seek an adjudication of the parties’ rights and obligations under the 2008–09 reinsurance contract.

<sup>4</sup> The Trust objects to and does not concede any fact or legal conclusion contained within n.3, none of which are material to the Motions, and reserves all rights with respect to Aspen contract no. K0A0DKT08A0E.

38. In this action, the Trust has also sued ACE under four policies issued to Covidien: (1) policy no. XCP G23883983, effective for the period June 29, 2007 to November 15, 2008; (2) policy no. XCP G23891839, effective for the period November 15, 2008 to November 15, 2009; (3) policy no. XCP G24902444, effective for the period effective for the period November 15, 2009 to November 15, 2010; and (4) policy no. XCP G25828537, effective for the period November 15, 2010 to November 15, 2011. *See* Group Ex. 5 hereto (collectively, the “ACE policies”).

**RESPONSE: The Trust objects to Paragraph 38 and states that no response is warranted, because Paragraph 38 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 38 is uncontroverted for purposes of the Motions.**

39. The Aspen and ACE policies follow form to, and thus incorporate the terms, conditions, exclusions, and definitions of, four lead umbrella policies issued by Defendants American Home Assurance Company or National Union Fire Insurance Company of Pittsburgh, PA (“National Union”), specifically: (1) policy no. BE 9835077, effective for the period June 29, 2007 to November 15, 2008; 2) policy no. BE 2227062, effective for the period November 15, 2008 to November 15, 2009; (3) policy no. BE 27471560, effective for the period November 15, 2009 to November 15, 2010; and (4) policy no. BE 15972632, effective for the period November 15, 2010 to November 15, 2011. *See* Group Ex. 6 hereto (collectively, the “American Home and National Union policies”). *See also* Group Ex. 4 at ASPEN000012, ASPEN000020; Group Ex. 5 at ACE-IU00004825, ACE-IU00005392, ACE-IU00005402, ACE-IU00006437, ACE-IU00006453, ACE-IU00005704, ACE-IU00005723.

**RESPONSE: Paragraph 39 is uncontroverted for purposes of the Motions.**

40. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, provide coverage for claims seeking damages within the “Products-

Completed Operations Hazard” (“PCOH”) only if the claims are first made against Mallinckrodt and also first reported to Aspen and ACE during the corresponding policy period:

The provisions of this endorsement [entitled “Products-Completed Operations Hazard Claims Made Retained Limit Endorsement”] are limited to **Claims** or **Suits** seeking damages included within the **Products-Completed Operations Hazard** for all healthcare products, medications, medical devices and pharmaceuticals[.]

\* \* \*

B. This policy applies, only if:

\* \* \*

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
- b. written notice of the **Occurrence** is received by us during the **Policy Period** pursuant to **Section VI. Conditions, Paragraph G. Duties in the Event of an Occurrence, Claim or Suit.**

C. A **Claim** by a person or organization seeking damages will be deemed to have been made at the earlier of the following times:

1. when notice of such **Claim** is received and recorded by any **Insured** in writing and reported to us during the **Policy Period** or any applicable Extended Reporting Period, or
2. when we make settlement in accordance with Paragraph A. above.

All **Claims** for damages because of **Bodily Injury** to the same person, including damages claimed by any person or organization for care, loss of services or death resulting at any time from the **Bodily Injury**, will be deemed to have been made at the time the first of those **Claims** is made against any **Insured**.

See Group Ex. 6 (American Home and National Union policies) at AIGINS-MNK00002253–54, ASPEN000253–54, ASPEN003195–96, and ASPEN006265–66.

**RESPONSE: The Trust objects to Paragraph 40 and states that no response is warranted, because Paragraph 40 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 40 is uncontroverted for purposes of the Motions.**

41. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, define the “Products-Completed Operations Hazard” (or “PCOH”) as follows:

**Products-Completed Operations Hazard** means all **Bodily Injury** and **Property Damage** occurring away from premises you own or rent and arising out of **Your Product** or **Your Work** except:

1. products that are still in your physical possession; or
2. work that has not yet been completed or abandoned. However, **Your Work** will be deemed completed at the earliest of the following times:
  - a. when all of the work called for in your contract has been completed;
  - b. when all of the work to be done at the job site has been completed if your contract calls for work at more than one job site; or
  - c. when that part of the work done at a job site has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

**Products-Completed Operations Hazard** does not include **Bodily Injury** or **Property Damage** arising out of:

1. the transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by you and that condition was created by the loading or unloading of that vehicle by any **Insured**; or
2. the existence of tools, uninstalled equipment or abandoned or unused materials.

*See id.* at AIGINS-MNK00002206, ASPEN000201–02, ASPEN003143–44, and ASPEN006212–

13.

**RESPONSE: Paragraph 41 is uncontroverted for purposes of the Motions.**

42. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, define “Your Product” as follows:

Your Product means:

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.

**Your Product** includes:

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.

**Your Product** does not include vending machines or other property rented to or located for the use of others but not sold.

*See id.* at AIGINS-MNK00002207–08, ASPEN000202–03, ASPEN003144–45, and ASPEN006213–14.

**RESPONSE: Paragraph 42 is uncontroverted for purposes of the Motions.**

43. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, define “Your Work” as follows:

**Your Work** means:

1. work or operations performed by you or on your behalf; and
2. materials, parts or equipment performed by you or on your behalf.

**Your Work** includes:

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.

*See id.* at AIGINS-MNK00002208, ASPEN000203, ASPEN003145, ASPEN006214.

**RESPONSE: Paragraph 43 is uncontroverted for purposes of the Motions.**

44. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, define “Claim” as “a demand for money or ‘Suit’.” *See id.* at AIGINS-MNK00002257, ASPEN000257, ASPEN003199, ASPEN006270.

**RESPONSE: The Trust objects to Paragraph 44 and states that no response is warranted, because Paragraph 44 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 44 is uncontroverted for purposes of the Motions.**

45. The Aspen and ACE policies, and the National Union policies to which they follow form, define “Suit” as:

**Suit** means a civil proceeding in which damages because of **Bodily Injury, Property Damage, or Personal and Advertising Injury** to which this policy applies are alleged. **Suit** includes:

1. an arbitration proceeding in which such damages are claimed and to which the **Insured** must submit or does submit with our consent; or
2. any other alternative dispute resolution proceeding in which such damages are claimed and to which the Insured submits with our consent.

*See id.* at AIGINS-MNK00002207, ASPEN000202, ASPEN003144, ASPEN006213.

**RESPONSE: The Trust objects to Paragraph 45 and states that no response is warranted, because Paragraph 45 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 45 is uncontroverted for purposes of the Motions.**

46. The Aspen and ACE policies, and the American Home and National Union policies to which they follow form, define “Pharmaceutical” as follows:

For the purpose of this [“Products-Completed Operations Hazard Claims Made Retained Limit”] endorsement, the term “**Pharmaceutical**” shall mean the manufacture, processing, formulation, sale and/or distribution of active

pharmaceutical ingredients supplied by Mallinckrodt in either Bulk or Dosage quantities included in the Generic Pharmaceuticals, Brand Pharmaceuticals, Contract Manufactured Pharmaceuticals and/or Nuclear Medicine available as either Over the Counter Medication or Prescription Pharmaceuticals intended as curative, palliative, diagnostic or treatment of disease or symptoms.

Pharmaceutical Products includes but is not limited to:

1. Active Pharmaceutical Ingredient(s), and/or
2. Imaging Products

manufactured, sold and/or distributed for diagnosis and/or treatment of disease, illness or injury.

*See id.* at AIGINS-MNK00002259, ASPEN000259, ASPEN003201, ASPEN006271.

**RESPONSE: The Trust objects to Paragraph 46 and states that no response is warranted, because Paragraph 46 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 46 is uncontroverted for purposes of the Motions.**

47. For claims seeking damages outside the scope of the PCOH, the Aspen and ACE policies, and the American Home and National Union policies to which they follow form, provide coverage for “bodily injury” caused by an “occurrence,” so long as the “bodily injury” takes place within the policy’s period. *See id.* at AIGINS-MNK00002186, ASPEN000180, ASPEN003122, ASPEN006191.

**RESPONSE: Paragraph 47 is uncontroverted for purposes of the Motions.**

48. None of the exemplar complaints at issue in this motion were first made against Mallinckrodt during the 2009–11 Aspen policy periods, and no claims were reported on behalf of Mallinckrodt to Aspen during the 2009–11 Aspen policy periods. *See* Ex. 7 hereto (Trust’s Responses to Aspen’s Requests for Admission) at 9. Neither Mallinckrodt nor Covidien provided notice of any opioid claims or lawsuits against Mallinckrodt during the 2009–11 Aspen policy periods described above. *See id.* at 8.

**RESPONSE: The Trust objects to Paragraph 48 and states that no response is warranted, because Paragraph 48 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 48 is uncontroverted for purposes of the Motions.**

49. None of the exemplar complaints at issue in this motion were first made against Mallinckrodt during the 2007–11 ACE policy periods, and no claims were reported on behalf of Mallinckrodt to ACE during the 2007–11 ACE policy periods. *See* Ex. 8 hereto (Trust’s Responses to ACE’s Requests for Admission) at 6–8.

**RESPONSE: The Trust objects to Paragraph 49 and states that no response is warranted, because Paragraph 49 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 49 is uncontroverted for purposes of the Motions.**

50. Neither Mallinckrodt nor Covidien provided notice of any opioid claims or lawsuits against Mallinckrodt during the 2007–11 ACE policy periods described above. *See id.* at 6–7.

**RESPONSE: The Trust objects to Paragraph 50 and states that no response is warranted, because Paragraph 50 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 50 is uncontroverted for purposes of the Motions.**

51. On or about June 22, 2017, Mallinckrodt informed its insurers of the first opioid lawsuit filed against it (*Barry Staubus, et al. v. Mallinckrodt PLC, et al*, case no. C41916, filed in the Sullivan County Circuit Court of Kingsport, Tennessee) under the June 28, 2016 to June 28, 2017 policy period then in effect—specifically policies which provided claims-made-and-reported coverage for claims falling within the scope of the PCOH—and also stated that the claim would likely give rise to subsequent “related claims.” *See* Group Ex. 3 at PCOH-MSJ-000165 (June 22,



2017 “Notice of Claim, Notice of Related Claims and Circumstance”), PCOH-MSJ-000243–45 (2016–17 Followed Policy).<sup>5</sup>

**RESPONSE: The Trust objects to Paragraph 51 and states that no response is warranted, because Paragraph 51 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 51 is uncontroverted for purposes of the Motions.**

52. Then, on or about June 27, 2017, Mallinckrodt was served with the *Staubus* lawsuit, which Mallinckrodt described as “assert[ing] claims for, among other things, damages allegedly sustained by Baby Jane Doe for Neonatal Abstinence Syndrome, and damages allegedly sustained by governmental entities arising out of the alleged diversion, illegal distribution, and abuse of, and addiction to, opioids.” *See id.* at PCOH-MSJ-000276 (June 27, 2017 “Notice of Claim, Notice of Related Claims and Circumstance”), PCOH-MSJ-000279 (Internal Mallinckrodt Opioid Coverage Chart).

**RESPONSE: The Trust objects to Paragraph 52 and states that no response is warranted, because Paragraph 52 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 52 is uncontroverted for purposes of the Motions.**

53. Also on or about June 27, 2017, Mallinckrodt provided a purported notice of the *Staubus* lawsuit to an additional set of insurers who issued “Life Science Liability” policies for the June 28, 2016 to June 28, 2017 policy period then in effect, which provided claims-made-and-reported coverage for claims falling within the scope of the PCOH. *See id.* at PCOH-MSJ-000276 (June 27, 2017 “Notice of Claim, Notice of Related Claims and Circumstance”), PCOH-MSJ-000303 (2016–17 CNA Life Sciences Liability Primary Policy).

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<sup>5</sup> Insofar as concerns Aspen and ACE, the 2016–17 policy period is not at issue in and is not the subject of this motion.

**RESPONSE: The Trust objects to Paragraph 53 and states that no response is warranted, because Paragraph 53 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 53 is uncontroverted for purposes of the Motions.**

54. Because subsequent opioid lawsuits were filed after the 2016–17 policies expired, on June 22, 2018 Mallinckrodt provided purported alternative notice (which included the exemplar lawsuits) under policies effective June 28, 2017 to June 28, 2018 which also provided claims-made-and-reported coverage for claims falling within the scope of the PCOH. *See id.* at PCOH-MSJ-000356 (June 22, 2018 “Notice of Serial Claim”), PCOH-MSJ-000454–56 (2017–18 Followed Policy).

**RESPONSE: The Trust objects to Paragraph 54 and states that no response is warranted, because Paragraph 54 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 54 is uncontroverted for purposes of the Motions.**

55. By email dated April 22, 2020, Mallinckrodt’s broker, Kenneth Boland of Marsh USA Inc., advised Mark Huddleston of Mallinckrodt that AIG had been denying coverage for the opioid product claims “based on the Products exclusion” and that “[t]o me it makes sense to exclude” AIG from future notices. *See* Group Ex. 17 (April 29, 2020 Mallinckrodt/Marsh Email Exchange) at PCOH-MSJ-000484–85.

**RESPONSE: The Trust objects to Paragraph 55 and states that no response is warranted, because Paragraph 55 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 55 is controverted in part, insofar as it is unsupported by admissible evidence.**

56. That same day, Mr. Boland sent Mr. Huddleston another email, recognizing that the opioid suits against Mallinckrodt were indeed product claims: “[T]he question is do we end sending these to AIG since there is no product coverage.” *See id.* at PCOH-MSJ-000484.

**RESPONSE: The Trust objects to Paragraph 56 and states that no response is warranted, because Paragraph 56 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 56 is controverted in part, insofar as it is unsupported by admissible evidence.**

57. By email dated April 24, 2020, Lauren Lubick of Marsh Risk Consulting wrote to Mr. Huddleston of Mallinckrodt, again recognizing that the opioid claims now at issue are product claims:

We would like to send the next monthly batch of notices to the insurers and wanted to follow up with you to determine whether you would like to exclude AIG from future notices. Per emails from Ken below, *these are GL policies that contain products/completed ops exclusions and therefore unlikely they would apply to opioid claims.*

*See id.* at PCOH-MSJ-000483 (emphasis added).

**RESPONSE: The Trust objects to Paragraph 57 and states that no response is warranted, because Paragraph 57 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 57 is controverted in part, insofar as it is unsupported by admissible evidence.**

58. By email dated April 28, 2020, Mr. Huddleston agreed with Ms. Lubick that the opioid claims are product claims and wrote: “Lauren, please exclude AIG from the notice distribution.” *See id.* at PCOH-MSJ-000482–83.

**RESPONSE: The Trust objects to Paragraph 58 and states that no response is warranted, because Paragraph 58 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 58 is controverted in part, insofar as it is unsupported by admissible evidence.**

59. At no time prior to the Trust’s filing of this lawsuit on June 16, 2022 did Mallinckrodt, or any entity on behalf of Mallinckrodt, advise Aspen or ACE that the opioid claims were believed to arise from anything other than Mallinckrodt’s opioid products.

**RESPONSE:** The Trust objects to Paragraph 59 and states that no response is warranted, because Paragraph 59 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 59 is uncontroverted for purposes of the Motions.

**IV. In 2020, Mallinckrodt Filed for Bankruptcy Protection from Its Liability Arising Out of Its Activities in Manufacturing, Marketing, and Distributing Opioid Products.**

60. On October 12, 2020, Mallinckrodt filed for bankruptcy to resolve its liability for lawsuits it described as “concerning the production and sale of its opioid products.” *See* Ex. 9 hereto (Mallinckrodt’s June 17, 2021 Bankruptcy Disclosure Statement) at 48.

**RESPONSE:** The Trust objects to Paragraph 60 and states that no response is warranted, because Paragraph 60 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the Mallinckrodt’s statements to which Paragraph 60 refers speak for themselves, and the Trust respectfully refers the Court to Mallinckrodt’s statements for their true, accurate and complete contents. To the extent a response is required, Paragraph 60 is uncontroverted in part for purposes of the Motions, insofar as Mallinckrodt’s description of the lawsuits included, but was not limited to, the description reproduced in Paragraph 60. Paragraph 60 is controverted in part, insofar as it is an incomplete reproduction of Mallinckrodt’s description of the lawsuits, which also included that “[t]he lawsuits assert a variety of claims, including, but not limited to . . . claims arising from the manufacturing, distribution, marketing and promotion of opioids,” Aspen and Ace Ex. 9, at 49, and as “relating to opioids.” *Id.* at 83. In addition, on January 8, 2021, the Bankruptcy Court entered a Voluntary Injunction order prohibiting Mallinckrodt from engaging in the “promotion of opioids or opioid products, including but not limited to by . . . using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for promotion of opioids or opioid products,” among other things. *Id.* at 62.

61. On March 2, 2022, the bankruptcy court entered an order confirming Mallinckrodt’s fourth amended plan of reorganization (the “reorganization plan”). *See* Ex. 1 at

¶ 5.

**RESPONSE:** The Trust objects to Paragraph 61 and states that no response is warranted, because Paragraph 61 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 61 is uncontroverted for purposes of the Motions.

62. Mallinckrodt’s reorganization plan ultimately established the Trust (*i.e.*, the plaintiff in this case) to pursue insurance to pay underlying opioid claims. *See id.* at ¶¶ 6–7.

**RESPONSE: The Trust objects to Paragraph 62 and states that no response is warranted, because Paragraph 62 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 62 is uncontroverted for purposes of the Motions.**

63. In furtherance of the Trust’s objective to pursue insurance in connection with the underlying opioid claims, Mallinckrodt’s reorganization plan transferred Mallinckrodt’s rights, if any, under certain insurance policies, including the Aspen and ACE policies, to the Trust. *See id.* at ¶ 7.

**RESPONSE: The Trust objects to Paragraph 63 and states that no response is warranted, because Paragraph 63 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 63 is uncontroverted for purposes of the Motions.**

64. In approving and entering into the reorganization plan, the Trust was provided at least nominal authority to sue insurance policies, such as the Aspen and ACE policies, under which Mallinckrodt had never before submitted opioid claims for coverage.

*See id.*

**RESPONSE: The Trust objects to Paragraph 64 and states that no response is warranted, because Paragraph 64 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 64 is uncontroverted for purposes of the Motions.**

65. Separately, a “Personal Injury Trust” was created to accept claims from individuals who allege that they have suffered injuries as a result of using opioid products manufactured by Mallinckrodt. *See, e.g.*, “Frequently Asked Questions about the Mallinckrodt Plc Settlement,” *Official Website of the Commonwealth of Massachusetts*, [https://www.mass.gov/info-details/frequently-asked-questions-about-the-mallinckrodt-plc-settlement#\(2\)-can-individuals-](https://www.mass.gov/info-details/frequently-asked-questions-about-the-mallinckrodt-plc-settlement#(2)-can-individuals-)

[harm-ed-by-mallinckrodt-opioids-see-k-to-recover-from-the-personal-injury-trust?-](#) (last visited July 16, 2024) (“This page provides answers to frequently asked questions about how individuals who believe they were injured by *Mallinckrodt opioids* can seek to recover from the Personal Injury Trust established in connection with Mallinckrodt’s bankruptcy.”) (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 65 and states that no response is warranted, because Paragraph 65 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 65 is uncontroverted for purposes of the Motions.

V. **After Mallinckrodt Achieved Bankruptcy Protection Against Claims Arising Out of Opioid Products, the Trust Initiated This Insurance Litigation Arguing That Mallinckrodt’s Extinguished Liability Does Not, in Fact, Arise Out of Its Activities in Manufacturing, Marketing, and Distributing Opioid Products.**

66. On June 16, 2022, the Trust filed the instant action seeking coverage for the underlying opioid claims discharged in Mallinckrodt’s bankruptcy under certain insurance policies, including the Aspen and ACE policies. *See generally* Trust’s original Petition for Declaratory Relief in this matter.

**RESPONSE:** The Trust objects to Paragraph 66 and states that no response is warranted, because Paragraph 66 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 66 is uncontroverted for purposes of the Motions.

67. The Trust’s First Amended Petition in this case acknowledges that Mallinckrodt’s liability for underlying opioid claims arises out of Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

Since at least 1995, the Debtors developed, manufactured, marketed, promoted, and sold both *branded* and *generic* opioid pharmaceuticals, and their *APIs* were included in opioid pharmaceuticals manufactured *by the Debtors and others*...

\* \* \*

The Debtors’ liability for the Opioid Mass Tort Claims arises from the Debtors’ role in creating, perpetuating, and contributing to the nationwide opioid crisis,

including serious and wide-ranging bodily injuries caused by the use and misuse of opioid pharmaceuticals and illicit opioid drugs, in two respects: *supply and demand*.

\* \* \*

[T]he Opioid Mass Tort Claims allege that the Debtors *manufactured, marketed, and sold* substantial quantities of opioid pharmaceuticals that caused serious and wide-ranging bodily injuries among their users. The Opioid Mass Tort Claims further allege that Debtors failed to maintain effective controls over the distribution of opioids, by *selling and distributing far greater quantities of opioids than were necessary* for legitimate medical purposes, and by failing to report and halt suspicious orders, both of which led to an oversupply of pharmaceuticals and fueled the illegal secondary market for opioids, and caused serious and wide-ranging bodily injuries among their users.

\* \* \*

...[T]he Opioid Mass Tort Claims allege that, through their *marketing and promotion of opioid pharmaceuticals, including the use of unbranded advertising*, paid speakers and key opinion leaders, and industry-funded organizations posing as neutral and credible professional societies, the Debtors and their co-defendants throughout the supply chain changed the prevailing practices in the medical community for the treatment of chronic pain, and the perception of the risks posed, by opioid pharmaceuticals. [Footnote: “According to the allegations in the Opioid Mass Tort Claims, key opinion leaders are medical experts who appeared to be independent, neutral actors who were paid to deliver deceptive messages about opioids because of their ability to influence their peer prescribers, but were in fact neither independent, nor neutral.”]...*The Opioid Mass Tort Claims allege that Debtors and their co-defendants’ facilitation of and participation in this unbranded advertising, in turn, led to the opioid epidemic as a whole, by among other things causing and increasing the use of and addiction to not only the Debtors’ opioid pharmaceuticals, but also opioids developed, manufactured, marketed, promoted, and sold by other pharmaceutical companies and to illicit opioids, such as heroin and fentanyl*, distributed through black market channels, and in turn causing and increasing the serious and wide-ranging bodily injuries associated with that use and addiction.

See Ex. 1 at ¶¶ 2, 96–98 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 67 and states that no response is warranted, because Paragraph 67 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from the Trust’s statement of its legal position. To the extent that Paragraph 67 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the Trust’s statements to which Paragraph 67 refers speak for themselves, and the Trust respectfully refers the Court to the statements for their true, accurate and complete contents. To the extent a response is required, Paragraph 67 is uncontroverted in part for purposes of the Motions, insofar as the underlying lawsuits include, but are not limited to, the allegations described in Paragraph 67. Paragraph 67 is controverted in part, insofar as it is an incomplete recitation of the Trust’s allegations.

68. The Trust also alleged that Mallinckrodt’s discharged liability arose from something other than Mallinckrodt’s manufacture, marketing, and distribution of its opioid products:

The Opioid Mass Tort Claims include claims by individuals who suffered bodily injuries due to the use of Debtors’ opioid pharmaceuticals, and to the use of other manufacturers’ opioid pharmaceuticals, and illicit opioid drugs, for which Debtors were responsible...

\* \* \*

In many instances, the Debtors are allegedly jointly and severally liable with other manufacturers and distributors for injuries caused by opioids that are not the Debtors’ products. *These injuries do not arise out of the Debtors’ sales or representations about their 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.*

Based on these allegations and related facts, the Opioid Mass Tort Claims seek to hold the Debtors liable for bodily injuries, and costs incurred because of bodily injuries, allegedly caused by: (1) the Debtors’ products; (2) the Debtors’ alleged conduct in creating and fueling the nationwide opioid crisis; (3) the opioid products of other manufacturers; and (4) illicit opioids.

*See id.* at 3, and ¶¶ 100–01 (emphasis added).



**RESPONSE:** The Trust objects to Paragraph 68 and states that no response is warranted, because Paragraph 68 is not a “fact,” but is instead a legal conclusion that Defendants Aspen and ACE draw from the Trust’s statement of its legal position. To the extent that Paragraph 68 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the Trust’s statements to which Paragraph 68 refers speak for themselves, and the Trust respectfully refers the Court to the statements for their true, accurate and complete contents. To the extent a response is required, Paragraph 68 is uncontroverted for purposes of the Motions.

69. According to the Trust:

[T]he claims seeking damages not within the “products-completed operations hazard” are those that “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 that “seek to hold the Debtors liable for bodily injuries allegedly caused by the Debtors’ conduct in creating and fueling the nationwide opioid crisis,” specifically injuries suffered from “the opioid products of other manufacturers and illicit narcotics.”

See the Trust’s November 23, 2022 Opposition to Aspen’s Motion to Dismiss and Motion for More Definite Statement at 3–4 (citing Trust’s First Amended Petition at ¶ 134).

**RESPONSE:** The Trust objects to Paragraph 69 and states that no response is warranted, because Paragraph 69 is not a “fact,” but is instead a repetition of the Trust’s statement of its legal position. To the extent that Paragraph 69 is a “fact,” it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the Trust’s statements to which Paragraph 69 refers speak for themselves, and the Trust respectfully refers the Court to the statements for their true, accurate and complete contents. To the extent a response is required, Paragraph 69 is uncontroverted for purposes of the Motions.

70. Mallinckrodt’s discharged liability arises not just from its own finished dosage opioid products, but also from active pharmaceutical ingredients or “APIs” manufactured by Mallinckrodt and sold to other manufacturers for use in their products. According to the Trust:

[Mallinckrodt] developed, manufactured, marketed, promoted, and sold both branded and generic opioid pharmaceuticals, and their *APIs* were included in opioid pharmaceuticals manufactured by both the Debtors *and others*. In many instances, the Debtors are allegedly jointly and severally liable with other manufacturers and distributors for injuries caused by opioids that are *not the Debtors’ products*. These injuries do not arise out of the Debtors’ sales or

representations about their 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."

*See* Ex. 1 at ¶¶ 99–100 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 70 and states that no response is warranted, because Paragraph 70 is not a "fact," but is instead a characterization in part and a repetition in part of the Trust's statement of its legal position. To the extent that Paragraph 70 is a "fact," it is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the Trust's statements to which Paragraph 70 refers speak for themselves, and the Trust respectfully refers the Court to the statements for their true, accurate and complete contents. To the extent a response is required, Paragraph 70 is uncontroverted for purposes of the Motions.

71. In the two years since the filing of this action, the Trust has "acknowledge[d] that it is not seeking coverage under the Aspen Policies' coverage for "Products-Completed Operations Hazard." *See* Ex. 10 hereto (Trust's Supplemental Responses to Aspen's First Set of Interrogatories) at 14.

**RESPONSE:** The Trust objects to Paragraph 71 and states that no response is warranted, because Paragraph 71 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 71 is uncontroverted for purposes of the Motions.

72. In the two years since the filing of this action, the Trust has "acknowledge[d] that it is not seeking coverage under the ACE Policies' coverage for "Products-Completed Operations Hazard." *See* Ex. 8 at 5.

**RESPONSE:** The Trust objects to Paragraph 72 and states that no response is warranted, because Paragraph 72 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. To the extent a response is required, Paragraph 72 is uncontroverted for purposes of the Motions.

73. In the two years since the filing of this action, the Trust has acknowledged in its pending fraud action against Mallinckrodt's former parent, Covidien, that Mallinckrodt's unbranded marketing was part of a plan to increase sales of Mallinckrodt's own products:

Mallinckrodt's opioid-related liability *arising from its products* and from its role in creating and perpetuating the opioid crisis, including through its unbranded opioid promotional campaign, ultimately led to the filing of more than 3,000 lawsuits against Mallinckrodt around the country seeking massive damages based on allegations that Mallinckrodt's opioid products and, because of Mallinckrodt's unbranded promotional campaign, the opioid products of other pharmaceutical companies and illicit opioid drugs, caused bodily injuries and death.

\* \* \*

Mallinckrodt engaged in highly aggressive branded *and unbranded* promotional activities for *its* opioid products and opioids generally.

\* \* \*

Mallinckrodt faced crushing liability as a result of its conduct. It was subject to government investigations and beset by an "all-consuming tidal wave of litigation" *concerning the production and sales of its opioid products and unbranded promotional activities regarding those products*.

See Ex. 2 at ¶¶ 2, 3, 6 (emphasis added).

**RESPONSE:** The Trust objects to Paragraph 73 and states that no response is warranted, because Paragraph 73 is not material, as the only issue presented by the pending motions is a question of policy interpretation that is solely a legal issue. Further, the allegations in the lawsuit to which Paragraph 73 refers speak for themselves, and the Trust respectfully refers the Court to the allegations for their true, accurate and complete contents. To the extent a response is required, Paragraph 73 is uncontroverted for purposes of the Motions.

Dated: September 18, 2024  
St. Louis, MO

**RIEZMAN BERGER, P.C**

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*Attorneys for the Opioid Master  
Disbursement Trust II a/k/a  
the Opioid MDT II*

## CERTIFICATE OF SERVICE

Pursuant to Missouri Rule of Civil Procedure 55.03(a), the undersigned hereby verifies that he signed the original foregoing document.

The undersigned hereby certifies that on September 18, 2024, a true copy of the foregoing was served, via electronic filing pursuant to Missouri Rules of Civil Procedure Rule 103.08, to all parties of record, and that a true copy of the foregoing was served via email pursuant to Missouri Rules of Civil Procedure Rule 43.01(c)(1)(D), to all such parties.

*/s/ P. Tyler Connor*  
P. Tyler Connor, MBN 69049