

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

<p>In re:</p> <p>MALLINCKRODT PLC, <i>et al.</i>,</p> <p style="text-align: center;">Debtors.¹</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>Chapter 11</p> <p>Case No. 20-12522 (JTD)</p> <p>(Jointly Administered)</p> <p>Objection Deadline: May 12, 2023 at 4:00 p.m.</p> <p>Hearing Date: May 24, 2023 at 1:00 p.m.</p> <p>Re: D.I. Nos. 6510 & 6660</p>
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**MOTION FOR CLARIFICATION OF THE QUALIFIED
OPIOID LIST AND TIER 1 LEVEL A DEFINITION FOR THE
MALLINCKRODT OPIOID PERSONAL INJURY TRUST**

COMES NOW, Edgar C. Gentle, III, the Trustee for the Mallinckrodt Opioid Personal Injury Trust (the “MNK Trust”), and hereby submits this *Motion for Clarification of the Qualified Opioid List and Tier 1 Level A Definition for the Mallinckrodt Opioid Personal Injury Trust* (the “Motion”) by the entry of an Order, substantially in the form attached hereto as **Exhibit A** (the “Order”). In support of this Motion, the Trustee states as follows:

1. On July 20, 2021, the Debtors filed the draft trust distribution procedures (D.I. 3282), which was then revised and amended by filings on October 8, 2021 (docket number 4639) and May 29, 2022 (D.I. 7530).
2. By Order entered June 6, 2022 (docket number 7586), this Court approved the Opioid MDT II Cooperation Agreement (the “Cooperation Agreement”).
3. The Trustee and his staff have reviewed so far approximately 18,000 claims filed for the NON-NAS PI Claims, and we have developed written internal protocols, to ensure that

¹ A complete list of the Reorganized Debtors in these chapter 11 cases may be obtained on the website of the Reorganized Debtors’ claims and noticing agent at <http://restructuring.ra.kroll.com/Mallinckrodt>. The Reorganized Debtors’ mailing address is 675 McDonnell Blvd., St. Louis, Missouri 63042.

the claims scoring is consistent, accurate and fair. The Trustee would like to report to the Court that, in applying the protocols, the Trustee has thereby established for review and approval of claims, but has encountered a couple of issues: (1) what is a qualified opioid for the NON-NAS PI Claims, with the issue being moot for the NAS Claims? and (2) is a Mallinckrodt Opioid required to be listed on a death certificate or in a toxicology report in order to determine that a deceased claimant is entitled to a Tier 1 Level A Payment under the MNK PI Trust Non-NAS PI TDP (the “TDP”)?

4. Even though your Trustee may have the authority to adjust the protocols, the Trustee believes that judicial scrutiny of and public knowledge of these two protocol issues and their resolution, as evidenced by this Motion and a subsequent requested Approval Order, is justified under the principles of Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306 (1950), by providing impacted parties with reasonable notices of these protocol modifications. These modifications will result in the inclusion of some claimants who would be excluded from the protocols contemplated by the current trust distribution procedures, with these impacted claimants not otherwise being provided adequate notice of these protocol modifications, and a reasonable opportunity to apply for inclusion in this Settlement, in the absence of the publication through filing of this Motion and its approval by this Court’s Order.

5. In reviewing the claims submissions, the Trustee has found entries for a number of prescription medications which were not found on the original list of opioids but which appear to have been manufactured by MNK or its subsidiaries. These prescription medication NDC codes seem to have been retired. By utilizing the websites, www.hipaaspace.com, www.findacode.com/ndc/search.php, <https://ndclist.com/search-advanced.php>, and <https://dailymed.nlm.nih.gov/dailymed/advanced-search.cfm>, the Trustee and his staff confirmed

that these retired NDC codes were for prescription medications manufactured by MNK or its subsidiaries. The Trustee and his staff have utilized these websites to update and enlarge the proposed list of Qualified Opioids, with the proposed resulting list being found in **Exhibit B**.

6. The Trustee has notified the Debtors, in accordance with Article II of the Opioid MDT II Cooperation Agreement, pursuant to Section 3.11, of his intent to submit the list, in **Exhibit B**, of Qualified Opioids to the Court for its approval. The Debtors were given the opportunity to review the list to confirm if they believe an opioid is listed as an MNK product, and should not be, or if we were missing an opioid MNK product, which needs to be added. The Debtors, by the email in **Exhibit C**, did not object to this list and had nothing to add thereto. The Trustee respectfully requests that this Court find that the list in **Exhibit B** is the updated all-inclusive list of Qualified Opioids under the MNK PI Trust Non-NAS PI TDP.

7. Section 5.3(a)(ii) of the TDP provides that, for the Tier 1 Level A Payment, “a PI Claimant must meet the criteria of the Tier 1 Base Payment and demonstrate death caused by an opioid. If making a claim for a Tier 1 Level A Award based on death, the death certificate of the Decedent as well as any toxicology reports or autopsy reports must be provided. The **records** do not have to coincide in time with the provided Qualifying Opioid use.” [Emphasis added.] In applying this standard for claimant scoring, the Trustee and his staff request the Court to adopt and authorize the following clarification so that there is no question as to the application of the grading protocol:

“. . . A PI Claimant must meet the criteria of the Tier 1 Base Payment and demonstrate death caused by an opioid. If making a claim for a Tier 1 Level A Award based on death, the death certificate of the Decedent **must indicate that death is due to an opioid. Alternatively, if the death certificate does not list an**

opioid as the cause of death but the toxicology and/or autopsy report demonstrates a therapeutic dose of opioids was present in the body at the time of death (i.e. greater than trace amounts) and the cause of death was otherwise attributed to a drug or combination of drugs (e.g., if benzodiazepines or polysubstance are listed as the cause of death but the toxicology shows therapeutic amounts of opioids in the body) OR the toxicology reveals such a lethal dose of opioids there is a reasonable degree of medical probability that opioids played a contributing role in the death regardless of the stated cause of death (or if no such cause is made), then the case qualifies for Tier 1 Level A. The manufacturer need not be listed on the death certificate, or toxicology or autopsy report. The death does not have to coincide in time with the provided Qualifying Opioid use.”

WHEREFORE, for the foregoing reasons, the MNK Trust Trustee respectfully requests that this Court issue an Order substantially in the form attached hereto as **Exhibit A** providing the following requested below:

1. Finding that the list in **Exhibit B** is the updated all-inclusive list of Qualified Opioids under the MNK PI Trust Non-NAS PI TDP; and
2. Clarifying the standard and protocol for scoring a Tier 1 Level A Award as stated above.

Dated: April 28, 2023

CROSS & SIMON, LLC

/s/ Christopher P. Simon

Christopher P. Simon (No. 3697)

1105 North Market Street, Suite 901

Wilmington, Delaware 19801

Tel: (302) 777-4200

csimon@crosslaw.com

*Counsel to Edgar C. Gentle, III, Trustee for the
Mallinckrodt Opioid Personal Injury Trust*

the District of Delaware, 824 North Market Street, 5th Floor, Courtroom #5, Wilmington, Delaware, 19801.

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

Dated: April 28, 2023

CROSS & SIMON, LLC

/s/ Christopher P. Simon

Christopher P. Simon (No. 3697)
1105 North Market Street, Suite 901
Wilmington, Delaware 19801
Tel: (302) 777-4200
csimon@crosslaw.com

*Counsel to Edgar C. Gentle, III, Trustee for the
Mallinckrodt Opioid Personal Injury Trust*

Exhibit A

Proposed Order

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

)				
In re:)				Chapter 11
)				
MALLINCKRODT PLC, <i>et al.</i> ,)				Case No. 20-12522 (JTD)
)				
Debtors.)				(Jointly Administered)
)				
)				
)				Re: D.I. No.

**ORDER CLARIFYING QUALIFIED OPIOID LIST AND TIER 1 LEVEL A
DEFINITION FOR THE MALLINCKRODT OPIOID PERSONAL INJURY TRUST**

Upon the Motion of the Personal Injury Trustee, Edgar C. Gentle, III, for the entry of an Order clarifying and adopting the proposed Qualified Opioid List and Tier 1 Level A Definition for the Mallinckrodt Opioid Personal Injury Trust (the “Trust”) for NON-NAS PI Claims; and the Court having jurisdiction to consider the Motion and the relief requested therein; and consideration of the Request and the relief requested therein being a core proceeding under 28 U.S.C. § 157(b); and venue being proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409; and due and proper notice of the Motion having been provided to the Noticed Parties, and it appearing that no other or further notice need be provided; and the Court having reviewed the Motion and held a hearing to consider the relief requested therein (the “Hearing”); and the Court having determined that the legal and factual bases set forth in the Request and at the Hearing establish just cause for the relief granted in this order; and the Court having determined that the relief requested is necessary for the consistent scoring of claims submitted under the MNK PI Trust Non-NAS PI TDP, and is in the best interest of the Debtors, their estates, creditors, and all parties in interest; and the publication of the requested relief in the Motion and this Order helps afford impacted parties with reasonable notice thereof; and upon all of the proceedings had

before the Court and after due deliberation and good and sufficient cause appearing therefor;

IT IS HEREBY ORDERED THAT:

1. The Motion is **GRANTED** as provided therein.
2. The Court finds that the list in **Exhibit B** to the Trustee's Motion is the updated all-inclusive list of Qualified Opioids under the MNK PI Trust Non-NAS PI TDP.
3. The Court finds that Section 5.3(a)(ii) of the TDP provides, for the Tier 1 Level A Payment, "a PI Claimant must meet the criteria of the Tier 1 Base Payment and demonstrate death caused by an opioid. If making a claim for a Tier 1 Level A Award based on death, the death certificate of the Decedent as well as any toxicology reports or autopsy reports must be provided. The records do not have to coincide in time with the provided Qualifying Opioid use." [Emphasis added.] In applying this standard for claimant scoring, the Court hereby adopts and authorizes the following clarification to Section 5.3(a)(ii) of the TDP:

“. . . A PI Claimant must meet the criteria of the Tier 1 Base Payment and demonstrate death caused by an opioid. If making a claim for a Tier 1 Level A Award based on death, the death certificate of the Decedent must indicate that death is due to an opioid. Alternatively, if the death certificate does not list an opioid as the cause of death but the toxicology and/or autopsy report demonstrates a therapeutic dose of opioids was present in the body at the time of death (i.e. greater than trace amounts) and the cause of death was otherwise attributed to a drug or combination of drugs (e.g., if benzodiazepines or polysubstance are listed as the cause of death but the toxicology shows therapeutic amounts of opioids in the body) OR the toxicology reveals such a lethal dose of opioids there is a reasonable degree of medical probability that

opioids played a contributing role in the death regardless of the stated cause of death (or if no such cause is made), then the case qualifies for Tier 1 Level A. The manufacturer need not be listed on the death certificate, or toxicology or autopsy report. The **death** does not have to coincide in time with the provided Qualifying Opioid use.”

Exhibit B

Proposed Qualified Opioids List

Proposed Exhaustive List of MNK Qualified Opioids:

Compound	NDC (Labeler Prefix and Drug Code)
Hydrocodone Bitartrate And Acetaminophen	0406-0123
Hydrocodone Bitartrate And Acetaminophen	0406-0124
Hydrocodone Bitartrate And Acetaminophen	0406-0125
Hydrocodone Bitartrate And Acetaminophen	0406-0357
Hydrocodone Bitartrate And Acetaminophen	0406-0358
Hydrocodone Bitartrate And Acetaminophen	0406-0359
Hydrocodone Bitartrate And Acetaminophen	0406-0360
Hydrocodone Bitartrate And Acetaminophen	0406-0361
Hydrocodone Bitartrate And Acetaminophen	0406-0362
Hydrocodone Bitartrate And Acetaminophen	0406-0363
Hydrocodone-Acetaminophen	0406-0364
Hydrocodone Bitartrate And Acetaminophen	0406-0365
Hydrocodone Bitartrate And Acetaminophen	0406-0366
Hydrocodone Bitartrate And Acetaminophen	0406-0367
Hydrocodone-Acetaminophen	0406-0375
Hydrocodone Bitartrate And Acetaminophen	0406-0376
Hydrocodone Bitartrate And Acetaminophen	0406-0377
Hydrocodone Bitartrate And Acetaminophen	0406-0378
Acetaminophen And Codeine Phosphate	0406-0483
Acetaminophen And Codeine Phosphate	0406-0484
Acetaminophen And Codeine Phosphate	0406-0485
Oxycodone and Acetaminophen	0406-0512
Oxycodone and Acetaminophen	0406-0522
Oxycodone and Acetaminophen	0406-0523
Methadone Hydrochloride (Methadose)	0406-0527
Oxycodone w/ Acetaminophen	0406-0532

Compound	NDC (Labeler Prefix and Drug Code)
Methadone Hydrochloride (Methadose)	0406-0540
Oxycodone Hydrochloride	0406-0552
Oxycodone Hydrochloride	0406-0554
Oxycodone with Acetaminophen	0406-0562
Oxycodone with Acetaminophen	0406-0582
Oxycodone Hydrochloride	0406-0593
Oxycodone Hydrochloride	0406-0594
Oxycodone Hydrochloride	0406-0595
Oxycodone Hydrochloride	0406-0596
Oxymorphone Hydrochloride	0406-1009
Oxymorphone Hydrochloride	0406-1010
Naltrexon Hydrochloride	0406-1170
Methadone Hydrochloride	0406-1510
Propoxyphene N-Acetaminophen	0406-1721
Propoxyphene N-Acetaminophen	0406-1772
Levorphanol Tartrate	0406-2224
Methadone Hydrochloride	0406-2540
Hydrocodone Acetaminophen	0406-5361
Hydrocodone Acetaminophen	0406-5362
Hydrocodone Acetaminophen	0406-5363
Methadone Hydrochloride	0406-5755
Methadone Hydrochloride	0406-5771
Methadone Hydrochloride	0406-6974
Buprenorphine and Naloxone	0406-1923
Buprenorphine and Naloxone	0406-1924
Buprenorphine and Naloxone	0406-8020
Pentazocine-Naloxone HCl	0406-3118
Hydromorphone Hydrochloride	0406-3243

Compound	NDC (Labeler Prefix and Drug Code)
Hydromorphone Hydrochloride	0406-3244
Hydromorphone Hydrochloride	0406-3249
Hydromorphone Hydrochloride	0406-3308
Hydromorphone Hydrochloride	0406-3312
Hydromorphone Hydrochloride	0406-3316
Hydromorphone Hydrochloride	0406-3332
Methadose	0406-3454
Hydrocodone Acetaminophen	0406-4357
Methadone Hydrochloride	0406-4123
Methadone Hydrochloride	0406-6221
Methadone Hydrochloride	0406-6225
Meperidine HCl	0406-7113
Meperidine HCl	0406-7115
Tramadol HCl	0406-7171
Morphine Sulfate	0406-8003
Buprenorphine Hydrochloride-Naloxone	0406-8005
Buprenorphine Hydrochloride-Naloxone	0406-8020
Oxymorphone Hydrochloride	0406-8091
Oxymorphone Hydrochloride	0406-8092
Oxymorphone Hydrochloride	0406-8093
Oxymorphone Hydrochloride	0406-8094
Oxymorphone Hydrochloride	0406-8095
Oxymorphone Hydrochloride	0406-8096
Oxymorphone Hydrochloride	0406-8097
Morphine Sulfate	0406-8315
Morphine Sulfate	0406-8320
Morphine Sulfate	0406-8330
Morphine Sulfate	0406-8380

Compound	NDC (Labeler Prefix and Drug Code)
Morphine Sulfate	0406-8390
Oxycodone Hydrochloride	0406-8515
Oxycodone Hydrochloride	0406-8530
Oxycodone Hydrochloride	0406-8556
Oxycodone Hydrochloride	0406-8557
Oxycodone Hydrochloride	0406-8558
Oxycodone Hydrochloride	0406-8668
Methadose (sugar free)	0406-8725
Fentanyl (transdermal patch)	0406-9000
Fentanyl (transdermal patch)	0406-9012
Fentanyl (transdermal patch)	0406-9025
Fentanyl (transdermal patch)	0406-9037
Fentanyl (transdermal patch)	0406-9050
Fentanyl (transdermal patch)	0406-9062
Fentanyl (transdermal patch)	0406-9075
Fentanyl (transdermal patch)	0406-9100
Fentanyl (transdermal patch)	0406-9112
Fentanyl (transdermal patch)	0406-9125
Fentanyl (transdermal patch)	0406-9150
Fentanyl (transdermal patch)	0406-9175
Fentanyl Citrate	0406-9202
Fentanyl Citrate	0406-9204
Fentanyl Citrate	0406-9206
Fentanyl Citrate	0406-9208
Fentanyl Citrate	0406-9212
Fentanyl Citrate	0406-9216

Also: MLNK Qualifying Branded Opioids:

Roxicodone, Exalgo, Methadose, Anexsia

Exhibit C

Debtors' Email Regarding the Proposed Qualified Opioids List

Chris Smith

From: Edgar C. Gentle III
Sent: Sunday, January 15, 2023 3:04 PM
To: Anne Andrews; Rochelle Guiton; Joseph Steinfeld; Imiskowiec@askllp.com; John Thornton; Sean Higgins; Rob Siko; Edward Neiger; Jennifer A. Christian; Alexandra Robertson; Marianna Udem; James Patton; Roger Frankel; Rick Wyron
Cc: Terry D. Turner Jr.; Kip Harbison; Chris Smith; Hannah Trucks; Gena Alexander
Subject: Fwd: Confidential MNK Proposed Definitive List of MNK Opioids; 6773-1-DDD

Dear All,

I hope you're well.

Here's the Debtors' response to our suggested qualified non NAS PI claim opioid list.

We will now fine tune the proposed follow up submission to the Court for your review.

Thanks,

Ed

Sent from my iPhone

Begin forwarded message:

From: Anu.Yerramalli@lw.com
Date: January 12, 2023 at 3:24:09 PM CST
To: "Edgar C. Gentle III" <egentle@gtandslaw.com>
Cc: jason.gott@lw.com
Subject: RE: Confidential MNK Proposed Definitive List of MNK Opioids; 6773-1-DDD

Ed,

In response to this letter, the company confirms that the table embedded in the letter are APIs and are appropriately excluded.

The company had no comments on the attached list. If there are other internet sources to provide, I will let you know.

Thanks,
Anu

Anupama Yerramalli

LATHAM & WATKINS LLP
1271 Avenue of the Americas | New York, NY 10020
D: +1.212.906.1312 | M: +1.973.650.1684

From: Edgar C. Gentle III <egentle@gtandslaw.com>
Sent: Tuesday, December 27, 2022 3:45 PM
To: Yerramalli, Anu (NY) <Anu.Yerramalli@lw.com>
Cc: Gott, Jason (CH) <Jason.Gott@lw.com>
Subject: Re: Confidential MNK Proposed Definitive List of MNK Opioids; 6773-1-DDD

Thanks Anu! Ed

Sent from my iPhone

On Dec 27, 2022, at 2:41 PM, Anu.Yerramalli@lw.com wrote:

Ed,

The attached is received. We will review with MNK.

Happy New Year.

Best,
Anu

Anupama Yerramalli

LATHAM & WATKINS LLP
1271 Avenue of the Americas | New York, NY 10020
D: +1.212.906.1312 | M: +1.973.650.1684

From: Edgar C. Gentle III <egentle@gtandslaw.com>
Sent: Tuesday, December 27, 2022 3:39 PM
To: mark.casey@mnk.com; Gott, Jason (CH) <Jason.Gott@lw.com>; Yerramalli, Anu (NY) <Anu.Yerramalli@lw.com>
Subject: Confidential MNK Proposed Definitive List of MNK Opioids; 6773-1-DDD

Dear Counsel for the Debtor,

Please review.

Thanks and Happy New Year,

Ed Gentle

Sent from my iPhone

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, disclosure, reliance or distribution by others or forwarding without express permission is strictly prohibited. If

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