Annex 1

MALLINCKRODT INJUNCTIVE RELIEF
TERM SHEET

I. DEFINITIONS

A. "Bankruptcy Court" shall mean the United States Bankruptcy Court for the District of Delaware.

B. "Cancer-Related Pain Care" shall mean care that provides relief from pain resulting from a patient's active cancer or cancer treatment, as distinguished from treatment provided during remission.

C. "CDC Guideline Recommendations" shall mean the 12 enumerated Recommendations published by the U.S. Centers for Disease Control and Prevention (CDC) for the prescribing of opioid pain medication for patients 18 and older in primary care settings as part of its 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines), as updated or amended by the CDC.

D. "Chapter 11 Cases" means the proceedings to be commenced by Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGX LLC and certain of their affiliates under chapter 11 of the United States Bankruptcy Code.

E. "Chapter 11 Plan" shall mean the plan of reorganization under chapter 11 of the United States Bankruptcy Code that includes Mallinckrodt Enterprises LLC, Mallinckrodt LLC and SpecGx LLC.

F. "Confirmation Order" shall mean the order of the Bankruptcy Court (or other court of competent jurisdiction) confirming the Chapter 11 Plan.

G. "Downstream Customer Data" shall mean transaction information that Mallinckrodt collects relating to its direct customers' sales to downstream customers, including but not limited to chargeback data tied to Mallinckrodt providing certain discounts, "867 data," and IQVIA data.

H. "Effective Date" shall mean the date on which the Chapter 11 Plan goes effective.

I. "End-of-Life Care" shall mean care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.

J. "Health Care Provider" shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products and any medical facility, practice, hospital, clinic or pharmacy.

K. "In-Kind Support" shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.

L. "Lobby" and "Lobbying" shall have the same meaning as "lobbying activities" and "lobbying contacts" under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq*., and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this document, "Lobby" and "Lobbying" include Lobbying directly or indirectly, through grantees or Third Parties.

M. "Mallinckrodt" shall mean Mallinckrodt Enterprises LLC, Mallinckrodt LLC, and SpecGX LLC, and each of their current and former subsidiaries, predecessors, successors, joint ventures, divisions and assigns. It shall also mean officers, directors, independent contractors, consultants, agents, employees, partners, and principals, provided that they are acting within the scope of their engagement or employment.

N. "Mallinckrodt's Opioid Business" shall mean Mallinckrodt's business operations relating to the manufacture and sale of Opioid Product(s) in the United States and its territories.

O. "OCC" shall mean the Official Committee of Opioid Related Claimants, appointed in the Debtors' Chapter 11 Cases.

P. "Opioid(s)" shall mean all naturally occurring, synthetic, or semisynthetic substances that interact with opioid receptors and act like opium.

Q. "Opioid Product(s)" shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration (FDA) and listed by the DEA as Schedule II, III, or IV drugs pursuant to the federal Controlled Substances Act, including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, tapentadol, and tramadol. The term "Opioid Products(s)" shall not include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage"; methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities; or raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories.

R. "OUD" shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5),* as updated or amended.

S. "Petition Date" shall mean the date on which the Chapter 11 Cases are commenced.

T. "Promote," "Promoting," and "Promotion" shall mean dissemination of information or other practices intended or that could be reasonably anticipated to increase sales, prescriptions, the utilization of prescription products, or that attempt to influence prescribing practices or formulary decisions in the United States.

U. "Qualified Researcher" shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.

V. "Settling State" means any State that becomes a party to a restructuring support agreement with respect to the Chapter 11 Plan or otherwise votes to accept the Chapter 11 Plan.

W. "Suspicious Order" shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous state laws and regulations.

X. "Third Party" shall mean any person or entity other than Mallinckrodt or a government entity.

Y. "Treatment of Pain" shall mean the provision of therapeutic modalities to alleviate or reduce pain.

Z. "Unbranded Information" shall mean any information that does not identify one or more specific products.

II. SCOPE AND ENFORCEMENT

A. All of the provisions of this Agreement shall apply both while Mallinckrodt is in bankruptcy and after Mallinckrodt emerges from bankruptcy, and they shall apply to the operation of Mallinckrodt's Opioid Business by any subsequent purchaser (regardless of whether Mallinckrodt is sold through the bankruptcy process or after bankruptcy, and regardless whether the purchaser buys all or just a portion of Mallinckrodt's Opioid Business). For the avoidance of doubt, nothing in this Agreement applies to the operation of a subsequent purchaser(s)' pre-existing opioid business.

B. The provisions of this Agreement will not apply to Mallinckrodt's parent or its parent's subsidiaries, other than those subsidiaries included in the above definition of Mallinckrodt, so long as Mallinckrodt's parent agrees in a legally binding manner that neither it, nor any of its other subsidiaries, will be involved in the sale or distribution of opioids classified as DEA Schedule II–IV drugs in the future.

C. In connection with its Chapter 11 Cases, Mallinckrodt consents to the entry of a final judgment or consent order upon the Effective Date imposing all of the provisions of this Agreement in state court in each of the Settling States. During the pendency of the Chapter 11 Cases, this Agreement is enforceable in the Bankruptcy Court. After the Effective Date, this Agreement is enforceable in state court in each of the Settling States. Mallinckrodt agrees that seeking entry or enforcement of such a final judgment or consent order will not violate any other injunctions or stays that it will seek, or that may otherwise apply, in connection with its Chapter 11 Cases or the confirmation of its Chapter 11 Plan.

D. The provisions of this Agreement that apply to the OCC shall no longer apply upon the effectiveness of a Chapter 11 Plan.

E. **Term**

1. Unless addressed in Section II.E.2–3, each provision of this Agreement shall apply for 8 years from the Petition Date.

2. The provisions of Section III.A ("Ban on Promotion"), Section III.B ("No Financial Reward or Discipline Based on Volume of Opioid Sales"), Section III.F ("Ban on Prescription Savings Program"), Section III.G ("Monitoring and Reporting of Direct and Downstream Customers"), Section III.H ("General Provisions"), Section III.I ("Compliance with All Laws and Regulations Relating to the Sale Promotion and Distribution of Any Opioid Product"), and Section V ("Public Access to Documents") shall not be subject to any term.

3. The provisions of Section VI ("Independent Monitor") shall apply for five years from the Petition Date. If, at the conclusion of the Monitor's five-year term, the Settling States determine in good faith and in consultation with the Monitor that justifiable cause exists, the Monitor's engagement shall be extended for an additional term of up to two years, subject to the right of Mallinckrodt to commence legal proceedings for the purpose of challenging the decision of the Settling States and to seek preliminary and permanent injunctive relief with respect thereto. For purposes of this paragraph "justifiable cause" means a failure by Mallinckrodt to achieve and maintain substantial compliance with the substantive provisions of this Agreement.

F. Notice and Cure

1. For the purposes of resolving disputes with respect to compliance with this Agreement, should any State Attorney General have reason to believe that Mallinckrodt has violated a provision of this Agreement subsequent to the Petition Date, then such Attorney General shall notify Mallinckrodt in writing of the specific objection, identify with particularity the provisions of this Agreement that the practice appears to violate, and give Mallinckrodt 30 days to respond to the notification. Promptly after Mallinckrodt's receipt of any such written notice, Mallinckrodt shall provide such written notice to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC.

2. Upon receipt of written notice from such State Attorney General, Mallinckrodt shall provide a written response to the Settling States and to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC, containing either a statement explaining why Mallinckrodt believes it is in compliance with this Agreement or a detailed explanation of how the alleged violation occurred and a statement explaining how and when Mallinckrodt intends to remedy or has remedied the alleged violation.

3. Such State Attorney General may not take any action concerning the alleged violation of this Agreement during the 30-day response period. Nothing shall prevent such State Attorney General from agreeing in writing to provide Mallinckrodt with additional time beyond the 30 days to respond to the notice and Mallinckrodt shall promptly provide notice of any such additional response time to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC. However, such State Attorney General may take any action, including, but not limited to legal action to enforce compliance with the consent judgment specified by Section II.C, without delay if such State Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

4. Such State Attorney General may bring an action against Mallinckrodt to enforce the terms of the consent judgment specified by Section II.C, but only after providing Mallinckrodt an opportunity to respond to the notification as described above or within any other period as agreed to by Mallinckrodt and such State Attorney General.

5. Nothing in this Agreement shall be interpreted to limit any State Attorney General's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable state law, and Mallinckrodt agrees to comply with a CID or investigative subpoena issued pursuant to such authority.

6. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Agreement after the Petition Date, or to compromise the authority of any State Attorney General to take action for any failure to comply with this Agreement.

7. Nothing herein shall compromise the OCC's right to enforce its specific information rights and consultation rights set forth in this Agreement in the Bankruptcy Court during the pendency of the Chapter 11 Cases.

III. INJUNCTIVE RELIEF

A. Ban on Promotion

1. Mallinckrodt shall not engage in the Promotion of Opioids or Opioid Products, including but not limited to, by:

    a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or patients or to persons that influence or determine the Opioid Products included in formularies;

b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;

c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to Opioids or Opioid Products;

d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products;

e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;

f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and

g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

2. Notwithstanding Section III.A.1, III.A.5, and III.C, Mallinckrodt may:

a. Maintain a corporate website;

b. Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider;

c. Provide information or support the provision of information as expressly required by law or any state or federal government agency with jurisdiction in the state where the information is provided;

d. Provide the following by mail, electronic mail, on or through Mallinckrodt's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products or other prescribing information for Opioid Products that are published by a state or federal government agency with jurisdiction in the state where the information is provided;

e. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider consistent with the standards set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011, as updated or amended by the FDA) and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009, as updated or amended by the FDA);

f. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling or to speak with a licensed Health Care Provider without describing the safety or effectiveness of Opioids or any Opioid Product or naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product;

g. Provide Health Care Economic Information, as defined at 21 U.S.C. § 352(a), to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis consistent with standards set forth in the FDA's Draft Questions and Answers Guidance for Industry and Review Staff, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities* (Jan. 2018), as updated or amended by the FDA;

h. Provide information, through a product catalog or similar means, related to an Opioid or Opioid Product, including, without limitation, pricing information, weight, color, shape, packaging size, type, reference listed drug, National Drug Code label, and such other descriptive information (including information set forth in a standard Healthcare Distribution Alliance Form or technical data sheet and the FDA approval letter) sufficient to identify the products available, to place an order for a product, and to allow the product to be loaded into a customer's inventory and ordering system or a third party pricing compendia;

i. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved Risk Evaluation and Mitigation Strategy (REMS) program or other federal or state law or regulation applicable in the state where the program is provided through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of Mallinckrodt;

j. Provide Unbranded Information in connection with managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to: the use of

Opioids for managing such pain, as long as the Unbranded Information identifies Mallinckrodt as the source of the information;

k. Promote medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" or methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities;

l. Promote raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such raw materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories; And, notwithstanding this exception, Mallinckrodt will not promote raw materials, active pharmaceutical ingredients and/or immediate precursors to Healthcare Providers or patients; and

m. Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying Groups, Group Purchasing Organizations, and Pharmacy Benefit Managers, except as prohibited by Section III.G.

3. Mallinckrodt shall not engage in the following specific Promotional activity relating to any products for the treatment of Opioid-induced side effects (for the avoidance of doubt, "Opioid-induced side effects" does not include addiction to Opioids or Opioid Products):

a. Employing or contracting with sales representatives or other persons to Promote products for the treatment of Opioid-induced side effects to Health Care Providers or patients;

b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of products for the treatment of Opioid-induced side effects;

c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to products for the treatment of Opioid-induced side effects;

d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; and

e. Engaging in any other Promotion of products for the treatment of Opioid-induced side effects in a manner that encourages the utilization of Opioids

or Opioid Products or normalizes the use of Opioids or Opioid Products for chronic pain.

4. Notwithstanding Section III.A.3 directly above, Mallinckrodt may engage in other Promotional activity for products that may be used for the treatment of Opioid-induced side effects but also have non-Opioid related indications, so long as such Promotion does not explicitly or implicitly associate the product with Opioids or Opioid Products, except for linking to the FDA label associated with that product.

5. Treatment of Pain

   a. Mallinckrodt shall not, either through Mallinckrodt or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

   b. Mallinckrodt shall not, either through Mallinckrodt or through Third Parties, Promote the concept that pain is undertreated in a manner that directly or indirectly encourages the utilization of Opioids or Opioid Products.

   c. Mallinckrodt shall not disseminate Unbranded Information, including Unbranded Information about a medical condition or disease state, that contains links to branded information about Opioid Products or generates leads for sales of Opioid Products.

6. To the extent that Mallinckrodt engages in conduct permitted by Sections III.A.2 and A.4 above, Mallinckrodt shall do so in a manner that is:

   a. Consistent with the CDC Guideline Recommendations, as applicable; and

   b. Truthful, non-misleading, accurate, non-deceptive, and does not omit any relevant information.

B. No Financial Reward or Discipline Based on Volume of Opioid Sales

1. Mallinckrodt shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products. Notwithstanding the foregoing, this provision does not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or Mallinckrodt's generics business, as measured by EBITDA, revenue, cash flow or other similar financial metrics.

2. Mallinckrodt shall not offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, to or from any person in return for the prescribing or use of an Opioid Product. For the avoidance of doubt, this shall not

prohibit the provision of rebates and/or chargebacks to the extent permitted by Section III.A.2.m.

3. Mallinckrodt's compensation policies and procedures shall be designed to ensure compliance with this Agreement and other legal requirements.

C. Ban on Funding/Grants to Third Parties

1. Mallinckrodt shall not directly or indirectly provide financial support or In-Kind Support to any Third Party that Promotes or is for education about Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects, including educational programs or websites that Promote Opioids, Opioids Products, or products intended to treat Opioid-related side effects but excluding financial support otherwise allowed by this Agreement or required by a federal or state agency.

2. Mallinckrodt shall not create, sponsor, provide financial support or In-Kind Support to, operate, or control any medical society or patient advocacy group relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

3. Mallinckrodt shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

4. Mallinckrodt shall not use, assist, or employ any Third Party to engage in any activity that Mallinckrodt itself would be prohibited from engaging in pursuant to this Agreement.

5. Mallinckrodt shall not enter into any contract or agreement with any person or entity or otherwise attempt to influence any person or entity in such a manner that has the purpose or foreseeable effect of limiting the dissemination of information regarding the risks and side effects of using Opioids.

6. Mallinckrodt shall not compensate or support Health Care Providers, other than Mallinckrodt employees, or organizations to advocate for formulary access or treatment guideline changes that would have the effect of increasing access to any Opioid Product by third-party payers, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. Nothing in this provision affects the limitations on Mallinckrodt employees set forth in Section III.A. Notwithstanding anything to the contrary in this Agreement, this provision does not prohibit the payment of customary rebates or other pricing concessions to third party payors, including state Medicaid programs, as part of an overall pricing agreement, except as prohibited by Section III.F.

7. No director, officer, or management-level employee of Mallinckrodt may serve as a director, board member, employee, agent, or officer of any entity, other than Mallinckrodt plc or a wholly owned subsidiary thereof, that not incidentally engages in Promotion relating to Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects. Any director, officer, or management-level employee of Mallinckrodt that serves as a director, board member, employee, agent or officer of any entity shall recuse himself or herself from any decisions in that capacity that are related to the Promotion of Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

8. Mallinckrodt shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity that not incidentally engages in Promotion relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.

9. The prohibitions in Section III.C shall not apply to engagement with Third Parties based on activities related to (1) medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" or methadone 5 and 10 mg tablets, to the extent they are sold to addiction treatment facilities; (2) raw materials, active pharmaceutical ingredients and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, active pharmaceutical ingredients and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United States or its territories; or (3) education warning about drug abuse or promoting prevention or treatment of drug misuse.

10. Mallinckrodt will be in compliance with Sections III.C.2 and III.C.3 with respect to support of an individual Third Party to the extent that the Independent Monitor or the Settling States determines that such support does not increase the risk of the inappropriate use of Opioids and that Mallinckrodt has not acted for the purpose of increasing the use of Opioids.

D. Lobbying Restrictions

1. Mallinckrodt shall not Lobby for the enactment of any provision of any federal, state, or local legislation or promulgation of any provision of any rule or regulation that:

   a. encourages or requires Health Care Providers to prescribe Opioid Products or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids;

   b. would have the effect of limiting access to any non-Opioid alternative pain treatments; or

c. pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.

2. Mallinckrodt shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation that supports:

a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use, including but not limited to third party payment or reimbursement for such therapies;

b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated, including but not limited to third party reimbursement or payment for such prescriptions;

c. The prescribing of the lowest effective dose of an Opioid, including but not limited to third party reimbursement or payment for such prescription;

d. The limitation of initial prescriptions of Opioids to treat acute pain;

e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to third party reimbursement or payment for naloxone;

f. The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed, including but not limited to third party reimbursement or payment for such testing;

g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD, including but not limited to third party reimbursement or payment for such treatment; or

h. The implementation or use of Opioid drug disposal systems.

3. Mallinckrodt shall not Lobby against the enactment of any provision of any federal, state or local legislation or promulgation of any provision of any rule or regulation creating or expanding the operation or use of PDMPs, including but not limited to provisions requiring Health Care Providers to review PDMPs when Opioid use is initiated and with every prescription thereafter. For the avoidance of doubt, Mallinckrodt may Lobby in support of a particular PDMP proposal.

4. Notwithstanding the foregoing restrictions in Sections III.D.1–3, III.A, and III.C, the following conduct is not restricted:

a. Lobbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments;

b. Challenging the enforcement of, or suing for declaratory or injunctive relief with respect to legislation, rules or regulations referred to in Section III.D.1;

c. Communications made by Mallinckrodt in response to a statute, rule, regulation, or order requiring such communication;

d. Communications by a Mallinckrodt representative appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order or subpoena commanding that person to testify;

e. Responding, in a manner consistent with this Agreement, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing specifically to Mallinckrodt from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;

f. Communicating with a federal or state agency in response to a Federal Register or similar notice or an unsolicited federal or state legislative committee request for public comment on proposed legislation; and

g. Responding to requests from the DEA, the FDA, or any other Federal or state agency and/or participating in FDA or other agency panels at the request of the agency.

h. Participate in meetings and other proceedings before the FDA, FDA advisory committee or other FDA committee in connection with the approval, modification of approval, or oversight of its own products.

5. Mallinckrodt shall require all of its officers, employees, and agents engaged in Lobbying to certify in writing or by appropriate electronic means to Mallinckrodt that they are aware of and will fully comply with the provisions of this Agreement with respect to Lobbying on behalf of Mallinckrodt.

E. Ban on Certain High Dose Opioids

1. Mallinckrodt shall not commence manufacturing, promoting, or distributing any Opioid Product that exceeds 30 milligrams of oxycodone per pill.

F. Ban on Prescription Savings Programs

1. Mallinckrodt shall not directly or indirectly offer any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

2. Mallinckrodt shall not directly or indirectly provide financial support to any Third Party that offers coupons, discounts, rebates or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

3. Mallinckrodt shall not directly or indirectly assist patients, Health Care Providers, or pharmacies regarding the claims and/or prior authorization process required for third-party payers to approve claims involving any Opioid Product.

G. Monitoring and Reporting of Direct and Downstream Customers

1. Mallinckrodt shall operate an effective monitoring and reporting system in compliance with 21 C.F.R. § 1301.71(a), 21 C.F.R. §1301.74(b), 21 U.S.C. § 823(d) and Section 3292 of the SUPPORT for Patients and Communities Act, that shall include processes and procedures that:

   a. Utilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;

   b. Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product;

   c. Utilize all information Mallinckrodt receives that bears upon a direct customer's or a downstream customer's diversion activity or potential for diversion activity, including reports by Mallinckrodt's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media; and

   d. Upon request (unless otherwise required by law), report to any requesting State Attorney General or State controlled substances regulatory agency any direct customer or downstream customer in such requesting State Attorney General's or agency's State identified as part of the monitoring required by (a)-(c), above, and any customer relationship in such State terminated by Mallinckrodt relating to diversion or potential for diversion. These reports shall include the following information, to the extent known to Mallinckrodt:

      i. The identity of the downstream registrant and the direct customer(s) identified by Mallinckrodt engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number;

      ii. The dates of reported distribution of controlled substances by direct customers to the downstream registrant during the relevant time period;

iii. The drug name, drug family or NDC and dosage amounts reportedly distributed;

iv. The transaction or order number of the reported distribution; and

v. A brief narrative providing a description of the circumstances leading to Mallinckrodt's conclusion that there is a risk of diversion.

2. Mallinckrodt shall not provide to any direct customer an Opioid Product to fill an order identified as a Suspicious Order unless Mallinckrodt's DEA Compliance Department investigates and finds that the order is not suspicious. Where Mallinckrodt has investigated a potentially Suspicious Order and determined that the order is not suspicious, Mallinckrodt must document the bases for its determination, and provide such documentation to the Monitor, any State Attorney General, or State controlled substances regulatory agency, upon request.

3. Upon request, Mallinckrodt shall provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices.

4. Mallinckrodt agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy location or Health Care Provider. Nothing in this provision, however, prevents Mallinckrodt from (i) acting as a distributor of medications relating to (x) the treatment of opioid use disorders; (y) the treatment of opioid abuse, addiction, dependence, or overdose, including medication-assisted treatment for opioid addiction; and (z) rescue medications for opioid overdose; or (ii) providing an Opioid Product directly to a mail order pharmacy, distribution center serving a chain pharmacy, or pharmacy provider that exclusively serves long-term care or hospice providers and their patients.

H. General Terms

1. To the extent that any provision in this Agreement conflicts with federal or relevant state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in the Agreement is in conflict with federal or relevant state law such that Mallinckrodt cannot comply with both the statute or regulation and a provision of this Agreement, Mallinckrodt may comply with such statute or regulation. Mallinckrodt will provide advance written notice to the affected State Attorney(s) Generals of the statute or regulation that Mallinckrodt intends to comply under this paragraph, and the provision of this Agreement that is in conflict with the statute or regulation. In the event any State Attorney General disagrees with Mallinckrodt's interpretation of the conflict, such State Attorney General reserves the right to pursue any remedy or sanction that may be available regarding compliance with this Agreement.

2. Mallinckrodt shall not make any written or oral statement about Opioids or any Opioid Product that is unfair, false, misleading, deceptive or unconscionable. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" as well as methadone 5 and 10 mg tablets.

3. Mallinckrodt shall not represent that Opioids or any Opioid Product(s) have approvals, characteristics, uses, benefits, or qualities that they do not have. For purposes of this paragraph, "Opioid Product" shall also include medications with a FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage" as well as methadone 5 and 10 mg tablets.

4. For the avoidance of doubt, nothing in this Agreement is intended to or shall be construed to prohibit Mallinckrodt in any way whatsoever from taking legal or factual positions with regard to its Opioid Product(s) in defense of litigation or other legal proceedings or investigations.

5. Upon the request of any State Attorney General or the OCC, Mallinckrodt shall provide the requesting State Attorney General, or the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC, with copies of the following, within 30 days of the request:

   a. Any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Mallinckrodt's Opioid Product(s); and

   b. Warning or untitled letters issued by the FDA regarding Mallinckrodt's Opioid Product(s) and all correspondence between Mallinckrodt and the FDA related to such letters.

I. Compliance with All Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product

1. Mallinckrodt shall comply with all laws and regulations that relate to the sale, promotion, distribution, and disposal of any Opioid Product including but not limited to:

   a. State controlled substances acts, including all guidance issued by applicable state regulator(s), and related regulations;

   b. The Federal Controlled Substance Act, including all guidances issued by the DEA;

   c. The Federal Food, Drug and Cosmetic act, or any regulation promulgated thereunder;

d. FDA Guidances;

e. State consumer protection and unfair trade practices acts; and

f. State laws and regulations related to opioid prescribing, distribution and disposal.

J. Compliance Deadlines

1. As of the Petition Date, Mallinckrodt must be in full compliance with the provisions included in this Agreement with the exception of the provisions in Section V ("Public Access to Mallinckrodt Documents").

K. Training

1. Mallinckrodt shall provide regular training, at least once per year, to relevant employees on their obligations imposed by this Agreement.

IV. CLINICAL DATA TRANSPARENCY

A. Data to Be Shared

1. Mallinckrodt shall share the following clinical data through a third-party data archive that conforms to the requirements defined below to increase the transparency of its clinical research.

a. Mallinckrodt shall make available all previously disclosed data and/or information regarding Mallinckrodt Opioid Products;

b. Mallinckrodt shall make available all previously unreleased data regarding Mallinckrodt Opioid Products, for both approved and unapproved indications, including:

i. Full analyzable data set(s) (including individual participant-level data de-identified by an independent biostatistician);

ii. The clinical study report(s) redacted for commercial or personal identifying information;

iii. The full protocol(s) (including the initial version, final version, and all amendments); and

iv. Full statistical analysis plan(s) (including all amendments and documentation for additional work processes) and analytic code.

c. Mallinckrodt shall make available the above information for all studies for any new Mallinckrodt Opioid Product or new indications that are

approved within 30 days after regulatory approval or 18 months after study completion, whichever occurs later.

B. Third-Party Data Archive

1. Mallinckrodt shall share the above information via a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal.

2. The data archive shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.

3. The panel may exclude research proposals with a commercial interest.

C. Non Interference

1. Mallinckrodt shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.

D. Data Use Agreement

1. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for Mallinckrodt's pharmacovigilance staff. Every agreement shall require the lead qualified researcher to inform Mallinckrodt's pharmacovigilance staff within 24 hours of any determination that research findings could detrimentally impact the risk-benefit assessment regarding the product. The lead Qualified Researcher may also inform regulatory authorities of the safety signal impacting the risk-benefit assessment. Mallinckrodt's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying regulatory authorities or the public.

E. Cost

1. Mallinckrodt shall bear all costs for making data and/or information available.

V. PUBLIC ACCESS TO MALLINCKRODT DOCUMENTS

F. Documents Subject to Public Disclosure

1. The following documents shall be produced by Mallinckrodt to each Settling State and are subject to public disclosure in perpetuity as part of an industry-wide document disclosure program, except for the redactions authorized by Section V.B:

a. All documents, indices, and privilege logs Mallinckrodt produced to any of the Settling States prior to the Petition Date, including in litigation and in response to investigative demands or other formal or informal requests related to opioids.

b. All documents, indices, and privilege logs Mallinckrodt produced in the Opioid Multi-District Litigation (*In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio)) and the New York litigation (*In re Opioid Litigation*, 400000/2017 (Suffolk County)) prior to the Petition Date.

c. All documents, indices, and privilege logs Mallinckrodt has produced in other litigation related to opioids, excluding patent litigation.

d. All filings, motions, orders, court transcripts, deposition transcripts, and exhibits in the possession, custody, or control of Mallinckrodt from litigation related to opioids, excluding patent litigation.

2. All documents produced under this provision shall be provided in electronic format with all related metadata. Mallinckrodt and the Settling States will work cooperatively to develop technical specifications for the productions.

B. Information That May Be Redacted

1. The following categories of information are exempt from public disclosure:

a. Information subject to trade secret protection. A "trade secret" is information, including a formula, pattern, compilation, program, device, method, technique or process, that (a) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure and use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Even if the information falls within the definition, "trade secret" does not include information reflecting sales or promotional strategies, tactics, targeting, or data, or internal communications related to sales or promotion.

b. Confidential personal information. "Confidential personal information" means individual Social Security or tax identification numbers, personal financial account numbers, passport numbers, driver license numbers, home addresses, home telephone numbers, personal email addresses, and other personally identifiable information protected by law from disclosure. "Confidential personal information" does not include the names of Mallinckrodt's officers, directors, employees, agents, or attorneys.

c. Information that is inappropriate for public disclosure because it is subject to personal privacy interests recognized by law (*e.g.*, HIPAA), or contractual rights of third parties that Mallinckrodt may not abrogate.

d. Information regarding Mallinckrodt employees' personal matters unrelated to Mallinckrodt, including emails produced by Mallinckrodt custodians discussing vacation or sick leave, family, or other personal matters.

C. Redaction of Documents Containing Protected Information

1. Whenever a document contains information subject to a claim of exemption pursuant to Section V.B, Mallinckrodt shall produce the document in redacted form. Such redactions shall indicate that trade secret and/or private information, as appropriate, has been redacted. Redactions shall be limited to the minimum redactions possible to protect the legally recognized individual privacy interests and trade secrets identified above.

2. Mallinckrodt shall produce to each Settling State a log noting each document redacted. The log shall also provide fields stating the basis for redacting the document, with sufficient detail to allow an assessment of the merits of the assertion. The log is subject to public disclosure in perpetuity. The log shall be produced simultaneously with the production of documents required by Section V.F.

3. In addition to the redacted documents, Mallinckrodt shall, upon any Settling State's request, also produce all documents identified in Section V.A above in unredacted form to such Settling State at the same time. The redacted documents produced by Mallinckrodt may be publicly disclosed in accordance with Section V.E below. The unredacted documents produced by Mallinckrodt to a Settling State shall be available only to such State unless Mallinckrodt's claim of exemption under Section V.B is successfully challenged in accordance with Section V.C.4 or the trade secret designation expires in accordance with Section V.D.

4. Anyone, including members of the public and the press, may challenge the appropriateness of redactions by providing notice to Mallinckrodt. If the challenge is not resolved by agreement, it must be resolved in the first instance by a third party jointly appointed by the Settling States and Mallinckrodt to resolve such challenges. The decision of the third party may be appealed to a court with enforcement authority over this Agreement. If not so appealed, the third party's decision is final. In connection with such challenge, a Settling State may provide copies of relevant unredacted documents to the parties or the decisionmaker, subject to appropriate confidentiality and/or in camera review protections, as determined by the decisionmaker.

D. Review of Trade Secret Redactions

1. Ten years after Mallinckrodt completes the production of its documents in accordance with Section V, Mallinckrodt shall review all trade secret assertions made in accordance with Section V.B.1 and all non-manufacturing trade secret designations shall expire. The newly unredacted documents may then be publicly disclosed by a Settling State in accordance with Section V.E. Mallinckrodt shall produce to each Settling State an updated redaction log justifying its designations of the remaining trade secret redactions as manufacturing trade secrets.

E. Public Disclosure through a Document Repository

1. Each Settling State may publicly disclose all documents covered by Section V through a public repository maintained by a governmental, non-profit, or academic institution. Each Settling State may specify the terms of any such repository's use of those documents, including allowing the repository to index and make searchable all documents subject to public disclosure, including the metadata associated with those documents. When providing the documents covered by Section V to a public repository, no Settling State shall include or attach within the document set any characterization of the content of the documents. For the avoidance of doubt, nothing in this paragraph shall prohibit any Settling State from publicly discussing the documents covered by Section V.

F. Timeline for Production

1. Mallinckrodt shall produce all documents required by Section V.A within nine months from the Petition Date.

G. Costs

1. Mallinckrodt shall be responsible for its allocable share of all reasonable costs and expenses associated with the public disclosure and storage of Mallinckrodt's documents through any public repository.

H. Suspension

1. Mallinckrodt's obligation in Section V shall be suspended on the nine-month anniversary of the Petition Date, unless and until two corporate defendants in opioid-related litigation other than Mallinckrodt have agreed or been ordered to publicly disclose opioid-related documents. For the avoidance of doubt, Insys Therapeutics, Inc. shall constitute one of the two necessary defendants based on the "Liquidating Trustee Disclosure Requirement" provisions of the Second Amended Joint Chapter 11 Plan of Liquidation confirmed by the United States Bankruptcy Court for the District of Delaware on January 16, 2020.

VI. INDEPENDENT MONITOR

A. Appointment of Monitor

1. Mallinckrodt agrees that it will retain an outside, independent individual (the "Monitor") to evaluate and monitor Mallinckrodt's compliance with this Agreement.

2. Experience with internal investigations or the investigative process (which may include prior monitorship or oversight experience) and expertise in the pharmaceutical industry, relevant regulatory regimes, and internal controls and compliance systems may be considered in selecting the Monitor.

3. Within 30 days of the Petition Date, Mallinckrodt and the Settling States shall exchange pools of recommended candidates based in part on the above qualification and considerations to serve as the Monitor. The pools shall each contain the names of three individuals, groups of individuals or firms. A copy of each pool of candidates shall be shared with the OCC when such pools are exchanged between Mallinckrodt and the Settling States. The OCC may make suggestions for each side to consider.

4. After receiving the pools of Monitor candidates, Mallinckrodt and the Settling States shall have the right to meet with the candidates and conduct appropriate interviews of the personnel who are expected to work on the project, provided, that the OCC may participate as an observer at any such interviews with the consent of the Settling States and Mallinckrodt. Mallinckrodt and the Settling States may veto any of the candidates, and must do so in writing (with a copy to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC) within 30 days of receiving the pool of candidates. If all three candidates within a pool are rejected by either Mallinckrodt or the Settling States, the party who rejected the three candidates may direct the other party to provide up to three additional qualified candidates within 15 days of receipt of said notice (and shall provide a copy of such direction to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC). Notice of such additional qualified candidates shall be given to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC upon the names of such candidates being given to the other party.

5. If Mallinckrodt or the Settling States do not object to a proposed candidate, Mallinckrodt or the Settling States shall so notify the other in writing (with a copy to the OCC for informational purposes only pursuant to the confidentiality provisions of the by-laws between Mallinckrodt and the OCC) within 30 days of receiving the pool of candidates. If more than one candidate remains, the Settling States shall select the Monitor from the remaining candidates. Mallinckrodt and the Governmental Ad Hoc Committee (as such term is defined in the restructuring

support agreement) shall jointly seek the Bankruptcy Court's approval of the selected Monitor candidate.

6. Unless justifiable cause exists, the Monitor appointed by the Bankruptcy Court shall continue to serve after the Effective Date. For purposes of this paragraph, justifiable cause exists if the Monitor resigns or a court finds that the Monitor: (a) develops a conflict of interest that would undermine public confidence in the objectivity of his or her work; (b) has unreasonably failed to fulfill his or her material obligations under this Agreement or pursuant to the Work Plan (as defined in Section VI.B3), (c) has engaged in any act of dishonesty, misappropriation, embezzlement, intentional fraud, or similar conduct; or (d) has engaged in an intentional act of bias or prejudice in favor or against either party. Justifiable cause shall not include Mallinckrodt's or the Settling States' disagreements with the decisions of the Monitor pursuant to this Agreement, unless there is a clear pattern in the Monitor's decisions that demonstrates that the Monitor has not been acting as an independent third party in rendering decisions.

7. If a new Monitor must be appointed, Mallinckrodt and the Settling States and the OCC shall follow the procedures and timeline set out above in subparagraphs 3-5. Court approval shall not be sought if Mallinckrodt is no longer under the Bankruptcy Court's jurisdiction..

B. Monitor's Responsibilities

1. Between the Petition Date and the Effective Date, the Monitor's duties shall be as follows:

   a. The Monitor shall perform its duties according to the terms of this Agreement and shall be vested all rights and powers reasonably necessary to carry out such powers, duties, and responsibilities enumerated herein.

   b. The Monitor shall work with all diligence perform his or her duties in a manner that does not unreasonably disrupt the operation of Mallinckrodt's business to confirm and oversee compliance with this Agreement.

   c. The Monitor shall review and provide reports as outlined below.

   d. Subject to any legally recognized privilege and as reasonably necessary to perform his or her duties hereunder, the Monitor shall have full and complete access to Mallinckrodt's personnel, books, records, and facilities, and to any other relevant information, as the Monitor may request. Mallinckrodt shall develop such information as the Monitor may request and shall fully, completely and promptly cooperate with the Monitor. The Monitor may raise with the Bankruptcy Court any issues relating to any failure of or delay in such cooperation for an expedited resolution by the Bankruptcy Court.

e. The Monitor shall serve, without bond or other security, at the cost and expense of Mallinckrodt, with the Monitor's fees subject to final approval by the Bankruptcy Court. The Monitor shall have the authority to employ, upon written consent from Mallinckrodt, such consent not to be unreasonably withheld, delayed or conditioned, and upon Court approval, at the cost and expense of the Debtors' estates, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's responsibilities. Requests to employ such individuals should be directed to Mallinckrodt's General Counsel, and will be decided upon no later than ten (10) days from their receipt. The Monitor will work in good faith with Mallinckrodt to ensure such approved consultants will follow Mallinckrodt's policies and procedures with respect to any payments remitted directly by Mallinckrodt.

f. The Monitor shall have no obligation, responsibility, or liability for the operations of Mallinckrodt.

g. The Monitor shall sign onto any Protective Order entered by the Bankruptcy Court, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties, and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants shall also sign onto any Protective Order entered by the Court, and any confidentiality agreement consistent with any Protective Order as deemed necessary by the parties; provided, however, that nothing shall restrict the Monitor from providing any information to the Court and the parties consistent with the terms of any Protective Order.

h. The Monitor shall promptly seek an order from the Bankruptcy Court requiring compliance or such other remedies as may be appropriate under the circumstances should Mallinckrodt not comply with this Agreement.

i. The Monitor shall make a good faith effort to leverage Mallinckrodt's existing compliance mechanisms when reviewing Mallinckrodt's compliance with this Agreement.

j. The Monitor shall make a good faith effort to perform his or her duties in a manner that does not unreasonably disrupt Mallinckrodt's business operations. In this regard, Mallinckrodt shall designate senior officials within the Office of the General Counsel to serve as the primary points of contact for the Monitor in order to facilitate the Monitor's access to documents, materials, or staff necessary to review Mallinckrodt's compliance with this Agreement. The Monitor shall communicate any request for documents, materials, or access to staff to the designated contacts, unless otherwise instructed. For the avoidance of doubt, nothing in this paragraph shall be interpreted to prohibit the Monitor from speaking with a current or former employee of Mallinckrodt.

2. **Reporting**:

   a. Within 45 days of the Petition Date, Mallinckrodt shall file a report with the Bankruptcy Court regarding its compliance with the terms of this Agreement (the "Mallinckrodt Compliance Report"). To the extent permissible by law, this report (in whole or in part) may be filed under seal or subject to such other confidentiality restrictions contained in a Protective Order.

   b. The Monitor must file a report with the Bankruptcy Court regarding compliance by Mallinckrodt with the terms of this Agreement no later than 45 days after the Work Plan (as defined in Section VI.B.3) is finalized, and then additional reports every 90 days thereafter (the "Monitor Reports"). The Court may, in response to such reports, provide further direction to the Monitor as it deems appropriate. To the extent permissible by law, these reports (in whole or in part) may be filed under seal or subject to such other confidentiality restrictions contained in a Protective Order. The content of Monitor Reports shall be set forth in the Work Plan. The frequency of Monitor Reports may decrease to every 180 days after the Effective Date.

   c. Prior to issuing any Monitor Report, the Monitor shall confer with Mallinckrodt, the Settling States, and the OCC, either jointly or separately (in the discretion of the Monitor), regarding its preliminary findings and the reasons for those findings. Mallinckrodt shall have the right to submit written comments to the Monitor, which shall be appended to the final version of the Monitor Report.

   d. In the event the Monitor Report identifies a potential violation of this Agreement, Mallinckrodt shall have the right to cure any potential violation within 30 days.

3. **Work Plan**: The manner in which the Monitor will carry out his or her compliance responsibilities under this Agreement, the general scope of information that the Monitor will seek to review in fulfilling his or her duties and, where applicable, the methodologies to be utilized shall be set forth in a work plan (the "Work Plan"). Within 30 days after the Monitor's appointment by the Bankruptcy Court, the Settling States and Mallinckrodt, upon consultation with the OCC, shall agree with the Monitor on the Work Plan. If the Monitor, the Settling States, and Mallinckrodt (upon consultation with the OCC) fail to reach agreement on the Work Plan within the designated time frame, the Monitor, Settling States, and Mallinckrodt will submit any disputed issues to the Bankruptcy Court for resolution.

4. **Post-Emergence**: Before the Effective Date, the parties will work in good faith to establish procedures for resolving disputes (including disputes over the Work Plan) and overseeing the Monitor's obligations after Bankruptcy Court approval

of the Plan, and to make any other adjustments the parties agree to be reasonably necessary. The parties expect and agree that the principal obligations and conditions imposed by Section VI.B will otherwise remain in effect. After the Effective Date, all reasonable and necessary fees and costs of the Monitor shall be paid by Mallinckrodt.