Mallinckrodt Pharmaceuticals

Via email – opioids@finance.senate.gov

February 16, 2018

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Recommendations to Address Opioid Use and Substance Use Disorders

Dear Chairman Hatch and Ranking Member Wyden:

Mallinckrodt Pharmaceuticals ("Mallinckrodt" or the "Company") appreciates the opportunity to provide policy recommendations to combat opioid use disorder ("OUD") and substance use disorder ("SUD") in programs under the Senate Finance Committee's (the "Committee's") jurisdiction, such as Medicare and Medicaid.[1] Mallinckrodt thanks you both for your leadership on this important issue, and for the important questions posed in your open letter dated February 2, 2018.

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics. The Company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The Company's Specialty Brands segment includes branded medicines and its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing.

Consistent with the request, in this letter we provide comments on each specific question posed, which include the following topics:

[1] United States Senate, Committee on Finance, (Feb. 2, 2018) available at https://www.finance.senate.gov/imo/media/doc/2.2.18%20Hatch-Wyden%20Opioid%20Input%20Solicitation%20Letter_Redacted.pdf.

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- **Support Use of Multimodal Analgesia ("MMA").** The use of pharmaceutical alternatives to opioids are an essential part of any effective plan to combat opioid abuse and misuse, and yet Medicare and Medicaid policy does too little to ensure that a balanced, multimodal approach to pain management is required by practitioners and other providers, through, for example, appropriate reimbursement. In addition, Medicaid should encourage Medicaid waiver requests from states that support the development of MMA.

- **Increase Access to Medication Assisted Treatment ("MAT").** Adequate coverage and reimbursements for MAT is needed urgently. Despite the widespread acceptance and acknowledgement that MAT is effective, access to MAT is still limited in both the Medicare and Medicaid programs. In order to address this disturbing gap in coverage, we support legislation and policies that would ensure coverage of MAT in Part B and increase access to all MAT therapies under state Medicaid programs.

- **Encourage Limited Supplies of Opioids.** Mallinckrodt supports Medicare and Medicaid policies limiting the supply of opioids in appropriate cases.

- **Improve Prescriber Education.** Prescriber and pharmacy education is absolutely essential to reducing opioid use. We support developing an NPI-based system that would provide a transparent, national system to document the completion of controlled substance related training by Medicare and Medicaid providers.

- **Support Improvements to Prescription Drug Monitoring Programs.** Prescription Drug Monitoring Programs ("PDMPs") have proven to be an effective tool in reducing prescription drug abuse. Increased integration of state and federal systems and further development of "real-time" access to those systems by prescribers and pharmacists is essential. The Medicare and Medicaid programs should also track and review high opioid prescribers and coordinate those identification and review efforts.

- **Ensure Appropriate Disposal and Take-Back Programs.** Mallinckrodt supports expanding programs that encourage appropriate storage and disposal of opioids as well as drug take-back days and drug drop boxes with local law enforcement agencies. We believe that local, state and federal agencies, including CMS, can do more to make these programs more readily available and effective.

I. How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?

We encourage the Committee to expand its scope to consider evidence-based care for both chronic and acute pain patients. In fact, research suggests a link between the treatment of acute pain episodes and opioid dependence later in chronic pain patients.[2]

[2] Rathmell, *The Link Between Acute and Chronic Pain*, Inter Anesthesia Research Society, IARS Course Lectures, 2012; McGreevy, et al. *Preventing Chronic Pain following Acute Pain: Risk Factors, Preventive Strategies, and their Efficacy,* Eur J Pain Suppl. 2011; 5(2): 365–372.

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Although evidence-based protocols for chronic and acute pain management that reduce OUD and SUD are still developing, established guidelines and best practices support the use of multimodal analgesia ("MMA"), as discussed below. MMA combines the use of a non-opioid and opioid medication to reduce pain. Importantly, MMA involves a variety of potential combinations of pharmaceutical and non-pharmacological options. For instance, MMA may involve anesthetic techniques, cooling pads, nonsteroidal anti-inflammatory drugs, and COX-2 selective inhibitors, as well as non-opioid pain medications such as Mallinckrodt's Ofirmev, which is indicated for the management of mild to moderate pain in adult and pediatric patients 2 years and older; the management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older; and reduction of fever in adult and pediatric patients.

Over-reliance on the use of opioid monotherapy leads to a significant increase in adverse events, including respiratory depression, sedation, nausea, ileus, constipation, falls, delirium, vomiting, and death.[3] In addition, monotherapy leads to higher doses of opioids, risking OUDs and SUDs.[4] This is precisely why many stakeholders strongly support MMA. In March 2016, the Centers for Disease Control and Prevention ("CDC") released opioid prescribing guidelines for chronic pain, which support the use of alternatives to opioids. CDC concluded that, because "opioid therapy prescribed for acute pain [is] associated with greater likelihood of long-term use," alternatives to opioids should be considered in treating both acute and chronic pain.[5] The Joint Commission also recognizes the benefit of using an "individualized, multimodal treatment plan to manage pain," including the use of "non-opioid pain medications."[6]

Accordingly, we believe that the Medicare and Medicaid programs can significantly reduce opioid use by instituting payment policies that incentivize MMA. For instance, the programs could: (1) reimburse practitioners based on their evaluation of pain patients by thoroughly considering MMA options, and (2) requiring MMA evaluations as a condition of payment for inpatient and outpatient services involving episodes of chronic or acute pain, such as surgical services.[7] Moreover, the reimbursement system currently disincentivizes the use of sometimes more costly non-opioid pain medications than less costly opioid medications. Additional reimbursement for non-opioid medications could decrease opioid use, consistent with the Committee's interests.

In addition, existing demonstration authorities can play an important role in helping to further develop evidence-based protocols for the treatment of acute and chronic pain. For instance, existing Medicare and Medicaid demonstration authority could be used to study how incentives for MMA help reduce opioid use. The Committee could also consider requesting a MedPAC or

[3] Eve Shaffer et al., Estimating the Effect of Intravenous Acetaminophen (IV-APAP) on Length of Stay and Inpatient Costs, Regional Anesthesiology & Acute Pain Medicine (Mar. 31, 2016 – Apr. 2, 2016).
[4] Kathleen Brady, et al., Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update, Am. J. Psychiatry 173(1): 18-26 (Jan. 2016).
[5] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, Recommendations and Reports / March 18, 2016 / 65(1);1–49 available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[6] The Joint Commission, Sentinel Event Alert, *Safe Use of Opioids in Hospitals* (Aug. 8, 2012).
[7] The implementation of process metrics was raised in a letter from Sen. Grassley and Sen. Feinstein to then-Acting Administrator Andy Slavitt in April 2016. Sen. Grassley and Sen. Feinstein Letter to Acting Administrator Andy Slavitt, Alternative Metrics for Opioids (Apr. 15, 2016).

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Government Accountability Office study regarding how the programs can support the development of evidence-based protocols, including MMA treatment pathways.

II. What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?

Although the use of pharmaceutical alternatives to opioids are an essential part of any effective plan to combat opioid abuse and misuse, Medicare and Medicaid policy does too little to ensure that a balanced, multimodal approach to pain management is required by practitioners and other providers, including hospitals and skilled nursing facilities. The programs should mandate that pain assessments begin with consideration of non-pharmaceutical and non-opioid pain management alternatives, including non-opioid pain medications. Further, as noted above, reimbursement policies under both Medicare and Medicaid incentivize the overuse of opioids, which are an inexpensive treatment option. Non-opioid treatments should be supported, where appropriate, with increased reimbursements. The cost savings that can be generated by these kinds of investments would be enormous to the programs, to the health care system as a whole, and to society.

Although CMS has made important changes to the pain related questions that are a part of the Hospital Consumer Assessment of Health Providers and Systems ("HCAHPS") Survey, we are concerned that CMS' survey of patients regarding their pain during hospital stays creates a barrier to MMA. CMS' questions still incentivize providers concerned about their HCAHPS Survey results to prescribe opioids. Accordingly, CMS should consider further changes to the HCAHPS Survey to include non-pharmaceutical and non-opioid alternatives.

III. How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?

Medication Assisted Treatment ("MAT") is critically important to successful OUD treatment for many patients. MAT, particularly when combined with counseling and behavioral therapy, has demonstrated its effectiveness in helping to ensure long-term, sustained recovery.[8] As such, Mallinckrodt supports policies that ensure that all patients with an OUD or SUD have access to appropriate treatment, including counseling, behavioral therapy, and appropriate MAT. Unfortunately, despite the widespread acceptance and acknowledgement that MAT is effective, access to MAT is still limited in both the Medicare and Medicaid programs.

CMS does not currently cover methadone, for instance, as an MAT under Part D. In order to address this gap in Medicare coverage, we support passage of a bill supported by the American Association for the Treatment of Opioid Dependence, the "Medicare Beneficiary Opioid Addiction Treatment," which, if enacted, would ensure that all opioid treatment program ("OTP") costs, including methadone, are reimbursed under Part B. We also note that the President's Fiscal Year 2019 budget proposes to address this important issue as well, by testing and

[8] See https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy2016.pdf.

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expanding nationwide a bundled payment for community-based MAT, including Medicare reimbursement for methadone treatment for the first time. We support this effort. Currently, OTPs report that the inadequacy of Medicare coverage and reimbursement for MAT, related counseling, and other needed services forces OTPs to operate with limited hours. Those restricted hours impede access for many patients, particularly those who cannot receive treatment in the early morning when medications are often supplied to control dispensing and other costs.

Although some state Medicaid programs cover MAT drugs, such as methadone, on their preferred drug lists ("PDL"), many do not. The Substance Abuse and Mental Health Services Administration ("SAMHSA") released a report in 2014 that examined Medicaid coverage of drugs for alcohol and opioid dependence.[9] According to the report, only 31 states included methadone on their PDLs for substance abuse treatment.

Though not a problem specific to Medicare and Medicaid, both programs are adversely affected by a number of state and local laws that limit the creation of new OTPs. The Medicare and Medicaid programs are dependent on each community having adequate facilities in place. Facility shortages impede basic access to needed treatment under both programs. We believe a further study of challenges facing OTP programs is warranted.

IV. Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?

Mallinckrodt supports Medicare and Medicaid policies limiting the supply of opioids in appropriate cases. For example, we support limiting prescriptions of opioids to a seven (7) day supply for opioid naïve patients experiencing acute pain. Sending these patients home from a minor surgery with a 30 day supply of opioids unnecessarily risks abuse or misuse of those medications, particularly for those patients that have never been exposed to opioids. Although cancer and other patients whose pain is likely to extend beyond seven days should not be subject to this kind of limitation, limited and partial fill policies for appropriate patients could significantly reduce opioid use within the programs.

V. How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?

Prescriber and pharmacy education is absolutely essential to reducing opioid use. Mallinckrodt has strongly advocated for continuing medical education for physicians, pharmacists, and personnel regarding appropriate prescribing and the warning signs of opioid abuse and diversion. The Company will continue to advocate for strengthened state and federal policies that mandate such education. The Medicare and Medicaid programs can do more to support appropriate education.

The programs' demonstration authority could be used to develop and test the impact on prescribing of innovative educational programs. Regional differences in educational needs and effective solutions could be identified using demonstrations, too. The ability to create

[9] SAMHSA, Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders (2014).

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reimbursement incentives in Medicare and Medicaid demonstrations could fundamentally transform the nature and effectiveness of provider education.

In order to track and make publicly available whether providers have completed necessary education on opioid prescribing, CMS could include a feature in the Open Payments National Provider Identifier-based system that would allow for physicians to document their successful completion of controlled substance prescriber education by Medicare and Medicaid providers. This kind of tracking would promote education and accountability and would help to reduce the use of opioids overall.

VI. What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?

Prescription Drug Monitoring Programs ("PDMPs") are a proven, effective tool in reducing prescription drug abuse. PDMPs help reduce doctor shopping, shorten the time needed to conduct investigations, improve clinical decision-making, and lower overall rates of abuse and diversion. For example, as early as 2002, a Government Accountability Office report found that Kentucky, Nevada, and Utah reported less diversion of prescription drugs as compared to the level reported in previous years because they had implemented PDMPs.

While PDMPs have been shown to be effective, there is significant room for improvement. Increased integration of state and federal systems and further development of "real-time" access to those systems by prescribers and pharmacists is essential. The Medicare and Medicaid programs can encourage the states to integrate their systems. Similarly, the federal programs can encourage physicians, pharmacists, and facilities to report issues, as required by state law, by mandating reporting as a condition of participation in Medicare and Medicaid.

The Medicare and Medicaid programs should also track and review high opioid prescribers and coordinate those identification and review efforts. We appreciate that the President's proposed budget also would require states to track and act on high prescribers and utilizers of prescription drugs. If the programs were to pool their data to identify high opioid prescribing that is not justified by the legitimate pain management needs of cancer and other patients, they could make a significant contribution to reducing abuse and misuse of opioids.

VII. What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

Several states have effectively supported the development of MMA. For example, California created a Chronic Non-Malignant Pain Management Project to "improve primary care providers' and care teams' ability to identify, and manage chronic non-malignant pain using a function-based, multimodal approach." The Project is part of California's Public Hospital Redesign and Incentives in Medi-Cal (PRIME) initiative that is one of four initiates in the Medi-Cal 2020 waiver approved in 2016. We support such state initiatives to encourage alternatives to opioids where appropriate and hope that CMS continues to support such state initiatives. Medicaid should encourage waiver requests from other states that support the development of MMA.

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VIII. What human services efforts (including specific programs or funding design models) appear to be effective in preventing or mitigating adverse impacts from OUD or SUD on children and families?

Mallinckrodt supports expanding programs that encourage appropriate storage and disposal of opioids to prevent unused medications from ending up in the wrong hands. We have donated nearly two million drug deactivation and disposal pouches to community groups, law enforcement, schools, patients and families across the United States. We have also supported drug take-back days and drug drop boxes with local law enforcement agencies. A partnership in St. Louis, MO alone helps dispose of approximately 3,500 pounds of prescription drugs every quarter. We believe that local, state and federal agencies, including CMS, can do more to make these programs more readily available and effective.

* * *

Mallinckrodt appreciates the opportunity to comment on this important issue. We look forward to continuing to work with the Committee to combat opioid abuse and misuse.

Sincerely,

Mark Tyndall
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Government Affairs, Policy and Patient Advocacy

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