

## **A Prescription for America's Opioid Epidemic: Six Integrated Policy Initiatives to Address Opioid Abuse and Misuse**

As an **industry pioneer** in addressing the problem of prescription drug diversion and misuse and a **strong and committed partner** to those focused on addressing the problems of drug abuse, Mallinckrodt has developed a unique perspective on potential policy solutions to address the significant problem facing rural areas, towns and cities in virtually every state across the U.S.

For years, the company has worked with policymakers, law enforcement, patient groups and other stakeholders on the issue of opioid diversion and abuse, in particular, and will strongly advocate for public policies directed at prevention and treatment. The company believes that by implementing six integrated policy initiatives, significant and measurable progress can be made in the fight against prescription drug abuse in America.

1. **Use Opioids Sparingly:** With the overall well-being of the patient in mind – serving dual goals of adequately managing pain while minimizing undesirable opioid-related side effects that can lengthen hospital stays – a **balanced, multimodal approach to pain management** must be the **preferred standard of care**. Mallinckrodt will advocate for and support incentives, policies, initiatives and treatment guidelines that aim to change the paradigm for treatment of pain to begin with alternative therapies (including non-opioid pain medications) and focus opioid use on patients or cases where a physician determines that adequate pain management cannot be otherwise achieved. Mallinckrodt and others offer such alternative medication options today and the company also supports creation of treatment guidelines to advance this approach.

To ensure that the needs of Americans living with pain are not neglected, these public policy initiatives include:

- incentives for hospitals to assess each patient for risk of dependency, addiction and abuse of opioids and implement a multimodal, opioid-sparing approach to pain management;
  - acknowledgment that when physicians and healthcare providers determine that opioids present the most appropriate patient treatment, the treatment regime should begin with the lowest dose possible to manage acute and chronic pain;
  - enactment of partial fill legislation, as proposed by the American Medical Association, to allow patients to partially fill a Schedule II controlled substance; and
  - policies that stimulate research and development and provide manufacturer incentives to invest in innovative approaches to treat pain and prevent abuse, including non-opioid compounds and abuse-deterrent products.
2. **Expand Access to Medication-Assisted Treatment (MAT):** MAT, combined with counseling and behavioral therapy, has been shown to be the most effective treatment for opioid use disorder, particularly for sustaining long-term recovery.<sup>1</sup> As such, Mallinckrodt supports policies that ensure all patients with a substance use disorder have access to appropriate treatment, including counseling, behavioral therapy and appropriate medication. Moreover, barriers to treatment access at the federal and state levels should be eliminated. As such, Mallinckrodt will advocate for and support policies that:
    - increase state and federal funding and access to MAT (currently more than a dozen states deny reimbursement for methadone and buprenorphine treatment for substance use disorders);

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<sup>1</sup> See <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf>.

- eliminate prohibitions on new opioid treatment programs from opening or expanding services into underserved communities, which will help ensure timely intervention by physicians or healthcare professionals with a treatment option that is tailored to the individual patient.
  - enforce parity laws (e.g., Mental Health Parity and Addiction Equity Act), requiring insurance plans to consistently cover mental health and addiction treatment; and
  - provide financial incentives through Centers for Medicare and Medicaid Services quality metrics to ensure hospitals are routing patients who are identified as having an abuse or misuse problem to appropriate treatment, instead of simply discharging them when an acute episode is treated.
3. **Mandate Advanced Education for Healthcare Providers:** Given the critical role played by physicians and pharmacists as gatekeepers to opioid access, healthcare providers should be required to pursue advanced education as a condition of licensure to gain a critical understanding and identify the risks associated with opioids so they may help prevent opioid misuse and abuse before it begins. This requirement should include mandatory continuing medical education (CME) for physicians (including dentists and veterinarians), and education of pharmacists and hospital personnel on appropriate prescribing and warning signs of abuse and diversion. More specifically, Mallinckrodt will continue its long-held advocacy for strengthened state and federal policies to:
- implement mandatory CME for physicians and prescribing professionals, including training for pharmacy professionals on signs of “doctor shopping” and diversion; and
  - advance development of best practices in pain management for use in hospitals, including greater reliance on multimodal analgesia and alternatives to opioids.
4. **Enhance Regulatory Standards and Data Usage to Prevent Diversion:** Mallinckrodt believes there are opportunities for the U.S. Government to improve understanding of the prescription drug abuse problem and to clarify the manner in which manufacturers can assist the Drug Enforcement Administration (DEA) in identifying suspicious opioid orders. A substantial portion of the recent increase in drug overdose deaths is attributable to the increased availability of illicitly manufactured opioids, which the Centers for Disease Control (CDC) does not distinguish from opioid medications manufactured under the authority of the Food and Drug Administration and under DEA-established quotas. We call on the appropriate agencies to clearly define and appropriately classify the scope of the opioid overdose epidemic and provide clear guidance regarding supply chain management for manufacturers and suppliers of legitimate opioid medications.

Moreover, electronic state prescription drug monitoring programs (PDMPs) should be better funded and aligned across the country, and better use of PDMP data should be mandated. Measures in this area can potentially stop opioid abuse and misuse before it begins.

Specifically, Mallinckrodt will advocate for policies to:

- clarify the DEA’s suspicious order monitoring guidance, particularly the scope of responsibility for each step in the supply chain from manufacturer through dispenser, and provide greater funding for DEA to support suspicious order monitoring programs;
- require CDC to better identify, surveil and quantify opioid drug use and overdose data by bifurcating illegal counterfeit opioids from legitimate, pharmaceutical-grade opioid medications, further informing policymakers on the sources of prescription drug abuse;
- enhance PDMPs – a vital tool for physicians, pharmacists, and law enforcement – to further strengthen and align data collection and interoperability between the states, including:
  - greater funding and federal support for interoperability between state PDMPs and better real-time, high-quality prescribing data;

- linking mandatory training and use of PDMPs by prescribers to state licensure and/or DEA registration; and
- requiring prescribers of Schedule II drugs to affirm in the patient record and, where applicable, PDMP entry that a patient prescribed an opioid was screened for risk of abuse or misuse, deemed low risk, and provided appropriate counseling, particularly where a patient has been prescribed an opioid therapy for chronic pain.

5. **Urge Safe Drug Storage and Disposal:** Several national statistics reveal that home medicine cabinets are one important source of diverted prescription opioids, and so it is critically important to form public and private partnerships to provide ways to safely and responsibly store medications and dispose of unused and unneeded medication. As one such solution, Mallinckrodt has donated approximately 1.5 million drug disposal pouches across the United States and will increase that number incrementally to 2 million by the first quarter of 2018. Some states have also purchased drug disposal pouches for their residents, and Mallinckrodt will advocate for funding to continue these efforts.

6. **Fund Community-Based Education and Intervention:** Education on opioid abuse and community interventions with youth and at-risk populations are critical to achieving healthy and drug-free communities. Mallinckrodt will continue to advocate for federal funding, made available through the Comprehensive Addiction and Recovery Act, and state funding to support community-based education and intervention programs. Examples of such support include:

- congressional appropriations for the Drug-Free Communities Grant Program, administered by the Substance Abuse and Mental Health Services Administration, are a vital source of funding for community-based organizations that carry out drug prevention education; and
- congressional appropriations for the Community-Based Coalition Enhancement Grants, created by the Comprehensive Addiction and Recovery Act, are an important source of funding for communities that are particularly hard-hit with opioid abuse issues.

Mallinckrodt believes that, taken together and with the cooperation of government and partners, these six policy initiatives have the potential to make a significant impact on reducing opioid abuse and misuse in communities across the United States. The company will continue to actively engage with policymakers, law enforcement, patient groups, and other stakeholders to achieve these policy goals. For more information on Mallinckrodt's work to combat prescription drug abuse and misuse, please visit [www.mallinckrodt.com/solutions](http://www.mallinckrodt.com/solutions).

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