Mallinckrodt plc Opioid Risk Oversight Shareholder Report

March 31, 2020

Introduction

Mallinckrodt plc ("we," "Mallinckrodt," or the "Company") is a global biopharmaceutical company united around a powerful mission – Managing Complexity. Improving Lives. Since its founding in 1867, Mallinckrodt has been advancing the fields of science and medicine, and today, is focused on developing innovative branded therapies and cutting-edge technologies to improve the lives of underserved patients with severe and critical conditions. Since we were spun out of Covidien plc as a stand-alone public company in 2013, we have endeavored to build a strong branded commercial platform and pipeline in Specialty Brands with specific focus on autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. The Specialty Generics business operated by our wholly owned subsidiary SpecGx LLC and its predecessor entities ("SpecGx") includes a comprehensive portfolio of specialty generic drugs for pain management, substance abuse, attention deficit hyperactivity disorder ("ADHD") and bulk Active Pharmaceutical Ingredients ("APIs").

We believe that the widespread abuse of opioids in the United States is a tragic and complex, but solvable national crisis that demands and deserves a comprehensive policy response. To truly make an impact on opioid abuse and misuse, all stakeholders – including, policymakers, regulators, law enforcement agencies, drug distributors, drug manufacturers (including Mallinckrodt), pharmacists, prescribing physicians, patients and caregivers must work together to thoughtfully balance the need for effective treatment of pain for legitimate patients, while concurrently addressing the complex issues and risks of opioid addiction and abuse.

The Company, including its Board of Directors (the "Board"), takes its commitment to deterring opioid abuse seriously. Mallinckrodt has been and continues to be an industry pioneer in addressing prescription drug abuse, misuse and diversion, and is collaboratively engaged with key stakeholders on efforts to address these problems across the United States. The Company has devoted significant resources to preventing opioid abuse and mitigating the corresponding devastating effects on communities, and SpecGx, as the holder of Drug Enforcement Administration ("DEA") registrations, has a demonstrated record of meeting and exceeding the requirements of U.S. federal and state laws governing the manufacturing, sale, and distribution of controlled substances. Furthermore, the Board and its committees, in particular the Governance and Compliance Committee, is actively engaged in monitoring the financial and reputational risks to the Company related to its subsidiaries' opioid business, as further described in this report.

Purpose of this Report

On May 15, 2019, the Company's shareholders approved a proposal at the 2019 Annual General Meeting (the "AGM") requesting the Board assemble a report on the governance measures the Company and SpecGx have implemented since 2012 to more effectively monitor

and manage financial and reputational risks related to the opioid crisis in the United States, given SpecGx's sale of opioid medications and APIs used in the manufacture of opioid medications. The requested report was to include whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company lobbying activities.

This report was prepared in response to that shareholder feedback, and discusses the actions taken by the Board since its creation in 2013 (concurrent with the spin-off of the Company from Covidien plc), through its oversight of Company and SpecGx management, to mitigate the business risks related to SpecGx's manufacturing and sale of generic and non-promoted branded opioid medications, in particular highlighting the steps the Company and SpecGx have taken to prevent and address prescription drug diversion, misuse and abuse.

Board Oversight and Monitoring

Since its establishment in 2013, the Board has been committed to cultivating and maintaining a culture of corporate responsibility throughout the Company and believes that its approach to corporate governance establishes a solid framework of principles and practices to guide the organization at every level. The Board oversees an enterprise-wide approach to risk management designed to support the achievement of organizational objectives, including strategic objectives, to improve long-term organizational performance and enhance shareholder value. A fundamental part of risk management is not only understanding the risks Mallinckrodt faces and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for Mallinckrodt as a whole.

The involvement of the full Board in approving our overall business strategy is a key part of its assessment of management's appetite for risk and the determination of what constitutes an appropriate level of risk for the Company. In this process, risk is assessed throughout the company's businesses, focusing on three primary areas: (1) financial risk, (2) legal/compliance risk and (3) operational/strategic risk. The Board's oversight also includes opioid-related risks. While the full Board has oversight responsibility for the enterprise-wide risk management process, various committees of the Board also have targeted responsibility for risk management which is detailed below. At every regular meeting of the Board, each committee chair reports out on the proceedings of his or her respective committee so that all directors are fully up to speed on the scope of work being undertaken, including with respect to matters related to risk oversight as detailed below.

In addition, as mandated by our Corporate Governance Guidelines, the Board has complete access to contact and meet with any Company employee, and directors are encouraged to visit Company operations and facilities and meet with local management. In addition, members of senior management and other key employees are invited to attend meetings and make presentations to the Board, and a number of senior executives have regular communications with directors outside of formal meetings as well. Specifically as relates to litigation risk, the Board regularly receives detailed, privileged updates on the status of all material litigation from the Chief Legal Officer, including opioid-related litigation. In addition, from time to time outside advisors, including outside counsel, are asked to present to the Board on material matters,

including as relates to financial and reputational risk to the Company. In all of these sessions, the directors are able to ask questions and receive direct feedback from the presenters.

Governance and Compliance Committee

In its general leadership role in overseeing Mallinckrodt's corporate governance and compliance with applicable laws and regulations, the Governance and Compliance Committee regularly assesses the Company's governance structure to ensure it is following best practices and ensuring appropriate oversight of the organization. It also has oversight of regulatory, healthcare compliance, public policy and corporate social responsibility matters – including legal and compliance matters related to prescription opioids – and works with our legal and regulatory groups to understand and assess related risks. The Chief Compliance Officer and the Chief Counsel, Litigation, each give regular reports to this Committee on matters for which they are responsible. In addition, this Committee conducts an annual assessment of the risk management process, and along with the Human Resources and Compensation Committee, receives regular reports from the Chief Compliance Officer and other members of management regarding incentive compensation programs for non-executive sales teams in order to ensure appropriate risk management in light of healthcare compliance requirements.

The Governance and Compliance Committee also monitors the Company's political activities and receives annual updates on the manner in which political funds are spent on behalf of Mallinckrodt. These activities are also guided by outside legal experts in political and lobbying law to help the Company ensure compliance with U.S. federal, state and local campaign finance and lobbying rules. Mallinckrodt recently released its first annual Political Transparency Report which covers political spending and related external engagements in calendar year 2018. The report helps to fulfill the Company's goal of greater transparency around its political and policy activities, particularly in response to shareholder interest, as reflected by a recently approved company-supported measure regarding an annual report on political and lobbying activities.

Audit Committee

The Audit Committee focuses on financial risk and oversees the integrity of the Company's financial statements, the independence and qualifications of its independent auditors, the performance of its internal auditors and independent auditors, compliance with certain legal and regulatory requirements and the effectiveness of the Company's internal controls. In addition, the Audit Committee receives an annual risk assessment report from internal auditors.

Human Resources and Compensation Committee

The Human Resources and Compensation Committee (HRCC) reviews and approves compensation and benefits policies and objectives, determines whether our officers and employees are compensated according to those objectives and carries out the Board's responsibilities relating to executive compensation. In setting compensation, this Committee assesses risks related to incentive compensation to ensure that all such programs align with Mallinckrodt's business strategy and do not pose undue risk across all variables.

The HRCC regularly evaluates the Company's compensation policies and programs to respond to changing market practices and legal and regulatory requirements. The executive compensation practices put in place by the Board emphasize a balanced performance

philosophy and reward performance when financial, operational and strategic performance goals are achieved.

The HRCC meets periodically with management to review compensation policies and specific levels of compensation paid to officers and other key personnel and approves compensation and programs for executive officers other than our CEO. The HRCC reports to the Board on compensation paid to officers and other key personnel and makes recommendations to the full Board regarding CEO compensation policies and programs. In addition, our CEO makes recommendations to the HRCC regarding salary adjustments and the setting of annual and long-term incentive targets and awards for executive officers other than himself, including the other Named Executive Officers (NEO). Further, the HRCC, along with the Governance and Compliance Committee, receive regular reports from the Chief Compliance Officer and other members of management regarding incentive compensation programs for non-executive sales teams in order to ensure appropriate risk management throughout the Company's compensation structure.

To help inform executive compensation decision-making, the HRCC may utilize the services of independent compensation consultants from time to time and periodically reviews the compensation practices of reasonably similar sized companies that may be in competition with the Company for talent. Given the rapidly changing business landscape of the pharmaceutical industry, including consolidations, it is important to maintain a current view of peer competitors.

The Board expects executives to be fully accountable in pursuing the Company's short and long-term objectives, and has implemented policies and practices that provide appropriate checks and balances to ensure proper compliance and discourage excessive risk-taking behavior. For example, the Corporate Governance Guidelines have mandated that the Company have a Board-approved compensation recovery (or "clawback") policy for recoupment of incentive compensation. This policy was originally implemented by the Board in 2014, was amended in 2018 in response to a productive engagement between members of the Board and certain shareholders, and was amended again in 2019 as a result of another shareholder proposal that was presented and approved by shareholders at the AGM. The clawback policy states that in the event of (i) a restatement of financial or operating results due to material non-compliance with financial reporting requirements or (ii) misconduct resulting in a material violation of the Company's policies that results in significant harm to the Company, the HRCC is authorized to recover any incentive compensation that was overpaid to certain employees, including NEOs, taking into account such factors as the HRCC deems appropriate. In addition, the policy also requires the Company to annually disclose the recoupment of any incentive compensation from senior executives in its public filings.

Under Mallinckrodt's policy, the Company will disclose annually whether, at any time during the last completed fiscal year, the Board required recoupment or forfeiture of any incentive compensation received by certain employees, including NEOs, (1) if required by law, and (2) if not required by law, so long as the disclosure (a) would not violate any individual's privacy rights, (b) is not likely to result in or exacerbate any existing or threatened employee, shareholder or other litigation, arbitration, investigation or proceeding against the Company and (c) is not otherwise prohibited. Subject to the exceptions described in the previous sentence, if any such recoupment or forfeiture under this policy occurred, the Company will disclose the general circumstances of the recoupment and/or forfeiture, and if no such recoupment or forfeiture occurred during the last completed fiscal year, the Company will disclose that no such event occurred.

The Board believes the Company's current compensation structure, including its clawback policy, strikes an appropriate balance between motivating senior executives to deliver long-term results for our shareholders, while simultaneously holding our senior leadership team accountable and ensuring the proper "tone at the top" is established to drive appropriate behavior throughout the organization.

General Background on Mallinckrodt's Role in Pain Management

Pain-relieving medicines, when prescribed and taken appropriately, play a significant and meaningful role in pain management. They can be critical in managing the often debilitating pain associated with acute injuries and serious illnesses, such as cancer. They can also offer humane relief from pain in the final days of life. Medical researchers, leading healthcare providers and expert scientific organizations, including the U.S. Food and Drug Administration (FDA), have long recognized the legitimate, and, in fact, essential role of opioids in sound medical practice.

Mallinckrodt's subsidiaries have developed and produced pain-relieving medicines since the first processing of morphine in 1898. Today, those subsidiaries manufacture a range of high-quality, cost-effective generic prescription opioid medicines and controlled substances for conditions like ADHD, as well as APIs like acetaminophen used in popular over-the-counter pain and cold and flu medicines.

Opioid medicines categorized as Schedule II controlled substances, like oxycodone and hydrocodone, are produced according to a regulatory quota set annually by the DEA, which determines the total quantity of opioids needed each year to meet legitimate medical, scientific and research needs in the U.S. SpecGx, as a DEA registrant, cannot and does not produce more opioids than the annual limit set forth by the DEA.

Overall *less than 10%* of Mallinckrodt's total annual revenues are derived from opioid-based products. Today, the solid dose generic and non-promoted branded opioids (i.e., pills) produced by SpecGx are sold to DEA-approved distributors, the distribution centers of retail chain pharmacies and mail order pharmacies. The distributors subsequently sell those products to retail chain pharmacies chains, independent pharmacies, government entities, hospitals, hospice providers and long-term care providers. These entities in turn dispense medications to patients based on prescriptions that are written by health care providers who are DEA-registered to prescribe controlled substances, including opioids. SpecGx also ships methadone, an opioid agonist used to treat opioid addiction, and a product containing buprenorphine, a partial opioid agonist, directly to Opioid Treatment Programs.

SpecGx is a generic manufacturer that does not advertise, market or promote its opioid products to physicians or patients. The national account managers who handle sales of our opioid products are not compensated based on sales volume of or sales quotas for opioid products.

Industry Leading Efforts to Address the U.S. Opioid Epidemic

As the parent company of a manufacturer of generic and non-promoted brand opioids, Mallinckrodt has long taken its responsibilities very seriously, and the leadership team devotes significant resources to proactive management of the risks attendant to the opioid-related business. Since even before becoming an independent company in 2013, Mallinckrodt has been at the forefront of the industry in developing a comprehensive and multifaceted approach to prevent or reduce the unlawful diversion and abuse of prescribed pain relievers so they can remain available for legitimate, proper medical use.

For example, the Company, through its subsidiary SpecGx, operates an industry-leading anti-diversion program and provides direct assistance to law enforcement to help prevent and prosecute opioid-related criminal activity. It has partnered with leaders in pain management, healthcare professionals and patient advocacy groups to develop science-based educational resources for healthcare providers and patients to support responsible opioid prescribing and safe use. Additionally, Mallinckrodt has been a vocal advocate for the establishment of a prescription drug monitoring program in Missouri, the only U.S. state that had not established such a state-wide program, and continues to build public awareness about the importance of proper medication storage and disposal through its drug disposal pouch donation initiative.

Under the Board's oversight, Mallinckrodt has implemented numerous initiatives and programs to help combat the opioid epidemic, both directly and through its subsidiaries, and continues to work collaboratively with policymakers, law enforcement, patient groups and other stakeholders to address the complex issues of opioid abuse and addiction.

Anti-Diversion Programs

A comprehensive anti-diversion program is an important component of addressing opioid abuse, and Mallinckrodt, through its subsidiary, has invested — and continues to invest — significant resources in this area. Over the last several years, SpecGx has consistently and continually improved its innovative, industry-leading anti-diversion program and believes that it meets, and in many cases exceeds, the requirements of DEA regulations regarding maintaining a system to detect suspicious orders of controlled substances.

This belief is supported by the fact that SpecGx has been contacted by distributors and other manufacturers over the years wanting to learn about its anti-diversion program and has worked with a number of key players to share best practices in this area. The Company and the Board believe that appropriate dialogue and information exchange between the DEA, manufacturers and wholesalers will help to strengthen solutions addressing the opioid addiction crisis in the United States.

Law Enforcement Collaboration

Mallinckrodt, through SpecGx, provides direct assistance to federal, state and local law enforcement to help prevent and prosecute opioid-related criminal activity. This assistance includes providing no-cost placebo tablets imitating SpecGx manufactured opioids for use in law enforcement operations, providing free "dummy" tracking pill bottles that assist law enforcement with apprehending pharmacy robbery suspects, and contributing testimony on behalf of the prosecution in drug diversion cases. Since 2012, SpecGx, has placed over 7,000 GPS tracking pill bottles in pharmacies and provided free of charge to law enforcement nearly 500,000 placebo tablets.

Healthcare Provider Education

Mallinckrodt's Specialty Generic's business helped found the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors, to collaborate and share best anti-diversion practices with the purpose of improving each member's opioid anti-diversion programs. While each of the participating companies maintains its own programs, we believe our collective contributions can go beyond what we are able to do individually – and that, by collaborating and exchanging ideas we can take additional meaningful steps toward reducing diversion and abuse. The ADIWG, along with the National Association of Boards of Pharmacy® created an educational video entitled, "Red Flags," to help pharmacists identify the warning signs of prescription drug abuse and diversion when dispensing controlled substance prescriptions.

Mallinckrodt and SpecGx also support a variety of initiatives to increase responsible prescribing of opioid pain medications. It supports the class wide Risk Evaluation and Mitigation Strategy (REMS) – a drug safety program that can be required by the FDA for medicines with significant safety risks.

The Company invested several million dollars in the development of REMEDIES, an innovative, two-year, opioid prescribing training program aimed at improving the quality of care for opioid-tolerant pain patients. With this type of program, participating prescribers would be better able to:

- develop individualized treatment plans that take a more holistic approach for patients with chronic pain, including patients with medical or psychiatric comorbidities;
- devise a rationale and clinical plan for the initiation, safe use, adjustment and appropriate rotation of opioid therapy in patients with persistent pain;
- demonstrate a current understanding of pain terminology, tolerance and related phenomena in opioid-based pain management (e.g., dependence, tolerance, addiction, misuse, abuse, diversion); and
- improve patient diagnosis and management through appropriate use of currently available treatments.

The REMEDIES program demonstrated a high level of success in achieving its educational goals with final outcome assessments showing meaningful changes in opioid prescribing behavior and improvements in pain-patient outcomes.

Prescription Drug Monitoring Program (PDMP)

For many years, Mallinckrodt has been a vocal advocate in fighting for a PDMP in Missouri, the only state that did not have a statewide program, and supporting modernization of other PDMP programs – an essential tool for fighting opioid misuse, abuse and addiction – around the country. In 2016, the Company spearheaded a grassroots coalition of more than 40 organizations, called PDMP NOW, as well as engaged in an extensive multi-media campaign and direct executive outreach to legislative leadership to help pass legislation in Missouri to implement a PDMP.

A fully implemented PDMP supports prescribers and can help prevent abuse by providing timely data for the treatment of patients. These programs help identify potentially illicit activities such as obtaining duplicate prescriptions from multiple doctors, something called "doctor shopping."

Evidence shows PDMPs also lead to better health outcomes, shorten the time needed to conduct law enforcement investigations, and lower overall abuse and diversion rates. Having a robust PDMP in every state is a primary recommendation of the U.S. Centers for Disease Control and Prevention to reduce abuse of pain medications.

Furthermore, because experience has shown that abusers often will travel from one jurisdiction to another to secure opioids, it is critically important to make data available on a nationwide basis. In order to respect both the state and federal interests found here, Mallinckrodt advocates for the formation of a joint state and federal commission with the authority to set and implement uniform standards for data reporting and transparency to prescribers and pharmacies.

Safe Medication Storage and Disposal

Focused on building public awareness about the importance of proper medication storage and disposal to prevent unused medications from ending up in the wrong hands, Mallinckrodt has purchased and will donate more than two million drug deactivation and disposal pouches to community groups, law enforcement, schools, patients and families across the U.S. These disposal pouches have been distributed through partnerships with community leaders and organizations such as the Boys and Girls Club of America, Community Anti-Drug Coalitions of America (CADCA), the JED Foundation, the National Council on Alcoholism and Drug Abuse and local law enforcement and emergency management services offices.

The Company also worked to build broader awareness of the drug disposal program in Congress and has coordinated events with Members of Congress and numerous elected officials at the state and local levels. The program demonstrates the Company's commitment to being a principled partner in fight against the opioid epidemic. Once fully implemented, this drug disposal pouch program will have been distributed to more than 250 individual community coalitions and law enforcement agencies and thousands of physician offices across the country.

Moreover, Mallinckrodt has supported drug take-back days and made charitable donations of drug disposal drop boxes to local law enforcement agencies. While local, state and federal agencies have significantly improved drug take-back programs, the Company continues to offer input and assistance to make these programs more effective.

Public Policy Initiatives

Given SpecGx's long history as a manufacturer of complex generic pharmaceutical products, including opioids and other controlled substances, the Company took the initiative in 2017 to release a multi-prong action plan which outlines six integrated policy initiatives at the federal and state levels that we believe, if implemented, could have a significant, positive effect on the issue of prescription drug abuse and misuse and result in measurable progress in the country's efforts to combat the current opioid epidemic. Entitled "A Prescription for America's Opioid Epidemic: Six Integrated Policy Initiatives to Address Opioid Abuse and Misuse", the plan includes the following:

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 supports 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's Specialty Generics business offers 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.[1] As such, Mallinckrodt supports policies that ensure all patients with an opioid 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 supports policies that:
    - increase state and federal funding and access to MAT (currently nearly a dozen states deny reimbursement for methadone and buprenorphine treatment for substance use disorders);
    - 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;
    - 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;
    - address the estimated 65% of US prison population that has an active substance use disorder (according to the National Academy of Sciences, only 5% of people in jail and prison settings receive medication treatment). Studies show that MAT in the criminal justice system decreases opioid use, criminal activity post-incarceration,

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

infectious disease transmission and that overdose deaths following incarceration were lower;[2] and

- prevent states from blocking access to generic formulations of MAT by mandating high-cost, brand name drugs on Medicaid preferred drug list as the only covered treatment option, and prevent MAT prior authorization requirements by managed Medicaid and private insurance plans.

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 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 FDA 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 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 supports policies that:

    - 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;

[2] https://www.drugabuse.gov/publications/drugfacts/criminal-justice

- 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 significant 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 purchased and will donate two million drug disposal pouches to communities across the U.S. 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 carryout 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 has actively lobbied and encourage the adoption of these measures to as an important step toward addressing opioid misuse and abuse.

Collaborative for Effective Prescription Opioid Policies (CEPOP)

SpecGx joined in the creation of a national coalition that engages diverse stakeholders behind a comprehensive and balanced public policy strategy to reduce prescription opioid abuse and promote treatment options, both for those living with chronic pain and confronting addiction. Co-convened by CADCA and other leaders, CEPOP is growing rapidly with involvement from patient and family advocacy, provider, public health, dispensing, distribution, and manufacturing organizations. To date, over 60 organizations have participated in this effort.

Strategic Partnerships

Mallinckrodt and SpecGx collaborate with and support a variety of third party organizations, including community coalitions, professional societies, patient advocacy groups, as well as government representatives at local, state and federal levels, to advance education, raise awareness, influence legislation and develop innovative ways to keep our communities safe, healthy and drug-free.

For example, the Company engaged in a collaborative research partnership with The Partnership for Drug-Free Kids, The American Cancer Society, and The American Academy of Pain Management that highlighted the disconnect between healthcare providers and patients in discussing the importance of safe use, storage and disposal of pain medications at home. We also worked with CADCA and the Florida Rural Water Association in a pilot study to better understand what motivates people to safely dispose of unused medications.

In addition, Mallinckrodt joined the Massachusetts Health & Hospital Association to announce the release of the Pain Stewardship Program (PSP) for providers and clinical staff. Developed in collaboration with a multidisciplinary team of expert advisors, the mission of the PSP is to educate hospital stakeholders on multimodal analgesia-based acute pain management to support improvements in in-hospital opioid use, length of stay and satisfaction with treatment. This program provides – at no charge – evidence-based, educational pain management tools to help assess current hospital protocols and identify areas for improvement.

Abuse-Deterrent Technology

SpecGx is committed and continues to make investments in its product lines to develop abuse-deterrent technologies. In 2019, SpecGx resubmitted its 505(b)2 new drug application to the FDA for approval of MNK-812 – its investigational abuse-deterrent, immediate-release reformulation of Roxicodone (oxycodone hydrochloride) tablets. If approved, the reformulated drug – which is designed with properties to deter intravenous and intranasal abuse – could have the potential to mitigate opioid abuse and misuse. SpecGx continues to meet with the FDA on its application and pending approval by the FDA, will evaluate the MNK-812 technology platform across its opioid portfolio as appropriate.

Global Compliance Program

Mallinckrodt is committed to establishing and maintaining an effective Compliance Program in accordance with the applicable laws, regulations, and codes of the countries within which it operates. Our global Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct. The Company has robust internal compliance policies and programs in place to systematically and comprehensively mitigate the risk of non-compliance with the myriad, highly complex regulatory and legal requirements that apply to all those operating on behalf of a global pharmaceutical company such as Mallinckrodt, including all employees.

The Company’s Compliance function is independent of manufacturing and commercial operations functions, and is responsible for implementing our multifaceted compliance programs. It is overseen by the company’s Chief Compliance Officer, who reports directly to the Chief Legal Officer and the Board’s Governance and Compliance Committee.

Mallinckrodt's Guide to Business Conduct (the "Guide") is approved by the Board and is an expression of the expected standards of behavior for everyone who conducts business on behalf of the Company. The Guide establishes compliance responsibilities, supports applicable laws and regulations, and reinforces corporate policies and procedures. The Guide articulates our fundamental principles, values and framework for ethical conduct.

The Company conducts ongoing compliance training programs for all stakeholders and maintains a 24-hour ethics and compliance reporting hotline with a strict policy of non-retaliation. All employees are required to review and certify, in writing, their adherence to the Guide each year. Furthermore, Mallinckrodt's policies and procedures are regularly reviewed and enhanced to respond to the ever-evolving compliance environment and to address new business and legal risks. Described below are the fundamental elements of Mallinckrodt's Compliance Program.

- *Compliance Officer and Compliance Committee:* Our Chief Compliance Officer is responsible for overseeing the administration and implementation of the Compliance Program and reports quarterly on compliance related matters to Governance and Compliance Committee of the Board. The Chief Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment.

- *Written Policies and Procedures:* As part of our commitment to the highest standards of ethical conduct, Mallinckrodt has implemented policies and procedures that are consistent with the applicable country laws and regulations. These policies and procedures are reviewed regularly to ensure relevancy to Mallinckrodt's operations and the evolving healthcare regulatory environment.

- *Effective Training:* A critical element of our Compliance Program is the education and training of our employees and contractors on their legal and ethical obligations under applicable polices, laws, and regulations. Mallinckrodt is committed to taking necessary steps to effectively communicate our standards and procedures to all affected personnel. Mallinckrodt will regularly review and update its training programs, and also works to identify additional areas of training on an "as needed" basis.

- *Effective Lines of Communication:* Mallinckrodt is committed to encouraging dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of policy violations, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted principles regarding confidentiality and the prohibition of retaliation as outlined in the Mallinckrodt Guide to Business Conduct. Employees are expected to report suspected violations of Company policy by contacting their Manager, the Legal Department, Human Resources, the Compliance Department, or via the Compliance Integrity Hotline. General questions or concerns can always be directed to the Compliance email inbox at Compliance.Dept@mnk.com

- *Auditing and Monitoring:* Mallinckrodt's Compliance Program includes monitoring, auditing, and evaluating adherence to the Company's compliance activities. The nature

and frequency of our reviews vary according to a number of factors, including new regulatory requirements, changes in business practices, and other considerations.

- *Responding to Potential Violations and Corrective Actions:* Mallinckrodt's Compliance Program strives to ensure that the consequences of violating the law or Company policy are clearly understood and that the appropriate, consistent disciplinary action is enforced. As such, our Compliance Program requires the Company to evaluate each case and reasonably respond to potential violations of law or Company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations.

SpecGx's Controlled Substances Compliance Function

SpecGx's Controlled Substances Compliance Function is independent of manufacturing and commercial operations functions, and is responsible for implementing SpecGx's compliance program related specifically to the handling of controlled substances by the Specialty Generics business. It is overseen by the company's Director of Controlled Substances Compliance, a former Diversion Program Manager with DEA who recently retired from DEA after a distinguished 33-year career. The Director reports up through the General Counsel of the Specialty Generics business to the Chief Legal Officer. The Controlled Substances Compliance Function oversees those activities required by DEA regulations – such as the operation of a Suspicious Order Monitoring ("SOM") Program, which monitors incoming orders from SpecGx's customers – distributors, distribution centers of retail chain pharmacies and mail order pharmacies. It also oversees actions beyond those required by DEA regulations – such as the analysis of downstream sales of SpecGx's products that distributor customers have made to the distributors' dispensing customers to identify distributor customers or other downstream registrants that may represent a risk of diversion of controlled substances.

SpecGx has limited visibility into these downstream sales through "chargeback data" transmitted to SpecGx in connection with a customer's request for a chargeback payment. A chargeback payment is a contractual payment SpecGx is obligated to remit to a distributor if that distributor sells a SpecGx product to its customer for less than the price the distributor paid SpecGx for the product. In other words, a chargeback is a mechanism designed to make a distributor financially whole. Chargebacks are common in the pharmaceutical industry. When the distributor requests payment of a chargeback, it provides support for that payment request that includes information about the sale the distributor made to its customer. To the extent distributors submit chargeback requests, that information may provide SpecGx limited insight into the pharmacies that have purchased SpecGx products from distributors.

If the purchasing activity of a downstream registrant, such as a pharmacy, is identified as warranting further review, SpecGx contacts the distributor customers that recently have sold Mallinckrodt products to that pharmacy to engage the distributors in trying to determine whether the pharmacy's purchasing volumes or patterns are explainable by legitimate factors. If distributors are unable to provide sufficient explanation and SpecGx believes that the downstream registrant poses a risk of diversion, we restrict chargeback payments to any distributors for any SpecGx product sold by the distributors to the pharmacy in question. These restrictions impose a financial incentive on distributors to halt shipments of SpecGx controlled substances to potentially concerning pharmacies. SpecGx also reports its decisions to restrict

chargeback payments on distributor sales to a pharmacy directly to the DEA and SpecGx's other distributor customers

In addition, this function also works in conjunction with security personnel to manage the placebo and tracker bottle programs described above.

Interactions with Healthcare Providers

Mallinckrodt believes ethical, transparent relationships benefit all of our stakeholders. We want every interaction to inspire trust in our Company and our products, and expect our employees to always operate with integrity, honesty and transparency. Mallinckrodt complies with the international, national and local requirements that apply to our business, as well as complies with codes of conduct that govern our industry including (but not limited to) Medtech and EFPIA in Europe, Pharmaceutical Researchers and Manufacturers of America (PhRMA) and AdvaMed in the United States, Medicines Australia and Innovative Medicines and Medec Canada. Collectively, these rules and regulations address not only how we research, develop and manufacture our products, but also how we promote, market and distribute them. SpecGx does not promote or sell opioid products directly to physicians or other healthcare providers.

Specifically with regard to drug products, Mallinckrodt abides by the PhRMA Code on Interactions with Healthcare Professionals – an ongoing effort to ensure that biopharmaceutical marketing practices and informational activities comply with the highest ethical and professional standards. The PhRMA Code focuses on interactions with health care professionals that relate to the marketing of our products and contains detailed provisions specific to the conduct and training of speakers.

Conclusion

The Board is committed to ensuring that Mallinckrodt maintains a broad culture of corporate responsibility at the Company and emulating best practices in governance, executive compensation and compliance across the entire enterprise. Mallinckrodt takes its commitment to combatting the opioid epidemic very seriously, and the Board and leadership team devote significant time, attention and resources to proactive management of the financial and reputational risks to the company related to its Specialty Generics business.

The Board firmly believes that its existing enterprise-wide risk oversight approach, multi-committee governance structure and available resources, including access to internal and external experts, are sufficient to carry out appropriate oversight of the Company’s subsidiaries role in and exposure to the opioid marketplace.

As demonstrated by this report, Mallinckrodt and SpecGx are committed to being part of the solution and will continue working with policymakers, law enforcement, patient groups and other stakeholders to address the complex issues of opioid addiction and abuse across the U.S.