



**Independent Directors' Report**

**October 2018**

## **INTRODUCTION**

Since its founding as a family business in 1920, Endo International plc (“we,” “Endo” or the “Company”) has evolved into a generics and specialty branded pharmaceutical company with an innovative suite of branded and generic medications helping millions of patients lead healthier lives. Our specialty branded products include therapies to treat and manage conditions in urology, urologic oncology, endocrinology, pain and orthopedics, together with lifesaving sterile injectable products. Our generic products include solid oral extended-release tablets, solid oral immediate-release tablets, liquids, semi-solids, patches, powders, ophthalmics and sprays in several therapeutic areas, including urology, central nervous system disorders, immunosuppression, oncology, women’s health, cardiovascular disease and pain management.

We are deeply concerned about the opioid abuse crisis, a public health challenge unprecedented in scope, severity and complexity. We believe ameliorating this crisis will require intensive collaboration among the multiple stakeholders involved in our healthcare system working to balance access to pain care medications for appropriate patients while aggressively mitigating the risks of opioid abuse.

We have strived to implement this balance in our own business and have voluntarily taken numerous steps to mitigate risks related to the sale of opioid medications that benefit millions of patients who use them as prescribed. We maintain a robust corporate compliance program, voluntarily ceased promotion of opioid medications, voluntarily eliminated the Company’s entire pain salesforce, voluntarily withdrew Opana ER from the market, voluntarily discontinued research and development on new opioid products and enhanced anti-diversion measures.

## **BOARD OVERSIGHT AND MONITORING**

Endo’s compliance program, which is overseen and monitored by the Company’s Board of Directors (the “Board”), is critical to helping maintain Endo’s compliance with the various laws and regulations applicable to pharmaceutical companies, including with respect to the sale of opioid medications. The program also facilitates the Company’s compliance with internal policies, which in some cases go beyond what laws and regulations require. (Please see below under “Historical and Existing Compliance Measures” for a more fulsome discussion of Endo’s compliance program.)

As part of the Board’s compliance oversight and monitoring function, it established a standing Compliance Committee comprised of independent directors.<sup>1</sup> The Compliance Committee assists the Board by reviewing and overseeing compliance with federal health care program and FDA requirements as well as the obligations of Endo’s 2014 Corporate Integrity Agreement

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<sup>1</sup> Until 2014, the Audit Committee was responsible for assisting the Board with its compliance oversight and monitoring function. In 2014, the Board established a Subcommittee of the Board’s Operations Committee which assumed compliance oversight responsibilities from the Audit Committee. In 2018, the Operations Committee changed its name to the Compliance Committee.

(“CIA”). Prior to joining the Compliance Committee, all members receive training regarding the responsibilities of board members and corporate governance. In addition, all Board members receive annual compliance training. The Compliance Committee meets formally at least quarterly, with regular informational meetings occurring between the formal meetings, during which the Compliance Committee receives updates from the Chief Compliance Officer on various key matters, including compliance program requirements and related activities, the adoption and implementation of policies, procedures and practices designed to achieve compliance with applicable federal health care program and FDA requirements, monitoring and investigations, and external developments. The meetings include executive sessions with the Chief Compliance Officer and the Compliance Committee’s independent external legal counsel (Covington & Burling LLP).

In addition to the Compliance Committee’s oversight of compliance matters, the Board also oversees the management of risks associated with the evolving opioid litigation through Endo’s Chief Legal Officer, who provides the Board with a comprehensive report of all material litigation matters affecting Endo on at least a quarterly basis. The Chief Legal Officer separately engages in regular discussions with individual Board members on litigation matters. The Chief Executive Officer also holds regular teleconferences with individual Board members and a teleconference with the full Board on at least a monthly basis.

The Board is regularly apprised of Endo’s policies and procedures relating to lobbying activities, both direct and indirect, as well as the process utilized by Endo’s Political Action Committee for decision making and resource allocation in connection with lobbying and advocacy efforts. Endo seeks to educate policymakers through well-informed policy positions on issues that impact its business. Endo’s Code of Conduct (the “Code”) governs how the Company participates in the political process as well as how its employees, in their capacity as such, engage in political activities so that such political participation is appropriate, ethical and lawful. Contributions and expenditures are disclosed on Endo’s website at <http://www.endo.com/our-responsibility/advocacy-and-lobbying> as required by law and pursuant to the Company’s September 2013 agreement with Trillium Asset Management and the Christopher Reynolds Foundation.<sup>2</sup>

### **RECENT RISK MITIGATION EFFORTS**

Since Paul Campanelli became Endo’s President and Chief Executive Officer in September 2016, the Company has voluntarily taken numerous steps, including some to the financial detriment of the Company, to mitigate risks related to the sale of opioid medications. These steps include: (i) ceasing promotion of all opioid medications, including the elimination of the Company’s entire pain product salesforce; (ii) withdrawing Opana ER (oxymorphone hydrochloride extended release) from the market (as more fully discussed in the following

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<sup>2</sup> Endo acknowledges receipt of additional materials relating to advocacy and lobbying efforts from the Investors for Opioid Accountability (the “IOA”). We will review the materials and endeavor to work with the IOA regarding board oversight and disclosure of our political lobbying and advocacy efforts.

paragraph); (iii) discontinuing the research, development and launch of all new opioid medications; and (iv) enhancing anti-diversion measures, including product serialization aimed at thwarting counterfeiting and theft to protect patient safety; (v) supporting continuing medical education under the FDA's Risk Evaluation and Mitigation Strategy ("REMS") program.

Effective January 2017, Endo voluntarily ceased promotion of all opioid medications in the U.S. and eliminated its entire U.S. pain product salesforce. Endo believes it was the first pharmaceutical company to take this step. In 2018, we also stopped promoting opioid medications to healthcare providers in Canada. As a result, Endo no longer promotes opioid medications to healthcare providers ("HCPs") anywhere.

In March 2017, the U.S. Food and Drug Administration's (the "FDA") Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees (the "Advisory Committee") voted 18 to eight, with one abstention, that the benefits of reformulated Opana ER no longer outweighed its risks in light of misuse, abuse and diversion of the product. During the Advisory Committees' discussion, a majority of members expressed their preference that reformulated Opana ER remain on the market with additional regulatory restrictions to mitigate the risk of abuse. Nevertheless, in June 2017, the FDA requested that Endo voluntarily withdraw Opana ER from the market. The FDA noted that this was the first time it had requested the market withdrawal of a currently marketed product due exclusively to the public health consequences of abuse rather than the product's safety and efficacy when used as intended. After careful consideration and consultation with the FDA, Endo began voluntarily coordinating an orderly market withdrawal of Opana ER during the second quarter of 2017 and ceased its sales of the product completely by September 2017. Endo subsequently requested that the FDA withdraw its approval of the product's New Drug Application and expects that the FDA will act on that request in the coming months.

In the meantime, Endo continues to provide support for continuing medical education ("CME") programs as required by the FDA's extended-release, long-acting opioid REMS. The REMS CME support obligations apply class-wide to all manufacturers of extended-release, long-acting opioids. Recent CMEs supported pursuant to the REMS have included programming by Johns Hopkins University, Boston University and state medical societies addressing safe opioid prescribing. Endo is also required by the FDA to participate in certain opioid-related post-marketing research activities.

As a manufacturer of controlled substances, including certain opioid medications, the Company maintains programs for overseeing and tracking shipments for signals of potential diversion. The programs use various suspicious order management validation methods to evaluate individual orders. If an investigation determines that an order is suspicious, the order is not shipped and prompt notification is provided to the U.S. Drug Enforcement Agency in the United States or to Health Canada in Canada. Endo's Pharmacovigilance and Risk Management Department reviews adverse event reports received via post-marketing surveillance. When the Company

promoted its opioid medications to HCPs, it also monitored a number of secondary surveillance databases (including the NAVIPPRO and RADARS databases) and the FDA Adverse Reporting System for signs of potential abuse and/or misuse of certain branded opioid products.

### **HISTORICAL AND EXISTING COMPLIANCE MEASURES**

Endo's Code of Conduct governs the Company's internal and external interactions, including with patients, healthcare providers, payors, suppliers, government officials, the healthcare community and shareholders. The Code applies to every person conducting business for Endo and to all Endo locations, subsidiaries and affiliates. Due to local law, some Code provisions may be supplemented by policies or standards to address local requirements. Any employee who violates the Code, Company policy or applicable laws is subject to disciplinary action, up to and including termination. The Code is publicly available at [www.endo.com](http://www.endo.com).

The Code details, among other things, the role of Endo's Compliance and Business Practices Department (the "Compliance Department"). The Compliance Department, which directly oversees Endo's compliance program, establishes clear rules of business conduct, educates and trains employees, and conducts ongoing monitoring to confirm that the compliance program is operating as intended and to enhance its effectiveness.<sup>3</sup> The Compliance Department also maintains Global and U.S. Compliance Committees comprised of members of the Company's Executive Leadership Team and other senior leaders. The Global and U.S. Compliance Committees oversee, assess and enhance Endo's compliance program as needed across all of Endo's business segments.

Endo's robust compliance program, operated by the Compliance Department, has continued to evolve since its establishment in 2004. Endo's policies and procedures have been periodically updated and augmented to respond to changes in the compliance environment and to address new business and legal risks. Endo's compliance program incorporates the fundamental elements of an effective compliance program including:

- Written policies, procedures and standards of conduct to provide guidance on proper promotional activities and policies designed to prohibit improper promotion of our products;
- Chief Compliance Officer and Compliance Committee;
- Training, education and implementation of standards;
- Effective lines of communication including messages from senior level leaders regarding commitment to compliance;

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<sup>3</sup> As discussed above, Endo's Board oversees the compliance program through a Compliance Committee that receives at least quarterly updates on Endo's compliance program through Endo's Chief Compliance Officer, who reports directly to Endo's Chief Executive Officer.

- Auditing and monitoring;
- Oversight and enforcement of standards including well-publicized disciplinary guidelines; and
- Prompt corrective responses.

In addition, the Compliance Department promotes and supports ongoing education and training of employees on legal requirements and Company policies and procedures. It also oversees the monitoring and auditing of compliance with those requirements, policies, and procedures, including compliance with the requirements of the CIA.

In February 2014, Endo entered into the CIA, which is a 5-year agreement with the U.S. Department of Health and Human Services Office of the Inspector General (“OIG”). Pursuant to the CIA, Endo developed and implemented a Field Force Monitoring Program (“FFMP”) to evaluate and monitor its sales representatives’ interactions with HCPs<sup>4</sup> as well as a Non-Promotional Monitoring Program (“NPMP”) to evaluate adherence to policies and procedures for consultant arrangements, research-related arrangements, and grants for Independent Medical Education. These programs promote adherence to policies and procedures and inform corrective actions, including employee coaching, policy and procedure changes, and enhanced training and communications.

During the term of the CIA, the OIG has required Endo to perform records reviews for two opioid products. Endo also conducted live speaker program monitoring and field sales ride-alongs for branded opioid products. Endo reported findings from the reviews and the monitoring and ride-along programs to OIG. No material errors were found during the required CIA Independent Review Organization review of Endo’s systems, processes, policies, procedures and practices relating to CIA-covered functions, which included review of certain transactions related to branded opioid medications.

The Compliance Department has also implemented a Risk Assessment and Mitigation Process (“RAMP”) to standardize and centralize risk assessments relating to promotional activities. Specifically, RAMP is designed to identify risks associated with the sales, marketing and promotion of products that are actively promoted. Based on the outcome of the risk identification component of RAMP, Endo develops risk mitigation tactics designed to address those identified potential risks.

Endo’s Compliance Department plans to continue with the FFMP, NPMP and RAMP programs following the expiration of the CIA for the non-opioid medications that are actively promoted, which are the only kind of products promoted by Endo.

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<sup>4</sup> The FFMP includes (1) Speaker Program Monitoring; (2) direct field observations of sales representatives; and (3) monitoring and review of other records related to sales representatives’ interactions with HCPs.

Endo's Code of Conduct mandates compliance with legal requirements and Company policies and procedures, including those related to (1) the review and approval of promotional materials; (2) salesforce training, conduct and oversight; and (3) the identification of HCPs eligible for sales calls. These provisions are summarized below.

### **1. Review and approval of promotional materials**

The Code mandates that promotional materials and communications be approved by appropriate personnel, be on label, accurate and not misleading, and comply with applicable legal, regulatory and local standards. To help facilitate compliance with these standards, the Company maintains a Marketing and Advertising Review Committee ("MARC"). MARC's functions include review and approval of promotional materials. MARC is a cross-functional team comprised of representatives from the Company's legal, regulatory, medical science, and marketing departments. MARC review is intended to result in promotional materials that, as the Code requires, are "accurate, truthful, non-misleading, and compliant with all applicable Legal, Regulatory Affairs, Medical Science requirements, and Endo policies."

As noted above, the Company voluntarily disbanded its entire U.S. pain salesforce and ceased promoting opioid medications throughout the United States effective January 2017. Up to that point, MARC reviewed and approved all branded opioid-related promotional materials, including internal sales training materials. Promotional materials approved by MARC for distribution to external audiences such as HCPs were also submitted to the FDA's Office of Prescription Drug Promotion ("OPDP") with Form 2253, as required by 21 C.F.R. § 314.81(b)(3), prior to their first use. The Form 2253 process provides OPDP with the opportunity to review promotional materials used by pharmaceutical companies for compliance with the Federal Food, Drug and Cosmetic Act and applicable FDA regulations, and to issue warning letters in the event that OPDP's review reveals a potential violation. Pursuant to this process, the Company submitted to the FDA all branded opioid-related promotional materials meant for distribution to external audiences and the FDA never issued a warning letter to Endo regarding such materials.

A similar process applied in Canada prior to Endo's voluntary decision to cease opioid promotion in that country. Canadian promotional materials were reviewed by a cross-functional team, and materials meant for distribution to external Canadian audiences were submitted to the Pharmaceutical Advertising Advisory Board ("PAAB") prior to use. PAAB is a Canadian regulator whose preclearance service is required by Health Canada for advertising directed to healthcare professionals. The Company's opioid-related promotional materials were pre-cleared by PAAB and only those pre-cleared materials were used by the Company.

### **2. Salesforce training and oversight**

The Code sets forth standards for employee interactions with healthcare professionals. With respect to all of the Company's pharmaceutical medications, including opioid products, the Code

requires “truthful and ethical communications that will help healthcare professionals make informed and independent decisions” about such products using only approved “promotional materials and communications that are on label, accurate, not misleading and [that] comply with applicable regulatory and local standards” and “[p]rovide fair balance.”

When the Company had a pain product salesforce, that organization was trained and monitored for compliance with the Code and related policies and procedures. Training materials and presentations consistently informed and reminded the pain product sales organization of their obligations under the Code, which included conveying not only the features and benefits of the product, but also product limitations and risks, including as applicable black box warnings about the risks of misuse, abuse and addiction. These requirements were reiterated in regular training sessions as well as during regional and national salesforce meetings. To encourage and monitor compliance with policies and trainings, district managers and regional directors regularly supervised pain product sales representatives in the field. A formal component of that supervision process was observation of, and feedback about, the individual sales representative’s presentation of fair and balanced messaging. Consistent adherence to the approved fair and balanced messaging during discussions with appropriate HCPs was also a component of performance evaluations for pain product sales representatives. Failure to comply with policies on responsible promotion could be grounds for termination or other employee disciplinary actions.

### **3. Identification of healthcare providers eligible for sales calls**

When the Company had a pain product salesforce, Endo took steps to limit which prescribers would receive sales calls for branded opioid products based on various criteria, such as approved specialties.

The Code requires employees to report any knowledge or suspicion about the improper handling, transfer, loss or diversion of a controlled substance. The Company’s Abuse and Diversion Detection Program (“ADD Program”) has included: (1) establishing procedures and avenues for employees to report any suspected abuse, diversion or inappropriate prescribing; (2) training employees on their obligation to report any such activities; and (3) establishing disciplinary consequences for non-compliance. Among other things, the ADD Program required the pain product salesforce to report to Endo’s legal department situations suggesting that a healthcare provider might be involved in the abuse or diversion of opioids. The Company maintained a list of healthcare providers suspected of inappropriate prescribing for internal purposes and forbade its salesforce from promoting to anyone on the list as Endo did not want its products promoted to prescribers with even suspected diversion or inappropriate prescribing habits.

In addition, as a manufacturer of opioid medication, Endo maintains robust, highly specialized suspicious order monitoring (“SOM”) programs, which evaluate orders for opioid medication based on quantity, size, and frequency. A customer’s historical order data is used to calculate



benchmark amounts and, if an order is greater than the set benchmark amount, such order will be placed on hold, pending further investigation. If an order of interest is ultimately not determined to be a suspicious order, the order is released and shipped to the customer. However, if the investigation reveals that the order of interest is a suspicious order, the order is not shipped and the U.S. Drug Enforcement Agency is notified.

### **INCENTIVE COMPENSATION TIED TO COMPLIANCE WITH ENDO'S POLICIES AND PROCEDURES**

Incentive compensation for sales personnel is linked not only to overall Company sales performance and attainment of sales goals but also to compliance objectives. Historically, incentive compensation for the pain product sales organization was dependent upon compliance with the Code (including all applicable laws and regulations as well as Company policies and procedures) and conduct consistent with Endo's Core Values<sup>5</sup> and other Company guidance. The incentive compensation program was designed to avoid incentivizing inappropriate promotion. For example, if it was determined that a sales representative met sales goals or objectives in an unethical and/or non-compliant manner, the policy required withholding of such sales representative's incentive compensation for the quarter during which the violation occurred. Additionally, a report would be filed with the Compliance Department. Endo could also withhold incentive compensation for additional quarters, depending on the facts and circumstances. Any sales representative who violated the Code was also subject to discipline up to and including termination.

Endo's non-sales personnel incentive compensation program rewards the achievement of overall Company financial objectives and takes into account strategic, operating and compliance considerations. Awards are also based on employees' individual performance<sup>6</sup> and achievement against individual objectives and their demonstration of Endo's Core Values.

In addition, pursuant to discussions with the Investors for Opioid Accountability and in light of its request, the Company recently expanded its compensation recovery policy, applicable to senior management, to permit the Company to (1) recover cash incentive awards in addition to equity-based incentive awards and (2) seek recoupment of incentive awards for material financial harm to the Company caused by the senior management employee's material misconduct or gross negligence, as well as fraud or intentional misconduct.

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<sup>5</sup> Endo's Core Values shape how employees work together and define the behaviors that drive Endo's success. The Core Values are: Customer Focus – deliver quality products and superior service to those who rely on us; Performance Driven –execute flawlessly to achieve results; Integrity –uphold an ethical and honest character; Collaboration – unite to empower and build strong working relationships; and Quality and Continuous Improvement –fulfill a promise to deliver the best.

<sup>6</sup> All employees pledge the following when they submit their annual performance goals: "Compliance Integrity Pledge: With this submission, I am acknowledging that my performance towards my goals and objectives will be achieved in accordance with Endo's Code of Conduct and company policies."

## **CONCLUSION**

Endo is deeply concerned about the effects of the opioid abuse crisis. The Company has voluntarily taken several steps to help mitigate risks while continuing to serve the legitimate needs of the millions of patients suffering from acute or chronic pain. Our position on this matter is set forth on Endo's website ([www.endo.com](http://www.endo.com)) under "Endo's Open Letter on the Opioid Abuse Crisis." We remain committed to helping ameliorate the opioid abuse crisis and to continuing Endo's longstanding mission of improving patients' lives.