



July 18, 2018

Policy, Planning and International Affairs Directorate, Health Products and Food Branch  
Address Locator: 2005A, Ottawa, Ontario, K1A 0K9, Department of Health

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## **Re: Notice of Intent to Restrict the Marketing and Advertising of Opioids**

We are writing in response to Health Canada's request for comments on its Notice of Intent to Restrict the Marketing and Advertising of Opioids. Specifically, we would like to provide input in relation to the potential benefits of regular mandatory reporting on marketing and advertising of opioids.<sup>1</sup>

With approximately C\$6 billion in assets under management, NEI Investments' approach to investing incorporates the thesis that companies can mitigate risk and take advantage of emerging business opportunities by integrating best environmental, social and governance (ESG) practices into their strategies and operations. From an investor perspective the economic and social significance of addressing the opioid crisis is clear: if the potential societal, financial, legal and reputational risks related to the manufacturing and sale of opioids are not well governed, this not only represents a social risk that can negatively affect patient's lives, the workforce, society and the economy, but it can also negatively affect the value of investee companies. We appreciate the opportunity to provide input to the consultation.

### **Investors for Opioid Accountability**

In this context, we would like to bring to your attention the work of Investors for Opioid Accountability (IOA)<sup>2</sup>, of which NEI Investments is a member. IOA is a diverse coalition of 44 investment institutions representing North American state treasurers, comptrollers, asset managers, faith-based, public and labour funds with more than U.S.\$2.2 trillion in assets under management. It was established in July 2017 out of heightened concerns that opioid companies' risks may threaten shareholder value and have profound long-term implications for the economy and society across North America. Many IOA members are long-term shareholders in opioid manufacturers with clients who are directly or indirectly impacted by the opioid crisis. Since its inception IOA members have used the special rights that come with shareholder status to successfully engage with investee companies on the need for best corporate governance practices that strengthen corporate culture, board accountability, compensation incentives and risk mitigation; important governance practices that the coalition has identified as part of a root cause assessment of companies' role in the crisis.

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<sup>1</sup> <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/restrict-advertising-opioids.html>

<sup>2</sup> <https://www.prnewswire.com/news-releases/13-trillion-investor-coalition-probes-pharma-on-opioid-accountability-300545282.html>

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## **Potential risks, benefits and impacts of regular mandatory reporting by opioid manufacturers, to Health Canada and the public, of their marketing and advertising activities, objectives and budgets**

Public disclosure enables investors to assess risks and hold the companies in their portfolios to account. We outline below a range of corporate disclosures that IOA investors have been promoting, for Health Canada's consideration in developing potential reporting requirements.

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IOA investors have been requesting that the board of directors of opioid manufacturers and distributors prepare a report to shareholders on measures the companies have taken to mitigate business risks related to their opioid business. Specific governance and risk mitigation measures on which IOA investors have been seeking disclosure include:

- **Role of Opioids Business in Long-Term Strategic Plan:** Current and future projections of sales and percentage of total revenue related to opioids, and the role of opioid manufacturing in the company's long-term strategic plan;
- **Board Oversight:** Discussion of board oversight responsibility for monitoring business risks related to opioid sales, including which committee carries specific responsibilities, and any mention in committee charters of opioid risk-related issues;
- **Public Policy Principles:** Principles that guide board-level deliberations on opioid business issues including public policy recommendations promoted externally;
- **Corporate Political Spending and Lobbying:** Process for board oversight of corporate political spending and lobbying expenditures related to laws, regulations and policy input on opioid-related issues (particularly relevant in the U.S. context);
- **Salesforce and Promotional Programs:** Changes in salesforce levels and promotional programs related to opioid products, and efforts made to decrease risk exposure for companies including changes in sales, supply chain and distributor business relations;
- **Compensation:** Transparency around opioid sales incentives for relevant staff, including executives; executive compensation incentive metrics or goals related to compliance, including clawback of incentives in case of misconduct;
- **Compliance:** Investment in and implementation of operational anti-diversion programs both globally, nationally and regionally; compliance reporting functions related to the opioid line of business, which could include compliance certifications for managers or other requirements for employees that support the company's code of conduct and other business conduct standards; how opioid-related compliance is organized across the business enterprise and within key business segments of the company, ranging from the line manager up to the relevant board committees;
- **Corporate Responsibility Initiatives:** Implementation of principles on community investment, provider and patient education related to opioid use, addiction and overdose.

Additional disclosure of potential interest to shareholders is transparency on payments made to individual physicians for activities such as delivering speeches, sitting on advisory boards, and travelling to conferences, akin to what is required under the U.S. Physician Payments Sunshine Act.<sup>3</sup> Ontario recently passed legislation

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<sup>3</sup> <https://news.ontario.ca/mohltc/en/2017/12/ontario-passes-legislation-to-strengthen-transparency-in-health-care.html>

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on this topic and British Columbia is assessing the potential for legislation. This type of disclosure could help investors to identify potential risks related to Canadian sales and marketing practices of investee pharmaceutical companies.

Lastly, we note Health Canada's recent decision in an amendment to the Food and Drug Regulations (Opioids)<sup>4</sup> to allow the Minister of Health to require companies to develop and implement risk management plans (RMPs) to appropriately monitor, quantify, characterize, and mitigate the risks associated with post-market use of these products, including the preclearance of opioid-related materials provided to health care professionals. Public disclosure of RMP content could enable investors to evaluate portfolio companies' opioid-related risks more fully.

Please do not hesitate to contact us if you have any questions in relation to this submission.

Sincerely,  
**NEI Investments**

A handwritten signature in black ink that reads "Michelle de Cordova".

Michelle de Cordova

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cc:  
Board of Directors, NEI Investments  
Responsible Investment Executive Committee, NEI Investments  
Ms. Rosa van den Beemt, Senior ESG Analyst, NEI Investments

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<sup>4</sup> <http://www.gazette.gc.ca/rp-pr/p2/2018/2018-05-02/html/sor-dors77-eng.html>

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