

August 13, 2021

Viatriis Inc. Report on U.S. Opioid Abuse

On November 16, 2020, Viatriis Inc. (“Viatriis” or the Company”) was formed through a combination of Mylan N.V. and Pfizer Inc.’s Upjohn business. Viatriis empowers people worldwide to live healthier at every stage of life. The Company provides access to medicines, advances sustainable operations, develops innovative solutions and leverages its collective expertise to improve patient health. As part of its mission, Viatriis is committed to addressing some of the world’s most pressing public health issues, and the challenges pertaining to opioid abuse in the U.S. is no exception.

Viatriis’ Board of Directors supports publication of this report to provide shareholders and other stakeholders with relevant details pertaining to Viatriis’ commitment to doing its part to help in the nationwide fight against opioid addiction, abuse, and misuse.

I. Viatriis’ Opioid Products

Opioid products, which the U.S. Food and Drug Administration (FDA) has recognized provide benefits when used according to the label, are an insubstantial part of the Company’s business. Viatriis does not promote its opioids products. Given that Viatriis was just formed at the end of 2020, we will not have full-year data available concerning Viatriis’ sales of opioid-containing products until the completion of 2021. However, according to IQVIA data, Viatriis’ legacy Mylan business on average supplied approximately 1% of all opioid-containing products sold in the U.S. from 2016-2020, by total volume (doses) and Viatriis’ legacy Upjohn business has virtually no sales of opioid-containing products in the United States.

Moreover, U.S. revenues for opioid-based products of Viatriis’ legacy Mylan business generally have been declining for several years and represented only a small share of the total revenues of Viatriis’ legacy Mylan business. In fact, total net sales of opioid-containing drugs in the U.S. made up only 2.9% of Viatriis’ legacy Mylan business in the U.S. in 2020. Excluding the Company’s generic buprenorphine/naloxone (which is indicated for the treatment of opioid dependence) and branded Ultiva products (which is an intravenous anesthesia medication administered in surgery center, in-patient settings), sales of opioid-containing products only made up approximately 1% of net sales of Viatriis’ legacy Mylan business in the U.S. in 2020.

Other than its branded Ultiva product, Viatriis’ opioid products consist of generic products, which typically are automatically substituted for branded products by pharmacies. These products include FDA-approved products across the range of U.S. Drug Enforcement Administration (DEA) schedules, such as acetaminophen/codeine phosphate tablets and diphenoxylate hydrochloride and atropine sulfate tablets. Viatriis’ opioid pain products provide

important therapeutic benefits for appropriate patient populations, when prescribed and used responsibly.

One of Viatris' opioid products is the Fentanyl Transdermal System, which is a generic version of Johnson & Johnson's branded fentanyl patch product, Duragesic™. Viatris' Fentanyl Transdermal System is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. Its patch design utilizes a matrix technology in which the fentanyl is incorporated into the adhesive layer of the patch. Accordingly, Viatris' patches have no drug reservoir containing fentanyl gel and are among the products containing the least amount of fentanyl needed to deliver the labeled dose. At the time of its approval in January 2005, the matrix technology design represented an important innovation. In addition, Viatris offers intermediate dosing strengths to allow physicians to select appropriate dosing to provide additional treatment options.

Illicit fentanyl is a significant part of opioid abuse in the United States and federal authorities have acknowledged that lawful fentanyl products are not driving the national fentanyl problem. In its 2018 National Drug Threat Assessment, the DEA concluded that “[c]landestinely produced fentanyl is trafficked into the United States primarily from China and Mexico, and is responsible for the ongoing fentanyl crisis. In contrast, the diversion of pharmaceutical fentanyl in the United States occurs on a small scale, with the diverted fentanyl products being intended for personal use and street sales.”

Viatris' sole branded opioid product, Ultiva®, is not part of the national discussion on opioids, as it is an intravenous anesthesia medication administered exclusively and directly by healthcare providers in surgery-center, in-patient settings.

In 2019, Viatris' legacy Mylan business launched a generic, combination product of buprenorphine and naloxone (generic Suboxone) – which is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. When the FDA announced its approval of this generic Suboxone sublingual film product, then-FDA Commissioner Gottlieb stated: “The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure these medicines are accessible to patients who need them. That includes . . . facilitating market entry of generic versions of approved drugs to help ensure broader access.”

II. Comprehensive Responses to Help Fight Opioids Abuse

a. The Company's Non-Opioid Products

Given its extensive scientific capabilities, the Company is taking a leading role in finding pharmaceutical solutions to combat opioid addiction, misuse, and abuse. As the FDA has recognized, steps taken to confront this public health challenge must be balanced against “the needs of patients in accessing appropriate pain management.” FDA Statement on the FDA’s benefit-risk framework for evaluating opioid analgesics dated June 20, 2019. *See* <https://www.fda.gov/news-events/press-announcements/statement-fdas-benefit-risk-framework-evaluating-opioid-analgesics>

- The Company has more than 20 non-opioid medications that are used to treat pain (among other indications) including Celebrex® – which is used to treat pain and inflammation – and Lyrica®, which is used to treat pain caused by nerve damage due to diseases such as diabetes, spinal cord injury, or fibromyalgia.
- In 2014, Viatris’ legacy Mylan business launched a generic, injectable, single-vial version of naloxone, a product that is indicated for the complete or partial reversal of opioid depression induced by some natural and synthetic opioids, as well as for diagnosis of suspected or known acute opioid over-dosage. In the summer of 2016, Viatris’ legacy Mylan business launched a multiple-vial version of naloxone and thereby increased supply for customers, physicians, and other providers seeking additional inventory of this important therapy. The Company’s injectable naloxone products are primarily used by hospitals. Today, the Company’s naloxone presentations have some of the lowest list prices in the overall U.S. naloxone market. The Company stands ready to continue to provide reliable supply and access to naloxone, including through a commitment to develop an auto-injector drug-device combination for naloxone.
- The Company is also developing a novel delivery system for meloxicam, a non-opioid pain medication. The Company is committed to bringing this product to market, has filed an investigational new drug application for the product, and initiated Phase II clinical studies in 2020. Promoting the development of non-opioid pain treatments is one of the areas the FDA focused on as part of its efforts to address this public health challenge.

b. The Company's Commitment to Compliance with Controlled Substances Regulatory Obligations

Viatris manufactures and supplies its opioid products within quota amounts established by the DEA. The Company takes seriously its responsibilities to help ensure that its opioid medications are held and distributed appropriately.

Viatis' efforts include physical security controls and employee screening programs which comply with the federal Controlled Substances Act (CSA) and DEA regulations at all locations where controlled substances are held. The physical security controls for Viatis facilities receive advance approval by the relevant local DEA offices prior to implementation at the facilities.

Viatis also has designed and operates a system to identify suspicious orders of controlled substances consistent with federal regulatory obligations. We have a cross-functional team including members from Compliance, Customer Relations, Controlled Substance Monitoring, Global Security, Distribution Center, Regulatory Legal, Regulatory Affairs, State Licensing and DEA that works to vet customers and orders, and maintain and continuously enhance our strong programs designed to detect and prevent diversion within the supply chain.

For example, the Company has established a suspicious order monitoring (SOM) system that consists of internal controls to identify suspicious orders and prevent the sale of controlled substances, including opioid-containing products, where there may be a risk of diversion. For example:

- Orders for controlled substances, including opioid products, are not sent for distribution center processing until they are approved for release.
- Order information for controlled substances is transmitted to the SOM system, which performs statistical modeling calculations to identify potential suspicious orders. A suspicious order of a controlled substance may include, but is not limited to, an order of unusual size or deviating substantially from a normal pattern, and orders of unusual frequency.
- If the SOM system's statistical modeling "flags" an order as needing additional review, the order is placed on hold and will not be shipped unless the order is deemed to not be suspicious after investigation.
- Orders flagged by the Company's SOM system are vetted by the Company's trained Controlled Substance Monitoring Team (CSMT) and, if needed, routed to the Regulatory Affairs/DEA Compliance Team for further consideration and resolution.

The Company's SOM processes are set forth in clear, comprehensive written policies and Standard Operating Procedures (SOP) that outline the purpose and scope of the SOM program and relevant employee responsibilities. Applicable Company personnel are required to complete training on the SOM Program and to understand the importance of DEA compliance.

c. Participation in REMS

For certain of its products, Viatris also participates in a shared industry Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesics. A REMS is a “drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.” The FDA has determined that a REMS for certain opioid analgesics is necessary to ensure that the benefits of these drugs continue to outweigh the risks. The REMS is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, and addiction.

d. Commitment to Compliance

i. Structure of Compliance Program

Everyone at Viatris – and those acting on our behalf – is personally responsible and accountable for the Company’s reputation and dedication to doing business with integrity. Viatris works to provide the adequate procedures and guidance to support that individual responsibility. Viatris’ Chief Compliance Officer has the operational responsibility to ensure that the Company’s Corporate Compliance Program is effective and robust and directs its day-to-day implementation. To help ensure broad perspectives and independence in the Compliance Department, the Company’s Chief Compliance Officer reports to the Board’s Compliance Committee and the Chief Executive Officer.

Viatris’ Compliance Department is organized by operating regions and Global Centers of Excellence (CoE) to efficiently support the organization. The Compliance Department and the Company’s Global Compliance Program are structured in a manner consistent with the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) Resource Guide for Measuring Compliance Program Effectiveness. The Chief Compliance Officer leads the regional heads of Compliance and the global CoEs that support the Company’s global operating regions and business. A senior leader manages each respective CoE, which focuses on policies, training and communications, global compliance risk, audit and monitoring, due diligence, and investigations. The Compliance Department oversees the development, maintenance and recordkeeping of global policies and procedures, and performs various periodic and needs-based operational audits throughout the year, often in conjunction with Internal Audit.

The Chief Compliance Officer reports quarterly to the Compliance Committee as well as the Risk Oversight Committee of the Board, which is described in greater detail later in this report.

ii. Code of Business Conduct and Ethics

More broadly, the Company's operations are governed by a Code of Business Conduct and Ethics, also known as the Code, which is administered by the Compliance Department. It is a condition of employment that Viatris employees comply with the Code and the applicable laws of the countries in which Viatris does business. Viatris employees receive annual training on the Code and must periodically certify that they have read the Code and will, to the best of their knowledge and belief, comply with the Code. Among other obligations, the Code requires adherence to current good manufacturing and good laboratory practices, prompt reporting of concerns regarding product quality and adverse events, and compliance with established internal controls. The Company, at its sole discretion, may take action – including termination of employment or preventing participation in the Company's incentive compensation program – against anyone for violating the Code, applicable law, or Company policy.

iii. Interactions with Healthcare Providers and Promotional Activities

Viatris is not promoting or marketing any of its opioid products. As a matter of global corporate policy, Viatris' Code requires that promotional activities and materials must comply with all applicable laws, regulations and codes, and the Company's own marketing and advertising review policies, and must be truthful, accurate, not misleading, consistent with approved product labeling and properly substantiated. Promotional activities and materials must never involve promotion of drugs for off-label indications, uses, or doses or populations. All personnel involved in product marketing or promotion must familiarize themselves with the applicable standards for interaction with healthcare providers and all related policies and procedures governing the creation, review, approval and use of promotional materials. Use of unapproved promotional materials is prohibited.

iv. Reporting Compliance Concerns

Viatris encourages open communication, provides a variety of channels for reporting potential compliance violations, and strictly prohibits retaliation relating to any reports made in good faith. The Company provides several options for employees and others to report possible violations of applicable laws, regulations, policies, or the Code to Viatris' Compliance Department, either online or via telephone, mail or email. For example, employees are encouraged to discuss compliance matters with their supervisor, Human Relations, the Legal Department, their local compliance leader or the Global Compliance Department. They also can use the Viatris Compliance Line, which is available 24/7 and permits anonymous reports in all countries in local languages where permitted by law.

With respect to investigating, resolving and remediating reported events, our Global Policy on Reporting and Investigating Compliance-Related Matters outlines a clear process that includes a thorough, impartial and timely investigation of each report in coordination with Human Relations, our Legal Department and other functions as appropriate; and fair and consistent disciplinary measures, when necessary. In addition, Viatris considers any appropriate policy and procedure changes in connection with its investigations.

III. Board Engagement and Executive Compensation Related to Opioids

a. Board-Level Committees

Several of the committees of Viatris' Board of Directors exercise oversight with respect to issues related to the Company's processes for management of its opioids products. In particular, the Compliance Committee is charged with overseeing global policies related to Viatris' business methods and operations, including with respect to policies related to the Company's pricing and/or commercialization of products, which covers opioids. A majority of the members of the Compliance Committee are independent directors, and the Committee charter includes provisions that memorialize relevant oversight responsibilities. A copy of the Compliance Committee charter can be found at the Corporate Governance section of Viatris' website.

Moreover, the Compliance Committee is responsible for overseeing the Company's policies and procedures for corporate political and lobbying expenditures and making recommendations concerning those policies and procedures to the Board as appropriate. Viatris is committed to responsible legislative efforts to, among other things, protect patient access to important generic medicines at affordable prices. Viatris files a quarterly report of expenses associated with lobbying the federal government in accordance with the U.S. Lobbying Disclosure Act. That report can be found on the U.S. Senate Office of Public Records website or the U.S. House of Representatives Office of the Clerk website. Viatris also files monthly political contribution reports (FEC) with the U.S. government. The Company relies on outside legal counsel to support these filings. In addition, Viatris' semiannual Political Contribution & Trade Association Memberships report is made available on our website.

The Viatris Board also has a Risk Oversight Committee to assist in its oversight of the Company's enterprise risk management framework. In addition to enterprise risk, the Committee's charter states that it is charged with overseeing management efforts with respect to global social responsibility, which includes the social impact of the company's products. The Committee consists entirely of independent directors, and – at least semi-annually – consults with the Chairs of other Board Committees to discuss risk-related matters delegated to those Committees and the Company's enterprise risk management. A copy of the Risk Oversight Committee charter can be found at the Corporate Governance section of Viatris' website.

Both the Compliance Committee and the Risk Oversight Committee meet at least quarterly, and in executive session at least two times per year, and report key matters discussed at those meetings to the full Board.

b. Commitment to Shareholder Engagement

Viatisr' Board and management are committed to robust engagement with shareholders regarding a variety of topics, and welcome discussions regarding topics of interest to shareholders, including opioid abuse in the United States.

c. Executive Compensation Metrics and Policies

Consistent with the Company's limited role in the opioids market and the breadth of its global business, executive officer compensation metrics and policies are not tied to opioid product sales. Rather, the Compensation Committee, which is comprised of independent directors, considers both qualitative and quantitative factors in determining executive compensation (or, in the case of the Executive Chairman and CEO, compensation recommendations to be made and approved by independent, non-executive members of the Board). These compensation evaluations are undertaken by the Committee at least annually, taking into account a mix of objective performance measures and the Committee's analysis of compensation trends and developments. The Committee also considers different metrics, such as Global Regulatory Submissions, designed to mitigate potential risks that compensation could become overly dependent on any single product.

The Compensation Committee considers risk management in determining compensation policies and believes that the Company's programs are designed to encourage outstanding, consistent, sustainable business performance over extended periods of time. The Company's management and the Compensation Committee consider and discuss the risks inherent in the Company's business and the design of the Company's compensation plans, policies and programs that are intended to drive the achievement of the Company's long-term business objectives while avoiding excessive short-term risk-taking. In addition, the Company utilizes a mix of objective performance measures, so that undue emphasis is not placed on one particular product or measure, and the Company employs different types of compensation to provide economic opportunities over the short-, medium- and long-term. These performance measures are reevaluated annually in light of business needs and other factors, including the prospective risk environment facing our business. When making compensation decisions, the Committee also considers qualitative factors to avoid the potential consequence that an overly formulaic approach may have on excessive risk-taking by management, as well as compliance with the Code of Business Conduct and Ethics, Company policy and applicable law, and has the authority to exercise negative discretion. At least annually, the Compensation Committee also receives a

report from Meridian Compensation Partners, its independent compensation consultant, on risk management in connection with the Company's compensation program.

The Board also has a clawback policy relating to incentive compensation programs. The provisions of the policy allow the Company to recoup certain bonus and equity-based incentive compensation gains resulting from specified misconduct that causes the Company to materially restate its financial statements. The policy also includes a misconduct standard covering material violations of law or Company policy as well as failure to manage or monitor another individual who committed such misconduct. The Board or a designated Board committee will disclose the circumstances of any recoupment relating to such misconduct if required by law or regulation or if it determines that disclosure is in the best interests of the Company and its shareholders. In addition, the Company has a number of other policies in effect that govern our executive team's behavior and that set out clear ethical expectations. Those policies, including our Code of Business Conduct and Ethics, empower the Company to take a full range of disciplinary responses for any violations, and the Board and the Compensation Committee are not otherwise constrained from seeking to claw back from or deny compensation to any member of the executive team in response to any breach of duties or ethics.

IV. Litigation

This report provides important information and context about the Company's limited opioids products as well as our commitment to being part of the solution to address this public health challenge. Despite this factual backdrop of minimal involvement in the distribution of opioids, the Company has been named in the U.S., along with numerous other manufacturers, distributors, pharmacies, pharmacy benefit managers, and/or individual healthcare professionals, in civil lawsuits brought by various plaintiffs asserting claims related to sales, marketing and/or distribution practices with respect to prescription opioid products. Most of these lawsuits have been consolidated in the multidistrict litigation pending in the United States District Court for the Northern District of Ohio. The Company believes that the claims against it in these lawsuits are without merit and intends to defend against them vigorously. The Company's Board appropriately monitors this and other significant litigation.

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Viatrix appreciates the interest of shareholders and other stakeholders in these important matters. As this report reflects, the Company is committed to balancing support of physicians' decisions regarding the patient benefits of opioid pain products against the risks associated with the abuse or misuse of such products and remains dedicated to collaborating, both internally and externally, to identify ways in which the Company can continue to help efforts to address this public health challenge.