



Johnson & Johnson To Appeal Flawed Opioid Judgment in Oklahoma

August 26, 2019

Company did not cause opioid crisis; neither facts nor law support this outcome Company confident it has strong grounds for appeal

NEW BRUNSWICK, N.J., Aug. 26, 2019 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) and its Janssen Pharmaceutical Companies today announced they will appeal the \$572 million civil judgment entered in Cleveland County District Court in the State of Oklahoma's lawsuit against opioid manufacturers. The Company is confident it has strong grounds to appeal this decision.

The judgment disregards the Company's compliance with federal and state laws, the unique role its medicines play in the lives of the people who need them, its responsible marketing practices and that since launch, DURAGESIC[®], NUCYNTA[®] and NUCYNTA[®] ER have accounted for less than one percent of total opioid prescriptions in Oklahoma as well as the United States.

"Janssen did not cause the opioid crisis in Oklahoma, and neither the facts nor the law support this outcome," said Michael Ullmann, Executive Vice President, General Counsel, Johnson & Johnson. "We recognize the opioid crisis is a tremendously complex public health issue and we have deep sympathy for everyone affected. We are working with partners to find ways to help those in need."

Judgment Not Consistent with Facts or the Law

The decision in this case is flawed. The State failed to present evidence that the Company's products or actions caused a public nuisance in Oklahoma. The State's claims violate fundamental principles of due process by seeking to hold a company liable for conduct permitted under federal law and regulations. It also disregards 100 years of precedent in public nuisance law, which traditionally has been applied to resolve property disputes, not lawsuits involving the sale of goods.

"This judgment is a misapplication of public nuisance law that has already been rejected by judges in other states," said Ullmann. "The unprecedented award for the State's 'abatement plan' has sweeping ramifications for many industries and bears no relation to the Company's medicines or conduct."

Appeal Process and Other Litigation

The Company will move to stay enforcement of the judgment pending the resolution of its appeal. The length of the appeal process varies from case to case, taking into account time for post-trial motions, preparation of the trial record and briefing to the appellate court. In this case, it is anticipated to extend into 2021. The Company is confident it has strong grounds for appeal.

The opinion in Oklahoma does not have a binding impact on other courts, including those involved in ongoing federal litigation, litigation in other states, or how the Company approaches those matters given the different laws, defendants and claims in these other cases. The upcoming federal multidistrict litigation (MDL) currently scheduled for October 2019 includes multiple defendants and a number of different claims. The Company remains open to viable options to resolve these cases, including through settlement.

Janssen Prescription Pain Medicines

In addition to the legal deficiencies of the State's case, the facts do not align with or support the outcome of the trial.

Janssen developed two types of Schedule II prescription opioid medicines – a patch and a crush-resistant tablet – designed to help patients suffering from severe pain. DURAGESIC[®], NUCYNTA[®] and NUCYNTA[®] ER are U.S. Food and Drug Administration (FDA)-approved and since launch, have accounted for less than one percent of total opioid prescriptions in Oklahoma as well as the United States. The FDA-approved labels of these medicines provide clear information about their risks and benefits.

The Centers for Disease Control (CDC) estimates nearly 50 million Americans suffer from chronic pain. These patients should not be ignored.

Former Johnson & Johnson Affiliates

Several of the State's allegations focused on Noramco and Tasmanian Alkaloids, former affiliates of Johnson & Johnson, that produced and supplied medical-grade ingredients for opioid pain medications. At every stage of the supply chain, these companies were governed by and complied with international and federal regulations and quotas. These included importation and manufacturing quotas established by the U.S. Drug Enforcement Administration (DEA) and FDA. The State did not contest that these affiliates complied with the regulations at all times.

Importantly, as suppliers, these former affiliates played no role in the manufacturing, sales or marketing of the finished products of other DEA-regulated manufacturers. Johnson & Johnson sold Noramco and Tasmanian Alkaloids in 2016.

Oklahoma law bars liability for the supply of these raw materials, and a comprehensive federal regulatory program authorized and painstakingly regulated the importation, manufacture and sales of those materials.

Johnson & Johnson Response to the Opioid Crisis

The opioid crisis is a complex public health issue that demands a public health response. The Company continues to collaborate to help patients, families and communities in need.

Building on our legacy in public health, we are working with frontline health care professionals, academic institutions, policymakers, online communities and others to address the unmet needs of those impacted by this crisis. To date, the Company has sponsored independently developed education programs for tens of thousands of doctors, nurses and pharmacists across America, helping to better equip them to fight substance abuse and addiction. The Company is also collaborating with academic institutions to identify evidence-based best practices that can empower nurses and other health care practitioners to effectively respond to the opioid crisis at the community level. Based on more than 130 years of experience, these collaborations are where the Company can have the greatest impact.

Additional Information

Janssen Prescription Medicines

DURAGESIC[®] (fentanyl transdermal system) CII is an FDA-approved transdermal patch. DURAGESIC[®] has child-resistant packaging and is part of an FDA-approved and required Risk Evaluation and Mitigation Strategy (REMS) program, which outlines strategies to manage known or potential risks associated with these products to help ensure that the benefits of a drug outweigh its risks. Although Janssen continues to make DURAGESIC[®] available, marketing of this medicine ceased in 2008. For full prescribing information, instructions for use, and medication guide for DURAGESIC[®], please visit <http://bit.ly/duragesicPI>.

Janssen marketed two forms of NUCYNTA[®] (tapentadol) - an immediate release tablet and an extended-release tablet. Both medicines are FDA-approved and NUCYNTA[®] ER was launched with an FDA-approved REMS program. Janssen sold the U.S. marketing rights for NUCYNTA[®] in April 2015. For full prescribing information and medication guides for NUCYNTA[®] and NUCYNTA[®] ER, please visit <http://bit.ly/nucyntaPI> and <http://bit.ly/nucyntaER-PI>.

Data presented at trial show DURAGESIC[®], NUCYNTA[®] and NUCYNTA[®] ER had low rates of abuse and diversion. All brand marketing materials were submitted to the FDA and company sales representatives were thoroughly trained to provide accurate information on the risks and benefits of these medications. In 2015, Janssen stopped marketing these medications in the U.S., focusing its attention on other areas of significant unmet medical need.

Other Litigation

As disclosed in the Company's most recent [Form 10-Q](#), the Company has been named in more than 2,000 lawsuits brought by certain state and local governments related to the marketing of opioids. Some of these have been consolidated into a federal multidistrict litigation (MDL) proceeding. Defendants include different companies spanning the opioid supply chain, including manufacturers, distributors and pharmacies. Two of those cases have been selected for an initial trial beginning October 21, 2019.

Links

We invite you to learn more about the Company's position on the litigation and public health initiatives at <https://www.factsaboutourprescriptionopioids.com/>.

A summary of our legal arguments can be found in our Findings of Fact & Conclusions of Law filing of July 31, 2019, available on our site at https://www.factsaboutourprescriptionopioids.com/assets/pdfs/FindingsOfFactCOL_Filed073119.pdf.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com. Follow us at @jniglobalhealth.

About the Janssen Pharmaceutical Companies

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at [www.twitter.com/JanssenGlobal](https://twitter.com/JanssenGlobal). Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the civil judgment entered in Cleveland County District Court in the State of Oklahoma's lawsuit against opioid manufacturers as well as other litigation in other jurisdictions. The reader is cautioned not to rely on these forward-looking statements. The information contained in this press release is for informational purposes only and should not be construed as a commitment by the Company to engage in any specific strategy or course of action. Although the Company plans to vigorously defend itself and appeal this decision, due to the inherent uncertainty of litigation, the Company cannot predict the timing, ultimate outcome or financial impact of this matter, or any other ongoing or future litigation. The forward-looking statements in this press release are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: significant adverse litigation or government action, including related to product liability claims; economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new and existing products; challenges to patents; the impact of patent expirations; the ability of the company to successfully execute strategic plans; the impact of business combinations and divestitures; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including tax laws and global health care reforms; trends toward health care cost containment; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and legal systems and sovereign risk; increased scrutiny of the health care industry by government agencies. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Any forward-looking statement made in this release speaks only as of the date of this release. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments. The Company expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.



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