

Lawsuit Accuses Drug Enforcement Administration of “Incompetence” in Public Health Crisis Over Shortage of ADHD Medications

DEA Seeks to Shutter Minority-Owned Business, Ascent Pharmaceuticals—one of the nation’s major makers of generic ADHD drugs—over mistaken recordkeeping violations

New York, NY, October 4, 2023 — Today, Walden Macht & Haran, on behalf of its client **Ascent Pharmaceuticals, Inc.** filed a federal lawsuit against **the Drug Enforcement Administration (DEA), a branch of the Department of Justice.** The emergency motion seeks to restore Ascent’s full manufacturing of generic ADHD drugs, after DEA wrongly blocked the company from raw materials necessary to make these critical medications. The U.S. is in the midst of a public health crisis over a critical shortage of ADHD medications. 62% of the more than 6 million children diagnosed with ADHD take medication. The U.S. is more than 1 billion dosage units short.

The lawsuit accuses DEA of misunderstanding its own recordkeeping requirements, blocking Ascent’s manufacturing over a series of the agency’s own errors and misunderstandings. The complaint alleges that, while there were some clerical errors in some of its records, none of them normally would cause a manufacturer from be shut down, particularly not in the middle of a crisis of scarcity over the drugs it makes. The nationwide shortage has been cited as increasing the risk of depression, anxiety, learning difficulties and suicide in ADHD patients, particularly children.

The lawsuit is supported by two nationally renowned experts of DEA’s own rules and regulations, one of whom called the shutdown “without precedent” and “particularly problematic.” Worse, the suit accuses the DEA of retaliation against Ascent, since its action came two days after Ascent filed suit to restore its access to procure materials necessary to manufacture ADHD medications. Ascent has been in business for twelve years and has never had any prior regulatory violations or sanctions.

The lawsuit was filed in the U.S. Court of Appeals for the Second Circuit by **Jim Walden** of Walden, Macht & Haran.

Walden, the lawyer for Ascent, says, “This case highlights the dangers of administrative agencies that act rashly and based on incorrect information, yet have a pervasively negative impact on health-care outcomes. ADHD patients do not deserve this and nor does Ascent. We hope the Court acts quickly to turn the situation around.”

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