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DOJ Settlement Looks to Set New Benchmarks for Suspicious Order Monitoring

I. Introduction

This week, the U.S. Department of Justice and Drug Enforcement Administration announced a \$35 million settlement with a major pharmaceutical manufacturer to resolve alleged failures to monitor and report suspicious orders for controlled substances. The resolution, negotiated by Ropes & Gray, represents DOJ's first attempt to impose civil liability on a manufacturer for failing to monitor sales of controlled substances between distributors and retailers downstream in the distribution chain. Through the settlement, DOJ purports to impose additional burdens on pharmaceutical manufacturers to root out suspicious activity—despite uncertain regulatory support—as government authorities struggle to combat the broader problem of prescription drug abuse.

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II. Suspicious Order Monitoring Allegations

Following several multimillion-dollar settlements with pharmaceutical distributors under the same regulation, this week's resolution with Mallinckrodt Pharmaceuticals marks the first time DOJ has attempted to enforce DEA's "suspicious order monitoring" requirement against a pharmaceutical manufacturer. DEA rules require all manufacturers and distributors of controlled substances to maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern. *See* 21 C.F.R. §1301.74(b). DEA has provided little guidance on how to implement that requirement, leading to substantial uncertainty regarding the scope of the obligation. That uncertainty was especially acute among manufacturers, which are often several steps removed from the point in the supply chain where diversion takes place.

DOJ nonetheless pursued aggressive allegations against Mallinckrodt regarding the alleged duty to monitor orders for its products. Mallinckrodt has long sold generic opioid pain relievers to DEA-registered pharmaceutical distributors, which in turn sell the products to DEA-registered pharmacies. The company maintained a suspicious order monitoring program consistent with industry standards throughout the relevant period. Yet DOJ alleged that, between 2008 and 2011, the company failed to report suspicious orders for oxycodone tablets, at a time when rates of opioid abuse were on the rise. DOJ argued that those failures exposed the company to expansive civil penalties under the Controlled Substances Act.

In what DOJ described as a "groundbreaking" shift, the government asserted that manufacturers must take steps to monitor not only sales to their distributor customers, but also sales between those distributors and downstream pharmacies with no involvement by the manufacturer. In particular, DOJ claimed that manufacturers must review data associated with chargebacks—a common pharmaceutical pricing mechanism—to the extent it reveals useful information regarding downstream distributions of controlled substance products. In essence, these allegations sought to extend the suspicious order monitoring obligation from a manufacturer's customers to its "customers' customers."

Mallinckrodt resolved the investigation for \$35 million, denying any violation of the suspicious order reporting regulation. In addition, the company entered a forward-looking Memorandum of Agreement governing suspicious order monitoring, review of data related to downstream distribution, physical security and recordkeeping. The

settlement also resolved allegations focused on DEA-required records at the company's manufacturing facility. Although DEA has historically addressed most recordkeeping issues informally, DOJ instead pursued civil penalties as part of an overall resolution with the company.

III. Key Take-Aways

DOJ indicates that it intends the settlement announced this week to set a benchmark for other manufacturers. Specifically, DOJ suggested that the resolution reflects a purported requirement that manufacturers examine their "customers' customers," and extend their monitoring to the "next level" down the supply chain. As one DEA official put it, manufacturers must "know[] the downstream customer" and use "all resources and tools" at their disposal to detect suspicious orders. The legal basis for those "requirements" remains uncertain at best, and DOJ's statements leave open many questions about how far manufacturers must go to comply with DEA rules.

Yet DOJ's statements make clear that the Department is ratcheting up expectations for manufacturers that have long been out of the line of fire in the fight against prescription drug abuse. At minimum, controlled substance manufacturers should take this opportunity to assess the current state of their suspicious order monitoring program, what additional data sources may be available, and the extent to which DOJ may argue that more should be done.