Should DEA Provide Guidance and Conduct Rulemaking on Suspicious Orders to Ensure a Balanced Approach to Reduce Abuse and Ensure Availability of Needed Medicine?

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I. INTRODUCTION

The increase in prescription drug abuse in the United States is the result of multiple factors (e.g., rogue Internet pharmacies, pain clinics, and doctor shopping) often requiring law enforcement and the regulated industry to play catch-up to address the ever-changing sources of diversion. However, the bulk of the Drug Enforcement Administration’s (DEA) enforcement efforts have been directed at placing more responsibility on the regulated industry, most notably wholesale distributors, to police its customers. While some legislation has been passed to assist both DEA and the industry to root out unlawful activity, most notably the Ryan Haight Online Pharmacy Consumer Protection Act, DEA has failed to provide sufficient guidance in areas, such as suspicious order monitoring and dispensing practices, to be effective.

The lack of a clear standard or understanding of DEA’s expectations for the regulated industry, especially as related to legal and regulatory requirements, is forcing companies to limit, and in some cases make arbitrary distribution or dispensing decisions, out of fear of facing significant enforcement action. DEA’s recent administrative and civil enforcement actions against distributors has, fairly or unfairly, reinforced these concerns.

In short, DEA should engage the regulated industry, healthcare professionals, and other stakeholders in discussions resulting in clear guidance and regulations that would allow stakeholders to comment on, and play a role in, establishing criteria that would identify suspicious and illicit activity and prevent diversion of prescription drugs. This approach not only would minimize the risk of controlled substances being diverted, but would also ensure that legitimate pharmacies and patients are able to obtain needed medicines.
II. BACKGROUND

Prescription drug abuse is acknowledged to be the fastest growing drug problem in the United States. The Centers for Disease Control and Prevention (CDC) has classified prescription drug abuse as an epidemic. At the center of this problem is the abuse of controlled substances, including narcotic drugs, which have a significant potential for abuse and dependence when not used for legitimate medical purposes.

Regulation of controlled substance prescriptions rests with DEA. DEA is primarily a law enforcement agency. However, Congress, in passing the Controlled Substances Act (CSA), established requirements to prevent, detect, and investigate the diversion and abuse of legitimate medicines while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific purposes; a delicate balance, to be sure. The Office of Diversion Control is the regulatory branch within DEA which carries out this function and has oversight over 1.4 million registrants.

The CSA establishes a “closed” system of controlled substance distribution under DEA oversight that is intended to account for controlled substances from manufacturing to the ultimate consumer. This is accomplished by requiring certain registration, quota, recordkeeping, inventory, security, and reporting requirements for all registrants who handle controlled substances. This regulatory scheme has been effective in ensuring that DEA and registrants track and account for controlled substances manufactured, stored, distributed, and ultimately dispensed to patients. However, the increase in prescription drug abuse has resulted not as much from theft or diversion of controlled substances, (although this is also a concern, especially given the increase in pharmacy thefts), but from new schemes devised by criminals to get access to controlled substances under the guise of legitimate medical practice.

POLICY RECOMMENDATIONS BOX

• DEA should engage in formal Administrative Procedure Act (APA) rulemaking procedures that provide distributors and other stakeholders notice and an opportunity to comment on proposed regulations to address the requirements for suspicious order reporting.

• DEA regulations should establish meaningful and clear criteria or other standards for identifying, monitoring, and reporting suspicious orders.

• DEA should communicate, collaborate, and partner with industry so that it can most effectively and efficiently engage in suspicious order identification, monitoring, and reporting responsibilities.
The use of fictitious prescriptions by rogue Internet pharmacies, which became increasingly problematic in 2004 to 2008, is one means by which controlled substances are diverted to individuals who do not have a legitimate medical need for such medicine or are able to receive the medicine without proper medical supervision. More recently, brick and mortar pain clinics have sprung up in many parts of the country, and while practitioners at these clinics almost always are appropriately licensed with both the state and DEA, authorities have questioned their prescribing practices and raised allegations that their practices have led to diversion and abuse.

DEA has taken action against a number of practitioners who fail to prescribe for a legitimate medical purpose in order to root out rogue pharmacies that fill fictitious prescriptions without medical care. DEA has also taken action against distributors in cases where DEA believes the industry has failed to meet its responsibilities. Such enforcement action has resulted in suspensions and significant civil penalties, primarily against distributors and some pharmacies. However, at the same time, DEA has failed to sufficiently establish a clear understanding of what it expects of the regulated industry in a manner supported by the law and regulations. It is clear from current action that DEA expects the regulated industry to police its customers and act as “gatekeepers” to preventing diversion. However, current regulations of the CSA and DEA provide little detail or guidance on the extent of these responsibilities. Registrants have implemented steps to develop suspicious order monitoring procedures and, in many cases, establish thresholds or limits on distribution of controlled substances. However, without clear guidance from DEA, many of these due diligence measures are arbitrary.

DEA’s enforcement actions have produced results. As DEA Administrator Michele Leonhart testified in May 2011 before Congress, as a result of DEA’s Distributor Initiative Program, some distributors voluntarily stopped selling controlled substances or voluntarily restricted sales to certain pharmacies and practitioners. She noted that from June 2006 through the middle of May 2011, distributors refused to sell controlled substances to approximately 1,517 customers who “the distributors believed were placing suspicious orders for controlled substances.” While the distributors’ actions have undoubtedly reduced the risk of controlled substance diversion, they have also created a chilling effect on the industry and appear to have adversely affected patient care.

For example, on October 2, 2012, a bipartisan group of thirteen congressional members penned a letter to Administrator Leonhart of DEA requesting “clarification, guidance and collaboration” with respect to DEA’s efforts to combat prescription drug abuse. While voicing support of DEA’s efforts, the letter states that recently “pharmacies across the country have identified a disturbing trend that is threatening the ability of legitimate patients from getting needed, lifesaving prescription drugs.” The letter asserts that small pharmacies have experienced difficulty obtaining certain controlled substances because wholesalers have severely limited or stopped sales. It expresses concern “that inconsistent interpretation and application of DEA policies, and a lack of clear guidance and communication from DEA to supply chain stakeholders, are leading to patient care issues and supply chain disruption.”
The concerns raised in this congressional letter illustrate that additional guidance is needed to not only prevent diversion, but to ensure that legitimate patients continue to have access to their medicine.

III. ISSUES IN DISPUTE

A. Lack of Statutory or Regulatory Criteria for Identifying and Reporting Suspicious Orders

The CSA requires distributors (and all registrants) to maintain effective controls to guard against the diversion of controlled substances into other-than legitimate medical, scientific, or industrial channels. Effective controls against diversion are among the public interest factors that DEA considers when issuing or taking action against a DEA registration. In addition, DEA regulations have long required non-practitioners, including distributors and manufacturers, to “design and operate a system to disclose suspicious orders of controlled substances” to the registrant and to “inform” the local DEA Field Division about suspicious orders upon discovery. Interestingly, there is no statutory requirement for suspicious orders. The suspicious order regulation broadly and somewhat vaguely defines suspicious orders as including “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” DEA also requires registrants, before distributing controlled substances, “to make a good faith inquiry” with DEA or the appropriate state authority to determine that the intended recipient is registered to possess controlled substances.

So, while DEA regulations provide that distributors must establish a system to detect suspicious orders, to report them when discovered, and to verify that their customers are properly authorized by DEA, and the state to handle controlled substances prior to distribution to them, DEA provides no specific criteria on how such systems should be maintained. In fact, the regulations do not even provide a method or procedure for how suspicious orders should be reported to DEA.

Prior to DEA’s recent initiatives, distributors historically filled controlled substance orders and reported to DEA those it deemed “excessive” (and thus possibly suspicious), usually at the end of every month. In many cases, these reports consisted of transactions that had exceeded the average purchase by some significant amount: they did not necessarily indicate that the registrant had found them to be suspicious. In fact, DEA worked with several distributors on the parameters of these reports and accepted this process for years without objection. Distributors filled and shipped “excessive” controlled substance orders, but the monthly reports allowed DEA to review the sales within a couple of weeks after shipment. We are aware of cases where DEA encouraged some distributors not to decline excessive orders for fear that such a denial might lead unscrupulous customers to buy smaller quantities from numerous distributors, and thus impede potential DEA investigations.

It was not until 2005, in response to the growing concern about diversion of hydrocodone by rogue Internet pharmacies, that DEA began to focus on the requirements for “suspicious orders.” However, more than just enforce the existing requirements, DEA’s “Distributor Initiative Program” imposed new standards for reporting suspicious orders. While not prohibited by either statute or regulation,
DEA began to expressly prohibit distributors from filling “suspicious orders” of controlled substances sought by DEA-registered pharmacies and other registrants. DEA also began using newly-created suspicious order identification and reporting “requirements” as a weapon against prescription drug abuse.

DEA’s Distributor Initiative Program drastically expanded the traditional gatekeeper responsibilities to supply “chokepoints” higher up the distribution chain, including distributors and even manufacturers. DEA now expects distributors to be accountable for their pharmacy customers’ dispensing of controlled substances pursuant to prescriptions that were issued (albeit by DEA-registered practitioners) for other than legitimate medical purposes.

DEA has taken significant actions against distributors for not, from DEA’s perspective, complying with their suspicious order responsibilities, though such criteria, duties, or other responsibilities are not defined in the law or DEA regulations. DEA has immediately suspended, revoked, and denied distributors’ DEA registrations for suspicious order monitoring and reporting violations. The Agency has also pursued significant civil penalties for failure to maintain systems to detect and report suspicious orders of controlled substances despite the lack of clear standards and criteria.


As part of its Distributor Initiative Program, DEA sent letters to all registered distributors in September 2006 and to every registered distributor and manufacturer in December 2007 “to reiterate” their suspicious order reporting responsibilities. However, these requirements were largely new to the industry and not created as part of any formal agency Administrative Procedure Act (APA) rulemaking process. The two form letters stated generally: (1) what a “suspicious order” may look like; (2) what a distributor may do to detect such orders, and (3) a threat that failure to comply with suspicious order monitoring and reporting “requirements” will subject registrants to administrative action and possibly revocation of their DEA registration. DEA also met with a number of distributor registrants throughout the country to address DEA’s suspicious order monitoring and reporting expectations.

1. DEA Letter of September 26, 2006

DEA sent its first letter to all distributors on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly stated that a distributor, in addition to reporting suspicious orders, has a statutory responsibility not to fill suspicious orders that might be diverted into illicit channels, and failure to do so could provide a basis for registration revocation or suspension. The letter cautioned distributors not to rely on customers holding a DEA registration and against “turn[ing] a blind eye to the suspicious circumstances.” The letter asserted that distributors must confirm the legitimacy of all orders before filling them. DEA’s letter set out indicators that pharmacy customers might be dispensing controlled substances for other than legitimate purposes. DEA concluded by warning that “[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA
will do when determining whether the filling of an order with the public interest is within the meaning of 21 U.S.C. § 823(e).”

The letter established that distributors must not fill orders where the controlled substances “might be diverted.” Most importantly, the letter did not provide any substantive guidance about what distinguishes a legitimate order from a suspicious, and therefore unfillable and reportable, order.

2. DEA Letter of December 27, 2007

DEA sent a second letter to both distributors and manufacturers on December 27, 2007. This letter advised distributors that they cannot construe any past “implicit or explicit approval” of a suspicious order monitoring system as meeting current DEA approval. DEA thus warned distributors that they cannot rely upon DEA’s prior explicit or implicit approval that their suspicious order monitoring and reporting systems comply with current DEA requirements.

The second letter noted that filling suspicious orders, but reporting them afterwards, “does not meet the regulatory requirement to report suspicious orders” and that distributors must independently analyze every order prior to completing a sale to determine whether controlled substances “are likely to be diverted.” DEA thus disavowed its longstanding practice of permitting distributors to fill orders and submit to DEA monthly excessive purchase reports. The letter explained that whether an order is also suspicious depends on ordering patterns of the customer, on patterns of the distributor’s customer base, and on “patterns throughout the relevant segment of the regulated industry.” So, registrants must know their customers and how their orders compare with those of other customers and with those of others in the industry. Lastly, the letter advised recipients to consult the obligations outlined in DEA’s final order in the Southwood Pharmaceuticals case.

In Southwood Pharmaceuticals, DEA revoked the manufacturer registration of a repackager of schedule III-V controlled substances. DEA noted that Southwood sold 44,087,355 dosage units of hydrocodone to Internet pharmacies in Florida between December 2005 and November 2006, with monthly sales escalating from 1.44 million dosage units to 5.78 million dosage units during that time. DEA found that “orders of the Florida-based Internet pharmacies were suspicious from the outset because of their large size, their frequency and the fact that controlled substances constituted the overwhelming percentage (and frequently 100 percent) of the products being purchased.” DEA also noted Southwood’s due diligence efforts were limited to verifying customers’ DEA registration and state licenses. DEA had discussed issues related to illegal Internet pharmacies and suspicious orders with Southwood representatives, yet in DEA’s opinion Southwood continued to sell large quantities of hydrocodone to Internet pharmacies, including to six specifically mentioned by DEA as “targeted.”

However, DEA revoked Southwood Pharmaceuticals’ DEA registration in part because the repackager continued to sell hydrocodone to six Internet pharmacies that DEA referred to in the briefing as “targeted.” Southwood personnel specifically asked DEA personnel during a DEA briefing whether it should stop shipping controlled substances to the Internet pharmacies, and
agency representatives responded that they “cannot tell a distributor whether a particular order is legitimate or not…and that whether to ship was a business decision.”

Therefore, while DEA identified a number of troubling issues related to distribution by Southwood, the Agency still has not taken any action to promulgate additional guidance or rulemaking to establish a comprehensive regulatory scheme or criteria to be followed by industry to identify and report suspicious orders.

IV. RESPONSE TO ISSUES

A. Ad Hoc Due Diligence Programs, Thresholds, and Suspicious Order Reporting

Distributors have responded to lack of guidance by adopting due diligence programs consisting of questioning situations, arbitrary thresholds, and creating reporting formats and criteria to satisfy DEA. However, the industry continues to struggle with legal and regulatory requirements and bases for DEA’s expectations concerning suspicious order identification, monitoring, and reporting.

Based on DEA’s communications with industry and its threat of enforcement actions during the past five years, most distributors have carefully, and repeatedly, reviewed and enhanced their customer due diligence, suspicious order identification, and reporting policies and procedures. These new policies include enhanced customer questionnaires and other due diligence inquiries. Some require on-site inspections of their customers’ facilities. Distributors have further grappled with how to review each and every controlled substance order. Distributors have set controlled substance order thresholds that range from the simple to the highly algorithmic. Some require reports that allow them to monitor where, what, and to whom their customers are dispensing, and to detect what products they buy from other sources. Some distributors have stopped selling controlled substances to pharmacies and other customers if even slight doubts are present. Despite all of their efforts and enhancements, distributors continue to lack confidence that they are complying with what DEA expects, especially given the lack of regulatory guidance.

B. Recommended DEA Actions

1. Notice and Comment Rulemaking

The APA sets forth the statutory process by which federal agencies announce and implement new rules and regulations. The APA defines a rule, in relevant, part as: “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy”—which is exactly the purpose that DEA intended its suspicious order monitoring and reporting guidance to serve.

DEA’s industry letters of April 2006 and December 2007 stated that its purpose was “to reiterate the responsibilities” of distributors with respect to suspicious orders. But the letters plainly established new substantive rules that specifically require distributors not to fill the orders they deem suspicious.
DEA combined this new prohibition with the longstanding requirement in 21 C.F.R. § 1301.74(b) that distributors design a system to detect suspicious orders and to inform DEA when they are discovered. DEA has exacted administrative sanctions and civil fines against distributors despite a clear standard under the CSA or the relevant suspicious order monitoring regulation, at 21 C.F.R. § 1301.74(b).

DEA’s reliance on industry letters and other ad hoc communications in lieu of formal notice and comment rulemaking to make a statement of “general or particular applicability … designed to … interpret or prescribe law or policy” is problematic for at least one additional reason. DEA claims it sent letters to all 814 registered distributors in September 2006 and all 819 registered distributors and 510 manufacturers in December 2007. However, there is no evidence this same information was provided to practitioners; a significant problem, given that practitioners have been the source of the current problem.

Reliance upon the letters alone, in addition to depriving notice to some registrants, also deprived all distributors as interested stakeholders of the ability to provide any comment upon DEA’s “new rule.” The APA states that after publication of an initial notice of rulemaking, the agency “shall give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments with or without the opportunity for oral presentation.” Then, “[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.”

A rulemaking would provide distributors and other interested persons, including practitioners, the opportunity to comment upon DEA’s proposed rule addressing suspicious order monitoring. DEA should consider and address invaluable industry and stakeholder input and public comments when finalizing suspicious order monitoring regulations. Prospectively, DEA should publish a proposed rule in the Federal Register, consider public comments, and then issue a final rule setting forth clear and concise standards for detecting and reporting suspicious orders of controlled substances.

As part of any regulation, DEA should identify a distributor’s responsibilities and include or otherwise address factors that indicate that orders may be suspicious. At present, there is no comprehensive criteria for distributor suspicious order identification and reporting requirements. Nor is there one for the so-called “red flags” to which DEA alluded in the 2006 and 2007 industry communications, and during distributor meetings. Distributors attempting to comply with DEA’s requirements are left to rely on an outdated regulation, 21 C.F.R. § 1301.74(b), DEA’s September 2006 and December 2007 letters (if the distributor received them), the DEA educational briefings (if the distributor was among those briefed) and the Southwood Pharmaceuticals case.

DEA may also consider conducting a negotiated rulemaking. Such action is provided for under the APA and is intended in cases like this where a discussion between industry and the government may benefit the public.
2. Increased DEA and Industry Communications

DEA stated that it designed its Distributor Initiative Program to educate distributors who were supplying rogue Internet pharmacies and, more recently, rogue pain clinics and pharmacies. Its goal was to increase distributor awareness and vigilance in an effort to cut off the source of supply for diversion. However, DEA's Distributor Initiative Program, through May 13, 2011, appears to have provided “educational briefings” to only 75 DEA-registered corporations and companies that control 215 distribution centers regarding their enhanced suspicious order responsibilities. There were 793 DEA-registered distributors in May 2011. Thus, during the Initiative’s first six years, DEA appears to have briefed only 215 distributors, or 27% of those registered with DEA, averaging one educational briefing per month.

Unlike registrants, DEA has access to data and other information sources that allows it to track customer purchases and dispensing. DEA receives data concerning schedule I, II, and III narcotics acquisition and distribution data from all distributors through its ARCOS database. DEA also has access to pharmacy dispensing information reported to a number of state Prescription Drug Monitoring Programs. DEA has significant visibility into certain aggregate and individual-controlled substance purchases and dispensing by individual pharmacies; distributors do not. DEA should provide meaningful information that it has gleaned from sources unavailable to individual distributors to assist them in their suspicious order monitoring efforts. DEA must refrain from simply using such valuable information against distributors and other registrants in enforcement proceedings.

Despite its primary law enforcement role, DEA needs to find ways to communicate with the regulated industry for the benefit of the public. Additional public meetings and forums would be a meaningful way for DEA and the industry to understand the problems of diversion and take steps to address these serious public health issues. DEA recently held a well-received public meeting on the disposal of controlled substances. This trend should continue. It is also worth noting that in relation to the suspicious transactions involving chemicals, Congress required DEA to establish a suspicious orders task force where industry and the Agency were able to discuss proposals and recommendations on “actions to curtail access to chemicals and other laboratory supplies while assuring legitimate needs are served.” DEA posted suspicious chemical order guidance developed by the task force on the Diversion Control website and published it in its Chemical Handler’s Manual. Such initiatives would be helpful in the current environment.

V. CONCLUSION

Prescription drug abuse is this nation's fastest growing drug problem and DEA is charged with taking action to reduce diversion and abuse. But as the recent congressional letter to DEA states, improved communication between DEA, distributors, and others in the supply chain “will ensure that these stakeholders understand and perform their legal and ethical responsibilities and will result in less prescription drug abuse.” In the current environment, distributors have been forced to develop ad hoc and, at times, arbitrary standards and thresholds in distributing to customers for fear of selling “too much,” which DEA may then view as a suspicious order. Minimizing the risk
of controlled substance diversion by selling to customers likely to divert while helping to ensure that legitimate patients receive needed medication requires regulations promulgated through notice and comment rulemaking to ensure a clear standards of universal applicability. A rulemaking proceeding would ensure that DEA identifies a legal and regulatory basis for requirements imposed on industry in regard to suspicious orders. It would also provide distributors and other stakeholders the opportunity to comment and establish clear and concise standards for identifying and reporting suspicious orders. DEA should also pursue additional ways to communicate and collaborate with industry to continue to develop policies and procedures to address the prescription drug abuse problem.

ENDNOTES

2. This article uses the term “distributor” and “distributors” to refer to DEA-registered distributors and manufacturers.
5. Id.
7. Id.
8. Id.
9. 21 U.S.C. § 823(a)(1), (b)(1), (d)(1) and (e)(1); 21 C.F.R. § 1301.71(a).
10. Id.
11. 21 C.F.R. § 1301.74(b).
12. In contrast, when Congress promulgated laws to address the diversion of precursor chemicals, it did establish a suspicious transaction reporting requirement for such chemicals only. [cite]
13. Id.
14. 21 C.F.R. § 1301.74(a).
15. Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA (Sept. 27, 2006).

16. Id.

17. Id.

18. Id.

19. Indicators included pharmacies that order: excessive quantities of a limited variety of controlled substances; a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered; excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs; or the same controlled substances from multiple distributors. Id.

20. Id.

21. Id.


23. Id.

24. Id.

25. Id.

26. Id.


28. Id. at 36,497.

29. Id. at 36,491.

30. Id. at 36,493.

31. Southwood, 36,493.

32. Id.


34. Id.

35. 5 U.S.C. § 553(c).
36. Id.

37. 5 U.S.C. §§ 561-570.

38. Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA, Before the Caucus in International Narcotics Control, United States Senate, July 18, 2012. 9.


41. 21 C.F.R. § 1304.33(b) and (c). GHB, a schedule III non-narcotic substance, is also subject to ARCOS reporting. 21 C.F.R. § 1304.33(c).


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