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Pharmaceutical Diversion – Risks and Steps to Address a Major DEA Focus

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I. Introduction

The opioid crisis, an ever-increasing focus of the Obama administration and 2016 Presidential Primary field, has highlighted the efforts of the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ) to address diversion of pharmaceuticals classified as controlled substances, which has long been a major DEA priority. Criminal and civil cases brought or settled by DEA and DOJ show the substantial risks involved for those in the chain of distribution of pharmaceuticals subject to the Controlled Substances Act. The following is a practical summary of these issues.

II. Overview of Criminal and Civil Risks

On the criminal side, DOJ and DEA have been very active. In April 2015, DOJ created a National Heroin Task Force co-chaired by U.S. Attorney David Hickton (W.D. Pa.) and White House National Drug Control Policy official Mary Lou Leary, designed to concentrate federal agency experts from law enforcement, medicine, public health, and education on coordinating a joint-response to the heroin crisis in America, including prescription opioid diversion and abuse. Approximately one month later, DEA and DOJ announced their largest-ever prescription drug operation -- "Operation Pilluted" -- which DEA touted as an unprecedented enforcement action across at least four states resulting in arrests of 22 doctors and pharmacists over 15 months, involving nearly a thousand law enforcement officers and 280 total arrests. Among other charges in the past year, DEA and DOJ also unsealed an indictment in October 2015 against three individuals and two pharmacies for a multimillion-dollar oxycodone distribution scheme that allegedly flooded New York City with illegal controlled substances.

Perhaps more ominously, in 2014, DOJ began pursuing a theory of novel criminality when it obtained an indictment charging FedEx with, among other things, conspiracy to distribute controlled substances and distribution of controlled substances. The crux of the FedEx indictment is the allegation that FedEx knew it was transporting controlled substances on behalf of allegedly illegal internet pharmacies. At the time, DOJ commented that the indictment highlighted the importance of holding corporations responsible for knowingly enabling illegal activity. FedEx disagreed strongly, and argued that it had asked the government for a list of illegal pharmacies, withheld its services from these pharmacies after receiving the government's list, and that the company should not be held responsible for determining the legality of its customers' businesses. This case is a potential game-changer if DOJ prevails, as it may put a higher burden on companies to conduct surveillance of their own customers to detect potential criminal activity involving controlled substances, perhaps like the burden the government already puts on financial services companies to file SARs,

reports of suspicious activity, where potential money laundering or other financial crimes may be afoot.

DOJ has also focused on taking action against individuals who may be responsible for criminal activity, not just their employer-companies. The call for DOJ to pursue individuals in white collar cases has grown amidst strong criticism for its failure to charge individuals in connection with the 2008 financial crisis. In September 2015, that call got louder when DOJ's Deputy Attorney General, Sally Quillian Yates, issued a memorandum to DOJ staff revising the principles guiding criminal and, indeed, civil enforcement in corporate criminal investigations. In it, she emphasized DOJ's focus on targeting individuals and introduced a new technique -- bringing civil lawsuits against individuals where criminal charges might fail, even if the individual has an inability to pay -- all to drive the deterrence message home. And corporations that seek to garner credit with DOJ for cooperating in criminal cases must provide DOJ with all relevant facts regarding individuals responsible for any misconduct to help DOJ build a criminal or a civil case.

On the civil side, DOJ and DEA have been equally aggressive in pursuing their anti-diversion agenda. In the fall of 2015, DEA settled with a major teaching hospital, which paid $2.3 million, the largest diversion settlement involving a hospital, after the hospital self-reported that rogue employees stole as many as 16,000 pills, primarily oxycodone. In 2013, a major pharmacy chain agreed to pay $80 million, a record amount, to resolve federal charges that it failed to properly control the sale of narcotic painkillers, including alleged record keeping and dispensing violations. Another such chain agreed to settle similar allegations in 2013 for $11 million, and then twice again in 2015 for $450,000 and $22 million. In 2008, DEA and DOJ extracted a total of $48 million to settle allegations against a company for allegedly failing to alert DEA to "suspicious" orders by Internet pharmacies. DEA has reached other significant settlements with a wide range of defendants, from major hospitals to small medical practices, arising from allegations that these entities failed to notify DEA of employee theft of controlled substances within the time frame required by federal regulations, failed to provide effective controls and procedures to guard against theft and diversion of controlled substances, or failed to maintain complete and accurate records and inventories of all controlled substances that they received, sold, delivered, or otherwise disposed of.

The bottom line is clear. The federal government's focus on diversion is highly unlikely to diminish, particularly in light of the attention currently being paid to opioid abuse, and it will seek to use criminal and civil penalties against companies and individuals to enforce the law. As a result, *every individual and company registered with the DEA to handle controlled substances ("registrant") in the supply chain* -- from manufacturers, to distributors, medical practices and pharmacies, and individual practitioners and pharmacists, regardless of size or prominence -- *as well as those that provide services for such companies*, like transportation or financial services companies -- *must be cognizant of the risks of government enforcement in this area*. DEA's intricate recordkeeping requirements are problematic for any registrant, whether a manufacturer, distributor, physician, or pharmacist. Moreover, while negligence is technically required to show a violation, registrants who act in good faith may still face investigations and sanctions. Each alleged violation carries with it a civil penalty of up to $10,000, and courts have not settled on a single method of tabulating individual violations, which provides DEA with leverage to pursue theories whereby a single alleged recordkeeping deficiency can carry multiple penalties.

Because of the risks inherent in this area, DEA registrants are well advised to focus on preventing violations before they occur, through comprehensive and thoughtful policies and procedures, and if issues do arise, to address them aggressively and proactively.

III. Enhancing Diversion Policies And Procedures

DEA's regime for enforcing potential diversion of otherwise legitimate pharmaceuticals is complex, particularly with regard to recordkeeping, reporting, and other related requirements. Adopting conservative policies, rather than permitting lawful but borderline conduct, is often wise.

Doing so requires carefully tailoring policies to the registrant's business needs. Even DEA's Practitioner's, Pharmacist's, and Chemical Handler's (i.e., manufacturer) Manuals, which each provide a helpful overview of the DEA's compliance requirements, contain disclaimers that they are only intended to "summarize and explain the basic requirements . . . under the Controlled Substances Act," not provide an exhaustive compendia of DEA's requirements. Moreover, DEA requires registrants to comply with state requirements as well, according to whichever requirement is "stricter." Such requirements vary from state to state, and interact differently with federal law and regulations.

Below is a summary of general recordkeeping and other related requirements most likely to trigger DEA scrutiny, which should be specifically tailored to a registrant's particular circumstances:

a. Registration

DEA regulations contain a host of requirements regarding who must register and who may be exempt from registration to handle controlled substances, which can vary in application for manufacturers, distributors, practitioners, and pharmacies. Regardless of these exemptions, the best practice may be to read these registration requirements broadly. Further, policies should require employees to be familiar with federal and state controlled substances requirements and expressly prohibit any conduct that violates them (including whichever source of law is stricter). They should also specifically prohibit:

- Filing a materially false application for registration to handle controlled substances;
- Mishandling controlled substance or listed chemicals;
- Having their DEA and/or state license or registration suspended, revoked, or denied; and/or
- Using a DEA registration number for any purpose other than to provide certification of DEA registration in transactions involving controlled substances, including for identification.

A registrant's policies should also mandate that registrations be kept current, renewed, and on hand as required by applicable law and regulation, and note that disciplinary action, up to and including termination, may occur if they are violated. Companies should provide appropriate training to comply with these requirements.

b. Ordering Controlled Substances

DEA generally requires that controlled substances in Schedules I and II not be ordered or transferred unless accompanied by DEA's order form (DEA Form 222). Businesses that handle and transfer controlled substances should expressly identify those individuals authorized to transfer substances using DEA Forms 222 and prohibit all others from doing so. Registrants should also require that the transfer of controlled substances in schedules III-V be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred, and also include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

c. Inventorying Controlled Substances

DEA's inventorying regulations vary for manufacturers, practitioners, and pharmacists. Generally, however, businesses should consider appointing a specific employee or group of employees in each place of business with controlled substances on hand to be responsible for inventories, and should at a minimum:

- ensure all employees maintain and preserve inventories and records of controlled substances listed in Schedules I and II separately from all other records, and records of controlled substances in Schedules III, IV, and V separately or in such a form that they are readily retrievable from ordinary business records;
- maintain and preserve records of receipt, prescription, dispensation, sale, administration, and distribution of controlled substances;
- maintain and preserve a log reflecting each deposit and withdrawal of controlled substances into or from the location in which controlled substances are required to be kept (for which there can be specific requirements depending on the type of business at issue);
- ensure that all records related to controlled substances are maintained and available for inspection for a minimum of two years;
- conduct and document an initial inventory -- a complete and accurate record of the controlled substances on hand -- reflecting the date that the initial inventory was conducted;
- perform and document a new inventory of all controlled substances on hand every two years and reflect the date that the inventory was conducted;
- require that all inventories be written, typewritten, or printed on an official inventory form adopted by the business, and be maintained at the registered location for at least two years from the date that the inventory was conducted;
    - additionally, whenever a controlled substance not previously listed on a Schedule becomes listed, and the business has such controlled substance on hand, the designated employee must ensure that that controlled substance is inventoried on the effective date of the regulation listing it and include it in each inventory thereafter;

- ensure that the business maintains records and inventories on a current basis of controlled substances received, distributed, administered, dispensed, or otherwise disposed of by the business, and including:
  - whether the inventory was taken at the beginning or close of business;
  - the name of the substance;
  - the size of each finished and unfinished form in metric weight or volume;
  - the number of units or volume of each finished and unfinished form;
  - the number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle);
  - the number of commercial containers of each finished form (e.g., four 100 tablet bottles);
  - the date received;
  - the name, address, and DEA registration number of the person from whom the substance was received;
  - the name, dosage and strength per dosage unit of each controlled substance administered or dispensed;
  - the name and address of the person for whom the controlled substance was administered or dispensed and whether administered or dispensed by delivery or dispensed by prescription;
  - the date of the administration or dispensing;
  - the written or typewritten name or initials of the person who administered or dispensed the controlled substance; and
  - the name and number of units or volume disposed of in any other way, including the date and manner of disposal.

Note also that while an inventory must be conducted and finalized biennially, certain information, e.g., the disposition of controlled substances (including dosage and number of units to specific patient and other information), must be entered and maintained on a current basis.

d. Reporting Stolen Or Lost Controlled Substances

This is perhaps the most problematic of DEA's requirements. DEA regulations require that a registrant promptly report stolen and "significant" losses of controlled substances to DEA in writing, including filing a DEA Form 106. Though there may be arguments to the contrary, the best practice is likely to require employees to report any loss or misplacement of controlled substances to a designated employee (or set of employees) responsible for determining whether any such theft or loss should be reported to DEA and/or an equivalent state agency, and who, if filing is deemed appropriate, will report such theft or loss using DEA Form 106 and any state equivalent promptly. Although some states may provide exemptions from reporting misuse of controlled substances by doctors or other medical

professionals, our experience is that DEA will resist the application of such programs to excuse reports to DEA of thefts or losses pursuant to DEA regulations.

e. Validly Using And Prescribing Controlled Substances

1. Prohibiting Misuse of Controlled Substances

Businesses should strictly prohibit misuse of controlled substances in any manner, specifically including controlled substances ordered, received, or otherwise possessed by the business for any unauthorized purpose, and also including use of such controlled substances for any purpose or use outside the registrant's business. Policies should also note that disciplinary action, up to and including termination may occur if these provisions are violated.

2. Prescribing Requirements

Businesses involved in prescribing, and/or dispensing controlled substances should, at minimum, require that prescriptions be dated and signed on the date issued, include the patient's full name and address, and also the prescriber's full name, address, and DEA registration number. The prescription should additionally include the:

- drug name;
- strength;
- dosage form;
- quantity prescribed;
- directions for use; and
- number of refills (if any) authorized.

Prescriptions for controlled substances should also be written in ink or indelible pencil or typewritten and must be manually signed by the prescriber on the date issued, and should make the relevant registrant employee(s) responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both state and federal. In addition to being registered with DEA (and the appropriate state source(s)) to prescribe controlled substances, registrants may wish to further specify which employees may issue prescriptions in order to better monitor prescribing practices.

Moreover, a valid prescription requires a legitimate medical purpose and that the issuing practitioner is acting in the usual course of professional practice -- which the registrant's policies should specify. Prescriptions issued to obtain controlled substances for general dispensing to patients violate these requirements. Note also that prescription requirements vary according to whether Schedule II or Schedule III through V drugs are involved.

Policies should also make clear that practitioner employees responsible for properly prescribing and dispensing controlled substances are subject to the penalties of the Controlled Substances Act and DEA regulations, in addition to any other disciplinary action by the business.

Also, while primary responsibility for issuing a proper and valid prescription rests with the prescribing practitioner, a pharmacist filling a prescription has a "corresponding responsibility" to ensure the same. See 21 C.F.R. § 1306.04(a). "Corresponding

responsibility" is not defined in the Controlled Substances Act or DEA regulations, but in practice applies to pharmacists who should be on notice that a prescription is invalid because of, e.g.:

- prescriptions for the same drugs and quantities from the same doctor;
- prescriptions involving combinations of frequently abused drugs;
- a single address by customers filling substantially similar prescriptions on the same day;
- substantially similar and frequent prescriptions for multiple patients by the same practitioner;
- prescriptions of quantities and strengths beyond the usual course of practice;
- cash payments;
- prescriptions for treatments outside the practitioners scope of practice; and
- fraudulent prescriptions.

IV. Responding Effectively And Proactively To A DEA Investigation

Even the most comprehensive policies and corresponding compliance program will not necessarily prevent a rogue employee from violating DEA's requirements. However, having such policies and procedures in place will place registrants in the best possible position to defend themselves against claims arising from such violations.

On the civil side, DEA is required to take four factors into account in assessing an appropriate penalty:

(1) the willfulness of the violation;

(2) the profit generated by the violation;

(3) the harm to the public from the violation; and

(4) the defendant's ability to pay.

Putting the fourth factor aside (it will vary from case to case), a robust compliance program should greatly diminish the civil penalty amount DEA ultimately seeks, even where a rogue employee has intentionally misused or stolen controlled substances from a registrant. Foremost, it can erode the first factor -- the business has acted reasonably and responsibly to prevent a violation, not acted willfully to commit it. It similarly undercuts the second factor, and potentially the third -- it is unlikely that any profit came into the business by virtue of a rogue seeking to hide his or her misconduct from it. Moreover, any harm to the public should be properly attributed to the rogue employee, not the business.

On the criminal side, companies or individuals who are involved in handling controlled substances must stay alert to potential violations and, if such concerns arise, consider conducting an internal investigation to determine whether it has potential criminal exposure that is chargeable. If any issues are found, clients are strongly advised to:

- Preserve: Issue a litigation hold memorandum to all relevant corporate personnel to ensure all paper and electronic records regarding the matter are preserved.
- Avoid Obstruction: Ensure that employees potentially involved in wrongdoing do not destroy potential evidence or obstruct any investigation of their conduct.
- Cease Alleged Violations: If the problem is ongoing, take immediate steps to cut off issue -- e.g., change procedures, policies, personnel and practices.
- Investigate: Conduct a properly-developed internal investigation.

An internal investigation is essentially a genuine, even-handed investigation to determine whether there are any facts that could support a claim or a criminal charge against a company or any of its employees. If that sounds like it is designed to do the investigatory job for the government, it should -- that is what an internal investigation often becomes. Given the incentives to cooperate in federal law, particularly criminal law, it is the wisest course in many instances to conduct such an investigation and disclose its results to the government.

Conducting an internal investigation is complicated. A few principles are worth reviewing here:

Protect the Privilege: A company should ensure that any internal investigation is overseen by counsel. It is critical that an internal investigation be protected by the attorney-client privilege and attorney work-product doctrine, which generally shield from the government's scrutiny the communications between the company and its lawyers and its lawyers' assessment of the facts unless and until the company decides to disclose some of them to the government. The investigation should be structured and run accordingly to preserve the privilege.

Although factual circumstances vary and different answers may result, generally speaking, reliance on outside counsel to conduct an internal investigation is preferable to using in-house counsel. It is easier to demonstrate that the privilege attaches by using outside counsel. In addition, outside counsel are likely to be perceived by the government as independent and objective – and it is the government's perception that the company is trying to shape. Further, outside counsel may also provide subject matter expertise and contacts with the investigating agency which otherwise may not be available to the company. Corporate employees may also react more positively, and provide more candid information, when the investigation is conducted by independent, as opposed to in-house, lawyers.

Do Not Protect Wrongdoers: The government will scrutinize the authenticity of a corporation's cooperation. For this reason, companies cannot protect culpable employees and agents from prosecution. Instead, the government expects such wrongdoers to be exposed and the company to assist in their prosecution.

Preserve Evidence: The task of identifying and protecting documentary evidence is often the most time consuming, expensive, and potentially hazardous of the exercises in an internal investigation. Counsel must understand the company's hard copy and electronic document storage practices and policies. It is vital that counsel identify all hard copy and electronic record custodians and make contact with those with the most knowledge regarding the operation and weaknesses of those systems. Counsel should also identify and understand

the company's record keeping systems and methods to access paper and electronic records and take appropriate and immediate steps to preserve and collect all relevant documents.

Moreover, counsel must ensure that all employees understand their responsibilities for preserving documents and the serious criminal penalties and other sanctions for failure to do so, and document that these warnings were given to all employees. In many cases, counsel should consider whether it is appropriate to have employees acknowledge these warnings in writing. Counsel must also ensure that employees have complied with their obligations to locate and produce relevant documents. Counsel should consider whether to use written questionnaires showing that the employee has completely and fully executed a search for all relevant documents and provided all such documents to counsel, whether to conduct interviews on this score, and whether to conduct searches of employees' work spaces and computers to ensure that this process is completed appropriately. Counsel should also identify any in-site or off-site storage areas and ensure these areas are thoroughly searched for responsive records.

Counsel should be aware that methods followed in the normal course of business for destroying documents or re-using back-up computer media (tapes and the like) must be examined and understood at a minimum, and most likely stopped. Counsel should thus ensure that he or she has broadly considered all locations and custodians of documents to ensure that efforts to preserve documents are taken immediately. In addition, counsel should be aware that his or her focus should not solely be on just easily-locatable electronic documents. In some cases, deleted emails and records may need to be recovered. This may involve the retrieval of archive tapes of such communications, or the forensic recovery of deleted documents from the hard drives of identified computers. Counsel should consider extracting the hard drives from computers of particularly important employees, or "imaging" those hard drives – taking a snapshot of everything reflected on them at a given point in time. This will preserve those records for possible review later in the investigation.

Find the Relevant facts: Once documents are collected, counsel must ensure they are examined for relevance and privilege, if applicable. In addition, to ensure the integrity of the evidence, counsel must protect these records against manipulation. For instance, in an appropriate case, relevant documents and computer media should be placed under counsel's control, and perhaps in a locked room. Counsel should also take steps to restrict employees from removing originals or even copies of relevant records from secure locations. To the extent privilege is going to be claimed, counsel must prepare a "privilege log," an index of documents withheld on the basis of privilege, which identifies the document adequately and explains the basis for the claim of privilege in enough detail to permit the government to challenge the designation if need be. Counsel should also be mindful of the work product protections going forward, if counsel seeks to shield this material from later discovery.

Reviewing emails is often the most expensive and time consuming part of an internal investigation, but it is vital. Reviews of emails should be structured to minimize the analysis of irrelevant materials and to ensure that most important messages and witnesses are identified for follow-up by counsel.

Conduct Interviews: Interviews of knowledgeable employees, informed by a thorough review of the documentary evidence (including relevant e-mails), is often the most fruitful part of the

internal investigation, but also the aspect most fraught with difficulty. Company counsel generally represents the company alone, and not its employees, a point which must be made to employees during interviews. To ensure counsel does not mislead employees in this regard, he or she must administer what are known as Upjohn warnings. These warnings, derived from Upjohn Co. v. United States, 449 U.S. 383 (1981), are often oral (although, in appropriate cases, in writing), and typically include the following statements:

- That the attorney conducting the interview represents the company, not the employee;
- That the interview is covered by attorney-client privilege, but that the privilege belongs to company, not employee; and
- That the company may, in its sole discretion, decide to waive the privilege, and disclose the substance of the interview to third parties, including the government as part of its effort to cooperate.

In conducting these interviews, counsel must also bear in mind that individual employees who have criminal exposure may need separate counsel. However, counsel should exercise caution before recommending employees obtain such counsel, as doing so may chill the employees' cooperation.

Consider Remedial Steps: At the conclusion of the investigation, the company should consider what steps to take to punish employees for wrongdoing. Although this stage appears the easiest, it is not always the case. In some cases -- such as where an internal investigation is running parallel to a government investigation -- it may be wise for the company to carefully consider disciplining or terminating an employee the company has determined to have acted improperly if doing so results in the employee's refusal to continue to cooperate.

Consider Disclosure to the Government: Once the facts are in, the company should consider whether to disclose what it has learned to the government. In the case of lost or stolen controlled substances, such a report may be mandatory.

V. Conclusion

The best defense against a DEA enforcement action is a diligent, thoughtful, and comprehensive policy tailored to the registrant's business, whether a manufacturer, distributor, healthcare provider, or pharmacy. Failing that, a thorough internal investigation of possible wrongdoing and potential disclosure to the government may be wise next steps. Settlements with DOJ and DEA demonstrate this plainly: companies that uncover potential misconduct on their own and disclose it to the government affirmatively often enjoy lower penalties than those who do not. Thus, even if a rogue employee evades company policies and procedures regarding controlled substances, addressing those issues proactively may put the business in the best position to negotiate an acceptable resolution with DEA.

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