

Using internal investigations as a proactive risk management tool

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Whether it is triggered by a whistleblower's tip related to Foreign Corrupt Practices Act compliance, suspicions of deceptive sales and marketing practices, or hints of trade secret or other intellectual property theft, a regulatory investigation is nothing any pharmaceutical or medical device company wants. It allows the investigating agency to open a sweeping investigation that can encompass a company's entire document repository, draining an incredible amount of the company's time and resources.

To reduce this threat, legal departments are proactively searching for potential red flags, investigating suspected misconduct to assess and remediate any risks before they lead to formal investigations and enforcement actions. This article will discuss best practices, including those incorporating technology and machine learning/artificial intelligence, to move an investigation forward efficiently to a swift resolution.

PRESERVE AND COLLECT IMMEDIATELY — AND DISCREETLY

With respect to many internal investigations, you may have little to go on and probably will not know exactly who is involved or the precise circumstances. But you can go to the source of the documents that triggered the investigation and work backward, starting by interviewing the custodians who created those documents (so long as they do not appear to be involved) before expanding the scope of the investigation.

Since time is of the essence, a legal-hold application integrated with collection tools can expedite the investigation process. By sending known document custodians a questionnaire asking for additional information while simultaneously collecting their data and documents for review, you can efficiently prepare for in-person custodian interviews.

Because many internal investigations deal with potential employee misconduct, they should be approached with caution and discretion. If discretion is necessary, you can use remote collection tools that operate silently in the background without ever alerting the employee. Simultaneously, the information technology department can automatically suspend the routine destruction of data without tipping off the custodian.

At the same time, as new information surfaces, you can continue to define potentially relevant data sources and work with IT to defensibly preserve those sources, recover deleted data, gain access to password-protected files, and identify documents and system artifacts to piece together a chain of events. Taking this proactive approach early will aid your forensic examination efforts.

USE COMMUNICATION ANALYTICS TO IDENTIFY ADDITIONAL CUSTODIANS

The clock is the enemy when investigating potential trade secret theft. The goal is to get to the heart of the matter as quickly as you can by promptly identifying the key witnesses, documents and facts. The faster you can isolate the witnesses who hold critical documents and link them to other custodians, the faster you can unlock the insights that will enable you to accurately assess the matter.

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As you gather facts from your custodians, you can apply multiple layers of advanced analytics tools to unearth important details early. Analytics tools can help you understand the entire social network of communications across a document population and highlight the main players. Visual analytics can then reveal these individuals' communication patterns, pinpointing additional witnesses for interviews and targeted collection and, equally as important, identifying potentially critical external communications.

With the right visualization tools, you can simultaneously gain insight into the relationships between all of your documents, custodians, timelines and more, so you can drill down based on what is of most interest. Advanced tools can also help you avoid a fishing expedition. These tools create a methodical "breadcrumb" history of precisely how you arrived at the data in your current



searches, which you can organize into folders for further review and application of technology-assisted review.

USE EFFICIENT, TECHNOLOGY-ASSISTED REVIEW TECHNIQUES

Technology-assisted review, well-known for its proficiency in accelerating litigation document review, can play an equally important role in internal investigations.

Generally, early TAR tools start slowly: They ingest an entire collection at once and require iterative training rounds to refine their algorithm before yielding trustworthy results. These tools won't work in the quick-turn investigation setting. Your investigation can't wait until you've collected the full universe of potentially relevant documents, or you have to start over with the TAR system when you identify new custodians whose data warrants review (which is more often the case than not).

Centralizing legal documents is the key to a more efficient process.

Instead, choose a TAR tool based on a continuous active learning protocol, or CAL, so you can start review once you collect the first document. The CAL protocol refines its decision-making with every judgment it makes, incorporating documents seamlessly as you collect them. This allows you to prioritize the most important documents for the earliest review.

If you haven't identified pertinent documents at the start of an investigation, you can give a CAL-based tool a head start by creating a synthetic seed document that includes concepts essential to the investigation. After ingesting this document, the CAL protocol will recognize these central words and phrases and begin prioritizing similar documents. You won't need to start the training and review over again as you identify new custodians and collect new data because CAL incorporates both into its learning on a continual basis.

THE TAR TOOL MUST HAVE ROBUST FOREIGN LANGUAGE CAPABILITY

The pharmaceutical and medical device industries are global enterprises. Even midsize companies have a significant sales and/or manufacturing presence overseas. Coupled with this, statutes such as the Foreign Corrupt Practices Act and the UK Bribery Act, which create domestic culpability for conduct that occurs overseas, virtually guarantee that regulatory compliance matters will increasingly encompass documents in multiple languages.

Many legal teams involved in cross-border matters, however, still hesitate to use TAR, questioning its effectiveness and ability to handle non-English document collections. They

perceive TAR as a process that involves "understanding" documents. If the documents are in a language the system does not understand, then TAR cannot be effective, they reason.

The fact is that, done properly, a TAR tool based on CAL is just as effective for non-English documents as it is for English ones. This is true even for the complex Asian languages including Chinese, Japanese and Korean. Although these languages do not use standard English-language delimiters such as spaces and punctuation, they are nonetheless candidates for the successful use of TAR. When TAR is deployed on a properly tokenized, multi-language data set, users will see all the benefits a CAL protocol TAR tool can provide.

EFFECTIVELY EXPLORE THE UNKNOWN

When you're starting from scratch in an investigation, you may worry that your limited understanding of the situation has caused you to miss a key document. With first-generation TAR tools, that review bias may continue to eliminate important information because the algorithm looks only for documents using the concepts that you expected to see.

Modern TAR tools with CAL can locate contextually diverse documents — those with unexpected concepts or terms — that may shed additional light on your investigation. That means you won't risk missing the critical needle in the haystack of documents.

Applying the latest e-discovery technologies will not only make trade secret investigations faster and easier; they can also help companies spot and proactively address potential infractions while avoiding negative impact to what may be the organization's most valuable assets.

While the above suggestions constitute best practices and will streamline the investigative process, there are other steps pharmaceutical and medical device companies can take to be even more proactive. With evolving technology and a centralized approach, legal departments can evolve their approach to investigations beyond the traditional model. This would allow companies to more effectively manage day-to-day compliance, gain greater oversight and gain the ability to be proactive with potential misconduct — all while moving from a reactive, siloed approach to a knowledge-driven strategic business.

CENTRALIZING LEGAL DATA

Centralizing legal documents is the key to a more efficient process. When a siloed approach is used, coding decisions on documents from prior matters or regulatory investigations cannot be applied to future matters involving many of the same custodians and documents. Coding decisions and even attorney-client privilege documents may differ from one matter to the next, depending on the individual reviewer's judgments. This increases the company's risk of inadvertent exposure of sensitive information.

When working in silos, you miss the opportunity to “review once and produce many times.” So R&D documents that come up frequently in patent litigation (or even suits related to trade secret theft or misappropriation, unannounced products or related claims involving the same core compounds) need to be recollected and reprocessed, re-reviewed and reproduced each time — again, generating inefficiencies, unneeded cost and risk.

Storing your company’s legal documents in a single repository enables your team to leverage prior decisions and documents, and aggregate key metrics across cases to support informed business decisions. Centralization also helps keep your data secure by allowing in-house teams to more effectively manage documents throughout the data life cycle, controlling access and limiting the flow of sensitive information.

When using a multi-matter management system with a core repository, each new matter creates greater efficiency because data is collected and processed just once. When new matters arise, documents can be assigned from the core repository to a new matter without a need to collect or process the same data, and prior coding can be pre-populated — that is, coding decisions or “tags” such as privilege, confidentiality and other designations are retained for use across multiple cases.

This treatment saves on costs and creates greater efficiencies. Documents can then be efficiently reproduced across matters, allowing for a “review once, produce many times” workflow for commonly produced records

MOVING LEGAL TO A KNOWLEDGE-DRIVEN BUSINESS UNIT

Due to their regulatory burdens, lawyers and legal operations professionals at pharmaceutical and medical device companies are increasingly appreciating the opportunities

afforded by capturing and reusing historical work product and documents where possible and applying meaningful metrics to manage day-to-day discovery.

The traditional silo approach makes data reuse virtually impossible. By centralizing your data in a core repository and adopting a comprehensive business intelligence strategy, discovery efforts will result in substantial cost savings and move your department to a knowledge-driven strategic business.

In summary, there are both short-term and long-term best practices when it comes to compliance, many of which overlap. The key takeaway is that in their regulatory environment, pharmaceutical and medical device companies need to leverage technology so that investigations do not become too invasive and expensive.

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