Preventing Toxic Labels

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In an unprecedented development, the U.S. Department of Justice filed a permanent injunction on behalf of the U.S. Food and Drug Administration (FDA) against a company and its owner for alleged mislabeling matters. According to news coverage of the development, the legal action was the first time the agencies pursued a large supplement maker for failing to meet labeling compliance.

States also offer protection against mislabeling and misleading advertising, allowing consumers to file lawsuits against companies for erroneous labels, adding to the risks manufacturers and retailers face for incorrect labels. Earlier this year, the California Supreme Court ruled that consumers who purchased a product as a result of misleading advertising or labels can sue the product's manufacturer, even if the product is not defective or unsafe.

The ruling loosened the state's interpretation of the law on labeling lawsuits. While the scope of the claims allowed in these lawsuits may differ from state to state, many companies have faced lawsuits from consumers for mislabeled products.

While recalls can happen for any one of countless reasons — including a variety of safety hazards, or product adulterations or contaminations — some recalls can be easily prevented. One issue that can be prevented is product labeling errors; and as the FDA increasingly cracks down on companies and contract manufacturers for labeling issues, companies should not only be taking the necessary steps to prevent these recalls, but should also enhance labels to help ensure recall effectiveness by improving recall processing efficiencies regardless of the cause of a product recall.

Labeling requirements have evolved over the past several decades, getting stricter as the years pass. Detailed and accurate product labels are more important than

ever before, especially in the pharmaceutical, medical device and food industries, particularly since labels may often be the only communication channel between a manufacturer and consumers. This is one of the reasons why product labels must adhere to strict regulations under the U.S. Federal Food, Drug and Cosmetic Act.

Because a product label includes a list of ingredients, nutritional information, safety warnings and other critical consumer information, a misprinted label signifies a communication error that most often results in a Class III recall under the direction of the FDA. About 15 percent of pharmaceutical recalls reported by the FDA in 2011 can be attributed to labeling issues. Almost one-quarter of all Class III recalls are also the result of labeling issues.

The good news is that labeling errors, and the consequential product detentions, withdrawals or recalls that could follow, can be prevented.

Preventing Labeling Recalls

Despite the number of ways these issues can be prevented, labeling is also consistently responsible for 10 to 20 percent of all pharmaceutical recalls and more than 20 percent of product detentions in the United States.
Typically three primary types of labeling errors result in product withdrawals or recalls: incorrect identification of products, incorrect dosages or incorrect ingredient listings. Unfortunately, even the relatively minor labeling errors have been the cause of a significant number of recalls in recent years.

So whether your product has an incorrect label on an item or the label itself has a mistake, it is critically important that the situation is handled properly, and in full transparency with regulators and consumers. Proper labeling procedures, and by consequence effective recall prevention, requires knowledge of the likely scenarios that would trigger a recall event. In the case of labeling recalls, there are several common causes.

Incorrect labels could end up on products as a result of a mistimed packaging line changeover, the inadvertent use of an old or obsolete product label, a mismatched label in which either the front or back label is incorrect, decisions made on the production floor that change the production sequence or misapplied labels.

But companies that follow best practices for labeling systems during the production process can effectively prevent labeling errors. Moreover, a company that maintains control of the labeling process in house, rather than outsourcing it to outside vendors, is less likely to face errors.

Another option companies effectively use is an on-demand labeling system that prints only the labels needed for any given production run. When this system is paired with shorter print runs and manual confirmation for each label and each print run, mislabeling risks are exponentially decreased.

Withdrawing a product because of a labeling error can be frustrating and costly. But labeling errors can be prevented if you are diligent about double- and triple-

checking all your labels for redundancy, unclear language, and incorrect or omitted statements. Make sure that your company spends time validating and verifying the facts of the label, as well as the product. Failure to do so can lead to an expensive recall, risk to public safety and significant brand damage, all of which could result in decreased customer loyalty and lost revenue.

Manufacturers have also expressed to me how invaluable it is to have proper labeling practices not only during the production and distribution process, but also when managing reverse logistics.

Using Labels for Recall Management

Even if all reasonable safety precautions and quality control measures are in place, companies should still have an established recall plan in case something goes wrong and a recall is initiated. That recall plan should also account for proper labeling initiatives to ensure that all affected products are returned to the correct central location.

Having an effective labeling system in place can help companies effectively manage any return scenarios, withdrawals and recalls they may face, regardless of the cause. Proper labels can provide the manufacturer with important information during the complex and time-sensitive recall process, including detailed shipper and product return data, which ultimately drives reimbursement levels back to consignees.

In fact, we have heard from several companies how technological updates to product labels — from simple barcodes to radio frequency identification (RFID) technology — can help to effectively streamline the recall, withdrawal or field correction process, allowing for better tracking of products and packages, and compliant reporting to the FDA.

As part of recall planning, companies should consider not only how to keep their labels accurate, so as to prevent recalls, but also what they can do to make sure that any products that must be pulled from shelves carry the data necessary to track the logistics process. This tracking is necessary not only from a product's origin of manufacture and retail destinations, but also from the store shelf to recall storage locations if necessary.

But the best recall is one that never has to happen at all. The best advice is to pay careful attention to labeling, from the development of the language to the actual labeling of products, and to always be prepared should anything go wrong. As the FDA increases its oversight of consumer products, it is no longer a matter of if you will face a recall, but rather when.

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