Cannabis Forethought: Labeling, Warnings and Risk Mitigation

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Passage of the Marijuana Regulation and Taxation Act (MRTA) legalized adult-use recreational cannabis in New York State and opened the doors to a market projected to be worth billions of dollars. The legislation created a new Office of Cannabis Management governed by the Cannabis Control Board (collectively, OCM). The OCM will implement regulations governing the manufacturing, packaging, labeling, advertising and testing of cannabis products to protect consumers. The regulations are expected to be finalized later this year.

Savvy entrepreneurs have already begun considering what steps they need to take in preparation for submitting license applications to the OCM. While potential applicants should be undertaking initial preparatory actions, such as corporate entity formation, securing investment funding with written agreements, developing a supply chain, preparing quality controls and documentation procedures, and generating dialogue with local municipalities, it is never too early to begin considering how to maximize regulatory compliance and mitigate the risk of potential future product liability litigation.

While medicinal cannabis has been associated with positive health effects including pain relief and control of chemotherapy-induced nausea and vomiting, the OCM may limit or prohibit health and wellness claims. Some studies of cannabis have also identified potential health risks. Consequently, some federal agencies and professional medical societies have issued statements of caution regarding these potential health risks and the current understanding of their association with cannabis. Although official regulations have yet to be published, we do know that recreational cannabis products will be subject to packaging and labeling standards determined by the OCM. These standards will include warnings regarding potential harms and the products' expected effects. The OCM has not yet indicated what specific potential harms should be included in warnings to consumers. It is also unclear at this stage what information the OCM will rely upon to determine which harms are supported by sufficient scientific data to warrant a label warning, and who will be interpreting the available data underlying the OCM's decisions.

There are many factors to consider when interpreting published scientific literature, and it will be incumbent on the OCM to separate fact from fiction. For example, cannabis is sometimes used concomitantly with other substances such as tobacco, alcohol or illicit drugs, which may be responsible for observed adverse effects. Similarly, many studies rely on self-reporting, which may lead to misreporting of cannabis use and its timing, frequency and duration, as well as other potentially relevant confounders. The relationship may also depend not only on the quantity of cannabis product used and route of administration, but also on potency, which may not be known or fully evaluated. Improperly accounting for these factors can impact the strength of an association between cannabis and an observed outcome. Careful analysis of the methodological quality of a study is essential. If an increased risk of a health effect is reported in one study, it is important to examine whether the increased risk is statistically significant, and whether it is consistently observed and replicated across multiple independent and well-controlled studies.

Applicants should ensure their products comply with the labeling regulations and disclose health risks associated with cannabis based on available and reliable scientific evidence. Businesses should monitor the OCM for labeling updates and also consider staying abreast of the scientific literature themselves or working with an organization that is monitoring the scientific literature. Marketing and sales teams should be kept informed and up-to-date on required warnings and limitations on permissible wellness claims. Product liability litigation is often based on "failure-to-warn" theories of liability. Appropriate warnings can be the safe harbor in preventing and defending such litigation. In that regard, an ounce of prevention is worth a pound of cure.

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