

# Best Practices For Cannabis Cos. Managing A Product Recall

By **Joanna Borman and Amy Rubenstein** (December 15, 2022)

Cannabis market researcher BDSA estimated state legal adult-use and medical sales of cannabis in the U.S. to be \$25 billion in 2021, with the market expected to reach \$27 billion in 2022.[1]

Currently, most states have some legal cannabis structure — 39 for medical purposes and 21 for adult use — as does Washington, D.C.

As more states legalize cannabis, consumers increasingly have access to cannabis products. And cannabis businesses are increasing production to meet this expanding consumer market.

Expanded access to markets and additional consumers increase the risk of large-scale, costly product recalls. Broadly, cannabis recalls can result either from mislabeling and misbranding, or potential or actual adulteration.

Mislabeling and misbranding can result when the label on a cannabis product is false or misleading in some way — for example, a label that misstates a product's THC content can be said to be mislabeled.[2]

In contrast, potential or actual adulteration can result when contaminants such as mold, heavy metals or pesticides are present — or haven't been properly tested for — in a cannabis product.

While strong internal compliance programs can be the best way to prevent recalls by catching mislabeling, misbranding or adulteration before sale, even the best compliance efforts can have gaps.

So when mislabeling or adulteration happens, cannabis businesses facing a potential recall situation should have a plan prepared that focuses on three main goals: (1) protecting consumers' health and safety; (2) conducting a well-managed and efficient recall to mitigate the risk of expensive, inconvenient and disruptive litigation; and (3) using the recall to help build brand reputation and loyalty.

Many states have adopted regulations addressing cannabis recalls, which vary by state. Some states have regulated the recall process at a fairly granular level, while others require that a recall plan is developed but leave many of the specifics up to the discretion of cannabis businesses.[3] New Jersey even recommends conducting a recall drill or mock recall to prepare for the real thing.[4]

However, even in jurisdictions that leave recall mechanics largely within a cannabis business's discretion, participants in the legal cannabis market should develop a recall plan before they need it.

Guidance and regulations for product recalls from the U.S. Consumer Product Safety Commission and the U.S. Food and Drug Administration, as well as regulations at the state level, can help cannabis businesses develop a recall plan as described below.



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## **Best Practices to Manage a Cannabis Recall**

### ***Develop a recall team.***

Recalls involve coordination and communication across multiple stakeholders and interested parties, such as consumers, regulators and the media.

Developing a recall team can help cannabis businesses act quickly when an issue surfaces. For example, a recall team with members of senior management, production or manufacturing, communications, and compliance and legal would provide coverage across many facets of the recall process.

Additionally, some states require notice of the personnel responsible for implementing any recall procedures in order to sell cannabis products.[5]

The recall team can develop a recall plan and even conduct a mock recall to test out how well their procedures stack up in practice.

### ***Coordinate with the relevant agency related to the recall.***

Some states require notification to the relevant agency before a voluntary recall[6] or within 24 hours of initiating a recall.[7] Others require notification of certain adverse events, which can lead to product recalls.[8]

In either event, coordinating with the relevant state agency can be helpful to reach affected consumers quickly and minimize future risks to health and safety, as well as to keep regulators in the loop.

Even if a cannabis business is conducting a voluntary recall as opposed to a state-mandated recall, the process must involve the relevant state agency, and comply with any agency guidance or regulations.

Further, should any administrative actions arise from a recall, self-reporting often shows good faith conduct that can reduce a potential penalty, which may range from a civil monetary penalty to a license revocation.[9] If a recalled cannabis product results in severe illness or death, the potential for criminal liability exists as well.[10]

### ***Identify affected products.***

A recall must identify all affected products, sold and unsold. The scope of the recall will depend on the quantity and types of products affected.

In turn, the recall scope informs the most effective communication strategies — e.g., individual outreach to consumers, notice at the point of purchase, information on the seller's website or social media, or a statewide bulletin.

### ***Notify purchasers and follow up.***

Any products purchased by consumers must be identified to notify the affected purchasers ASAP. In many states, the in-place cannabis seed-to-sale requirements, which track cannabis from plant form to final retail product, make this an easier undertaking.

The notices can contain a product description, risks posed by using the product, and any

steps a purchaser must take, e.g., to return or dispose of the product.

If a business can identify purchasers quickly, it may be able to alert them before they consume the recalled product.

Once recall notices are issued to purchasers, responses should be tracked and a follow-up list developed. Following up with the nonresponders will help ensure that any affected consumers receive notice.

***Offer consideration in exchange for release.***

If permitted by state law, offering a full refund plus additional consideration — credit for a future purchase, free product or some other item of value — in exchange for release, with an arbitration clause included, can help cannabis businesses avoid costly and disruptive litigation over recalled products.

While class actions targeting cannabis companies may have once been less attractive due to the lack of insurance funds, the rapid state-led legalization movement has encouraged insurers to enter this marketplace.

Not surprisingly, with funds available, two class actions involving the sale of mislabeled and/or adulterated cannabis products have been filed in the past few years in the U.S. District Courts for the Southern District of Florida and the District of Oregon.[11]

***Provide notice to insurers.***

Where a cannabis business has secured insurance to cover expenses related to a recall, or even a general liability insurance policy that may cover expenses arising from a recall, providing prompt notice to an insurer is critical.

Not only does providing prompt notice help in any coverage determination, insurers also may provide additional support or resources to assist with the recall.

Additionally, cannabis businesses should keep track of all costs associated with a recall to support any insurance claim.

***Issue a litigation hold.***

Even when a cannabis business does everything properly in conducting a recall, disgruntled consumers, enterprising counsel or a governing agency may initiate litigation or an investigation.

A business should issue a litigation hold, which directs relevant employees to save any information related to the recall and the affected product, when litigation is reasonably foreseeable.

Arguably, any recall means that litigation is reasonably foreseeable. Issuing a litigation hold ensures that the company preserves data and information related to the product at issue and the recall process.

***Prepare a media standby statement and/or Q&A.***

Depending on a recall's scope, attorneys may need to work with public relations or

communications professionals to craft a public-facing statement about their client's recall.

The statement can include a description of the affected product, as well as alert the public to any potential safety issues from consuming the affected product.

This may also include a Q&A piece that anticipates commonly asked questions.

## **Conclusion**

While every company wants to avoid dealing with a product recall, it is almost an inevitable part of offering a consumer product.

As cannabis has become a recognized state-legal consumer good, businesses operating in the space should prepare for a potential recall by developing a strong internal compliance program and familiarizing themselves with the steps above, as well as the regulatory landscape in the relevant jurisdictions.

Conducting a recall safely, effectively and expeditiously can present an opportunity to build a brand's reputation in the consumer-focused cannabis industry, rather than harm its reputation.

Getting ahead of a cannabis recall can favorably demonstrate both commitment to consumer safety and well-being, as well as operational transparency.

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[1] Andrew DeAngelo, The Hockey Stick Turns Into Bell Curve: A New Report Sheds Light On Cannabis Industry Growth, Forbes, Oct. 4, 2022, <https://www.forbes.com/sites/andrewdeangelo/2022/10/04/the-hockey-stick-turns-into-bell-curve-a-new-report-from-bdsa-sheds-light-on-cannabis-industry-growth/?sh=20fef66466f2> (citing BDSA Updated Global Cannabis Markets Forecasts Fall 2022, (Sept. 2022) <https://bdsa.com/content/global-cannabis-market-forecasts-fall-2022/>).

[2] Williamson v. Curaleaf, No. 3:22-cv-782 (D. Or. May 30, 2022); Centeno v. Dreamfields Brands Inc., No. 22STCV33980 (Cal. Super. Ct. Oct. 20, 2022); Plumlee v. Steep Hill, Inc., No. 22-CV-00638 (E.D. Ark. July 12, 2022).

[3] Compare Conn. Agencies Regs. § 21a-421j-5 (2022) ("A producer...shall establish...written policies and procedures...for [h]andling mandatory and voluntary recalls of cannabis" that are adequate to deal with "with recalls due to any action initiated at the request of the commissioner and any voluntary action by a cannabis establishment to remove defective or potentially defective cannabis from the market, or any action undertaken to promote public health and safety by replacing existing cannabis with improved products") with N.J. Admin. Code § 17:30-9.17 (2021) (In contrast, New Jersey devotes an entire multi-page section to detailing required standard operating procedures for

recalls.).

[4] N.J. Admin. Code § 17:30-9.17(d) (2021).

[5] N.M. Code R. § 7.34.4.24 (2022).

[6] Utah Admin. Code R68-27-11 (2022).

[7] N.M. Code R. § 7.34.4.24 (2022).

[8] N.J. Admin. Code § 17:30-9.16 (2021).

[9] For example, the Arizona Department of Health Services can assess a civil penalty (in an amount not to exceed \$2,000) or "suspend or revoke, in whole or in part, any registration or license issued" for statutory or regulatory violations related to state's cannabis program. See Ariz. Rev. Stat. Ann. § 36-2854 (2022).

[10] In Rhode Island, the state's cannabis laws specifically do not exempt from criminal penalty or state prosecution the "[m]anufacturing or processing of cannabis products with the use of prohibited solvents" or the "distributing, cultivating, processing or manufacturing cannabis or cannabis products which do not satisfy" the state's requirements. R.I. Gen. Laws § 21-28.11-29.

[11] Davis v. CBD American Shaman, No. 0:20-cv-60897 (S.D. Fla May 4, 2020); Williamson v. Curaleaf, No. 3:22-cv-782 (D. Or. May 30, 2022).