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PHARMACEUTICALS

Into Thin Air

Business Decisions Await Regulation of E-cigarettes, Vaping, and Cannabis

WHITE PAPER

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BACKGROUND

Even as the Food and Drug Administration's focuses on COVID-19, enforcement of Electronic Nicotine Delivery Systems (ENDS) remains a top priority.

As recently as early June, the FDA updated its website to share more information about vaporizers, e-cigarettes and other Electronic Nicotine Delivery Systems. As part of its ongoing efforts to find the right approach to regulating ENDS and related product categories, the agency published updated guidance and enforcement priorities for products being sold without premarket authorization. To ensure stakeholders had the opportunity to weigh in on the issue, the FDA also extended to June 19, 2020 the comment period soliciting data and information involving vaping products associated with recent lung injuries.

ENDS "are **harmful to health and are not safe**," and "it is too early to provide a clear answer on the long-term impact of using them or being exposed to them."

- World Health Organization

While the FDA moves forward on the regulatory front, other agencies and health organizations remain involved. The Drug Enforcement Agency (DEA) continues to examine the entire vaping supply chain, the FTC remains focused on its consumer protection efforts pursuing action related to everything from sales and advertising methods to antitrust laws violations.

Meanwhile, the Centers for Disease Control and Prevention is keeping count of the cases associated with the growing problem and offering resources to the general public, healthcare providers, and state and local health departments. **This is in addition to the World Health Organization's January 2020 opinion that ENDS "are harmful to health and are not safe,"** even while noting that "it is too early to provide a clear answer on the long-term impact of using them or being exposed to them."

There are a number of agencies, lawmakers, and influencers with a vested interest in what ultimately happens, making it hard to keep track of them all. But that doesn't mean we can't learn from what has unfolded so far and plan for what could happen in the future.

Who's in the Crosshairs?

The short answer lies in the FDA's latest ENDS enforcement priorities and industry guidance. That document states:

For ENDS products marketed without FDA authorization, FDA intends to prioritize enforcement against:

- *Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);*
- *All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and*
- *Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.*

But that's not the complete answer. The truth is **anyone and everyone** connected to the vaping industry is at risk as the knowledge base grows.

When this crisis started, it may have looked like the FDA's primary target was industry leader Juul Labs Inc., which still faces a tough regulatory and legal road ahead resulting from Congressional hearings, FDA regulatory actions, FTC scrutiny, and mounting lawsuits.

But Juul was certainly not alone. RJ Reynolds Vapor Company, NJOY LLC, Nu Mark, Logic Technology Development, and Fontem US were also named in an FTC order requesting documents detailing business practices, marketing campaigns, and finances. The unraveling chain of events in that interaction should be studied as if it were a crystal ball.

But the ongoing issue impacts more than just e-cigarette makers. Tobacco companies and related interests with a vested interest in the success of ENDS, but the cannabis industry is also under scrutiny from career professionals inside Washington's regulatory agencies who are increasingly worried about a business with murky beginnings that is growing wildly without oversight.

The chairman of Aurora Cannabis, like many entrepreneurs in a budding industry (forgive the intended pun), went on the record when this crisis started, saying he is "very worried" about how the vaping crisis could impact cannabis-related regulations. He should be.

Over the last nine months, progress has been made in identifying the cause of e-cigarette, or vaping, product use-associated lung injury (EVALI). Notably, Vitamin E acetate has officially been linked to the EVALI outbreak after being found in both product and patient lung fluid samples. However, perhaps more importantly for the industry, CDC's position is that the "evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases."

In other words, no one is entirely confident that we have the answers needed to fully protect consumer health.

As long as that's true, there will be an alphabet soup of regulatory agencies and health organizations with skin in the game: the FDA, FTC, DEA, CDC and WHO, not to mention Congress. Each of these interested parties has its own purview and the authority to put the spotlight on any company, at any point in the supply chain, at any time. While significant action is unlikely to occur during the global COVID-19 crisis, this issue is still very much a priority.

Who's in the crosshairs? **Anyone and everyone connected to the vaping industry.**

WHAT'S NEXT?

Don't be fooled into thinking this is just about the new Big Tobacco. It's much bigger than that.

Tobacco was the product. In this case, the product is actually a device. One that can be used for ingesting nicotine, cannabis (in its many forms), or frankly any other liquid someone decides to use. That's an important factor when you consider what's coming next.

1. **Manufacturers and retailers should start thinking about "Foreseeable Misuse."** It's a topic more often associated with consumer product companies. But given the FDA's focus on ENDS as a delivery mechanism, and not just the flavored cartridges, it is time companies start thinking about who the products appeal to and how they will be used. Whether or not that was the intended use or intended buyer. Then plan for the regulatory and legal actions that could follow from these foreseeable risks.
2. **Marketing claims will remain a focus.** Marketing claims were a hot button issue since FTC's investigation launched in 2019. But as recently as April 2020 we saw the FDA issue warning letters to 10 retailers and manufacturers marketing unauthorized products. Expect this level of regulatory and legal action to not just continue but also evolve as the FDA's enforcement priorities broaden.
3. **Retailers will continue to feel the pressure.** There's a reason CVS never sold e-cigarette products once they stopped selling traditional tobacco products. Retailers like 7-Eleven and Wawa, as well as traditional tobacco product stores, should be ready to handle any changes in product offerings, marketing, and recall activity. That includes responding to FDA warning letters. If the FDA's published enforcement priorities aren't enough a warning, consider the nearly 100 warning letters sent to brick-and-mortar retailers in March and April 2020 alone (and that's during a global pandemic). If you're trying to slip under the radar, keep in mind it's only a matter of time before you're caught.

Don't be fooled into thinking this is just about the new **Big Tobacco**.

4. **This is about more than just product safety and consumer health.** With any public health and product safety crisis of this magnitude, all business practices come under scrutiny. Case in point is the FTC's antitrust action against Altria and JUUL. When a product safety inquiry starts to call a company's business practices into question, the risks for the entire industry increase exponentially. It's important to understand this in order to avoid your reputation being part of the collateral damage.

5. **The FDA will take its time on cannabis and CBD approvals.** Don't be fooled into thinking this is just about the new Big Tobacco. The fact is that the FDA likely could have prevented at least some of the EVALI illnesses from happening back in 2016 when Obama administration officials had the opportunity to ban flavored vaping liquids. They always say, hindsight is 20/20. So it should not be surprising if the FDA takes the opposite approach when it comes to cannabis – slow playing approvals and considering all related findings from this ENDS regulatory process in order to take an ultra-conservative approach and avoid a déjà vu experience.

6. **It will get personal.** Right now, the focus appears to be on corporations and businesses. But based on the nature of the criminal investigation and the regulatory agencies involved, there will be individuals who are held responsible. Whether the individual and company sink together will depend on a lot of factors. But survival, if possible, will be based on the company's ability to demonstrate its commitment to public health and safety.

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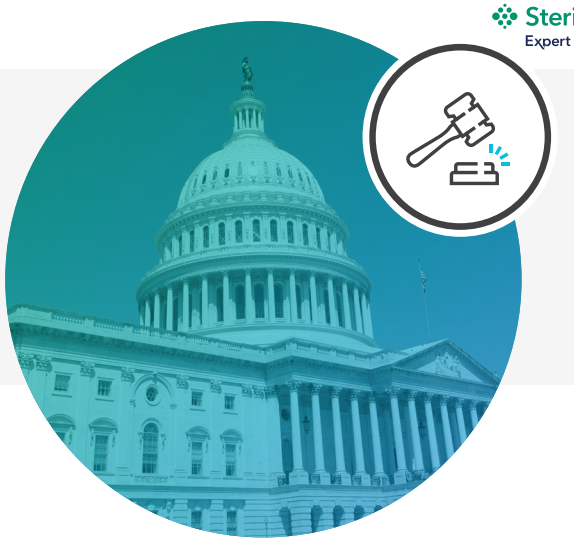
WHAT NOW?



When it comes to EVALI and the future of ENDS and related product categories, there are still as many questions as answers. While regulators, companies, and organizations are investing in learning more, one thing is for certain for companies either in the market or considering entry to it: **Sitting and waiting is the wrong approach.**

If you haven't, now's the time to start planning for the worst-case scenarios. Unfortunately, there's quite a list to consider, many of which are already playing out for manufacturers and retailers in the space:

- **FDA action**
- **FTC investigations**
- **Congressional hearings**
- **Criminal actions against businesses & executives**
- **Product liability lawsuits**
- **Product bans**
- **Product recalls**
- **Research clearly determining causation**
- **Increasing illness and death counts, particularly those that name your company**
- **Unfavorable test results associated with your product or those you sell**
- **Elimination of a line of products or an entire product category**

And this isn't all of them.

But the time and resources invested before the issue becomes a massive problem is what separates effective crisis management from irreparable brand damage.

To tackle issues like this effectively, find partners like Stericycle Expert Solutions who can identify the most likely problems ahead and help you plan your way around them. Such foresight will enable you to continue running the day-to-day business with the knowledge that you have a team of experts working for you who are managing even the most complicated of product safety-related events.

So when the next issue erupts into a crisis, you won't be the one with your hair on fire (sorry, final pun!).