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Regulatory Law

FEDERAL & MINNESOTA EDITION

*Brownson Norby, PLLC's annual Regulatory Law summary is useful to businesses seeking legal assistance in compliance and dispute resolution with federal, state, and local agencies –**Updated for 2018***

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Regulation & Rule-Making Overview

Most people are familiar with the process of making "law" through the legislature, where elected representatives propose and publicly debate a bill that becomes law when signed by the chief executive, such as the President, a governor or a mayor. ***In other cases, the legislature may pass a law that empowers federal, state or local agencies to make administrative "rules" that have the power of law.*** The rationale behind empowering non-elected administrators to make law is that regulatory agencies are assumed to have special expertise in complicated areas such as insurance, health, technology and agriculture. Often the expectation is that the legislative body will pass a law addressing a general public policy goal, and a designated government agency is then authorized to develop and enforce specific rules designed to accomplish that goal.

This process does not always go smoothly.

As public sentiment and political power shift, or when new information about a particular challenge comes to light, the desired alignment between legislative goals and administrative rules may become strained. Further, because regulatory agencies have affirmative authority to enforce rules and punish alleged offenders, legal conflicts with agencies may arise where consumers, industries, or other government officials take issue with the application of executive power to mandate or restrict certain activity. ***Ultimately, legal conflicts with agencies can be resolved by the courts, but short of litigation, there are other means to address conflicts with regulatory agencies.***

Proposals to enact or amend regulatory law at all levels is addressed through specific rule-making procedures.

At the federal level, agencies use a **"notice and comment"** process, which engages the industry and the public for comments on the proposed rule or activity. As might be expected, public comments submitted in response to controversial rule proposals can cover a broad divergent range of views. **However, the comment period is the only opportunity for direct public engagement with the agency, and a unified and consistent response from stakeholders can be an effective means to influence regulatory decisions.** After the close of the comment period, the agency considers all of the comments and in most cases publishes an official response to the issues raised in the comments. The agency may accept or reject alternative proposals, or may table the proposed rule for further review in light of issues raised in the comments. Final rules are published in the Federal Register and that point become law on the appointed date.

At the state level, Minnesota agencies follow a similar practice of "notice and comment" whereby the agency must solicit comments from the public regarding the subject matter of the proposed rule. **Unlike the federal process, Minnesota agencies only publish the general subject matter of the proposed rule – Minnesota agencies are not obligated to publish a draft of the actual proposed rule.** In addition, an administrative law judge will preside over a hearing at which both the agency and the public are offered opportunities to discuss the rule and address any questions or concerns. After the hearing and all comments and rebuttals have been reviewed by the administrative law judge, a report is issued that either approves the rule for adoption or identifies issues that must be corrected in order for the rule to be adopted. Final rules are published in the Minnesota State Register.

Regulation & Rule-Making Overview - *Continued*

At the local (city, township, village) level, in Minneapolis for example, the council first provides notice of intent to introduce a proposal for an ordinance at a formal meeting of the entire City Council. Then, at the next Calendar meeting, the proposal is formally introduced, a first reading is conducted, and the proposal is referred for evaluation by the Standing Committee. **The Standing Committee is only obligated to conduct public hearings on proposed ordinances when required by law, at which members of the public may submit testimony.** After consideration of the proposed ordinance and public testimony, the Standing Committee submits to the City Council a report in which it recommends either: approve, approve as amended, do not approve, or no recommendation at all. The report is then considered, a full City Council vote is conducted, and the proposed ordinance is either passed or adopted as amended, and submitted to the Mayor for approval; remanded back to the Standing Committee; or defeated by formal action. After approval by the Mayor, the ordinance is published in the Saturday edition of City's official newspaper. Final ordinances are published in the Minneapolis Code of Ordinances.

Brownson • Norby attorneys have prepared formal comments and have appeared before many state and federal agencies representing various industry stakeholders interested in determining regulatory intent and advocating for industry positions.

Regulatory Enforcement Actions

Regulations, rules, and ordinances have the force and effect of law, and are enforced as such by the applicable agency or authority. For example, violations of FDA regulations could result in the issuance of a warning letter, or a seizure of adulterated or misbranded products, or even criminal prosecution. Further, recent legislative changes authorize FDA officials to enter and inspect private property. The disciplinary action taken depends on the nature of the violation. Decisions of federal agencies can be appealed through an administrative hearing. To the extent the determination at the administrative hearing is unfavorable, and the agency processes are considered "exhausted", an appeal may be made to the federal court.

Brownson • Norby attorneys have successfully represented clients in informal negotiations and in formal seizure and violation proceedings before FDA, DEA and OSHA.

Tobacco and Electronic Nicotine Delivery Systems

The FDA rule deeming e-cigarettes and vapor products as "tobacco products" became effective in 2016. **The Deeming Rule** requires manufacturers, retailers, and importers of ENDS products to comply with various deadlines and paperwork submissions. The deadlines differ based on the product type (e.g. e-cigarettes have different requirements than cigars), and based on when the product was introduced into the U.S. market (e.g. products on the market on or before August 8, 2016 are subject to different deadlines than products introduced into the market after that date).

Deadlines that have already come and gone for covered entities with products on the market prior to August 8, 2016, include submission of tobacco health documents, registration of domestic entities, and the ceasing of manufacture of "modified risk" products. Looming deadlines include the submission of ingredient listings for covered products, the revision of packaging and labels to include mandated warning statements and information, the submission of data on harmful constituents, and, anticipated to be the most challenging of all, the submission of the PMTA (the Premarket Tobacco Application).

In addition to the new standards and rules for **ENDS** products at the federal level, **many states and local level authorities have passed rules and ordinances affecting the industry including an increase of the legal age for purchasing tobacco products from 18 to 21.** There has also been significant movement toward banning or restricting the sale of flavored tobacco products. The cities of Minneapolis and St. Paul have approved proposals to ban menthol, wintergreen and mint flavored tobacco products amid heated debate at standing room only public hearings. Many other states and cities are considering similar actions. While FDA did not take specific action concerning flavored ENDS products in the 2016 Deeming Rule, FDA published a proposed rule and comment period to revisit the issue (March 2018).

The market for ENDS products is undeniably growing, and manufacturers, distributors and retailers may find it difficult to keep track of compliance responsibilities in light of the numerous sources of regulation (federal, state and local). Brownson • Norby attorneys provide ENDS clients with up to date information about their compliance responsibilities.

Cannabinoids

With a growing number of states legalizing marijuana for medical or recreational use, there has been increased national interest in another cannabis-derived product: cannabidiol (a.k.a. CBD). **CBD** is a natural substance derived from hemp, but unlike marijuana (also derived from or defined as cannabis), CBD contains no active level of THC, which is the intoxicating agent in marijuana. Consumers, advocates and a growing number of independent medical researchers claim that CBD has many important qualities that can improve quality of life issues for many people. **While the FDA is currently reviewing new drug applications for CBD products, the DEA has declared that it considers CBD an illegal controlled substance.** As such, conflicting or absent legal definitions of exactly what constitutes "marijuana" (illegal: considered a Schedule I Controlled Substance under federal law) and "hemp" (legal: if in accordance with the 2014 Federal Farm Bill) are causing uncertainty within the CBD industry.

Navigating the regulatory and legal space as it concerns CBD is complicated and challenging given that different positions have been taken by various agencies across the state-to-federal landscape. As noted above, federal agencies are in disagreement as to its legal status (e.g. DEA defines CBD as marijuana, and thus an illegal controlled substance; Congress, through the Farm Bill, authorizes the production of industrial hemp products having less than .3% THC; and, FDA is reviewing new drug applications for CBD products). This lack of consistency is mirrored at the state level.

Many states that still consider marijuana illegal have specifically legalized the use of CBD products for medical use, based on reported medical benefits. ***Other states*** have declared CBD to be legal for all purposes, yet other states have specifically declared that CBD is not legal. ***At this point in 2018, given the uncertainty at the federal level and the disparate positions of the various states, most states have refrained from taking a formal position on CBD's legality.*** Overall, the balance seems to be shifting in favor of nationwide legality as state and federal officials learn more about the significant benefits and relative lack of risk of CBD, but difficulties in marketing this product within reasonable compliance guidelines remain.

Brownson • Norby attorneys advise CBD clients and provide real time, straight answers in difficult situations that arise given the complicated and presently inconsistent nature of the law on this issue.

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The partners at Brownson Norby are litigators and seasoned defense attorneys practicing in Minnesota, North Dakota, Wisconsin, and throughout the country.

Brownson Norby attorneys represent corporations, insurance companies, public entities and individuals in civil litigation matters in the state, federal and appellate courts, and before administrative agencies.

Our attorneys practice in insurance, asbestos and toxic exposure, professional liability, workers' compensation, and regulatory law defense.

Brownson Norby's mission is to deliver results that exceed expectations, offer the superior quality associated with large firms with the close personal attention typically found only in small firms, and serve as creative, efficient and experienced professionals for our clients.

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