Lawsuits challenge FDA e-cigarette rules

By Daniel J. Herling

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Patrons at an e-cigarette store, in New York, April 16, 2015.

For many years, tobacco use has been the subject of regulations and litigation. In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act which required a health warning on all cigarette packs. In 1970, President Richard Nixon signed the Public Health Cigarette Smoking Act, which banned cigarette ads on radio and television. It also required an updated warning on all cigarette packages which read "Warning: The Surgeon General has determined that cigarette smoking is dangerous to your health." In 1996, the Food and Drug Administration issued the "FDA Rule," which permitted the FDA to have authority over tobacco products and issued a rule intending to prevent the use of tobacco products by children. The intended regulations included prohibiting various additional advertising of tobacco products by schools and playgrounds, imposing more stringent advertising regulations and prohibiting brand name sponsorships (e.g., the Virginia Slims tennis sponsorship), among other things.

After the regulations were issued in 1996, several tobacco companies sued and in 2000, the U.S. Supreme Court, in *FDA v. Brown & Williamson Tobacco Corp.*, ruled that Congress had not given the FDA authority over tobacco and tobacco marketing. This was remedied in 2009, when Congress provided explicit authority to the FDA to regulate tobacco when it passed the Family Smoking Prevention and Tobacco Control Act, which was signed into law by President Barack Obama on June 22, 2009.

On Aug. 8 this year, the FDA rule regulating all tobacco products, including e-cigarettes or "vapes," became effective. This "deeming" rule brings certain types of products within the authority granted to the FDA by the tobacco control act to regulate "tobacco products." The more common forms of tobacco (e.g., cigarettes) were immediately subject to the provisions of the tobacco control act when the deeming rule was passed. The tobacco control act also provided the FDA with the authority to "deem" other tobacco products to fall under the tobacco control act. Among other compliance requirements for tobacco products as of Aug. 8:

- E-cigarette manufacturers and distributors will be prohibited from distributing free samples of their products
- E-cigarette manufacturers and distributors will be required to register their manufacturing establishments with the FDA and list their products
- Manufacturers will be required to submit their ingredient list to the FDA and to report harmful and potentially harmful constituents
- New warning label statements about tobacco's addictiveness will be required on packaging and advertisements

Compliance with the rules, including registration, has been estimated to cost in the range of $350,000 to $1 million.

In the face of these regulations, several lawsuits have been filed against the FDA attacking these rules. The lawsuits have been filed across the United States, including in federal district courts in the District of Columbia, West Virginia, Florida and Los Angeles.

In the cases pending in the U.S. District Court for District of Columbia, there is a consolidated action with lead plaintiff Nicopure Labs LLC, 16-cv-00878, who along with other groups filed a complaint alleging that the FDA's rules violate the First Amendment because the rule bans the companies from passing out free samples, which the groups claim is a protected form of nonmisleading speech.

The groups also claim that it was "unlawful and unreasonable" under the Administrative Procedures Act for the FDA to include Electronic Nicotine Delivery Systems (ENDS) under the tobacco control act's definition of a tobacco product. The complaint alleges that the "FDA intends to regulate these products despite the fact that they do not contain tobacco, are not derived from tobacco, and are not components or parts of an actual tobacco product." The complaint asserts that the agency offers no rationale based on the definition of "tobacco product" or the legislative history indicating that such definition can be stretched so far as to capture these types of ENDS products merely because they are used to consume tobacco products. Motions for summary judgment are pending, with a hearing scheduled for Oct. 19.

The second case pending in the D.C. district court involves a claim by John Middleton Co. LLC (a subsidiary of Altrea Group Inc.), 16-00996, which makes Black & Mild cigars, that the FDA's rules that ban the use of words such as "light" or "mild" on product labels on both cigars and e-cigarettes is impermissible. In its complaint, Middleton asserted that the rule "terminates the iconic brand name on the bare supposition that the word 'mild' impermissibly communicates to consumers that Black & Mild products are safer than other cigars and pipe tobacco." The complaint also alleges that the "FDA cited no evidence that the Black & Mild name conveys any message about the health risks of the products." "To the contrary, the FDA ignored unrebutted evidence — including a study by a leading expert on consumer perception — that the name 'Black & Mild' does not communicate anything about health, risk or safety."

In West Virginia, Larry Faircloth, a Republican in the West Virginia House of Delegates and an e-cigarette user, has brought an action claiming that he used e-cigarettes and other vaping devices to quit smoking and will "likely return to the unhealthy habit of using tobacco products" as a result of the rule. (16-005267). The complaint alleges:

- By operation of the deeming rule limitation on the availability of vape and e-liquid products, plaintiff's likely return to more dangerous tobacco products will result in additional health care costs to plaintiff.
- Based on Faircloth's smoking history, two packs per day and a life-expectancy of approximately 30 years, the complaint argues that the increase to plaintiff's health care costs will be an estimated $766,500.

Faircloth's complaint requests the court to strike the FDA rule.

Two actions invoke, among other claims, the Regulatory Flexibility Act (RFA). *Enrique Fernando Sanchez Icaza v. FDA*, 16-21967 (S.D. Fla.), and *Lost Arts Liquids LLC v. FDA*, 16-003468 (C.D. Cal.) claim the FDA failed to consider the effect this rule would have on small business in violation of the RFA.

The Los Angeles complaint states that, rather than focus on the overall costs and benefits of a particular regulation, the "RFA requires the Agency to undertake an analysis that determines the impact of the rule on small entities and then considers the alternatives that reduce or minimize those impacts" and the FDA failed to do that with these regulations.

It is clear that the FDA's new regulations will affect the e-cigarette, vaping and other tobacco products industry. What is not yet clear is whether the lawsuits addressed above, all attacking the rules from numerous different angles — violations of the First, Fifth and 10th Amendments; violation of the Administrative Procedures Act; violation of an individual's rights to cease tobacco smoking and violation of the RFA — will result in the FDA being required to modify the "deeming rule."

Regulations and litigation relating to tobacco and tobacco products had its initiation in the second half of the 20th century and appears to be continuing well into the 21st century. At this point, a prudent approach for manufacturers of tobacco products is to take the necessary steps to comply with the regulations.

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Ruling a win for pot, but Congress could change tomorrow

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ger prosecute medical marijuana suppliers and other individuals who are in full compliance with state medical marijuana laws, it leaves some areas where the feds can still take action against marijuana businesses.

The consolidated appeal at issue in *McIntosh* arises from criminal prosecutions in three different federal districts involving 10 different cases and 14 defendants. Two of the cases arose from activity in California, and one arose from activity in Washington. All three cases involved defendants operating without a permit "per se," and engaging in activities that, while pushing the boundaries of state law, were arguably within each state's medical marijuana laws.

The core issue at the heart of the court's decision was the interpretation of language contained in a spending rider for the 2014 and 2015 Appropriations Bills. The language of the rider stated that the Department of Justice was prohibited from using funds allocated to them to interfere with state implementation of medical marijuana laws.

Because this language was unclear and imprecise, the court had to interpret what it meant for the DOJ to "prevent" states from "implementing" their medical marijuana laws. And, specifically, the court had to determine whether prosecuting someone under the Controlled Substances Act (CSA) for conduct allowed under state law prevented that particular state from implementing its medical marijuana laws.

The DOJ argued that the language contained in the rider applied only to prosecution of state actors, such as licensing clerks, and did not apply to individual actors in the medical marijuana industry. Rejecting the DOJ's narrow interpretation of the rider language, the court concluded that if the DOJ punishes individuals for engaging in activities permitted under state law (such as the use, cultivation, distribution and possession of medical marijuana), then the DOJ is preventing state law from being implemented as a practical matter:

"DOJ, without taking any legal action against the Medical Marijuana states, prevents them from implementing their laws that authorize the use, distribution, possession, or cultivation of medical marijuana by prosecuting individuals for use, distribution, possession, or cultivation of medical marijuana that is authorized by such laws. By officially permitting certain conduct, state law provides for non-prosecution of individuals who engage in such conduct. If the federal government prosecutes such individuals, it has prevented the state from giving practical effect to its law providing for non-prosecution of individuals who engage in the permitted conduct."

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An employee works with medical marijuana at a dispensary in Arcata.

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The court's decision creates a barrier to federal prosecutions of individuals who can demonstrate strict compliance with their state's medical marijuana laws. Essentially, the ruling creates a defense to federal prosecution for medical marijuana producers where none existed before. The ruling has the effect of making a state's medical marijuana laws relevant in a federal prosecution, where the laws were previously irrelevant.

The court's ruling goes further to insulate medical marijuana actors from prosecution than the well-known "Cole Memo" of 2013, which laid out the priorities of the DOJ regarding the enforcement of the CSA. The Cole Memo, named for its author, then-Deputy Attorney General James M. Cole, established that jurisdictions that have legalized marijuana in some form (e.g., medical marijuana) pose less of a threat to federal priorities under the CSA, provided they have well-established regulatory schemes. The memo goes on to suggest that prosecution of individuals in those jurisdictions is the not the best use of DOJ time and resources, and signaled that the DOJ would generally leave it to the states to regulate such activity even though it violates the CSA.

Although the 9th Circuit's decision brings some much needed clarity to this area, there are a few notable caveats. While the court's ruling applies to medical marijuana regulation as discussed in the Cole Memo, it does not address participants and actors in the *recreational* marijuana industry. Additionally, the decision does nothing to protect individuals from prosecutions for conduct ancillary to medical marijuana activity, such as illegal firearms activity, money laundering and other criminal activity.

Perhaps the largest caveat to the court's decision is that it is subject to Congress re-authorizing the same limitation for future budgets. Without re-authorization, any impact this ruling has on the medical marijuana industry could completely change.

The unanimous 9th Circuit ruling was issued by a three-judge panel, two of whom are Republican appointees with a history of pro-law enforcement opinions.

Despite the outcome, however, Judge Diarmuid O'Scannlain wrote that medical marijuana purveyors should not feel immune from federal law: "Congress could restore funding tomorrow, a year from now, or four years from now," he wrote, "and the government could then prosecute individuals who committed offenses while the government lacked funding."

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