Heed the Change

FDA oversight of tobacco products has already started to unleash a wave of challenges for manufacturers and distributors. An intimate understanding of this new legislation, and the powers it grants the FDA, are crucial for safely navigating these uncharted waters.

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When President Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in June 2009, he set into motion a sea change for the tobacco industry and how it will be regulated going forward. The FSPTCA amends the Food, Drug and Cosmetic Act to provide the FDA the authority to regulate tobacco products. This transformation has already begun with the FDA's announced intention to create the Center for Tobacco Products, a stand-alone division of the FDA to be headed by Dr. Lawrence Deyton. It will oversee the implementation of the FDA's new sweeping powers to regulate the manufacturing, marketing, and sale of tobacco products.

In order to safely navigate these uncharted waters, it is crucial that tobacco product manufacturers and distributors have a comprehensive understanding of the FSPTCA, the FDA, and the FDA's process for promulgating rules and regulations.

HEEDING PRESUMPTIONS

A perfect example of this necessity is Section 916(b) of the FSPTCA, which could save state products liability actions from federal preemption of failure to warn claims allowing the application of "heeding presumptions."

A heeding presumption is "a rebuttable presumption that allows a fact-finder to presume that the injured plaintiff would have heeded an adequate warning if one had been given." A plaintiff who evokes the heeding presumption need not prove that the manufacturer's failure to warn of a product's danger caused the plaintiff's injury. Instead, the jury (or judge) presumes that an adequate warning would have been followed and the plaintiff would not have been injured, and the burden then falls on the manufacturer to rebut the presumption. The states that have adopted the presumption include Arkansas, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Missouri, North Dakota, New Jersey, New York, Nebraska, Ohio, Oklahoma, Texas, Vermont, and the District of Columbia. The device is frequently employed against tobacco manufactures in product liability cases based upon a failure-to-warn theory of liability.

The Federal Cigarette Labeling and Advertising Act ("FCLAA") of 1965, as amended in 1984, mandates cigarette labeling requirements and allows tobacco manufacturers and distributors to avoid the heeding presumption and failure-to-warn claims.

Specifically, Section 1334(b) of the FCLAA provides "[n]o requirements or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." Under this language, federally mandated cigarette labeling requirements imposed by the FCLAA allow tobacco manufacturers to avoid heeding presumptions and failure-to-warn claims altogether because the provision was found to preempt conflicting state based products liability law (Cipollone v. Ligget Group, Inc., 1992).

NEW AMENDMENTS TO CIGARETTE LABELING ACT IMPLEMENTED

The FSPTCA explicitly amends certain provision of the FCLAA that relate to labeling of tobacco products. Section 201 of the FSPTCA states "Section 4 of the Federal Cigarette Labeling and Advertising Act . . . is amended" and then directly alters the operative language of the FCLAA. The FSPTCA also amends the disclosure requirements for tar, nicotine, and other smoke constituents.

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Based on this interaction between the FSPTCA and FCLAA, Section 916(b) of the FSPTCA may potentially impact heeding provisions and federal preemption. Section 916(b) of FSPTCA provides "[n]o provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any state." This provision, in direct contradiction of Section 1334(b) of the FCLAA, appears to save state products liability actions from federal preemption and allow the application of state law heeding provisions.

AVOID RISK; HEED THE CHANGE

The passage of the FSPTCA, the existence of the requirements of the FCLAA, and what will soon be the creation of new rules by the FDA through its new division, places the tobacco industry in uncharted waters. A nuanced understanding of the FSPTCA, the FDA, and the FDA's process for promulgating rules and regulations is necessary to recognize the changes to come. It is critical for the tobacco industry to begin its education on who the FDA is, how it works, how it evaluates safety measures, and what it views as appropriate marketing and sales programs.

Tobacco manufacturers and distributors must be aware that Section 916(b) of the FSPTCA threatens federal preemption of failure to warn claims and state-law-based heeding presumptions. Of course, the contrary nature of Section 916(b) of the FSPTCA and Section 1334(b) of the FCLAA may ultimately require judicial resolution; however, it is still critical that tobacco manufacturers and distributors take into account this contradiction in any positions or arguments they take. The failure of tobacco manufacturers and distributors to educate themselves about the FDA will only serve to expose them to unnecessary risk.

In terms of education, tobacco manufacturers and distributors can look to how the FDA has behaved in the past to gain insight into the future. For example, knowledge of the FDA's positions on advertising of products under its authority may prove useful. The FDA strictly enforces advertising parameters on drugs such that virtually any deviation from the accepted advertising protocols will immediately result in the FDA issuing warning letters and possibly initiating enforcement actions. As another example, an understanding of Good Manufacturing Practices ("GMPs") may be helpful. The FDA establishes standards on GMPs for all products under its preview; deviations from these standards can result in enforcement actions. Lastly, and potentially of critical importance, is a working knowledge of how the FDA will define safety of tobacco products.

One of the FDA's primary missions is safety, and it is inevitable that it will develop rules concerning safety in regard to tobacco products. The FDA rule-making process will set forth how the statute will be implemented. This rule-making process will include the issuance of interim rules, a comment period, and then the issuance of final rules. It is key that the tobacco industry participate in defining safety by submitting comments during the comment period, which have now been extended to December 28, 2009 (visit www.fda.gov).

CONCLUSION

The enactment of the new laws and the rules which will follow will affect the business of the tobacco industry as will the risks and liabilities the industry will continue to face. To minimize risk and to be able to continue a vibrant tobacco business, the industry will have to get ahead of the sea change. S

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