

*Deeming Regulations.*—The Committee is encouraged that FDA has provided options for a way forward on distinguishing between premium cigars and other tobacco products in its recently proposed rule “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products” (Docket No. FDA-2014-N-0189). In particular, the Committee notes that FDA is considering excluding premium cigars from the scope of this proposed rule through Option 2. The Committee believes this could be a viable solution, given that the Family Smoking Prevention and Tobacco Control Act makes little mention of cigars throughout the legislation, and there is even less evidence that Congress intended to focus on the unique subset of premium cigars. The Committee notes that premium cigars are shown to be distinct from other tobacco products in their effects on youth initiation, the frequency of their use by youth and young adults, and other such behavioral and economic factors.

*Artificial Pancreas.*—The Committee commends FDA for taking critical steps in advancing artificial pancreas systems, including its recent approval of the threshold suspend system. The Committee encourages FDA to continue collaboration with key stakeholders to ensure that artificial pancreas systems are further developed, tested, and approved, ensuring timely access to safe and effective systems for patients with type 1 diabetes.

*Natural Claims.*—The Committee requests that the Commissioner submit to the Committees on Appropriations of both Houses of Congress a detailed document describing the agency’s current policy with respect to natural claims on food products within 90 days of enactment of this Act.

*Regulation of Tree Nuts.*—The Committee urges FDA to consider the exemption of tree nut producers from regulation under section 419 of the Federal Food, Drug, and Cosmetic Act if such tree nuts meet the criteria for “rarely consumed raw” and the recipient of the produce performs commercial processing that adequately reduces pathogens as described in the proposed regulation “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule”.

*Generic drug labeling.*—The Committee is deeply concerned with FDA’s proposed rule regarding “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products” that would change longstanding policy and allow generics to alter their label without FDA’s prior approval. Ironically, FDA published this proposed rule after the agency’s recent success in launching the Sentinel Initiative. This initiative helps to electronically track the safety of drugs once they reach the market, especially in terms of identifying drug safety communications.

The Committee is unaware of evidence of a need to change existing regulations. The proposed rule has the potential to threaten public health by creating unprecedented patient and provider confusion by having multiple labels for the same product, therefore undermining the longstanding policy of sameness. The Committee urges FDA to maintain a system where prescription drug labels on the market are FDA-approved, grounded in scientific evidence, and