An Overview of Current Tobacco Industry Reporting and Data Collection:

Differences in Tobacco Reporting Programs Authorized Under the Federal Cigarette Labeling and Advertising Act (FCLAA), the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) and the Family Smoking Prevention and Tobacco Control Act (FSPTCA)

Purpose:

- To identify the differences in tobacco industry reporting programs to the Department of Health and Human Services (HHS), with the idea of reducing any duplication, if it exists, and potentially open the ability to coordinate information sharing between HHS agencies.

Background:

- The Center for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) and the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) have engaged in discussions over their tobacco manufacturer reporting programs, determining that while similarities exist in the nature of information collected, there are key distinctions that make their program reporting non-duplicative.

Key Distinctions:

Product Data:

- FDA's regulatory authority requires data collection of ingredient content for cigarettes and smokeless tobacco, including paper, filter, & other components of these tobacco products. FDA regulations will detail information collection specifically regarding nicotine content.
  - Data includes/will include quantity of ingredients, and brand- and sub-brand-specific information.

- CDC's program requires data collection of ingredient components for cigarettes and smokeless tobacco. Nicotine data is collected for smokeless tobacco products only.
  - Data does not include the quantity of ingredients, or brand- or sub-brand-specific information. Such data is collected for smokeless tobacco nicotine content only.

Timeline of Collection:

- FDA's regulatory authority allows for a baseline collection of product information at least 90 days prior to market introduction (or 6 months after FSPTCA enactment for existing products already on the market) and again upon any changes in product formulation.
  - There is no periodic data collection.

- CDC's program allows for annual data reporting, regardless of changes to product formulation.

Summary Conclusions & Recommendations:

- While similarities exist in the nature of the information collected, key differences in the scope and detail of the information make these collections non-duplicative.
- Aligning the programmatic collection and sharing of information will improve the overall utility of data collected. This will allow the agencies to verify the reliability and accuracy of the data, given CDC's year-by-year program and ability to serve as an annual quality assurance check for FDA monitoring of tobacco product changes by manufacturers.
- The HHS agencies would benefit from the ability to share information received under the FCLAA, CSTHEA, and FSPTCA legislation.

Appendix:

Additional Information about FCLAA, CSTHEA, and FSPTCA:

- The Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1335a, requires each person who manufactures, packages, or imports cigarettes to submit to the Department of Health and Human Services (HHS) a list of ingredients added to tobacco in the manufacture of cigarettes. The Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) has the primary responsibility for this aspect of HHS' tobacco and health program.

- The Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), 15 U.S.C. 4403, requires each person who manufactures, packages, or imports smokeless tobacco products to report to the HHS a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and the quantity of nicotine in each smokeless tobacco product. CDC/OSH is also responsible for administering this aspect of HHS' program.

- The Family Smoking Prevention and Tobacco Control Act (FSPTCA), Public Law 111-31, establishes the authority of the Food and Drug Administration (FDA) to regulate the manufacture, marketing, and distribution of tobacco products. 21 U.S.C. 387, *et. seq.* As part of this authorization, section 904(a) (21 U.S.C. 387d(a)) requires tobacco product manufacturers or importers to submit to FDA a listing of the identity and quantity of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product. In addition, once FDA promulgates regulations, manufacturers and importers will be required to submit to FDA information on the content, form, and delivery of nicotine in each tobacco product, measured in milligrams of nicotine. 21 U.S.C. 387d(a)(2). It should be noted that at the current time, FDA has jurisdiction over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. 387a(b).

Reporting Program Comparison:

	FCLAA/CSTHEA (1969/1986)	FSPTCA (2009)
HHS Program Administration	CDC	FDA
Reference Section of US Code	15 U.S.C. 1335a / 15 U.S.C. 4403	21 U.S.C. 387
Cigarette Data Collected: Ingredients	Yes, no quantities, brands & sub-brands not specified	Yes, quantities, brands & sub-brands specified
Cigarette Data Collected: Nicotine	Not collected	Yes, after FDA promulgates regulations; quantities, brands & sub-brands specified
Smokeless Tobacco Data Collected: Ingredients	Yes, no quantities, brands & sub-brands not specified	Yes, quantities, brands & sub-brands specified
Smokeless Tobacco Data Collected: Nicotine	Yes, quantities, contained in each product	Yes, after FDA promulgates regulations; quantities, brands & sub-brands specified
Timeline of Collection	Annual	Baseline collection, with additional collection upon any changes to product
Confidentiality Provisions & Information Sharing	Information submitted is considered trade secret and confidential. Disclosures permitted only as authorized by legislation.	Information submitted is considered trade secret and confidential. Mandate to establish list of harmful or potentially harmful constituents. Other disclosures as permitted by legislation.