Tobacco Control Legal Consortium

Fact Sheet 5

Tar, Nicotine and Other Smoke Constituent Disclosures

Proposed Regulation of Tobacco Products by the U.S. Food and Drug Administration

S. 625/H.R. 1108

The FDA legislation would require tobacco product manufacturers to disclose ingredients, including tar, nicotine and harmful smoke constituents, in their tobacco products. Tobacco companies would be required to disclose to the FDA the following information for each tobacco product brand and sub-brand:

- All ingredients added to the product or its tobacco, paper, filter or other part
- A description of the content, delivery and form of nicotine in each product
- A list of all constituents, including smoke constituents, identified by the FDA as harmful or potentially harmful to health
- All documents relating to the health, toxicological, behavioral or physiological effects of current or future tobacco products or to their constituents, ingredients, components or additives

Manufacturers also would be required to inform the FDA of any changes to the contents of a given product, and to submit all such information at least 90 days prior to the introduction of new brands. The FDA, in turn, would be charged with publicly disseminating a brand-specific list of harmful and potentially harmful constituents.

The legislation would further require tobacco companies to provide, at the request of the agency, all documents relating to:

- Research on the health, harms or effects of tobacco products or any of their constituents or additives
- Whether the health risks of a tobacco product could be reduced by using a technology available or known to the tobacco company
- Tobacco product marketing research or the effectiveness of tobacco product marketing practices

Pursuant to regulations that the FDA would issue within 24 months following enactment, the companies would be required to test and report on all tobacco product constituents, ingredients and additives, including smoke constituents, by brand and sub-brand, that the FDA determined should be tested to protect the public health.

Though not specifically set forth in this legislation, existing federal law would require tobacco companies, upon direction from the FDA, to turn over all documents identified above in electronic form, thus protecting the agency against inundation with potentially millions of pieces of paper.

The legislation also would amend the Federal Cigarette Labeling and Advertising Act (FCLAA) to require a rulemaking proceeding to determine whether cigarette and other tobacco product manufacturers should be required to disclose tar and

nicotine levels on their advertising, packaging or labels. The FDA would be authorized to establish new methods for measuring tar and nicotine levels. The same amendment would allow the adoption of additional FCLAA-based rule-making that would require additional disclosures to the public—but not on product labels or ads—relating to other tobacco product constituents if such disclosure were determined to increase consumer awareness of the health consequences of tobacco use or otherwise benefit public health.

The legislation also provides that states would retain the power to require tobacco manufacturers to disclose ingredients and other information, including information currently exempt from disclosure under federal law, which the states would be required to treat as confidential trade secrets.