Congress Again Considers FDA Regulation

An inside look at the newest tobacco legislation being considered by Congress. >BY BRYAN M. HAYNES AND PAIGE S. FITZGERALD

The newest attempt by Congress to empower the Food and Drug Administration with the authority to regulate tobacco products has been given the seemingly innocuous title of the "Family Smoking Prevention and Tobacco Control Act." It has garnered powerful support — and equally powerful opposition. If passed in its current form, the legislation, introduced concurrently in both the Senate and House of Representatives on February 15, 2007, would grant the FDA wide-reaching authority to regulate current and new tobacco products and would place tight restrictions on tobacco marketing. But what exactly would this new legislation require?

NEW REGISTRATION AND RECORD-KEEPING REQUIREMENTS

In addition to the state-level certification requirements that tobacco product manufacturers must currently fulfill, this legislation imposes a completely new federal registration requirement upon manufacturers. Specifically, the legislation requires that on or before December 31 of each year, every person who owns or operates any business that is "engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary of Health and Human Services."

Manufacturers must supply a product list of all tobacco products manufactured or processed, and the Secretary may require production of all advertisements for a particular tobacco product. In addition, every new manufacturer must immediately register with the Secretary. The information submitted as part of the registration process can be made publicly available. Further, every manufacturer will be inspected by the designated agents of the Secretary at least once every two years.

The Act also imposes substantial ingredient reporting requirements and would require that within six months after the passage of the act, each tobacco product manufacturer or importer must submit the following to the Secretary of Health and Human Resources:

A listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of the date of filing, added by the manufacturer to the tobacco, paper, filter or other part of each tobacco product by brand and by quantity in each brand and sub-brand.

DESCRIBING, IN DETAIL, EACH TOBACCO PRODUCT

A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as being harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and sub-brand.

At the request of the Secretary, a tobacco product manufacturer or importer must submit data related to research and research findings conducted, supported, or possessed by the manufacturer related to the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents, ingredients, or additives. Also required is research related to marketing involving the use of tobacco products or marketing practices as well as the effectiveness of such marketing practices. This would require disclosure of the underlying scientific and financial information related to the company's marketing.

After reviewing and compiling this data, the Secretary would publish a brand-specific list of harmful and potentially harmful constituents within 12 months of the enactment of the Act. Finally, the Act requires manufacturers and importers to establish and maintain records to assure that their tobacco products are not adulterated or misbranded and to "otherwise protect public health."

ADDITIONAL REGULATION OF ADVERTISING

The Act authorizes additional regulation of tobacco product advertising if

the Secretary determines that "such regulation would be appropriate for the protection of public health." This broad statement leaves many unanswered questions for tobacco manufacturers as to how far the FDA might go in this area.

As a first step, however, in restricting advertising and marketing of tobacco product, the Act requires that the FDA's 1996 Rule, which restricted tobacco marketing and sales to minors, be republished within one month and take effect within one year of enactment of the Act. The major restrictions imposed would be:

- *Ban on all outdoor tobacco advertising within a thousand feet of schools and playgrounds;*
- *Ban on all remaining tobacco brand sponsorships of sports and entertainment events;*
- *Ban on giving away non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proofs of purchase;*
- *Ban on free samples and the sale of cigarettes in packages that contain fewer than twenty cigarettes;*
- *Requirement that all outdoor and point-of-sale advertising be in black-and-white text only;*
- *A limitation on advertising in publications with significant teen readership to black-and-white text only;*
- *A restriction on vending machines and self-service displays to adult-only facilities;*
- *A requirement that retailers verify the age of those who purchase tobacco products over-the-counter and additional provision for federal enforcement and penalties against retailers who sell to minors;*

>The Act would require adoption of stronger, more specific health warnings which would cover 30% of the front and rear panels of cigarette packages.

The Act specifically establishes that its provisions won't limit or diminish the authority of the Federal Trade Commission to enforce its own laws regulating the advertising, sale, or distribution of tobacco products. The Act would, however, eliminate the current federal law that prohibits states from banning or restricting the time, place or manner of cigarette advertising under the Federal Cigarette Labeling and Advertising Act. As such, states would be allowed to address the location, size, number, and placement of cigarette advertising resulting in an additional layer of regulatory compliance.

NEW LABELING REQUIREMENTS

The legislation also provides the Secretary of Health and Human Services with the authority to require prior approval of all statements contained on the labels of tobacco products. The Act would further require adoption of stronger, more specific health warnings which would cover the top 30% of the front and rear panels of the package and would bear the word "WARNING" in 17-point type. The FDA would be empowered to revise labeling requirements, which could include restrictions on text, format, size, and the use of color graphics. These same warning labels would be required for advertising and must comprise at least 20% of the area of the advertisement.

An area that has been the source of more recent controversy in the tobacco industry — flavored tobacco products — is also addressed by the Act. The legislation would prohibit cigarettes from

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containing any artificial or natural flavor (other than tobacco or menthol) or any herb or spice, including strawberry, grape, orange, vanilla, chocolate, cherry, cinnamon, or coffee. The Act would also ban the use on labels or advertising of terms such as "light," "mild," or "low."

NEW REGULATION OF TOBACCO PRODUCT "CONTENT STANDARDS"

The Act further requires the FDA to establish tobacco product standards to protect the "public health," such as the reduction or elimination of harmful ingredients, additives, and constituents (including those in tobacco smoke). The FDA would also be given the ability to reduce nicotine yields to any level other than zero, as the Act specifically provides that only Congress has the power to ban any tobacco product or reduce the allowable nicotine level to zero. However, the practical effect of the provision is that the FDA could require the reduction of nicotine to very minimal levels without further Congressional intervention.

OTHER PROVISIONS

The Act would establish an eleven-member "Tobacco Products Scientific Advisory Committee" to advise the FDA on nicotine and "other safety, dependence, or health issues." The Committee is required to include a representative from the tobacco industry and as well as a representative of tobacco growers. In addition, the bill includes very specific standards that must be met prior to FDA approval and sale of certain "reduced harm" tobacco products.

CONCLUSION

With all of these new layers of regulation, a question arises: who will bear the costs of this legislation if passed? The answer should be no surprise: the new FDA activity would be funded through a fee on tobacco product manufacturers allocated by market share. As this legislation works its way through Congress, it undoubtedly will be vigorously debated and if passed, the final version may be significantly different from the current bill. Thus, any participant in the tobacco industry would be well-advised to stay abreast of the developments in this important legislation. S

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