RJReynolds

August 20, 2004

The Honorable William M. Thomas
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Mr. Chairman:

We were astonished to learn that the Senate, with no committee process, no opportunity for amendment, and very limited debate, amended H.R. 4520 on July 15 to impose a tax increase in excess of $15 billion over the next ten years. In addition, the Senate amendment included a regulatory structure that will grant unprecedented regulatory power to the Food and Drug Administration (FDA) without any of the objective standards that normally accompany important federal regulatory statutes.

New Taxes. The FDA portion alone will result in an estimated $3 billion tax increase, including a built in inflation escalator that will impose new taxes estimated at $381 million by the tenth year. By comparison, the budget request for proposed FDA authority in 2000 was $34 million, and the entire FDA medical device budget for fiscal year 2004 is an estimated $191 million. This enormous new tax increase is in addition to the $19 billion already imposed annually on the industry in federal, state, and municipal taxes. It will result in significant decreases in additional master settlement payments and escrow obligations currently included in all 50 state budgets. Yet none of this was considered or even debated by the Senate.

The suggestion that tobacco product manufacturers can simply "absorb" these new costs is impossible. The new costs, in some cases, will exceed the annual operating income of our companies, and financially cripple others. Between 1998 and 2002, the government collected well over $135 billion in revenue from largely lower to middle income Americans. Singling out this group of adult consumers for additional pass-through taxation is unfair and unwise tax policy.

The sweeping regulation would be funded through user fees. User fees are imposed by agencies where industry benefits from more expedient agency action, such as in the case of drug or medical device approvals. In this instance, however, the FDA bill requires industry to directly pay the costs for the government to impose regulations that would burden, rather than benefit, that same industry. Moreover, it allows the agency to bypass the traditional oversight and control exercised by Congress through the appropriations process.

Unlimited Regulatory Power. The language allows FDA to regulate the sale, distribution, marketing, advertising, promotion and access to tobacco products based on whatever is deemed "appropriate for the protection of the public health." It allows the FDA to unilaterally mandate standards for levels of elements or compounds found in tobacco products on the same basis, including all elements or compounds found naturally in leaf tobacco. This unprecedented authority goes well beyond what is granted for the regulation of food products.

The new FDA authority would give the federal government de facto power to ban conventional tobacco products. FDA can preclude the use of any natural or added ingredients, or mandate reductions in

smoke constituents that would make the products unacceptable to all or nearly all adult consumers. The Senate language also lacks normal regulatory standards to guide the sweeping new authority granted to the federal government. Unlike many other major federal regulatory statutes, these new mandates can be imposed on manufacturers regardless of the cost, feasibility or even existence of suitable technology. There are no tolerance levels that must be established for residues or substances as under food statutes. And such standards are exempt from meaningful judicial review, because it is "the burden of any party challenging the proposed standards to prove that [it] will not reduce or eliminate the risk of injury or illness" – essentially requiring the industry to prove a negative. The bill also gives FDA special exemptions from laws that apply to other agencies, like the Administrative Procedures Act, laws regulating research "advances" for grants given by agencies, and laws requiring that government contracts be advertised in advance.

The new FDA authority will move the industry toward the operation of a single, heavily regulated monopoly. It appears to be the strategy of one manufacturer to pursue a "last one standing" approach to corner the future adult market. If Congress wishes to pursue a monopoly approach exclusively for the benefit of the largest single U.S. manufacturer, there are clearly less expensive and less complex ways.

Bureaucratic Duplication, Confusion, and Suppression. We have numerous concerns with the specific language passed by the Senate. It will result in several instances of regulatory duplication. It adds a layer of marketing and advertising authority to that which exists at the Federal Trade Commission. And it eliminates existing federal preemption of state limits on labeling, marketing, and advertising, thereby creating multiple new jurisdictional layers. The language also includes many duplicative terms that are undefined and appear to have similar meanings. As drafted, the bill is certain to produce multiple disputes regarding its interpretation.

The brief discussion on the Senate floor failed to consider what role the federal government should play in encouraging the development of new, "modified risk" tobacco products. There are varied opinions on this matter both within the industry and within the public health community. Whether intended or not, the Senate language creates confusion for all parties on the development of new products.

Unintended Side Effects. The new FDA authority will likely result in a substantial increase in black market activity such as counterfeiting and smuggling. The likely establishment of FDA standards that make the taste attributes of tobacco products unacceptable to adult consumers will increase incentives for black market activity. The illicit trade provisions in the bill will be inadequate to deal with this increase, just as current law and resources do not adequately deal with the growth in counterfeit and smuggling activity.

The new FDA authority will make domestic leaf less competitive in world markets. Nearly half of the tobacco leaf grown domestically is exported to foreign markets and not used in U.S. production facilities or consumed domestically. Yet the legislation makes no distinction between tobacco leaf used for domestic consumption and exported leaf. Since many of the changes within FDA's broad new powers will involve compounds that occur naturally in tobacco leaf, the most efficient way to meet new federal mandates will likely involve substantial changes in domestic farming practices. This will add cost to domestic farming processes and require changes in the leaf itself. The combination of added costs and the potential reengineering of tobacco leaf will make U.S. tobacco leaf far less attractive overseas.

The Senate FDA legislation also raises significant free speech concerns. The 1998 state tobacco settlement and voluntary restraints by manufacturers have resulted in broad marketing and advertising restrictions that have contributed to a decline in youth usage of tobacco products to the lowest level in twenty-eight years. However, the new FDA proposal goes well beyond these restrictions to include anti-competitive restrictions such as tombstone advertising and bans on self-service displays, even in adult-

only venues. The language promotes the sale of the current best-selling brand by authorizing FDA to restrict point-of-sale advertising. Such restrictions would severely limit a purchaser's exposure to alternative brands, often sold by smaller manufacturers, which are advertised only at point-of-sale. The broad, unlimited authority to restrict advertising by any means and to any extent "appropriate for the protection of the public health" will fundamentally limit commercial communication aimed exclusively at adult consumers.

It is ironic that more than 200 pages of tobacco restrictions were added to a "jobs bill" with virtually no debate. Quite clearly, the tax and regulatory burden imposed through this unprecedented grant of authority will have a severe impact on both manufacturing and grower jobs in the U.S.

All of these consequences are foreseeable, but none of them were discussed. The process by which this legislation was rammed through the Senate has simply not been fair. With the exception of defense and homeland security initiatives, the Senate tobacco package appears to represent the largest expansion of the federal bureaucracy in many years. We urge Congress to consider these many negative side effects and reject the Senate passed tax and regulatory proposal.

Peter Baenninger President Davidoff of Geneva, Inc.	Malcolm L. Bailey CEO S&M Brands, Inc.	Lynn Beasley President & COO R.J. Reynolds Tobacco Co.
Oscar Boruchin President Mike's Cigars Distributors, Inc.	Leonard K. Brick President Brick–Hanauer, Inc.	David Brunson President North Atlantic Trading Company
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Mark Finkle President King Maker Marketing, Inc.	Theo W. Folz President & CEO Altadis U.S.A.	Robert Franzblau President Thompson & Co. of Tampa, Inc.
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