



ELEVEN REASONS WHY S. 2461 IS BAD PUBLIC POLICY

1. Creates New Bureaucracy.

- Clinton Admin. FY00 budget request for FDA tobacco regulation was \$34 million.
- S.2461 includes a *tax increase of \$300 million* in 2006, adjusted for inflation thereafter. § 920(c)(4)(C) on pp. 115-16.
- By comparison, the entire Bush Admin. FY04 request for medical devices was \$185 million.

2. Broad Authority No Longer Tied to Reducing Youth Usage, but, Rather, to Adult Consumption.

- Bills to create a new tobacco regulatory program originally required that restrictions on sale, distribution, advertising or promotion of tobacco products be “appropriate for prevention of, or decrease in, the use of tobacco products by *children*” (emphasis added).

- Under S.2461, the broad authority to impose new restrictions requires only that the restrictions be “appropriate for protection of the public health.” *See, e.g.,* § 907(a)(3) on p. 53.

- Perhaps one reason for the switch is that HHS statistics (*see, e.g.,* the “Monitoring the Future” annual survey) show that *youth smoking has fallen to a 27-year low.*

3. FDA Will Be Hostile to Tobacco Products and Their Manufacturers.

- It is unprecedented for a regulatory agency to be given jurisdiction over a set of products and manufacturers it hates and wants to drive from the market.

- Therefore, the normal expectations as to how an agency will use discretionary powers will not apply here.

4. Grants De Facto Power to Ban Existing Conventional Tobacco Products.

- FDA may adopt tobacco product standards at any level, as long as they are “appropriate for protection of the public health.” § 907(a)(3) on p. 53.

- Such standards can regulate any aspect of “the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product” § 907(a)(4)(B)(i) on p. 55.

- FDA can preclude the use of any ingredients, or mandate reductions in smoke constituents that would make the products *unacceptable to all or nearly all adult smokers*. See, e.g., § 907(a)(4)(A)(i)-(ii) on p. 54.

- Such standards are exempt from meaningful judicial review, because it is “the burden of any party challenging the proposed standard to prove that [it] will not reduce or eliminate the risk of illness or injury” – which means proving a negative. § 907(b)(10)(C) on p. 58.

5. Will Dramatically Increase Black-Market Activity.

- The standard that governs the critical decisions under the bill -- “appropriate for protection of the public health.” – takes no account of product acceptability, cost, feasibility, or the likelihood of an increase in black-market activity. See § 907(a)(3) on p. 53.

- FDA standards that make conventional cigarettes unacceptable will create enormous incentives for increased black-market activity.

- The bill’s illicit-trade provisions will be inadequate to deal with a new surge in black-market activity caused by FDA mandates, just as current law does not adequately deal with the growth in counterfeit and smuggling

activity today.

6. Favors Larger Companies Over Smaller Companies.

- The bill creates enormous and unnecessary disclosure burdens that will disadvantage small competitors: including “any or all documents” relating to health or marketing. §§ 904(a)(2)-(4), 904(b) on pp. 30-32.

- The bill requires manufacturers to submit a list of all harmful or “potentially harmful” constituents, including smoke constituents, in each brand (not all of which have even been identified). § 904(a)(3) on pp. 30-31.

- It imposes on each manufacturer vague and potentially enormously burdensome and wasteful testing obligations. *See, e.g.*, § 907(a)(4)(B)(ii)-(iii) on p. 55

- It authorizes further limits on sale, distribution, advertising, and promotion – including retail display – of tobacco products; such limits benefit dominant tobacco product brands and the largest tobacco companies. § 906(d) on p. 45.

7. Favors Existing Products Over New Products.

- New conventional products (those making no health claims) are subject to a “pre-market approval process,” under which the approval “shall” be denied if it is not shown that the product “would be appropriate for the protection of the public health.” § 910 on pp. 69-83.

- It is likely that FDA will find that no new conventional tobacco product satisfies this standard.

8. Creates Insurmountable Barriers to Development of Reduced-Risk Products.

- No reduced-risk claim may be made in the marketing of any tobacco product unless an application is filed with and approved by FDA; there is no time limit for FDA action. § 911(a) on p. 83.

- The claim will be approved only if the product significantly reduces harm to users *and also* benefits the health of the population, including non-smokers; such approval is likely to be *unattainable*. § 911(g)(1)(A)-(B) on pp. 87-88.

- FDA may mandate the use of such reduced-risk technology in conventional products – *regardless of cost*. § 907 on pp. 52-62.

- Approval will be withdrawn once FDA imposes the reduced-risk technology on all conventional cigarettes by means of a regulatory standard. § 911(j)(3)(A) on pp. 96-97.

- Thus, manufacturers will have virtually no incentive to develop new technologies.

9. Limits the Ability to Communicate with Adult Consumers.

- The 1998 Master Settlement Agreement with state Attorneys General already eliminated the most youth-sensitive forms of marketing and advertising: it bans all outdoor and transit advertising (including billboards), limits the size of retail advertising, bans advertising in youth-oriented publications, limits corporate sponsorship, bans brand-name merchandise, and bans youth access to free samples.

- Additional restrictions potentially authorized by the bill, such as tombstone advertising and a ban on self-service displays, will, if constitutional, significantly impact adult consumers. *See* § 906(d) on p. 45; § 102 on pp. 120-22 (mandating re-promulgation of 1996 FDA final rule, § 897.32(a)-(b) of which limited cigarette and smokeless tobacco advertising to tombstone format, except in adults-only venues).

- The broad, unlimited authority in the bill to restrict advertising by any means and to any extent “appropriate for the protection of the public health” will fundamentally limit communication to adult consumers. § 906(d) on p. 45.

10. Eliminates Existing Federal Preemption of State Limits on Marketing, Advertising.

- The bill allows States and local governments to enact any restriction “that is in addition to, or more stringent than,” those in the bill. § 917(a)(1) on p. 106.

11. Grants FDA Indirect Authority to Mandate Changes in Farming Practices.

- The bill places no limits whatsoever on FDA authority to reduce or ban compounds found naturally in tobacco leaf (except that FDA may not require that nicotine be completely eliminated). §§ 907(a)(4)(A)(i)-(ii), 907(b)(3)(B).

- Many of the new mandates FDA is likely to adopt will be achievable only through dramatic changes in tobacco farming operations (for example, restrictions on the types of soils where tobacco may be grown, genetic modifications to seed, pesticide practice changes, and changes in cultivation practices or curing techniques).

- The so-called tobacco farmer protections in the bill are hollow, as they *do not protect tobacco leaf* produced on a farm and possessed by a manufacturer. See § 901(c)(2)(A)-(B) on pp. 23-24.

- FDA could use its authority to prescribe tobacco products standards and good manufacturing practices to impose restrictions on tobacco leaf used as raw materials by tobacco product manufacturers; such restrictions could affect growing and curing. See §§ 907 on pp. 52-62, §906(e) on pp. 47-52;