labeling and advertising regulations.'' As a specific example of potential separate and conflicting Federal standards, some of the comments noted that proposed § 897.34 would completely prohibit the use of some promotional items that are exempted by FTC from the congressionally mandated warning under the Cigarette Act.

FDA disagrees with these comments. When Congress enacted the Cigarette Act and the Smokeless Act, it very carefully considered the proper scope of preclusion applicable to Federal agencies in the regulation of tobacco products. The express terms of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a) clearly reflect the full scope of preclusion of Federal agencies intended by Congress.

Had Congress believed more preclusion to be necessary, it could have easily expanded the express scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a). (See *Banzhaf*, 405 F.2d at 1089 (Had Congress intended to foreclose other types of Federal regulation, ''it might reasonably be expected to have said so directly—especially where it was careful to include a section entitled 'Preemption' specifically forbidding designated types of regulatory action''); *Central Bank of Denver* v. *First Interstate Bank*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).) Indeed, Congress took this very approach with respect to the scope of preemption applicable to States under the Cigarette Act when it drafted 15 U.S.C. 1334(b) in a broad manner to encompass ''requirement[s]'' and ''prohibition[s].''

The discrepancy in Congress' choice of words with regard to the scope of 15 U.S.C. 1334(a) and (b) is significant in its implications. By not including ''requirement or prohibition'' in 15 U.S.C. 1334(a) and expressly foreclosing only ''statements'' relating to smoking and health, Congress clearly intended to narrowly limit the scope of foreclosure of regulation applicable to Federal agencies. (See *Brown* v. *Gardner*, 115 S. Ct. 552, 556 (1994) (''[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion'') (citation omitted).) In a similar fashion, Congress demonstrated an intent to restrict the scope of Federal preclusion under 15 U.S.C. 4406(a) by narrowly tailoring the language of that subsection.

Thus, given the narrow scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), the Cigarette Act and the Smokeless Act do not foreclose ''separate'' Federal requirements, other than cautionary health-based statements as discussed in sections X.A. and X.B. of this document. Although the final rule imposes requirements on tobacco product manufacturers, these requirements do not conflict with the Cigarette Act or the Smokeless Act and, consequently, are not precluded by those statutes. Moreover, that FTC might allow certain actions under its statutory mandate does not preclude FDA from prohibiting such actions under a different statutory mandate. (See *New York Shipping Ass'n* v. *Federal Maritime Comm'n*, 854 F.2d 1338, 1367 (D.C. Cir. 1988) (''there is no anomaly if conduct privileged under one statute is nonetheless condemned by another''), *cert. denied*, 488 U.S. 1041 (1989).)

(5) Some of the comments asserted that Congress intended that the sole health-based restraints that were to be imposed on the commerce of tobacco products were to be those provided in the Cigarette Act and the Smokeless Act.

FDA disagrees with this assertion. First, FDA clearly may exercise legal authority to regulate tobacco products when the evidence establishes that the products have intended uses that fall within the act's definition of a ''drug.'' Indeed, the agency has done so in several instances. (See, e.g., *United States* v. *354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States* v. *46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338–39 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease).) Moreover, the comments' assertion that health-based constraints can be imposed upon tobacco products only under the Cigarette Act and the Smokeless Act necessarily leads to the erroneous conclusion that much Federal and State regulation, such as health-based workplace smoking restrictions and health-based age limits on access, is foreclosed. As other comments recognized, Congress obviously did not intend for such broad preclusion to be the case. (See *Banzhaf*, 405 F.2d at 1089 (finding that ''[n]othing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation'').)

(6) Some comments asserted that FDA's proposed restrictions on certain advertising for tobacco products are at odds with congressional intent to allow the continued use of advertising for these products in conjunction with the statutorily required warnings.

FDA disagrees. As discussed in sections X.A. and X.B. of this document, preclusion of Federal regulation of advertising for tobacco products is very narrow in scope and does not encompass FDA's final rule. Moreover, as one court has noted:

> [T]here is no anomaly if conduct privileged under one statute is nonetheless condemned by another; we expect persons in a complex regulatory state to conform their behavior to the dictates of many laws, each serving its own special purpose.

(New York Shipping Ass'n, 854 F.2d at 1367)

Thus, the mere fact that certain advertising for tobacco products is permitted under the current regulatory scheme for those products does not preclude FDA from placing restrictions on such advertising.

(7) Some comments alleged that the 1995 proposed rule would conflict with Federal law and congressional intent because it would have an impact on the commerce of tobacco products.

FDA disagrees. Any proscriptive regulation of tobacco products inevitably imposes economic burdens upon commerce of those products. Thus, following the comments' line of argument, all proscriptive regulation of cigarettes is foreclosed by the Cigarette Act and the Smokeless Act. As explained in this section, however, by enacting 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), Congress chose the proper level of limitation on Federal regulations that it concluded was necessary to protect the commerce of tobacco products from being unduly economically burdened. Because requirements contained in the final rule are not precluded under those provisions, the fact that the requirements will have economic consequences upon the commerce of tobacco does not mean those requirements are foreclosed.

(8) One comment argued that the 1995 proposed rule is precluded because Congress could not have intended for any agency to have the authority to prohibit the sale of cigarettes. The comment derived this ''intent'' from pieces of legislation enacted by Congress that provide for the regulation of specific aspects of cigarettes but do not prohibit their sale.

FDA disagrees. Enactment of legislation giving other agencies authority over particular aspects of

cigarettes means only that Congress has decided to take those particular actions; it does not imply that Congress has determined that other Federal regulation is prohibited. Congress can implement policy in only one way: passage of a bill by the House and the Senate that is either signed by the President or approved by an overridden veto. (*INS* v. *Chadha*, 462 U.S. 919, 954–58 (1983); *Central Bank*, 114 S. Ct. at 1453.) Because Congress has not adopted any legislation that specifically prohibits FDA from regulating tobacco products, the final rule is not precluded.

In summary, FDA's final rule has been narrowly tailored so that it does not conflict with the existing statutory scheme governing tobacco products, and the final rule is not precluded.

2. The PHS Act

Section 1926 of the PHS Act conditions a State's receipt of the full amount of Federal block grants (to be used for prevention and treatment of substance abuse) upon the recipient State having in effect a law that makes it ''unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18'' (42 U.S.C. 300x-26(a)(1)).

(9) Some of the comments argued that section 1926 of the PHS Act demonstrates an intent on the part of Congress to preserve, and encourage enforcement of, State youth access restrictions. The comments asserted that because FDA regulation of youth access to tobacco products would have a preemptive effect upon some State regulation in this area, the 1995 proposed rule conflicts with this congressional intent. Accordingly, argued the comments, section 1926 of the PHS Act precludes FDA from regulating youth access.

While FDA agrees that section 1926 of the PHS Act indicates a congressional intent to encourage States to establish age limits on the purchase of tobacco products, neither the statute's language nor its legislative history prohibits Federal regulation of youth access. The restrictions in the final rule regarding the sale and distribution of tobacco products do not conflict with section 1926 of the PHS Act, and, in fact, facilitate the end result that Congress sought—reducing youth smoking—by ''reducing the appeal of cigarettes and smokeless tobacco to, and limiting access by, persons under 18 years of age.'' (See 60 FR 41314 at 41321.) Accordingly, FDA's regulation of youth access is not precluded by the existence of section 1926 of the PHS Act. (See 61 FR 1492, January 19, 1996.)

(10) One comment asserted that the 1995 proposed rule is precluded by section 1926 of the PHS Act because, ''in the legislative process that led to enactment of [section 1926], Congress considered and rejected a variety of specific requirements of the very type that FDA now proposes.'' The Supreme Court, however, has made clear that courts are '''reluctant to draw inferences from Congress' failure to act.''' (*Brecht* v. *Abrahamson*, 113 S. Ct. 1710, 1719 (1993) (citations omitted).) The mere fact that Congress, in enacting section 1926 of the PHS Act, did not incorporate requirements of the type FDA is now imposing in no way precludes FDA's final rule which was issued under the agency's regulatory authority under the act.

D. Occupation of the Field

(11) Numerous comments asserted that the 1995 proposed rule is impliedly precluded by the comprehensiveness of existing legislation relating to regulation of tobacco products. Several comments argued that Congress has specifically reserved the power to regulate tobacco for itself, and thereby has occupied the field. A number of comments asserted that the present system of congressional control over tobacco products precludes FDA regulation absent a new mandate from Congress.

FDA disagrees with these comments. The statutes enacted by Congress for regulation of tobacco products do not amount to a comprehensive scheme. Rather, they address only a few specific aspects relating to regulation of tobacco products. Moreover, even if Congress' actions in this area were ''comprehensive,'' Congress clearly did not intend for regulation under the Cigarette Act and the Smokeless Act to be exclusive. (See *Banzhaf*, 405 F.2d at 1089 (finding that Congress did not intend to foreclose Federal regulation of cigarettes outside the narrow scope of preclusion contemplated by the Cigarette Act).) As explained in greater detail in sections X.A., X.B., and X.C. of this document, the statutes that the comments cite, whether viewed individually or collectively, do not preclude FDA from regulating tobacco products.

First, as some comments noted, Congress has not taken action to exclude from FDA's jurisdiction tobacco products that fall within the act's definitions of ''drug'' and ''device.'' The face of the statute is the first place that a court must look to determine whether Congress has spoken to a particular issue and whether congressional intent in regard to that issue is clear. (*Kofa* v. *INS*, 60 F.3d 1084, 1088 (4th Cir. 1995); *Metropolitan Stevedore Co.* v. *Rambo*, 115 S. Ct. 2144, 2147 (1995).) Under the act, FDA has jurisdiction over products that are intended to address disease or to affect the structure or any function of the body. (See section 201(g) and (h) of the act, 21 U.S.C. 321(g) and (h); 60 FR 41314 at 41463.) Thus, the relevant language of the act—''intended to affect the structure or any function of the body''—does not on its face exclude tobacco products.

Congress is able to exclude and has excluded specific products, including tobacco products, from a statute's reach when it wishes to do so. For example, Congress has expressly excluded other products from FDA's jurisdiction under the act. (See, e.g., section 201(i) of the act (21 U.S.C. 321(i)) (excluding ''soap'' from definition of ''cosmetic''); section 201(s) of the act (excluding ''color additive'' from definition of ''food additive'').) Moreover, Congress has expressly excluded tobacco products from the reach of other regulatory statutes. (See, e.g., 15 U.S.C. 2052(a)(1)(B) (Consumer Product Safety Act); 15 U.S.C. 1261(f)(2) (Federal Hazardous Substances Act); 15 U.S.C. 2602(2)(B)(iii) (Toxic Substances Control Act); 21 U.S.C. 802(6) (Controlled Substances Act); 15 U.S.C. 1459(a)(1) (Fair Packaging and Labeling Act).) Indeed, tobacco is excluded from the definition of ''dietary supplement'' under the act, but no similar exclusion appears in the definition of ''drug'' or ''device.'' See section 201(g), (h), and (ff) of the act (21 U.S.C. 321(g), (h), and (ff)). The absence of an express exclusion for tobacco products from the act's definitions of ''drug'' and ''device'' eviscerates the contention that Congress clearly intended to preclude FDA from regulating tobacco products.

Second, as recognized by some comments, the fact that statutes such as the Cigarette Act and the Smokeless Act delegate some regulatory authority over tobacco products to other Federal agencies does not preclude FDA's rule. Numerous Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise. (See, e.g., *Rueth* v. *EPA*, 13 F.3d 227, 228 (7th Cir. 1993) (EPA and Army Corps of Engineers have concurrent jurisdiction under the Clean Water Act); *Public Utility Dist. No. 1* v. *Bonneville Power Admin.*, 947 F.2d 386, 395 (9th Cir. 1991) (FERC has concurrent jurisdiction

with other Federal agencies as well as States over hydroelectric projects), *cert. denied*, 112 S. Ct. 1759 (1992); *United Packinghouse, Food and Allied Workers Int'l Union* v. *NLRB*, 416 F.2d 1126, 1133–34 n.11 (D.C. Cir.) (NLRB and EEOC have concurrent jurisdiction over racial discrimination claims), *cert. denied*, 396 U.S. 903 (1969).) As discussed in section X.C. of this document, the fact that several agencies are already charged with regulating certain aspects of tobacco does not preclude FDA from asserting jurisdiction for different purposes. (See *Banzhaf*, 405 F.2d at 1089 (''Nothing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation'').)

In conclusion, FDA's final rule is not precluded by the existing regulatory scheme for tobacco products.

E. Preemption of State and Local Requirements Under Section 521(a) of the Act

Under proposed § 897.42, State or local requirements that are more stringent than, and do not conflict with, requirements imposed under FDA's final rule would not have been preempted under section 521 of the act (21 U.S.C. 360k).

(12) Several comments supported the intended exclusion from preemption under proposed § 897.42, noting that it is essential that State and local officials retain the ability to enact and enforce laws which they believe are most effective when actively enforced at the local level.

In contrast, several comments took issue with the proposed exclusion and asserted that regulation of tobacco products by FDA as drug delivery devices would result in the preemption of State and local laws. The comments characterized the ''blanket'' exclusion from preemption under proposed § 897.42 as being at odds with the statutory preemption established by section 521(a) of the act and with the exemption procedures established by section 521(b) and by FDA's regulations.

Several comments argued that proposed § 897.42 would conflict with congressional intent behind the act. One comment noted that preemption under section 521(a) of the act was intended to establish national uniformity in medical device regulation, protecting such products from onerous burdens on interstate commerce created by a patchwork of State and local requirements. The comment argued that the proposed exclusion from preemption would cause uniform Federal standards to become displaced by diverse State and local requirements. Another comment asserted that, by allowing more stringent State and local requirements, proposed § 897.42 was at odds with the act because Congress did not intend for FDA's device regulations to be minimum standards; rather, it intended for those regulations to be the governing standards unless local circumstances justified an exception.

Finally, one comment pointed out that the 1995 proposed rule would permit only those State and local requirements that are at least as ''stringent'' as the requirements imposed under FDA's rule. The comment asserted that FDA may not preempt any State laws, however, without first showing a ''clear and manifest congressional intent'' to authorize preemption of those State laws.

As a preliminary matter, two points of clarification are necessary. First, proposed § 897.42 would not have caused State and local laws to become Federal requirements, as one of the comments anticipated. Rather, the 1995 proposed rule would have allowed State and local laws to remain in force subject solely to State or local enforcement.

Second, proposed § 897.42 would not have ''resuscitated'' State and local laws that would otherwise be preempted by the Cigarette Act or the Smokeless Act, as some of the comments anticipated. Instead, the exclusion from preemption in proposed § 897.42 would have applied only to preemption under section 521 of the act.

Upon consideration of all of the comments relating to proposed § 897.42, the agency recognizes that significant concerns have been raised with regard to the validity of FDA's proposed preemption exclusion for all more stringent State and local legislative enactments. Most notably, the agency concurs that the notice and comment process of the current rulemaking does not provide the type of opportunity for an oral hearing contemplated under section 521(b) of the act. In light of this concern, FDA has deleted proposed § 897.42.

The agency's 1995 proposed rule to exclude all more stringent State and local requirements from any preemptive effect under this rule was based on a recognition of the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgment that more stringent State or local requirements are inappropriate. For example, FDA chose 18 as the age below which cigarettes and smokeless tobacco may not be marketed to children and adolescents. This choice reflected a finding that all but four States have a comparable restriction which addresses the most vulnerable population. However, many comments argued that a higher age would be more effective. While FDA has decided not to establish an age above 18 in the final rule, the agency may, under the exemption process established under section 521(b) of the act, defer to those States that conclude that a higher age is more effective and that apply for an exemption.

In implementing section 521 of the act, FDA has historically interpreted that provision narrowly and found it to have preemptive effect only for those State and local requirements that in fact clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements. (See § 808.1(d) (21 CFR 808.1(d)).) Moreover, section 521 of the act ''does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act'' (§ 808.1(d)(2)).

The agency's assertion of jurisdiction over tobacco products does not preclude any State or local requirements other than those expressly preempted by section 521(a) of the act. Moreover, consistent with FDA's interpretation of section 521(a) of the act, only a limited number of State and local requirements are preempted and even those may qualify for exemption from preemption under section 521(b) of the act.

Examples of State and local laws FDA believes are preempted, consistent with its longstanding approach to implementing section 521 of the act, are the following:

• *More stringent age restrictions*—Three States restrict cigarette sales to anyone under 19 years of age, and one State has 21 years as the minimum age. These restrictions are preempted because they are more stringent than the final rule, which prohibits sales only to individuals under age 18.

• *Restrictions on the distribution of free samples of tobacco products*—Approximately 40 States, the District of Columbia, and many local governments restrict the distribution of free samples of tobacco products. For example, Nebraska bans samples, coupons, and rebate offers for smokeless tobacco. Oklahoma and several other States prohibit the free distribution of tobacco to individuals under 18 and within 500 feet of schools, playgrounds, or other locations used primarily by individuals under 18. Approximately 12 States restrict where free samples may be distributed. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits any distribution of free samples.

• *Restrictions on placement of vending machines*—Most States, the District of Columbia, and several local governments impose restrictions on the placement of vending machines. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits the use of vending machines except in certain locations and under certain conditions.

• *Restrictions on outdoor advertising*—Restrictions on outdoor advertising are preempted to the extent that they are different from, or in addition to, the final rule, which restricts the location, format, and content of such advertising. For example, Ordinance 307, which was enacted by the Mayor and City Council of Baltimore, MD, prohibits the placement of any sign that ''advertises cigarettes in a publicly visible location,'' i.e., on ''outdoor billboards, sides of building[s], and free standing signboards.'' This ordinance was upheld by the Fourth Circuit in the face of a challenge based on preemption under the Cigarette Act and on First Amendment grounds. (See *Penn Advertising of Baltimore, Inc.* v. *Mayor and City Council of Baltimore,* 63 F.3d 1318 (4th Cir. 1995), *vacated and remanded,* 116 S. Ct. 2574 (1996).) Subsequently, the Supreme Court vacated judgment in *Penn Advertising* and remanded the case to the United States Court of Appeals for the Fourth Circuit for further consideration in light of *44 Liquormart, Inc.* v. *Rhode Island,* 116 S. Ct. 1697 (1996). If Ordinance 307 is ultimately upheld in its present form, it will be preempted under section 521 of the act to the extent that it is different from, or in addition to, the final rule.

• *Prohibitions and restrictions relating to free-standing displays*—Prohibitions and restrictions relating to free-standing displays are preempted to the extent that they are different from, or in addition to, the final rule, which allows free-standing displays but restricts the location, format, and content of such displays.

• *Requirements relating to identification checks for purposes of age verification*—Requirements relating to identification checks for purposes of age verification are preempted to the extent that they are different from, or in addition to, the final rule, which requires identification checks for anyone under the age of 26.

Examples of State or local laws or regulations that are not preempted include:

• *Equivalent age restrictions*—Most States establish 18 years as the minimum age for purchasing cigarettes or smokeless tobacco. These restrictions are not preempted because they are equal to, or substantially identical to, requirements imposed under the final rule. (See § 808.1(d)(2).)

• *Restrictions on the sale or distribution of tobacco products*—Several local governments restrict the locations (such as public parks, public buildings, etc.) at which tobacco products may be sold or distributed. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the locations at which tobacco products may be sold or distributed.

• *Restrictions on smoking in public places*—Approximately 48 states, the District of Columbia, and many local governments have some restrictions on smoking in public places. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to restrictions on smoking in public places.

• *Penalties on underage persons who purchase tobacco products*—These penalties are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to penalties on underage persons who purchase tobacco products.

• *Prohibition on use or possession of tobacco products by underage persons*—These prohibitions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to prohibitions on the use or possession of tobacco products by underage persons.

• *Age restrictions on persons who sell tobacco products*—Some local governments have statutes or regulations that establish a minimum age for persons selling tobacco products. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to age restrictions on persons who sell tobacco products.

• *Tobacco excise taxes*—All 50 States and the District of Columbia have excise taxes on cigarettes, and 42 States have excise taxes on smokeless tobacco. These excise taxes are not preempted because they are not ''requirements applicable to a device'' within the meaning of section 521(a) of the act. (See § 808.1(d)(8).)

• *Access-control mechanism requirements for vending machines*—Approximately six States and some local governments require access-control mechanisms on vending machines, such as locking devices or token acceptors. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to access-control mechanisms for vending machines.

• *Posting of signs*—Approximately 24 States have statutes requiring certain parties to post signs at vending machines stating that sales to underage persons are prohibited. One State requires owners or operators of vending machines to post signs warning of the dangers of cigarette use during pregnancy. In addition, many local governments require that signs be posted in areas in which smoking is prohibited by law. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the posting of signs.

• *License requirements*—Some local governments impose license requirements upon retailers of tobacco products. These requirements are not preempted because they are not ''requirements applicable to a device'' within the meaning of section 521(a) of the act. (Cf. § 808.1(d)(3).)

The examples set forth above reflect the types of State or local requirements of which the agency is currently aware.[254] There may be other State or local requirements pertaining to cigarettes and smokeless tobacco. With regard to particular State or local requirements that are not described above, any State, political subdivision, or other interested party may, in accordance with § 808.5 (21 CFR 808.5),

[254] State Legislated Actions on Tobacco Issues, Coalition on Smoking OR Health, Bartelt, J., ed., December 31, 1995.

request an advisory opinion from the agency as to whether such State or local requirements are preempted.

State and local requirements that are preempted by the requirements of FDA's final rule may be exempted from preemption in accordance with section 521(b) of the act and its implementing regulation, part 808 (21 CFR part 808). Section 521(b) of the act and part 808 provide that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local device requirement from preemption under such conditions as the Commissioner of Food and Drugs (the Commissioner), may prescribe if the requirement is: (1) More stringent than Federal requirements applicable to the device under the act; or (2) required by compelling local conditions, and compliance with the State or local requirement would not cause the device to be in violation of any requirement applicable under the act.

By a separate document to be published in the Federal Register, FDA will be informing all State and local governments that they may submit applications to exempt from preemption under section 521(b) of the act those State and local requirements pertaining to cigarettes and smokeless tobacco that are preempted by the final rule. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section and is consistent with the goals in the final rule. Exemptions from preemption that FDA grants apply only to preemption under section 521 of the act.

Because the issues raised by these applications for exemption will be similar or related, the Commissioner has determined that it would be advantageous for all concerned to propose a single regulation granting or denying exemptions for each particular State or local requirement, and, if necessary, to hold a single hearing covering all applications for exemption from preemption for requirements pertaining to cigarettes and smokeless tobacco. Although each application will be considered as part of a single proceeding, each individual application will be evaluated on its merits and the circumstances applicable to the particular submitting jurisdiction.

F. Preemption of State Product Liability Claims Under Section 521(a) of the Act

(13) Several comments asserted that, under section 521(a) of the act, State product liability claims would be preempted if FDA asserts jurisdiction over tobacco products as drug delivery devices.

Based on FDA's understanding of the theories of recovery advanced in tobacco product liability cases, and the nature of the Federal requirements being established in the final rule, FDA does not expect any of these Federal requirements to preempt any tort claims relating to tobacco products. The following analysis explains this conclusion.

The Supreme Court recently held that the scope of preemption under section 521(a) with regard to State product liability claims is very narrow. Indeed, a plurality of the Court noted that ''few, if any, common-law duties have been pre-empted by [section 521(a)].'' *Medtronic, Inc.* v. *Lohr*, 64 U.S.L.W. 4625, 4634 (U.S. June 26, 1996) (Nos. 95–754 and 95–886) (plurality opinion).

Preemption occurs ''only where a particular state requirement threatens to interfere with a specific federal interest.'' *Medtronic*, 64 U.S.L.W. at 4634. Thus, State requirements of ''general applicability'' such as State product liability claims are not preempted, except where they have ''the effect of establishing a substantive requirement for a specific device'' that is ''different from, or in addition to,'' a specific requirement imposed under the act (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4633–34). Moreover, Federal requirements must be ''applicable to the device'' in question, and they preempt State product liability claims only if the Federal requirements are ''specific counterpart regulations'' or ''specific'' to a ''particular device'' (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4634).

In summary, FDA is aware of no tort claims against tobacco products that will be preempted by the Federal requirements being established in the final rule.

XI. Miscellaneous Constitutional Issues

A. Takings Under the Fifth Amendment

(1) Several industry, retail, and individual comments argued that parts of the regulations effect takings compensable under the Fifth Amendment's Takings Clause (the Takings Clause), which provides that ''private property [shall not] be taken for public use, without just compensation.'' For example, comments argued that proposed § 897.34 will restrict or even prohibit tobacco manufacturers' use of their trademarks and copyrighted property, or that it will deprive industry members both of the goodwill generated by their sponsorship of sports and cultural events and of valuable tobacco trademarks. Comments argued that § 897.16(a) effects a taking of intellectual property because it prohibits the use of nontobacco trademarks (with grandfathered exceptions) to market tobacco products. Several comments argued that § 897.16(c) effects a taking of vending machines and self-service displays, as well as contractual rights to place tobacco vending machines on other people's property. Comments argued that the requirement that advertising use only black text on white background in § 897.32(a) effects a taking because nonconforming signs—for buses and on billboards, for example—will have to be destroyed, as would tobacco advertisements on billboards and signs within 1,000 feet of schools and public playgrounds under § 897.30(b).

Comments also argued that the proposed ban on mail-order sales of tobacco products would effect a taking of mail-order businesses. Mail-order sales, however, are not prohibited under the final rule. Many retailers argued that the prohibition of self-service displays and the corresponding requirement that tobacco products be shelved behind sales counters violate the Fifth Amendment.

The Food and Drug Administration (FDA) disagrees that any of these provisions effects a taking in violation of the Fifth Amendment.

In its final form, § 897.16(a) prohibits manufacturers from using the trade or brand name of a nontobacco product as the trade or brand name of a cigarette or smokeless tobacco product, with the exception of those names on both tobacco and nontobacco products that were sold in the United States on January 1, 1995. In its final form, § 897.16(c) prohibits the use of vending machines and self-service displays to sell cigarettes and smokeless tobacco, except that vending machines (including those that sell packaged, single cigarettes) and self-service displays may be used to sell these tobacco products in adult-only establishments. (As proposed in the 1995 proposed rule, § 897.16(c) would have prohibited their use entirely.)

In its final form, § 897.30(b) prohibits tobacco product advertisements within 1,000 feet of a public playground or a secondary or elementary school. In its final form, § 897.32(a) permits only advertising that uses black text on a white background (except in adult publications and in facilities where persons under 18 are not present or permitted). In its final form, § 897.34(a)

prohibits the sale of nontobacco items or services that bear the brand names or other indicia of identification for cigarettes or smokeless tobacco. In its final form, § 897.34(c) prohibits the sponsorship of athletic, musical, cultural, or other social or cultural events in the brand names or other indicia of identification for cigarettes or smokeless tobacco.

A takings analysis begins with a determination of what interest a person has in the thing that is allegedly taken—in this case, in vending machines and self-service displays, copyrighted material, and trademarks and goodwill—and whether that interest ''can be considered property for the purposes of the Taking Clause of the Fifth Amendment.'' (See *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1001 (1984).) If a cognizable property interest is identified, the Supreme Court has developed three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Id*. at 1005).

1. The Interests at Issue

Some of the interests affected by the final rule—vending machines, self-service displays, and existing nonconforming advertising on signs and billboards, for example—is tangible property, whereas contract rights, trademarks and goodwill, and copyrighted material (e.g., the nonconforming copyrighted material on signs and billboards) affected by these provisions are intangible property interests.

Tangible personal property—such as vending machines, self-service displays, and signs and billboards advertising tobacco products—is property for purposes of the Takings Clause (see *United States* v. *General Motors Corp.*, 323 U.S. 373, 383–84 (1945)), although personal commercial property is afforded less protection than real property under the Takings Clause (see, e.g., *Lucas* v. *South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992)).

Intangible interests may be compensable under the Takings Clause as well. For example, in *Ruckelshaus*, the Supreme Court determined that trade secret information—which is intangible—was property compensable under the Takings Clause. The Court noted that the extent of the property right in trade secret information ''is defined by the extent to which the owner of the secret protects his interest from disclosure to others,'' (that is, it is property only insofar as others are excluded from its use) and that it has ''many of the characteristics of more tangible forms of property''—for example, trade secret information is assignable, it can form the res of a trust, and it passes to a trustee in bankruptcy (*Ruckelshaus*, 467 U.S. at 1002).

Vending machine owners may have contracts that give them exclusive rights to sell tobacco products at a particular location. These contract rights would typically be assignable, they may form the res of a trust (see, e.g., *Wadsworth* v. *Bank of California*, 777 P.2d 975, 978 (Or. Ct. App. 1989)), and rights of action based upon them can become part of a bankruptcy estate (e.g., *In re Ryerson*, 739 F.2d 1423, 1425 (9th Cir. 1984)). (See also U.C.C. 9–106.) Such vending machine owners' contracts may therefore create contract rights that would be compensable property under the Takings Clause.

Material can be copyrighted if it is an original work of authorship—such as written, musical, pictorial, or graphic work—that is fixed in a tangible medium of expression from which the work can be reproduced (17 U.S.C. 102(a)). By Federal statute a copyright is assignable (17 U.S.C. 201), and there are rights to exclusive use (17 U.S.C. 106), subject to certain limitations (17 U.S.C. 107–20) and enforceable through infringement actions (e.g., 17 U.S.C. 501). A copyright can form the res of a trust (*Bartok* v. *Boosey & Hawkes, Inc.*, 523 F.2d 941, 948 (2d Cir. 1975)) and it can become property of an estate in bankruptcy (*United States* v. *Inslaw, Inc.*, 932 F.2d 1467, 1471 (D.C. Cir. 1991), *cert. denied*, 502 U.S. 1048 (1992)). Sharing many of the characteristics of more tangible property, a copyright is also compensable property under the Takings Clause.

Trademarks are words, names, symbols, devices, or combinations thereof that a person uses, or intends to use and has applied to register, to identify or distinguish his or her goods from others on the market and to identify their source (15 U.S.C. 1127). The primary purpose of trademarks is to protect consumers by preventing deceitful marketing of one product or service as another. As the Supreme Court has stated,

> [t]he law of unfair competition has its roots in the common-law tort of deceit: its general concern is with protecting *consumers* from confusion as to source. While that concern may result in the creation of ''quasi-property rights'' in communicative symbols, the focus is on the protection of consumers, not the protection of producers as an incentive to product innovation.

(*Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 157 (1989))

When associated with goodwill, trademarks also share—with trade secret information and copyrights—the features of more tangible property. For example, the Lanham Act (15 U.S.C. 1053 *et seq.*) allows assignment of a trademark only ''with the goodwill of the business in which the mark is used or with that part of the goodwill of the business connected with the use of and symbolized by the mark'' (15 U.S.C. 1060). Indeed, when Congress amended the Lanham Act in 1988 to allow intent-to-use applications for registration of trademarks, it prohibited assignment of such applications to be ''consistent with the principle that a mark may be validly assigned only with the business or goodwill attached to the use of the mark'' (S. Rept. 515, 100th Cong., 2d sess. 31 (1988), reprinted in 1988 U.S.C.C.A.N. 5577, 5593–5594).

Owners of trademarks also have rights of exclusive use of marks—that is, against infringement—because ''[b]y applying a trademark to goods produced by one other than the trademark's owner, the infringer deprives the owner of the goodwill which he spent energy, time, and money to obtain'' (*Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844, 854 n.14 (1982)). ''Registration bestows upon the owner of the mark the limited right to protect his goodwill from possible harm by those uses of another as may engender a belief in the mind of the public that the product identified by the infringing mark is made or sponsored by the owner of the mark'' (*Societe Comptoir de L'Industrie Cotonniere Etablissements Boussac* v. *Alexander's Dep't Stores, Inc.*, 299 F.2d 33, 36 (2d Cir. 1962)). Like trade secret information, a trademark can be the res of a trust (see *Coca-Cola Bottling Co.* v. *Coca-Cola Co.*, 988 F.2d 414, 430–432 (3d Cir. 1993)) and it can pass to the trustee in bankruptcy (*Inslaw*, 932 F.2d at 1471).

The agency notes that a trademark itself, unaccompanied by goodwill, lacks these characteristics of property. The agency therefore believes that a trademark itself is not property cognizable under the Takings Clause. Based on the foregoing analysis, however, the agency believes that a trademark and the accompanying goodwill together are property cognizable under the Takings Clause. These conclusions are consonant with the recognition that a trademark has

value as property for the owner ''only in the sense that a man's right to the continued enjoyment of his trade reputation and the good will that flows from it, free from unwarranted interference by others, is a property right, for the protection of which a trademark is an instrumentality'' (*Hanover Star Milling Co.* v. *Metcalf*, 240 U.S. 403, 413 (1916); see also S. Rept. 1333, 79th Cong., 2d sess. (1946), reprinted in 1946 U.S. Code Cong. & Admin. News 1274, 1277 (''the protection of trade-marks is merely protection to goodwill'')).

Nevertheless, this conclusion must be reconciled with Supreme Court precedent on takings of goodwill. In particular, the comments cited *Kimball Laundry Co.* v. *United States*, 338 U.S. 1 (1949), for the proposition that the Takings Clause requires compensation for a regulatory taking of goodwill. The general rule is that the Takings Clause does not require compensation for goodwill when the Government takes a place of business because the business's goodwill may be transferred to a new place of business (338 U.S. at 11–12 and 15; see also *General Motors*, 323 U.S. at 379 (when Government permanently takes land, ''compensation for that interest does not include * * * [even] the loss of goodwill which inheres in the location of the land'')). In *Kimball*, however, the Court allowed compensation for loss of a laundry business's goodwill, or going-concern value, incident to the physical taking of the laundry. It did so because the Government intended to operate the laundry *temporarily* during wartime, after which the laundry would revert to the business; the business could not invest in a new laundry because it would someday be the owner of two laundries, neither of which it could then operate profitably (338 U.S. at 14–15). The Court therefore likened the situation to those in which the Government takes a utility with the intention of operating it itself; the going-concern value of the utility is taken in those cases and is therefore compensable (Id. at 12–13).

Kimball and *General Motors* therefore indicate that goodwill is compensable under the Takings Clause only when no business remains after a taking to whose benefit the goodwill may inure. (See also *District of Columbia* v. *13 Parcels of Land*, 534 F.2d 337, 349 & n.7 (D.C. Cir. 1976).) With respect to goodwill associated with a trademark, use of which is limited by a regulation, these cases indicate that the property interest may be compensable only if the regulation allows no goodwill to inure to the benefit of the owner.

For purposes of the following analysis of whether the regulations effect a taking, the agency assumes that copyrighted material, the interests in trademarks and associated goodwill, contracts, self-service displays, vending machines, and tobacco advertising on signs and billboards are property interests that may be compensable under the Takings Clause if taken.

2. The Takings Analysis

> [W]hat constitutes a ''taking'' for purposes of the Fifth Amendment has proved to be a problem of considerable difficulty. While this Court has recognized that the ''Fifth Amendment's guarantee * * * [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole,'' this Court, quite simply, has been unable to develop any ''set formula'' for determining when ''justice and fairness'' require that economic injuries caused by public action be compensated by the government, rather than remain disproportionately concentrated on a few persons.

(*Penn Central Transp. Co.* v. *City of New York*, 438 U.S. 104, 123–24 (1978) (citation omitted) (alterations and deletions in original); Ruckelshaus, 467 U.S. at 1005)

Still, the Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Ruckelshaus*, 467 U.S. at 1005; *Penn Central*, 438 U.S. at 124).

The force of any one of these factors may be ''so overwhelming * * * that it disposes of the taking question'' (*Ruckelshaus*, 467 U.S. at 1005 (finding interference with reasonable investment-backed expectations by use of trade secret information in pesticide approval process to be decisive)). So, for example, if the economic impact is to rob real property of ''*all* economically beneficial uses,'' the regulation effects a taking (*Lucas*, 505 U.S. at 1019 (emphasis in original); see also *id.* at 1027–1028 (limiting holding to *real* property)). When examined in light of these three factors, FDA's proposed regulations do not effect a compensable taking under the Fifth Amendment of the Constitution.

3. The Character of the Governmental Action

With respect to the first factor, courts are more likely to find a taking when the interference with property can be characterized as a physical invasion by the Government (e.g., *United States* v. *Causby*, 328 U.S. 256, 261–62 (1946) (characterizing Government's use of flight path just over property as physical invasion)) than when the interference is caused by a regulatory program that ''adjust[s] the benefits and burdens of economic life to promote the common good'' (*Penn Central*, 438 U.S. at 124). Courts have accorded particular deference to governmental action taken to protect the public interest in health, safety, and welfare. (See *Keystone Bituminous Coal Ass'n* v. *DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125–26; *Atlas Corp.* v. *United States*, 895 F.2d 745, 757–58 (Fed. Cir.), *cert. denied*, 498 U.S. 811 (1990).) In addition, the Supreme Court has repeatedly rejected compensation claims when the Government has regulated in order to prevent harmful activity:

> The power which the States have of prohibiting such use by individuals of their property as will be prejudicial to the health, the morals, or the safety of the public, is not—and, consistently with the existence and safety of organized society, cannot be—burdened with the condition that the State must compensate such individual owners for pecuniary losses they may sustain, by reason of their not being permitted, by noxious use of their property, to inflict injury upon the community.

(*Mugler* v. *Kansas*, 123 U.S. 623, 669 (1887) (holding that State law prohibiting manufacture or sale of alcohol effected no taking of brewery even though law entirely destroyed brewery's beneficial use); see also *Keystone*, 480 U.S. 470 (1987) (no taking by law prohibiting mining of coal); *Goldblatt* v. *Town of Hempstead*, 369 U.S. 590 (1962) (no taking effected by regulation that closed gravel pit); *Miller* v. *Schoene*, 276 U.S. 272 (1928) (no taking effected by State-ordered felling of cedar trees); *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915) (no taking effected by ordinance prohibiting operation of brickyard in residential area); *Reinman* v. *City of Little Rock*, 237 U.S. 171 (1915) (no taking effected by ordinance prohibiting stable in residential area); *Powell* v. *Pennsylvania*, 127 U.S. 678 (1888) (no taking effected by law preventing manufacture of margarine)).

First, the final rule's interference with property interests cannot be characterized as a physical invasion of property. The final rule prohibits some uses of some types of property, but the Government is neither using nor acquiring property under the regulations (*Penn Central*, 438 U.S. at 128). For example, certain uses of vending

machines, self-service displays, and signs and billboards are prohibited, but the Government is itself neither using nor acquiring them. The same is true of the intangible property at issue, contracts, copyrights, and trademarks and the associated goodwill: The agency is prohibiting certain uses—indeed, all uses of tobacco trademarks on nontobacco items, including when tobacco companies have also registered the tobacco mark as a mark for nontobacco products or services—but the Government is not itself using these contract rights, copyrights, or trademarks (and thereby tobacco companies' goodwill). It ''has taken nothing for its own use'' (*Connolly* v. *Pension Benefit Guar. Corp.*, 475 U.S. 211, 224 (1986)).

Second, these final regulations seek to promote the public health by limiting access to tobacco products by consumers in the age group most likely to become addicted to them: Those under the age of 18. The regulations are intended to help reduce significantly the harms that use of tobacco products among this age group causes. They do so by prohibiting the sale of tobacco products to persons under the age of 18; that is, the regulations require modes of sale through which the retailer can verify the age of the purchaser or to which only those 18 or over will have access. In particular, the final rule permits vending machines and self-service displays and accompanying advertising only in places to which young people do not have access.

The final regulations also limit promotion of tobacco products to persons under the age of 18. They do so by prohibiting certain venues for tobacco advertising, namely, within 1,000 feet of schools and public playgrounds. They also require black text/white background advertisements in remaining venues with the exception of adult newspapers, magazines, periodicals, and other publications, and in adult-only establishments. They also prohibit use of tobacco trademarks on nontobacco products and in the sponsorship of events. As a consequence, use of tobacco industry trademarks, copyrights, and advertising techniques is limited, although not ended. Nonconforming signs and billboards will be prohibited, thereby reducing the remaining useful life of those currently in use when the regulations become effective. Use of nontobacco trademarks is limited only by prohibiting their use on tobacco products (except for nontobacco trademarks used on tobacco products in the United States on January 1, 1995).

These regulations substantially advance, and are rationally related to, FDA's legitimate interest in promoting the public health and reducing harm by limiting both youth access to tobacco products and, as discussed in the context of the First Amendment, their promotion to youth. (See *Keystone*, 480 U.S. at 485; see also *Pace Resources, Inc.* v. *Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) (''[T]he governmental action is entitled to a presumption that it does advance the public interest.''), *cert. denied*, 482 U.S. 906 (1987).) Moreover, they are directed at stopping activity that is illegal in every State: Sales of tobacco products to those under the age of 18 (*Keystone*, 480 U.S. at 492 n.22). This factor of the takings analysis indicates that these regulations effect no takings.

4. The Economic Impact of the Governmental Action

The second factor to consider is the economic impact of the governmental action. ''There is no fixed formula to determine how much diminution in market value is allowable without the fifth amendment coming into play'' (*Florida Rock Indus., Inc.* v. *United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1053 (1987)). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. (See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915)) (no taking even given reduction in value from $800,000 to $60,000); *Village of Euclid* v. *Ambler Realty Co.*, 272 U.S. 365 (1926) (no taking despite 75 percent diminution in value).) Mere denial of the most profitable or beneficial use of property does not require a finding that a taking has occurred. (See *Florida Rock*, 791 F.2d at 901; see also *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979).) Rather, courts look for drastic interference with a property's possible uses. (See *Pace Resources*, 808 F.2d at 1031.)

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the ''economically viable use'' of his property. (See, e.g., *Keystone*, 480 U.S. at 499.) Courts focus on the remaining uses permitted and the residual value of the property. (See *Pace Resources*, 808 F.2d at 1031.)

Although certain uses of copyrights and copyrighted material developed by tobacco companies and of tobacco and nontobacco trademarks will be prohibited or curtailed, other uses will remain once the final rule takes effect. That is, under § 897.16(a), nontobacco trademarks may not be used to market tobacco products (with the exception of trademarks that had such uses before January 1, 1995) and so they may lose the (speculative) value of such licensing arrangements, but they retain the vast bulk of their value as trademarks for the product or brand for which they were originally developed, and they retain the value of their potential use to market all legal, nontobacco products. Under §§ 897.30(b) and 897.32(a), some copyrighted advertising material that appears on billboards or signs within 1,000 feet of a school or playground or that is not black text/white background may be rendered useless when the rule becomes effective (the copyrighted design itself may be used in other venues, such as adult publications or in adult-only establishments). Under § 897.34(a), tobacco product brand names and logos may be used only to market tobacco products; they therefore lose the value of any use on nontobacco products and, under § 897.34(c), they lose the value of any use to sponsor events when the rule becomes effective. By and large, however, tobacco copyrights and trademarks will retain significant, economically viable uses when the rule becomes effective.

Tobacco companies have, however, registered some of their tobacco trademarks (e.g., Skoal Bandit on a race car as an entertainment service mark, Marlboro on tennis caps), or marks that incorporate a tobacco trademark (e.g., The Marlboro Country Store on, for example, hats and boots; Skoal Pro Rodeo promoting and sponsoring rodeos; Winston West promoting and sponsoring auto racing events), as marks for nontobacco products, services, or events. Under § 897.34, all use of these registered nontobacco marks will be prohibited when the rule becomes effective. With respect to these registered nontobacco trademarks, and indeed with respect to all tobacco company trademarks, their associated goodwill will remain with the tobacco companies and will inure to their benefit in the sale of tobacco products. Accordingly, this factor of the takings analysis indicates that the final rule effects no taking of these interests.

Section 897.16(c) prohibits the use of tobacco product vending machines and self-service displays except in adult-only establishments (where graphic advertisements will also be permitted). This restricted use may limit the number of venues in which these

vending machines and self-service displays may be used and may exclude venues where their use is most profitable. The value of vending machines and self-service displays may therefore drop. But diminutions in property value do not establish a taking. (See *Penn Central*, 438 U.S. at 131.) Indeed, ''[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law'' (*Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 413 (1922)). Vending machines and self-service displays may have to be moved from currently legal venues to adult-only establishments or to warehouses, or they may need to be retrofitted for use with other products if retrofitting is possible. Although compliance may require vending machine and self-service display owners to spend money, ''[r]equiring money to be spent is not a taking of property'' (*Atlas Corp.*, 895 F.2d at 756 (discussing regulatory requirement that mining corporations reclaim uranium and thorium tailings and decommission mills)). Finally, if there are not sufficient numbers of adult-only establishments, some vending machines and self-service displays may have no economically viable use because of the final regulation, but a regulation that makes personal commercial property ''economically worthless'' does not effect a per se taking, as it would with real property. (See *Lucas*, 505 U.S. at 1027–1028.) Contracts to offer exclusively tobacco products in vending machines at nonadult-only establishments may also become ''economically worthless'' once the regulation becomes effective. Likewise, although §§ 897.32(a) and 897.30(b) may shorten the useful life of advertising materials on placards and billboards that are not black text/white background or that are near schools and playgrounds (albeit with a grace period of at least the delayed effective date) and such materials may be ''economically worthless'' as a result, this does not effect a taking per se.

In summary, examination of the economic impact factor of the takings analysis suggests that the regulations, when they finally become effective, will effect no takings of trademarks and goodwill, copyrights, and many vending machines and self-service displays. It leaves open the possibility, however, that the rule may effect a taking of some vending machines and contracts, and of some self-service displays and of nonconforming signs and billboards.

5. Interference with Reasonable Investment-backed Expectations

The final factor to consider is whether a company has a reasonable investment-backed expectation in continuing to use the property at issue, whether it be vending machines, self-service displays, nonconforming signs and billboards, copyrighted material, or trademarks and goodwill. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. (See *Pace Resources*, 808 F.2d at 1033.) Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. ''In an industry that long has been the focus of great public concern and significant government regulation,'' *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be additional regulatory requirements. ''Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end'' (Connolly, 475 U.S. at 227 (citation omitted)). Given a long history of Government regulation of an industry, its members are ''on notice that [they] might be subjected to different regulatory burdens over time'' (*California Hous. Sec., Inc.* v. *United States*, 959 F.2d 955, 959 (Fed. Cir.), *cert. denied*, 506 U.S. 916 (1992)).

Commerce in tobacco products has been regulated for years on the Federal, State, and local levels. For example, States first began restricting tobacco sales to minors, distribution of free samples, and vending machine sales in the 1970's. By 1994 all 50 States prohibited tobacco sales to young people, 38 States restricted the distribution of free tobacco products, and 28 States imposed restrictions on vending machine sales (''State Legislated Actions on Tobacco Issues,'' Coalition on Smoking OR Health (Washington, DC 1994)). Tobacco manufacturers as well as distributors and retailers who have chosen to distribute or sell tobacco products have therefore had reasonable notice that the regulatory scheme to limit use of tobacco products by minors might change.

Moreover, the particular restrictions on access and on promotion adopted in these regulations, or variations thereof, have been proposed or considered for several years by Government bodies, including Congress, the States, and public health agencies. (See, e.g., H. Rept. 5041, 101st Cong., 2d sess. (1990); H. Rept. 1250, 101st Cong., 1st sess. (1989).) For example, on at least two occasions a tobacco industry representative testified before Congress that pending legislation would, like several previous legislative proposals, effectively ban advertisements for tobacco products (''Tobacco Control and Marketing: Hearings on H. Rept. 5041 Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce,'' 101st Cong., 2d sess. 491–494 (1990) (statement of Charles O. Whitley on behalf of The Tobacco Institute); ''Tobacco Issues: Hearings on H. Rept. 1250 Before the Subcomm. on Transp. and Hazardous Materials of the House Comm. on Energy and Commerce,'' 101st Cong., 1st sess. 302 (1989) (statement of Charles O. Whitley on behalf of The Tobacco Institute)), making for far more restrictive limits on advertisements and promotion than those imposed by this rule. Given these facts, a reasonable person should have expected the possibility of regulations such as these. In addition, when sales to young people are illegal, investments in promotions designed to appeal to young people cannot be considered reasonable (see discussion of R. J. Reynolds' use of promotional materials in the Joe Camel Campaign in section VI. of this document). In any case, once the agency gave notice of its proposed rulemaking with respect to tobacco, tobacco manufacturers, distributors, and retailers had notice that certain investments were risky, and they will enjoy the economic benefit of those investments and of investments that they had previously made until the rule is finally effective.

As discussed in section IV. of this document, the number of tobacco product vending machines fell by half between 1988 and 1993 and, since 1990, virtually no new tobacco product vending machines have been manufactured (60 FR 41314 at 41325); because the market in tobacco product vending machines is declining, investment-backed expectations in both vending machines and vending machine contracts are not reasonable. Moreover, many self-service displays were given to retailers by tobacco manufacturers (see 60 FR 41314 at 41323); to that extent, the retailers have no investment-backed expectation in them.

Finally, the Supreme Court has stated that it is unreasonable to have high investment-backed expectations in personal property:

[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the

property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless (at least if the property's only economically productive use is sale or manufacture for sale).
(*Lucas*, 505 U.S. at 1027–1028)

Since all of the property at issue here—vending machines, self-service displays, the advertising material on signs and billboards, contract rights, copyrights, and trademarks and associated goodwill—is personal property, there can be no reasonable investment-backed expectation that regulation will not render them economically worthless. Consideration of this factor of the takings analysis indicates that the final rule effects no takings of any property.

6. Summary

With respect to trademarks and goodwill and copyrights, the three factors in a takings analysis indicate that these regulations will effect no takings. Only the economic impact of the rule on advertising materials on signs and billboards and on some vending machines and related contract rights and some self-service displays leaves open the possibility that a taking may occur, but the impossibility of reasonable investment-backed expectations with respect to personal property used for sale strongly counters this factor, as stated by the Supreme Court in *Lucas*, as does the harm-prevention character of this regulation. Analysis of the three factors considered together shows that these final regulations do not effect a taking of vending machines, self-service displays, signs and billboards advertising tobacco products, contract rights, or copyrights and trademarks and goodwill. The agency concludes that the comments that argued that the regulation effects takings are, for the above-stated reasons, unpersuasive.

B. Substantive Due Process, Equal Protection, and Restrictions on Use of Trade Names

(2) Comments argued that § 897.16(a) (which restricts the use of nontobacco trade or brand names as the trade or brand name of cigarettes or smokeless tobacco) and § 897.34(a) (which prohibits the marketing of nontobacco items and services that bear tobacco brand names and other symbols of cigarettes and smokeless tobacco) violate the Due Process Clause of the Fifth Amendment to the Constitution and the Equal Protection Clause of the Fourteenth Amendment. One comment asserted that each of these provisions prevents companies from entering a completely legal business using their own trade names but provided no further explanation of its reasoning; FDA therefore understands it to suggest that these provisions classify companies as either tobacco or nontobacco companies, that this classification violates equal protection, and that these provisions violate due process in that they infringe on property interests in trade names by prohibiting companies from entering legal businesses using their own trade names. Another comment echoed this latter point and argued that the agency was denying tobacco companies due process because it has no authority to prohibit the lawful use of tobacco trademarks on other products.

The agency disagrees with these comments. The Fifth Amendment Due Process Clause states that ''[n]o person shall * * * be deprived of life, liberty, or property, without due process of law.'' Under due process as applied to economic regulation, ''[i]t is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it'' (*Williamson* v. *Lee Optical of Oklahoma, Inc.*, 348 U.S. 483, 488 (1955)). (The agency has addressed why it has the statutory authority to issue this rule in section II. of this document.)

The Fourteenth Amendment's Equal Protection Clause states that ''[n]o State shall * * * deny to any person the equal protection of the laws.'' By its terms, the Fourteenth Amendment does not apply to action by the Federal Government, as it is directed at the States. But the Supreme Court has held that the Fifth Amendment's Due Process Clause includes an equal protection component equivalent to the Fourteenth Amendment's Equal Protection Clause. (See *Bolling* v. *Sharpe*, 347 U.S. 497 (1954); see also *Buckley* v. *Valeo*, 424 U.S. 1, 93 (1976) (per curiam) (''Equal protection analysis in the Fifth Amendment area is the same as that under the Fourteenth Amendment'').) Under equal protection review, an economic regulation is valid as long as the classification that it makes is ''rationally related to a legitimate state interest'' (*City of New Orleans* v. *Dukes*, 427 U.S. 297, 303 (1976)).

Sections 897.16(a) and 897.34(a) easily pass muster under the requirements of both due process and equal protection. FDA's interest in the health and well-being of children and adolescents is certainly legitimate (indeed, it is a compelling interest). (See *New York* v. *Ferber*, 458 U.S. 747, 757–58 and n.9 (1982).) Moreover, because they limit trade and brand name uses that enhance the appeal and promote the use of cigarettes and smokeless tobacco to young people, the provisions are rationally related to this interest and are a rational way to reduce addiction to tobacco products and the health consequences that follow.

C. Procedural Due Process Under the Fifth Amendment

(3) An industry comment asserted that the regulation of tobacco manufacturers' use of their copyrights and trademarks affects a property interest so as to require an adjudication; put another way, the comment argued that use of rulemaking to adopt a regulation effecting these property interests violates the Fifth Amendment Due Process Clause, which states that ''[n]o person shall * * * be deprived of life, liberty, or property, without due process of law.''

The agency disagrees. The agency has issued this final rule under its ''authority to promulgate regulations for the efficient enforcement of the Act'' under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)) and its authority under section 520(e) of the act (21 U.S.C. 360j(e)) to issue regulations to restrict the sale, distribution, or use of a device. The agency issues such regulations under the rulemaking procedures established by the Administrative Procedure Act (APA) in 5 U.S.C. 553 and its own regulations in part 10 (21 CFR part 10), in particular § 10.40. Neither the act, the APA, nor the agency's regulations require a hearing for a rulemaking under sections 701(a) and 520(e) of the act.

The comment nevertheless contended that due process requires that tobacco manufacturers be provided the opportunity for a formal hearing (i.e., more than just an opportunity to provide written comments). A formal hearing is required, according to the comment, because FDA is asserting jurisdiction over cigarettes and smokeless tobacco based upon a determination of the intent of all tobacco manufacturers, but it is relying on evidence of intent with regard to only a subset of tobacco manufacturers.

As discussed in the 1996 Jurisdictional Determination annexed hereto, the evidence shows that cigarettes and smokeless tobacco are highly addictive, cause other psychoactive effects (such as relaxation and stimulation), and affect weight

regulation, and that these effects are widely accepted in the scientific community. Based on this evidence, it is foreseeable to any reasonable manufacturer that consumers will use such products for their addictive, psychoactive, and other pharmacological effects. The evidence also shows that actual consumer use of these products for their pharmacological effects is predominant and, in fact, nearly exclusive. Based on this evidence of the foreseeable and actual consumer use of these products for their pharmacological effects, the agency has concluded that all cigarette and smokeless tobacco manufacturers ''intend'' their products to affect the structure or function of the body, and that these products are, therefore, nicotine delivery devices under the act. In addition, the agency collected evidence of the tobacco industry's statements, actions, and research demonstrating awareness of the addictive and other pharmacological effects of these products, the industry's knowledge that consumers use these products for these effects, and the industry's deliberate manipulation of levels of nicotine in these products to ensure that adequate amounts of nicotine are delivered to consumers. These internal documents are further evidence in support of the conclusion that cigarette and smokeless tobacco manufacturers intend their products to be drug delivery devices, but they are not necessary for that conclusion. The agency, therefore, has not inferred the intent of one company based exclusively on the internal documents of another. Moreover, assuming that copyrights and trademarks are property protected by the Fifth Amendment's Due Process Clause, due process does not require that FDA provide tobacco manufacturers with a hearing beyond the opportunity for notice and comment that it has already provided. The Supreme Court has stated that the APA established ''the maximum procedural requirements'' that the courts can impose upon agencies in conducting rulemaking procedures and that the circumstances in which courts may require additional procedures, ''if they exist, are extremely rare'' (*Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council*, 435 U.S. 519, 524 (1978)). The Court further stated that due process may ''in some circumstances'' require ''additional procedures'' beyond those required by the APA ''when an agency is making a 'quasi-judicial' determination by which a very small number of persons are 'exceptionally affected, in each case upon individual grounds''' (*Id.* at 542 (*quoting United States* v. *Florida East Coast Ry.*, 410 U.S. 224, 242–245 (1973))).

By this test, due process does not require that the agency provide tobacco manufacturers with a hearing. Simply put, the agency is not making ''a quasi-judicial determination by which a very small number of persons are exceptionally affected, in each case upon individual grounds'' (*Vermont Yankee*, 435 U.S. at 542 (quotations omitted)). The final rule at issue here prospectively limits the sale and promotion of cigarettes and smokeless tobacco to individuals under the age of 18; it imposes conditions on all manufacturers, distributors, and retailers of tobacco products and will affect the access to tobacco products of millions of individuals under the age of 18. The final rule is therefore ''an agency statement of general * * * applicability and future effect designed to implement, interpret, or prescribe law or policy'' (5 U.S.C. 551(4)); in other words, it is a rule under the APA, and the agency followed APA rulemaking in formulating it (5 U.S.C. 551(5)). Like the nuclear fuel cycle rulemaking in Vermont Yankee, 435 U.S. at 528–530, and the rulemaking about ambient air quality standards for lead in *Lead Indus. Ass'n* v. *Environmental Protection Agency*, 647 F.2d 1130, 1136–1144 (D.C. Cir.), cert. denied, 449 U.S. 1042 (1980), this process is ''a rulemaking proceeding in its purest form,'' and not a ''quasi-judicial determination'' to which due process requirements beyond the requirements of the APA might apply. (See *Vermont Yankee*, 435 U.S. at 542 n.16; *Lead Indus. Ass'n*, 647 F.2d at 1171 n.119.)

In any case, manufacturers have had ample opportunity during the comment period for this rulemaking to submit evidence—including other internal tobacco industry documents or affidavits from their employees—that contradicts any evidence, including internal tobacco industry documents, that the agency has placed in the administrative record. And they have submitted voluminous comments with supporting documentation to the agency. The manufacturers have therefore been ''afforded a meaningful opportunity to be heard and to controvert the evidence. Fairness demands no more'' (*Lead Indus. Ass'n*, 647 F.2d at 1170 (quotations omitted)).

In summary, due process does not require that FDA provide manufacturers with an adjudicative hearing. The notice and opportunity for comment provided in this rulemaking are all that fairness and due process require here. And, as discussed in greater detail in section XII. of this document, this rulemaking meets all the requirements of the APA for informal rulemaking.

XII. Procedural Issues

A. Introduction

The Food and Drug Administration (FDA) went to great lengths to involve the public in this proceeding. On February 25, 1994, David A. Kessler, Commissioner of Food and Drugs (the Commissioner) wrote to Scott Ballin, chairman of the Coalition on Smoking OR Health, regarding the possibility of FDA regulation of cigarettes in response to certain petitions that had been filed with the agency. The Commissioner explained:

> [T]he agency has examined the current data and information on the effects of nicotine in cigarettes * * *. Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers * * *. This evidence * * * suggests that cigarette vendors intend the obvious—that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products * * *.

In the months that followed, the Commissioner testified twice before Congress regarding the accumulating evidence relating to the intended use of cigarettes.[255] That testimony was extensive and detailed.

In July and August of that year, FDA Associate Commissioner for Regulatory Affairs, Ronald G. Chesemore wrote to the major cigarette and smokeless tobacco companies requesting all documents relating to ''all research on nicotine * * *, including their pharmacological effects, and all documents relevant to the nicotine'' in their products. On August 1, 1994, FDA held a Drug Abuse Advisory Committee meeting that was fully open to the public on the subject of the abuse potential of nicotine.

On August 11, 1995, FDA provided the public with an extensive Federal Register document setting forth its

[255] Statement by the Commissioner on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994); Statement by the Commissioner on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (June 21, 1994).

rationale for proposing to restrict the sale of cigarettes and smokeless tobacco in a 60 page discussion supported by 442 endnotes (the 1995 proposed rule) (60 FR 41314 to 41375). The agency carefully documented each of the essential propositions offered in support of its reasoning. Indeed, most of the 442 endnotes in the 1995 proposed rule contain multiple authorities for the agency's position and, in all cases, the agency provided the reader with specific page references to the numerous studies, reports, and industry documents on which it relied.

In the same issue of the Federal Register in a document entitled ''Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products,'' FDA also provided an analysis of the agency's authority to assert jurisdiction over cigarettes and smokeless tobacco based on the evidence before the agency at that time (the 1995 Jurisdictional Analysis) (60 FR 41453 to 41787). In the text of the 1995 Jurisdictional Analysis, the agency supported its reasoning with appropriate citations to case law, statutes, and regulations. In addition, the 1995 Jurisdictional Analysis was supported by over 600 footnotes, each of which provided the factual context for the agency's legal position.

On August 16, 1995, the agency placed on public display some 20,000 pages of materials that it cited in the 1995 proposed rule and in the 1995 Jurisdictional Analysis. With the exception of three documents, which the agency referenced only in the 1995 Jurisdictional Analysis, the agency made available to the public all of the materials on which it was relying on as of that time for support.

On September 29, 1995, the agency supplemented the administrative record by putting on public display approximately 13,000 documents comprising some 190,000 pages of factual and analytical materials the agency considered in the course of issuing the 1995 proposed rule and the 1995 Jurisdictional Analysis. Although it was under no legal obligation to do so, the agency made these additional materials available because of the importance of this proceeding.

The agency also made two other significant additions to the public record. On December 1, 1995, the agency announced the findings of focus group studies concerning possible brief statements to be included on all cigarette advertising (60 FR 61670), and added to the record for the rulemaking proceeding a report of these findings and approximately 1,500 pages of supporting documentation. Second, in the Federal Register of March 20, 1996 (61 FR 11349), the agency published notice of an additional 30 day comment period limited to specific documents the agency added to the proposed rulemaking docket, and to the docket in support of the agency's analysis of its jurisdiction (61 FR 11419). These materials consisted of two declarations and a report from three former tobacco industry employees, as well as FDA memoranda to the record regarding adult publications and billboards.

In addition, the agency has added to the final record of this proceeding a comparatively small number of documents that expand upon or confirm information made available in the 1995 proposed rule or the 1995 Jurisdictional Analysis, or that address alleged deficiencies in the agency's initial record.

The administrative record now also includes the comments received from the public. The agency received over 700,000 comments, some directed to the 1995 Jurisdictional Analysis, some directed to the 1995 proposed rule, and many with overlapping discussions. Though many comments consisted of form letters, the agency received over 95,000 distinct or unique sets of comments. Five major cigarette manufacturers jointly submitted 2,000 pages of comments and 45,000 pages of exhibits. The major smokeless tobacco manufacturers jointly submitted 474 pages of comments and 3,372 pages of exhibits. The initial comment period remained open for 144 days.

(1) Despite the agency's extraordinary efforts to involve the public in this proceeding, FDA received several comments regarding the procedures the agency followed in providing notice of the 1995 proposed rule and in publishing the 1995 Jurisdictional Analysis. Some of these comments complained that the agency designated certain documents in the administrative record as ''confidential,'' and that the shielding of these documents denied the public a meaningful opportunity to participate in the rulemaking process. One of these comments also contended that FDA refused to disclose certain nonconfidential information on which the agency had relied. Some comments also argued that FDA failed to set forth a balanced view of the issues presented by the 1995 proposed rule, thereby rendering the notice inadequate and ''misleading'' under the Administrative Procedure Act (the APA). In their view, FDA concealed certain issues in order to deny the public the right to participate in the rulemaking process. Finally, at least one interested person maintained that the comment period for the 1995 proposed rule was so short as to be arbitrary and capricious.

As the discussion that follows in this section of the document demonstrates, the agency's notice, the public availability of the information the agency relied upon at the notice stage of this proceeding, and the opportunity for comment, went well beyond the requirements of the APA, well beyond what is required by case law construing the APA, and well beyond the agency's own procedural requirements for informal rulemaking.

B. Adequacy of the Record

(2) Several industry comments complained about the adequacy of the record in support of the 1995 proposed rule. They contended that the agency violated the APA, 5 U.S.C. 553(b) and (c), and the Due Process Clause of the Fifth Amendment to the Constitution, by failing to disclose all of the information the agency ''considered or relied upon in the proceeding.'' [256] In particular, these comments complained that the public was deprived of the opportunity to comment meaningfully because, according to these comments, the agency relied on confidential documents and on substantial amounts of undisclosed data. One comment went so far as to claim that ''a substantial portion'' of the material FDA relied upon was not made available for public scrutiny.

The record in support of the 1995 proposed rule provided the public not only with a ''reasonable opportunity'' for comment, but with an extraordinary opportunity to examine the agency's position. The claim that the agency withheld ''a substantial portion'' of the materials on which it relied is simply unfounded.

1. The Administrative Record

In an informal rulemaking proceeding, the APA itself requires only that the ''notice of proposed rule making'' include a statement of the time, place, and nature of the proceeding, ''reference to the legal

[256] Because the APA in this context provides the public at least as much protection as the Due Process Clause of the Constitution, the agency will address these procedural objections solely under the APA. See *Forester* v. *Consumer Prod. Safety Comm'n*, 559 F.2d 774, 787 (D.C. Cir. 1977); *Ass'n of Nat'l Advertisers, Inc.*, v. *Federal Trade Comm'n*, 627 F.2d 1151, 1166 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980).

authority under which the rule is proposed,'' and ''either the terms or substance of the proposed rule or a description of the subjects and issues involved'' (5 U.S.C. 553(b)). The APA, thus, does not expressly require disclosure of the information on which the agency relies in proposing a regulation.

Nevertheless, courts have implied under the APA a requirement that an agency give notice of the information on which it actually relies to support a proposed rule, and make that information available to the extent it is not readily accessible to the public. (See Davis, K. and R. Pierce, Jr., *Administrative Law Treatise*, vol. 3, section 7.3 at 305–09 (3d ed. 1994) (discussing one of the seminal cases on disclosure of data relied on to support a rulemaking proceeding, *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974)).) No court, however, has required the degree of public disclosure at the notice stage of a rulemaking proceeding that FDA undertook here.

Indeed, the primary cases cited by the comments, namely, *Portland Cement Ass'n, supra, United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), and *United States Lines, Inc.* v. *Federal Maritime Comm'n*, 584 F.2d 519 (D.C. Cir. 1978), address agency conduct that bears little resemblance to FDA's efforts in this proceeding. While FDA has provided a remarkable degree of factual support and procedural openness, these cases involved instances in which agencies provided the public with no information whatsoever or otherwise excluded a study that was critical to the administrative proceeding. In *Portland Cement*, the Environmental Protection Agency altogether failed to provide the public an opportunity to comment on the test results and procedures on which the agency relied as the critical'' basis for the emission control level adopted by the agency. That is, the agency set very specific pollution control limits, but failed to make public until after the close of the comment period the details of crucial tests relied upon to determine these limits (486 F.2d at 392).

In *Nova Scotia Food Prods.*, ''all the scientific research was collected by the agency, and *none of it was disclosed* to interested parties as the material upon which the proposed rule would be fashioned'' (568 F.2d at 251) (emphasis added). And in *United States Lines*, where a common carrier challenged an order of the Federal Maritime Commission amending a contract between two competitors, the court found that the Commission had made ''critical findings'' on the basis of data which was neither identified in its decision nor included in the administrative record. Rather, the Commission based its decision on ''reliable data reposing in the files of the Commission'' (584 F.2d at 533). The reviewing court simply had no idea of the factors or data on which the Commission had relied (*Id.*).

Thus, at best, the case law requires agencies to disclose studies and data actually relied upon by the agency. Even then, the cases that have struck down agency rulemaking are generally confined to instances in which the agency provided woefully inadequate information to the public or failed to disclose a critical piece of information. (See, e.g., *Kennecott Corp.* v. *Environmental Protection Agency*, 684 F.2d 1007, 1018–19 (D.C. Cir. 1982) (agency acted arbitrarily and capriciously when it failed to include in the public docket during the comment period any documents supporting a particular proposed regulation); *compare Personal Watercraft Indus. Ass'n* v. *Department of Commerce*, 48 F.3d 540, 544–45 (D.C. Cir. 1995) (while agency must disclose information critical to its decision to regulate a particular activity, absent prejudice an agency may rely on studies developed after close of comment period that are not critical to the underlying proposal).)

Finally, FDA's own procedural regulations require that the agency include with the notice of proposed rulemaking, among other things, ''references to all information *on which the Commissioner relies for the proposal* * * *'' (§ 10.40(b)(vii) (21 CFR 10.40(b)(vii)) (emphasis added); see 21 CFR 10.3 (defining the term ''administrative record'' to mean the materials on which the agency ''relies to support the action''). Thus, even under the agency's own procedural regulations, FDA is required—when it initiates informal rulemaking—to supply the public only with the materials the agency is relying upon to support the proposed action.

Here, the materials the agency relied on are the materials the agency cited in the 1995 proposed rule and the 1995 Jurisdictional Analysis. Not only did the agency provide these materials to the public, but it also provided the roughly 190,000 pages of factual and analytical materials the agency considered but did not rely upon in either the 1995 proposed rule or the 1995 Jurisdictional Analysis. Moreover, the agency provided over 1,000 endnotes and footnotes directing readers to each and every document, including every study, Government report, journal article, industry document, and agency record on which FDA relied to support the 1995 proposed rule and the 1995 Jurisdictional Analysis.

Out of all this material, the only nonpublic materials on which the agency relied were two confidential documents [257] and two lines of text the agency redacted from a document the agency placed on the public record. [258] The agency relied on this material only in the context of the agency's 1995 Jurisdictional Analysis. None of these documents is pivotal to the analysis of jurisdiction in that none provides the sole or principal basis for the agency's conclusion that cigarettes and smokeless tobacco are drug delivery devices under the Federal Food, Drug, and Cosmetic Act (the act). Further, as discussed in the 1996 Jurisdictional Determination annexed hereto, the decision to keep these materials confidential did not in any way undermine the quality of the public participation in this proceeding. In sum, the procedures the agency followed in assembling a public record in this proceeding simply are not in line with the facts described in cases like *Portland Cement, Nova Scotia Food Products*, and *United States Lines*.

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[257] The two confidential documents the agency directly referenced are the 1991 Handbook on Leaf Blending and Product Development (Confidential Document 75) and the unredacted summary of notes of FDA trip visits (Confidential Document 74). The summary was compiled from notes and handouts that are also designated as confidential (Confidential Documents 69, 70, 71, 72, and 73). The agency views the summary as a stand-alone document to the extent it distills a large volume of disparate handwritten notes and handouts. Also, the agency cited only to the summary itself. Nevertheless, even if the summary were counted as five documents rather than one, the agency at most relied on six confidential documents. The agency's basis for relying on these documents in the 1995 Jurisdictional Analysis is discussed in detail in the 1996 Jurisdictional Determination, annexed hereto.

[258] On page 255 of the 1995 Jurisdictional Analysis (60 FR 41453, 41716), the agency redacted several lines of text along with a footnote that identified the sources for the redacted text. The footnote consisted of references to two sources, both of which appeared on the agency's public docket for the 1995 Jurisdictional Analysis: J. E. Kiefer, ''Cigarette Filters for Altering the Nicotine Content of Smoke'' (Report No. 71 5003 7), Tennesee Eastman Co., pp. 1–2; August 18, 1971, and J. G. Curran, Jr., and E. G. Miller, ''Factors Influencing the Elution of High Boiling Components of Cigarette Smoke from Filters,'' *Beitr. Tabakforsch*, pp. 5 and 67, 1969. The Kiefer document appeared on the public docket with certain trade secret information redacted from the document. The Curran document was made available to the public in full.

2. The Agency's Use of Confidential Documents

a. *Confidential documents on which the agency did not rely*. The agency placed in a confidential docket 75 documents from the approximately 210,000 pages of materials the agency made available at the opening of this proceeding. The agency identified each of these 75 documents for the public in an index filed on September 29, 1995, on the public docket. (See 60 FR 66981 at 66982, December 27, 1995.) Of these 75 documents, 73 were not even relied upon by the agency to support either the 1995 proposed rule or the 1995 Jurisdictional Analysis.

Sixty-one of these 73 confidential documents consisted either of commercial information and trade secrets that the industry urged FDA to keep confidential (Confidential Documents 1–12, 16–21, and 62–73), or unpublished manuscripts for which the agency lacked the authors' permission, as of September 29, 1995, to make them available for widespread dissemination (Confidential Documents 22–52). The remaining 12 documents were either proprietary reports and other copyrighted information—such as financial reports generated by Dun and Bradstreet—which the agency lacked permission to reprint (Confidential Documents 13–15, and 53–58), or confidential documents that supported a pending new drug application (Confidential Documents 59–61).

Again, the agency did not rely on any of these 73 documents as support for the 1995 proposed rule. Therefore, the agency was not even required to include these documents in the administrative record of the notice of proposed rulemaking. (See 21 CFR 10.40(b)(vii).) It likewise follows that because the agency did not rely upon these documents, the decision to protect them cannot be said to have unfairly interfered with the public's ability to question the agency's rationale for the rule. (See *Mid-Tex Electric Coop., Inc.* v. *Federal Energy Regulatory Comm'n*, 773 F.2d 327, 344 (D.C. Cir. 1985) (agency's failure to disclose two studies was ''manifestly harmless'' because the agency did not rely on the studies to support any finding or conclusion); *Conference of State Bank Supervisors* v. *Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (there is no violation of the APA's notice requirements where the agency has declined to disclose materials on which it did not rely in proposing the rule); *B.F. Goodrich Co.* v. *Department of Transp.*, 541 F.2d 1178, 1184 (6th Cir. 1976) (only the basic data ''upon which the agency relied in formulating the regulation'' must be published for public comment), *cert. denied*, 430 U.S. 930 (1977); K. Davis, *Administrative Law Treatise*, section 7.3 at 307 (3d ed. 1994) (''If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators.'').) The agency went well beyond existing requirements to make publicly available thousands of additional documents for public review—in recognition of the uniqueness and public importance of this proceeding. This effort by the agency should not be used now as a basis for suggesting that the agency was required to publish all information that it had on hand.

Finally, at the close of this rulemaking proceeding and with the publication of the annexed 1996 Jurisdictional Determination, the agency will supplement the public docket with copies of those confidential items for which the agency previously lacked permission to publish, but for which permission has now been granted. Most of the unpublished manuscripts in the confidential docket—none of which were relied upon by the agency to support the rule—will be available through this addition to the public record.

b. *Confidential documents on which the agency relied*. In support of the 1995 Jurisdictional Analysis, FDA relied on only 2 of the 75 documents designated as confidential: A summary of notes taken by FDA investigators during site visits to manufacturing plants run by Brown and Williamson, Philip Morris, and R. J. Reynolds (Confidential Document 74); and a 1991 Brown and Williamson handbook on leaf blending and product development (Confidential Document 75).[259] In addition, the agency relied in its 1995 Jurisdictional Analysis on two lines of text that were redacted from a document that appeared on the public docket.[260] The 1995 proposed rule itself did not rely on any of these documents.[261] A thorough discussion of these three documents, and the agency's basis for relying on them to support its analysis of jurisdiction, is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

3. The Claim that FDA Relied on ''Unknown'' Undisclosed Data

(3) An association representing the tobacco industry also claimed that the agency withheld certain data and calculations used to construct a series of charts showing that nicotine and tar levels in smoke have risen steadily from 1982 to 1991. (See 60 FR 41453 at 41728 to 41731.) These charts appeared only in the context of the agency's 1995 Jurisdictional Analysis. A thorough discussion of how the agency constructed these charts, and on what data the agency relied, is provided in sections II. and VI. of the 1996 Jurisdictional Determination, annexed hereto.

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[259] The agency did not acknowledge ownership of the handbook in the 1995 Jurisdictional Analysis, or in the September 29, 1995, index to the administrative record. However, in a set of comments filed by Brown & Williamson, the company itself acknowledged publicly its ownership of the handbook. (See Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), pp. 37–38).

[260] Kiefer, J. E., ''Cigarette Filters for Altering the Nicotine Content of Smoke,'' Tennessee Eastman Co., Report No.71 5003 7, pp. 1–2, August 18, 1971.

[261] One comment noted that the agency relied in the 1995 proposed rule on undisclosed information gathered from former industry sales representatives and managers. (See 60 FR 41314 at 41323.) The reference in the rule to interviews with former sales representatives and managers appears in the discussion of proposed § 897.12 *Additional Responsibilities of Manufacturers*. The agency used the information gathered from these individuals to support the proposition that manufacturers direct their sales representatives to police retailers' cigarette and smokeless tobacco displays. Accordingly, the agency proposed to require sales representatives to be responsible for removing violative visual displays and advertising used in retail outlets. In light of comments received, the agency has decided to revise § 897.12 to eliminate this requirement. Because manufacturer sales representatives will no longer be held responsible for maintaining retailers' fixtures, the agency's reliance on the interviews in the 1995 proposed rule, and the issue of whether the agency should have made more information on this matter available to the public, is moot. Davis, K. C., and R. J. Pierce, Jr., *Administrative Law Treatise*, vol. 1, section 7.3 at p. 307 (3d ed. 1994) (''If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators''). Finally, as the agency explained in its December 27, 1995, Federal Register notice, the agency has not made such information available to the public because of the need to protect the identity of individuals who came forward during the agency's investigation and who might not otherwise have come forward (see 60 FR 66981, 66982). As discussed in section VI. of the 1996 Jurisdictional Determination, FDA believes there are circumstances in which an agency may rely on confidential information in a rulemaking proceeding, and that there are ways in which an agency may present such information in order to preserve the public's right to a reasonable opportunity to participate in the proceeding (60 FR 66981). The agency, however, has not relied on any such material in this final rulemaking.

4. The Claim that FDA Failed to Include in the Record New Drug Application (NDA) Data on Which it Relied

(4) One comment claimed that the agency relied on studies in seven NDA's for the proposition that a high proportion of smokers are addicted to nicotine, but failed to make adequate disclosure of these NDA's. In particular, this comment stated that the agency failed to include any information in the public docket for NDA 18–612 (Nicorette gum, 2 milligrams (mg)) and NDA 20–385 (Nicotine nasal spray), and included only summaries for five other NDA's the agency cited. To the extent the agency relied on any of these NDA's, it did so only in the context of the 1995 Jurisdictional Analysis. A comprehensive discussion of the agency's reliance on this material is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

5. The Agency's Reliance in the Final Rulemaking on New Materials

In an FDA informal rulemaking proceeding, the final administrative record must contain the proposed rule, including all information that the Commissioner identifies or files with the proposal, all comments received on the proposal, including all information submitted as part of the comments, and the notice issuing the final regulation, including all information that the Commissioner identifies or files with the final regulation (§ 10.40(g)). An agency may rely on information and data that were not included at the proposal stage that expands on or confirms information in the proposal or addresses alleged deficiencies in the preexisting data, provided that no prejudice is shown.[262] Otherwise, ''[r]ulemaking proceedings would never end if an agency's response to comments must always be made the subject of additional comments'' (*Community Nutrition Inst.* v. *Block*, 749 F.2d 50, at 58). Accordingly, the agency has cited in this preamble and in the 1996 Jurisdictional Determination annexed hereto, a small amount of information that is needed to respond fully to the comments or that otherwise supplements the information contained in or filed with the 1995 proposed rule. These documents include published scientific articles, reference texts, letters to tobacco industry counsel, an abstract that the tobacco industry asked to include in the record, three publicly released tobacco company documents, Congressional hearing transcripts, and newspaper articles. The agency has placed this cited information in the administrative record.

C. Adequacy of the Notice

(5) Two industry comments argued that the public's participation in the rulemaking process has been frustrated because the agency presented a ''one-sided'' view in its 1995 notice of proposed rulemaking. They claimed that FDA failed to satisfy the APA's notice requirement for informal rulemaking because the agency neither disclosed nor discussed the supposedly ''large body'' of information that is ''inconsistent with, or otherwise not supportive of, the proposed rule.'' Further, the agency did not, in their view, provide a ''reasoned explanation'' for departing from past precedent on the issue of whether FDA should regulate all cigarettes and smokeless tobacco.

These comments provided no legal authority to support the proposition that, at the notice stage of a proceeding, the agency is required to anticipate all challenges to its reasoning, and must attempt to answer those challenges. Rather, at the notice stage of a rulemaking proceeding, the agency's obligation is to include sufficient detail on the content of the rule, and on the basis in law and fact for the rule, to allow for meaningful and informed comment. (See *American Medical Ass'n* v. *Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995); *Home Box Office, Inc.* v. *Federal Communications Comm'n*, 567 F.2d 9, 35–36 (D.C. Cir.), cert. denied, 434 U.S. 829 (1977).)

More specifically, in an informal rulemaking proceeding, the APA requires public notice of an agency's intention to issue a regulation (5 U.S.C. 553(b)). The notice must include ''reference to the legal authority under which the rule is proposed,'' and ''either the terms or substance of the proposed rule or a description of the subjects and issues involved'' (5 U.S.C. 553(b)(2) and (b)(3)). FDA's own regulations require that a notice of proposed rulemaking include ''a preamble that summarizes the proposal and the facts and policy underlying it, * * * all information on which the Commissioner relies for the proposal, * * * and cites the authority under which the regulation is proposed'' (21 CFR 10.40(b)(vii)).

Under case law construing section 553 of the APA, notice of informal rulemaking must be ''sufficiently descriptive of the 'subjects and issues involved' so that interested parties may offer informed criticism and comments'' (*Ethyl Corp.* v. *Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir.) (en banc), *cert. denied* 426 U.S. 941 (1976)). Notice is sufficient under the APA ''if it affords interested parties a reasonable opportunity to participate in the rulemaking process'' (*Forester*, 559 F.2d at 787; *accord State of South Carolina ex rel. Tindal* v. *Block*, 717 F.2d 874, 885 (4th Cir. 1983), *cert. denied*, 465 U. S. 1080 (1984)). And, insofar as the 1995 proposed rule relied on a technical study or specific data essential to an understanding of the rule, the notice should have disclosed this information to the extent needed to allow for ''meaningful commentary'' (*Connecticut Light and Power Co.* v. *Nuclear Regulatory Comm'n*, 673 F.2d 525, 530–31 (D.C. Cir.), *cert. denied*, 459 U. S. 835 (1982)).

In this instance, the 1995 proposed rule met both the APA's notice requirements (as interpreted by prevailing case law), as well as FDA's own procedural requirements. The agency by any standard ''fulfilled its obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible'' (*Air Transport Ass'n of America* v. *Civil Aeronautics Board*, 732 F.2d 219, 225 (D.C. Cir. 1984) (quoting *Home Box Office*, Inc., 567 F.2d at 36)).

1. The Agency Provided Adequate Notice of the Key Legal and Factual Issues

Although the APA's notice requirements could have been met by a far briefer presentation, the agency chose to supply the public with a notice that explored in full the wide range of factual and legal issues presented. In doing so, the agency discussed the most significant issues that the two industry comments claimed were missing from the notice.

(6) The comments contended that the agency failed to discuss past instances

[262] See, e.g., *Personal Watercraft* v. *Department of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995) (''Agencies may develop additional information in response to public comments and rely on that information without starting anew unless prejudice is shown.''); *Solite Corp.* v. *Environmental Protection Agency*, 952 F.2d 473, 484 (D.C. Cir. 1991) (''[C]onsistent with the APA, an agency may use 'supplementary' data, unavailable during the notice and comment period, that expands on and confirms information contained in the proposed rulemaking and addresses alleged deficiencies in the preexisting data, so long as no prejudice is shown.''); *Community Nutrition Inst.* v. *Block*, 749 F.2d 50, 57–58 (D.C. Cir. 1984) (agency may rely on information that ''expanded on and confirmed'' information in the 1995 proposed rule and addressed alleged deficiencies in the record); see also Davis, K. C. and R. J. Pierce, Jr., *Administrative Law Treatise*, section 7.3 (3d ed. 1994).

in which it declined to exercise jurisdiction over cigarettes and smokeless tobacco, including FDA's response to a 1977 citizen petition. One comment in particular insisted that such a discussion would have alerted the public to the idea that Congress enacted preemptive legislation in reliance on FDA's past pronouncements, legislation which the comments argue bars FDA from regulating these products.

The agency acknowledged in the 1995 Jurisdictional Analysis, published in conjunction with the 1995 proposed rule, that it has in the past refrained from exercising jurisdiction generally over all cigarettes and smokeless tobacco (unless claims were made for the product) (60 FR 41453 at 41482 n. 5). Among other things, the agency referred readers to the published decision in *Action on Smoking and Health [ASH]* v. *Harris*, 655 F.2d 236 (D.C. Cir. 1980). That decision discussed, and indeed arose from, the 1977 citizen petition which, as one comment claimed, the agency ''conscientiously avoid[ed]'' in order to ''mislead[]'' the public. Not only does the *ASH* opinion discuss the petition and the agency's position at that time with respect to exercising jurisdiction generally over cigarettes, it also recounts for the reader the agency's historical position on the issue (*Id*. at 237–241). Moreover, the agency placed in the administrative record copies of documents in which FDA declined to exercise jurisdiction, including FDA's response to ASH's 1977 citizen petition. [263]

In addition, the agency attached as part of an appendix to its 1995 Jurisdictional Analysis copies of the Commissioner's testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on March 25, 1994 (Appendix 7). At the outset, the Commissioner stated:

Although FDA has long recognized that the nicotine in tobacco products produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. * * * With certain exceptions, we have not had sufficient evidence of such intent with regard to nicotine in tobacco products. * * *

Mr. Chairman, we now have cause to reconsider this historical view. * * * This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of that information. (Appendix 7 at 1–2 (footnote omitted))

This testimony, like the reference to the *ASH* decision, adequately put the public on notice of FDA's past position. [264]

Nor does FDA agree with the comment's argument that Congress, in reliance on past FDA pronouncements, enacted legislation precluding FDA from regulating tobacco products under the act. As discussed in detail in sections IV. and V. of the annexed 1996 Jurisdictional Determination, the agency has never categorically disclaimed jurisdiction over tobacco products and Congress has never expressly forbidden FDA from asserting jurisdiction over these products. The agency has no affirmative obligation to posit in its notice of proposed rulemaking arguments it believes are legally infirm. (Cf. *Florida Power and Light Co*. v. *United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).)

Two tobacco industry comments also claimed that the agency unfairly underplayed the complexity of issues such as ''intended use,'' product categorization, regulatory authority over combination products, and the applicability of the medical device provisions of the act to cigarettes and smokeless tobacco. Instead, one of these comments asserted that all the agency had done was publish ''a tendentious anti-tobacco, pro-FDA-regulation manifesto'' and, as such, the agency's notice was ''fraudulent.'' The agency disagrees with this characterization. More to the point, the agency disagrees with the argument that the agency somehow deprived the public of fair notice.

Again, to satisfy the APA's notice requirement, the agency must specify with particularity the legal authority on which its proposal is based (K. C. Davis & R. J. Pierce, Jr., *Administrative Law Treatise* (vol. 1, 3d ed. 1994) section 7.3 at 299). Notice must be ''informative'' and must ''fairly apprise'' interested persons (*Id*. at 299 and 300). The agency need not, however, unravel for the public each and every theoretical step in the analysis. (See *Chemical Waste Management, Inc.* v. *Environmental Protection Agency*, 869 F.2d 1526, 1535 (D.C. Cir. 1989) (even where agency statement in notice of rulemaking assumes rather than invites comments on an issue, notice is sufficient if it provides interested parties ''with a clear indication of the agency's intended course of action * * *.''); *Center for Auto Safety* v. *Peck*, 751 F.2d 1336, 1361 (D.C. Cir. 1985) (''It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record.'')).

Nevertheless, the agency provided the public a detailed explanation of why it regards cigarettes and smokeless tobacco as drug/device combination products, and why it believes the device provisions of the act may, and should, be used to regulate these products. The agency set forth its rationale for regulating these products as devices in both the August 11, 1995, proposed rule (see 60 FR 41314 at 41348 to 41350) and again in the August 11, 1995 Jurisdictional Analysis (see 60 FR 41453 at 41521 to 41525). Further, the agency identified the precise statutory provisions under which it proposed to regulate these products (see 60 FR 41314 at 41346 to 41352, and 41372).

The agency also put the public on notice, by referencing the Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, that preloaded drug delivery systems are often regulated using the drug authorities under the act. The agency adequately explained—for notice purposes—why in this instance it proposed a different approach (60 FR 41314 at 41348 to 41350).

With respect to the application of the concept of ''intended use,'' the lengthy discussion in Part II of the 1995 Jurisdictional Analysis provided the public with full disclosure of the agency's rationale for regulating cigarettes and smokeless tobacco based on the ''intended use'' of these products. The core facts and precedents on which

[263] Letter from D. Kennedy (FDA) to J. Banzhaf (ASH) of Dec. 5, 1977, (denial of 1977 petition); Letter from J. E. Goyan (FDA) to J. Banzhaf (ASH) of Nov. 25, 1980; Public Health Cigarette Amendments of 1971, Hearings Before the Consumer Subcommittee of the Committee on Commerce, U.S. Senate, 92d Cong., 2d sess., pp. 239–246.

[264] As discussed in section IV. of the 1996 Jurisdictional Determination, the agency's decision not to include a prolonged discussion of past agency decisions is based on the fact that the agency is now operating under a different set of facts. The agency did not commit a procedural error by failing to chronicle exhaustively decisions it made in a factually distinguishable context. Moreover, one of the comments faulted the agency for failing to give notice of the ''several'' citizen petitions filed since 1977 that requested that the agency regulate cigarettes. In fact, the agency incorporated by reference into the opening docket for the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the *ASH* litigation that relate to the agency's jurisdiction over cigarettes and other nicotine delivery systems. The index the agency provided to the public on September 29, 1995, in conjunction with the public display of the administrative record (as of that date), included a description of nine dockets the agency incorporated by reference into the record supporting the 1995 Jurisdictional Analysis.

the agency relied were displayed in a manner the agency believes invited maximum public scrutiny. The agency even provided the public with 11 different examples (9 from the 1980's and 1990's) of the application of the intended use concept to the determination of whether a product, absent express claims, may be regulated as a drug or a device (60 FR 41453 at 41527 to 41531). This level of explanation more than satisfied the notice requirements of the APA as interpreted by the relevant case law.

Finally, the quantity and quality of comments the agency received on the 1995 proposed rule and the 1995 Jurisdictional Analysis suggest that, in fact, the public was adequately notified of the relevant issues. The agency received more comments in this proceeding than it has ever received on any other subject, with over 700,000 comments (including form letters) and over 95,000 distinct or unique sets of comments. More important, the agency received hundreds of pages of comments on the very issues the agency is said to have hidden from the public. Indeed, the two industry comments who complained most vigorously about the supposed deficiencies in the agency's notice of proposed rulemaking themselves filed volumes of comments on the issues they claim the agency concealed.[265] Even the comments of interested nonindustry persons evidenced fair notice of the agency's reasoning for applying the device provisions of the act to cigarettes and smokeless tobacco.[266]

In *Chemical Waste Management*, the plaintiff complained that the Environmental Protection Agency's (EPA) notice of proposed rulemaking treated a certain controversial issue ''as an accomplished fact'' (869 F.2d at 1535). Like two of the comments here, the plaintiff in *Chemical Waste Management* argued that the APA required the agency to highlight the fact that its position was subject to debate and to solicit comments on the issue. The United States Court of Appeals for the District of Columbia rejected this argument because EPA had provided notice of its intended course and because the agency in fact received numerous comments on the issue (869 F.2d at 1535). (See also *Shell Oil Co.* v. *EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991) (recognition of a certain issue in comments may be used to infer that adequate notice of the issue was given); *Haralson* v. *Federal Home Loan Bank Board*, 678 F. Supp. 925, 926 (D.D.C. 1987) (same).)

As in cases such as *Chemical Waste Management*, the comments FDA received demonstrate that there is no serious claim to be made that the agency has concealed issues from the public. Interested persons representing both sides in this controversial proceeding commented on the very issues the agency supposedly underplayed in its notice of proposed rulemaking.[267]

The comments that challenge the adequacy of the agency's notice confuse the merits of the issue with procedure. The supposed deficiencies in FDA's legal reasoning, and the supposed failure to discuss contrary authorities, raise substantive issues to be resolved during the comment and response-to-comment phase of the proceeding. The possibility that some of the agency's legal conclusions may be subject to debate does not render the notice inadequate. (See *Chemical Waste Management, Inc.*, 869 F.2d at 1535; *Natural Resources Defense Council, Inc.* v. *Hodel*, 618 F. Supp. 848, 864–65 (E.D. Cal. 1985).)

2. The Agency Provided a ''Reasoned Explanation'' for its Current Position

Several tobacco industry comments also claimed that the agency violated the APA's notice provisions by failing to include a ''reasoned explanation'' for departing from past precedent on the issue of whether to regulate all cigarettes and smokeless tobacco. In their view, the 1995 proposed rule and the 1995 Jurisdictional Analysis were procedurally infirm because the agency did not adequately explain its basis for past decisions not to regulate these products, and did not distinguish those decisions from its present position. One of these comments likewise asserted that the agency was required to include in the administrative record each and every document ''that formed the basis for, or was an expression or reflection of, FDA's consistent position over more than 80 years that it does *not* have jurisdiction to regulate cigarettes.'' The absence of this material, according to the comment, demonstrates that the agency failed to consider ''obviously relevant'' contrary information in proposing to regulate these products.

The authorities cited in the comments at best require that, by the close of an administrative proceeding, the agency must provide a ''reasoned explanation'' to the extent the agency has departed from a prior formal position. (See, e.g., *RKO Gen., Inc.* v. *FCC*, 670 F.2d 215 (D.C. Cir. 1980) *cert. denied*, 456 U.S. 927 (1982) (challenge to final order of Federal Communications Commission denying renewal of television license); *Baltimore and Annapolis R. R.* v. *Washington Metro. Area Transit Comm'n*, 642 F.2d 1365 (D.C. Cir. 1980) (challenge to final order of transit commission); *Greyhound Corp.* v. *ICC*, 551 F.2d 414 (D.C. Cir. 1977) (challenge to final decision of the labor board); *International Union, United Auto Workers* v. *NLRB*, 459 F.2d 1329 (D.C. Cir. 1972) (challenge to final decision of labor board); see also *Motor Vehicle Mfrs. Assoc.* v. *State Farm Mutual Auto Ins.*, 463 U.S. 29, 43 (1983) (challenge to final rule rescinding passive restraint seatbelt requirement contained in a Department of Transportation standard).) None of these cases, which involved challenges to final agency orders and final rules, holds that at the notice stage of a proceeding, when an agency is proposing to depart from a prior position, the agency must provide a comprehensive ''reasoned explanation.''

The agency nevertheless agrees that the rulemaking proceeding, taken as a whole, should clearly and rationally justify changes in existing policies. Thus, FDA included in its notice of proposed rulemaking and 1995 Jurisdictional Analysis ample reference to its prior policy and a more than ample discussion of the agency's rationale for changing its policy. Indeed, the very intent of the 1995 Jurisdictional Analysis, and the 622 footnotes supporting the analysis, was to provide the public with a full view of the evidence that supports the need for the agency to take a different approach to the regulation of these products.

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[265] See, e.g., Joint Comments of the Smokeless Tobacco Manufacturers, Comment (January 2, 1996), at 43 to 73 (discussing the agency's historical position on agency jurisdiction over tobacco products), at 99–258 (discussing the agency's application of the concept of intended use to tobacco products), and at 259–307 (analyzing the agency's position that cigarettes and smokeless tobacco are combination products that may be regulated as restricted devices); Joint Comments of Cigarette Manufacturers at, among other places, Vol. I (discussing FDA's historical position on jurisdiction), Vol. II (discussing the concept of intended use), and Vol. V (discussing the regulation of cigarettes as medical devices).

[266] See, e.g., Public Citizen Litigation Group, comment (January 2, 1996); American Heart Association, comment (December 26, 1995).

[267] The agency also received a comment criticizing the agency for failing to discuss the June 1994 Federal Trade Commission's (FTC) decision regarding the ''Joe Camel'' advertising campaign. In section VI. of this document, the agency discusses the FTC's decision, showing that the FTC's decision in 1994 with respect to the ''Joe Camel'' campaign was neither relevant to, nor contradicted, FDA's discussion of the campaign in the 1995 proposed rule.

As FDA made clear at the outset of its 1995 Jurisdictional Analysis, its decision to propose to regulate these products, when in the past it chose not to (except where claims were made), is based on the fact that ''[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless products.'' (60 FR 41453 at 41464, n. 1.) Footnote 5 of the 1995 Jurisdictional Analysis, in particular, made clear that: (1) The agency in the past had declined to exercise jurisdiction generally over these products; and (2) the reason for taking a different position today is that the evidence before the agency regarding the intended use of these products ''has changed dramatically.'' (60 FR 41453 at 41482, n. 5). In addition, the agency repeatedly stated that its analysis was based on ''evidence now available to the agency'' (60 FR 41453 at 41464), ''current evidence'' (60 FR 41466), evidence accumulated since 1980 (60 FR 41482, n. 5), and evidence that has emerged since 1980 or was not widely known until recently (60 FR 41453 at 41483 to 41484, and 41539).

Neither the APA nor the case law cited in the comments requires an agency to provide a thorough ''reasoned explanation'' for departing from precedent at the notice stage of a proceeding. Rather, the APA at best requires that the agency give notice of its proposal to take a different position or view, and give enough information to allow the public a reasonable opportunity to comment. Not until the close of the proceeding, after public comment has been received, must the agency ensure that it has provided a ''reasoned explanation.'' The agency believes in this instance that its discussion at the notice stage met the standard that courts ordinarily do not impose until the close of an administrative proceeding. Nonetheless, the agency has provided a detailed discussion of the legal and factual bases for taking its current position in section IV. of the 1996 Jurisdictional Determination, annexed hereto.

Finally, the agency does not agree that it was required to include in the record, at the notice stage of the proceeding, each and every prior agency ''decision, statement, and finding.'' Rather, the agency appropriately included in the record enough documentation to give the public notice of the agency's prior position, and notice of the agency's prior reasoning for declining to exercise jurisdiction generally over these products (absent express claims). For example, the agency incorporated by reference into the administrative record supporting the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the 1977 *ASH* litigation that relate to the agency's jurisdiction over these products. In addition, the agency included in the record in support of its 1995 Jurisdictional Analysis its response to the original ASH citizen petition. The response to the ASH petition outlines in detail the ''contrary'' view the agency allegedly concealed, including full discussions of the agency's enforcement history with respect to tobacco products and the agency's significant past pronouncements on the subject. In any case, the tobacco industry itself, through its comments, has introduced many of the agency's earlier statements into the administrative record for this proceeding. Thus, unlike the facts presented in cases such as *Public Citizen* v. *Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) or *Walter O. Boswell Memorial Hospital* v. *Heckler*, 749 F.2d 788 (D.C. Cir. 1984), as referenced in the comment, the administrative record for this proceeding already contains the ''adverse'' information claimed to be lacking, by virtue of the agency's inclusion of documents in the record and the comments received by the agency.

D. Adequacy of the Comment Period

FDA received at least one comment urging that the comment period was unreasonably short in light of the complexity of the proposed rule, the number of materials the agency put on public display, and the possible impact of the rule on the tobacco industry. This comment argued that the agency acted arbitrarily and capriciously in deciding to ''limit'' the comment period to 144 days from the publication of the August 11, 1995, proposal and 95 days from the public release of the documents FDA considered but did not rely upon.

Far from having ''limited'' the comment period, FDA provided more than twice as much time for comment as the agency's regulations require. (See 60 FR 53560, October 16, 1995 (extending comment period for the proposed rule); 60 FR 53620, October 16, 1995 (extending comment period on Jurisdictional Analysis).)

The APA requires only that an agency ''give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments * * *.'' (5 U.S.C. 553(c).) This is all the APA requires; there is no statutory requirement concerning how many days an agency must allow, nor is there a requirement that an agency must extend the period at the request of an interested person. (See *Phillips Petroleum Co.* v. *EPA*, 803 F.2d 545, 559 (10th Cir. 1986).)

FDA's own regulations generally afford the public 60 days to comment on a proposed rule, unless the Commissioner shortens or lengthens the period for good cause (21 CFR 10.40(b)(2)). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period. (See 58 FR 69681, December 30, 1993.)

Here, the agency provided the public with 144 days from the publication of the notice, 139 days from the release of the documents the agency cited in support of the rule and the 1995 Jurisdictional Analysis (on August 16, 1995), and 95 days from the release of the materials the agency considered but did not directly rely upon (on September 29, 1995). Thus, even when counting from the date the agency released additional documents of no direct relevance to the 1995 proposed rule, the agency provided much more time for comment on the notice of proposed rulemaking than its regulations, or the Executive Order, require.

Further, on March 20, 1996, the Federal Register published a notice providing an additional 30-day comment period limited to specific documents the agency added to the proposed rulemaking docket (see 61 FR 11349, March 20, 1996) and to the docket in support of the agency's analysis of its jurisdiction (see 61 FR 11419, March 20, 1996). Although the agency expressly limited the scope of the matters on which interested persons could comment, the March 20, 1996, action did provide the public with yet another 30 days on which to comment on issues related to such core subjects as the manipulation of the nicotine content of cigarettes and smokeless tobacco. The March 20, 1996, action also reopened the comment period with respect to the record in support of the agency's proposal to regulate the advertising of these products in ''adult publications'' and billboard advertising.

The agency is not persuaded that any interested person has been unfairly prejudiced by the length of the comment period. First, FDA considers requests to extend the comment period on a case-by-case basis. Here, on the one hand, the

authors of the comment (the Tobacco Institute together with five major tobacco companies) presented in their request for additional time no compelling reasons to extend the period (such as a new, material study). On the other hand, FDA is faced with a matter raising serious public health concerns. For those reasons, the agency denied the request to extend the period for as long as had been requested (see 60 FR 53560).

Second, each of the five tobacco companies who submitted this joint comment complaining about the length of the comment period also filed suit against FDA 1 day before the Federal Register published FDA's notice of proposed rulemaking. The timing appears to indicate that these firms had been preparing to respond to an FDA proposal to regulate cigarettes and smokeless tobacco for some time. In any case, they were able, jointly, to submit 2,000 pages of comments and 45,000 pages of exhibits within the time allotted for commenting on the Jurisdictional Analysis and the proposed rule. Their submissions far outweigh any others. The agency, therefore, is not persuaded that these interested persons suffered prejudice as a result of FDA's allowing twice as much time as the agency's regulations require. (See *Conference of State Bank Supervisors* v. *Office of Thrift Supervision*, 792 F. Supp. 837, 844 (D.D.C. 1992) (in light of the comments received, court declined to find that 30-day comment period was insufficient to allow opportunity for meaningful public participation); *Phillips Petroleum Co.*, 803 F.2d at 559 (citing cases in which courts have upheld notice periods of 45 days or less).)

In sum, the agency believes it provided ample additional time for comments—nearly 90 days more than is provided for in the agency's own procedural regulation. Given that it received over 95,000 distinct sets of comments, the agency is not persuaded that the length of the comment period unfairly hampered the quality of the public debate on this matter.

E. Conclusion

Because of the importance of the issues involved in this proceeding, the agency compiled the most extensive administrative record in support of a proposed rulemaking in its history. FDA employed procedures that exceeded all legal requirements in giving the public a reasonable opportunity to participate in this matter.

XIII. Executive Orders

A. Executive Order 12606: The Family

Executive Order 12606 (E.O. 12606) directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. The preamble to the 1995 proposed rule stated that the rule would have ''no potential negative impact on family formation, maintenance, and general well-being.'' Specifically, the Food and Drug Administration (FDA) said that the rule would not affect family stability or marital commitments, would not have a significant impact on family earnings, and would not impede parental authority and rights in the education, nurture, or supervision of children. To the contrary, the preamble to the 1995 proposed rule said that the rule would ''help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco'' because ''[t]he pervasive promotion and easy availability of these products * * * severely hinder the individual family from carrying out this function by itself'' (60 FR 41314 at 41356).

In the Federal Register of August 11, 1995, the preamble to the proposed rule (60 FR 41314) (the 1995 proposed rule) also stated that, under section 1(g) of the Executive Order (which instructs agencies to ask about a rule's ''message'' to young people concerning their behavior, their personal responsibility, and societal norms), the rule would ''help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising'' that are attractive to children. This would enable young people ''to understand how prevalent tobacco use is in society and also appreciate how their decisions regarding cigarette and smokeless tobacco use can affect their health'' (60 FR 41314 at 41356).

In the 1995 proposed rule, FDA invited comments and suggestions on the rule's effect on the family.

FDA received several comments that disagreed with FDA's analysis.

(1) One comment said that the rule would have a significant economic effect on family earnings through increased costs (in order to comply with the rule) or the possible loss of jobs. Another comment said that the rule would destroy some family businesses, especially those dependent on vending machines selling cigarettes or on sponsorships by cigarette or smokeless tobacco manufacturers.

The agency disagrees with the comments. FDA reiterates that the rule does not affect sales to adults. It is narrowly drawn to reduce young people's access to cigarettes and smokeless tobacco and to reduce the appeal of those products to young people. In short, the rule is intended to prevent illegal sales to young people, and the agency has no evidence to suggest that a significant number of families depend on such sales.

FDA also notes that the final rule, as amended, permits vending machines in facilities that are inaccessible to young people and also permits sponsorships under certain restrictions. These changes to the rule should reduce the potential economic impact on families dependent on vending machine earnings or sponsorships or enable them to adjust their affairs to maintain family earnings.

(2) Several comments said that the rule interferes with parents' ability to raise their children, but did not elaborate on how the rule supposedly interfered in child-rearing.

The agency disagrees with the comments. The rule does not direct parents to educate or raise their children in any particular manner and, insofar as adults are concerned, does not regulate the use of cigarettes or smokeless tobacco by adults. It does reduce both their access and appeal to young people and, as a result, should help those parents who are trying to prevent their children from becoming regular users of these products. Thus, the rule does not interfere with parental authority or the manner in which parents educate, nurture, or supervise their children.

FDA, therefore, reiterates that the rule does not have a negative impact on family formation, maintenance, and general well-being and is consistent with Executive Order 12606.

B. Executive Order 12612: Federalism

Executive Order 12612 (E.O. 12612) requires Federal agencies to carefully examine regulatory actions to determine if they have a significant impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. E.O. 12612 directs Federal agencies that are formulating and implementing policies to be guided by certain federalism principles, such as encouraging a ''healthy diversity in the public policies adopted by the people of the several States according to their own

conditions, needs, and desires'' (section 2 of E.O. 12612).

Although § 897.42 of the 1995 proposed rule would have excluded from preemption under section 521 of the act more stringent State and local requirements that do not conflict with requirements imposed under FDA's final rule, FDA has deleted § 897.42 from the final rule because of significant concerns with regard to the validity of that section's proposed preemption exclusion. See discussion in section X. of this document. Thus, under the express provisions of section 521(a) of the act, FDA regulation of cigarettes and smokeless tobacco as nicotine-delivery devices will result in preemption of State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco when such requirements are different from, or in addition to, the requirements under FDA's final rule.

FDA received many comments on the 1995 proposed rule regarding its possible impact on State and local governments. Most comments came from individual State legislators in over 15 States (often using the same text or paragraphs). FDA also received comments from United States Senators and Representatives, four State governors, three lieutenant governors, as well as a number of State and local health departments, substance abuse programs, and law enforcement agencies. In addition, FDA received comments from industry trade associations and individual retailers. After careful consideration of these comments, FDA has assessed the rule's impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. As discussed below in this section, the agency concludes that the preemptive effects of the final rule are consistent with E.O. 12612.

(3) Many comments, including several from legislators, expressed opposition to the 1995 proposed rule on the grounds that the rule adversely affected State sovereignty by infringing on States' rights to regulate tobacco products, to protect their citizens, and to regulate businesses within the State. Some comments from State legislators criticized the rule, interpreting it as a statement that the State are ''unable to care for [their] own children,'' while other comments said that legislators, not FDA, should address issues affecting private citizens because legislators are elected officials who can be held politically accountable by their constituents.

Some comments asserted that the 1995 proposed rule would prevent States from experimenting with or trying different local approaches to reduce the accessibility and appeal of cigarettes and smokeless tobacco products. Some of these comments argued that their State laws were either adequate or superior to the 1995 proposed rule, citing, for example, State vending machine restrictions, State laws prohibiting distribution of tobacco products to minors, and State proof-of-age requirements. Moreover, some comments argued that FDA has failed to show that youth access to, and use of, tobacco products is a national (rather than State) concern warranting Federal action.

In contrast, several comments from State departments of health and State attorneys general noted that tobacco regulation is not solely a State issue. Moreover, some of the comments supported the rule for its potential impact on public health and on illegal sales of tobacco products to young people.

FDA recognizes the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

As explicitly recognized in E.O. 12612, however, Federal action limiting the discretion of State and local governments is appropriate ''where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope'' (section 3(b) of E.O. 12612). The final rule meets both of these conditions. First, the constitutional authority for the final rule is clearly rooted in the act which was enacted by Congress under the authority of the Commerce Clause of the Constitution, art. I, section 8, cl. 3. Second, youth access to cigarettes and smokeless tobacco is a problem of national scope that necessitates the provisions established by the final rule.

As discussed in the preamble to the 1995 proposed rule, approximately 3 million children under the age of 18 are daily smokers (60 FR 41314 at 41317). Moreover, every day, approximately another 3,000 young people become regular smokers (*Id*.). Children annually consume hundreds of millions of cigarettes, with the estimates ranging from 516 million to 947 million packages (*Id*.). Although most segments of the American adult population have decreased their use of cigarettes, smoking among young people has recently begun to rise (60 FR 41314 at 41315). With regard to smokeless tobacco, similar statistics demonstrate the extent of the problem in this area—an estimated 1 million adolescent males use smokeless tobacco (60 FR 41314). These figures clearly demonstrate a serious problem which exists at a national level. The health effects associated with cigarettes and smokeless tobacco are well established and have national social and health implications that warrant Federal attention.

As discussed in section X. of this document, FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgement that more stringent State or local requirements are inappropriate. Indeed, State and local governments may apply for exemption from preemption under section 521(b) of the act with regard to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section, and is consistent with the goals in the final rule. The availability of exemptions from preemption established under section 521(b) of the act enables State and local governments to preserve or enact more stringent requirements governing the sale and distribution of cigarettes and smokeless tobacco.

(4) Several comments asserted that States should be free to decide how to allocate their resources, including decisions as to whether any resources should be spent on tobacco control. Other comments expressed concern as to the rule's possible impact on State resources, explaining that States lacked resources to enforce the rule or predicting that FDA would lack sufficient resources to enforce the rule and, as a result, would have States handle enforcement matters.

FDA believes that these concerns are unfounded. First, because FDA is responsible for enforcing this rule, the rule should not require the expenditure of State resources for its enforcement. Second, with regard to State tobacco control, State and local governments will retain flexibility to choose the

appropriate allocation of their resources in this area through the availability of exemptions from preemption under section 521(b) of the act.

(5) Several comments also expressed strong concern regarding the rule's possible impact on the State economies, particularly with respect to farmers, manufacturers, distributors, and retailers. A detailed analysis of the rule's economic impact can be found in section XV. of this document.

Section 3(d)(3) of E.O. 12612 directs Federal departments and agencies to consult with appropriate officials and organizations representing the States in developing those standards. Similarly, section 4(d) of E.O. 12612 instructs Federal departments and agencies to consult, to the extent practicable, with State officials and organizations when the Federal department or agency ''foresees the possibility of a conflict between State law and federally protected interests within its area of regulatory responsibility.'' Moreover, section 4(e) of E.O. 12612 requires Federal departments and agencies to ''provide all affected States notice and an opportunity for appropriate participation in the proceedings'' when the Federal department or agency proposes to act through rulemaking to preempt State law.

The proposed rule published in the Federal Register of August 11, 1995, notified States and local governments of the Federal interest in regulating the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. FDA, through the comment period on the proposed rule, gave State and local governments notice and an opportunity to participate in the rulemaking process, as required by E.O. 12612. This final rule, as well as the exemption document, which appears elsewhere in this issue of the Federal Register, provide additional notice to State and local governments. Further opportunity for participation is provided by the availability of exemptions from preemption set forth in section 521(b) of the act.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with E.O. 12612.

C. Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights

Executive Order 12630 (E. O. 12630) directs Federal agencies to ''be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning and carrying out governmental actions so they do not result in the imposition of unanticipated or undue additional burdens on the public fisc'' (Section 3(a)). Section 3(c) of the order states that actions taken to protect the public health and safety ''should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose.'' Additionally, section 4(d) of E.O. 12630 requires, as a prerequisite to any proposed action regulating private property use for the protection of public health and safety, each agency to: (1) Clearly identify the public health or safety risk created by the private property use that is the subject of the proposed action; (2) establish that the proposed action substantially advances the purpose of protecting the public health and safety against the identified risk; (3) establish, to the extent possible, that the restrictions imposed on private property are not disproportionate to the extent to which the use contributes to the overall risk; and (4) estimate, to the extent possible, the potential cost to the Government should a court later determine that the action constitutes a taking.

The agency, in the preamble to the 1995 proposed rule, considered whether the rule would result in a ''taking'' of private property and concluded that, while some requirements might affect private property, the rule did not result in a ''taking'' of that property. (See 60 FR 41314 at 41357 through 41359.) In brief, the preamble to the 1995 proposed rule noted that the proposal would prohibit the use of a nontobacco product trade name on a tobacco product, eliminate vending machines and self-service displays, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibit all brand identifiable nontobacco items (such as hats and tee-shirts), and require established names and a brief statement on labels, labeling, and/or advertising. Sponsorship, under the 1995 proposed rule, would be limited to the corporate name. The preamble to the 1995 proposed rule explained that the rule did not result in a ''taking'' because the rule would not require the Government to physically invade or occupy private property and would not deny all economically viable uses of property. For example, the preamble to the 1995 proposed rule also stated that some items, such as vending machines, self-service displays, and nontobacco items, could be adapted to other uses. The preamble to the 1995 proposed rule also found that the rule substantially advanced the purpose of protecting the public health and that the restrictions were not disproportionate to the extent to which the use of the private property contributed to the public health risk (60 FR 41314 at 41357 through 41359). FDA also invited interested persons to submit information to enable the agency to determine the potential cost to the Government if a court found that the actions described in the 1995 proposed rule constituted a taking.

The final rule, as amended, prohibits the use of a trade name of a nontobacco item for any tobacco product, restricts the placement of vending machines and self-service displays, restricts outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibits all brand identifiable nontobacco items, such as hats and tee-shirts and requires established names on labels, labeling, and/or advertising, and places certain restrictions on sponsorship. Thus, the final rule, in many respects, is more lenient than the 1995 proposed rule. For example, the 1995 proposed rule would have eliminated the use of vending machines; the final rule permits vending machine sales to occur in locations that are inaccessible to young people. The 1995 proposed rule would have eliminated mail-order sales; the final rule permits such sales to continue. So, given that the 1995 proposed rule did not result in a ''taking,'' the final rule, being more lenient than the 1995 proposed rule, also should not result in a ''taking.''

Nevertheless, FDA received several comments asserting that the rule would effect a ''taking'' of private property. Most comments did not assign a specific monetary value to the private property which they felt would be ''taken'' or, instead, gave values or figures applicable to the entire industry rather than values or figures that would apply to the market (which, in this case, would be sales to people under age 18) affected by the rule.

(6) Several comments, particularly from retailers, claimed that the 1995 proposed rule's restrictions on self-service displays constituted a ''taking.'' A few comments explained that, for self-service displays, requiring the displays to be moved behind the counter would be analogous to a Government requiring an easement on real property and, as a

result, would violate the Fifth Amendment. FDA also received a small number of comments from firms that manufacture displays; these firms argued that the rule would essentially force them out of business and represent a ''taking'' of the business.

FDA disagrees with the comments. The final rule, as amended, permits self-service displays (merchandisers only) in facilities that are totally inaccessible to young people. Thus, in those facilities where merchandisers will be permitted, the rule will not require the merchandisers to be removed, and firms that manufacture merchandisers will continue to have a market for their merchandisers.

Retailers might be able to avoid or reduce the rule's impact on some merchandisers if those merchandisers could be adapted to other uses. For example, a merchandiser that consisted of bare shelves could be used to display products other than cigarettes and smokeless tobacco. Other merchandisers could be moved and, as a result, would retain their utility; for example, a counter display that stands near a cash register could be moved behind the counter and still be used for cigarettes and smokeless tobacco.

Additionally, as explained in greater detail in section XI. of this document, reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(7) Several comments asserted that the rule would eliminate the use of vending machines. In the preamble to the 1995 proposed rule, FDA cited an article from a vending machine publication to suggest that vending machines could be converted to sell other products and so, while the 1995 proposed rule would prohibit the use of vending machines for cigarettes and smokeless tobacco, the ability to convert a vending machine to other uses reduced the likelihood of a ''taking'' (60 FR 41314 at 41358). However, FDA received several comments explaining that some cigarette vending machines, particularly older models, cannot be adapted to other uses so that the 1995 proposed rule would destroy the value of those older vending machines.

As discussed earlier in this document, the final rule permits vending machines in facilities that are totally inaccessible to young people. While this may limit the number of places where vending machines may be used, may exclude vending machines from places where they were used most profitably, or, for those vending machines that cannot be moved, may compel the vending machine owner to convert the machine to other uses, if possible, the final rule's restrictions do not constitute a taking. Reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(8) Several comments asserted that the rule would reduce sales or tax revenues, prompt companies to terminate employees, or suspend sponsorship of events, thereby depriving States of revenues associated with those sponsored events or eliminating the event itself. For example, one State legislator claimed that the rule would adversely affect automobile racing events in the State, leading to a loss of 8 million dollars in revenue and adversely affecting the State's tourism department. Another State legislator asserted that the rule's sponsorship restrictions would end rodeo events in the State.

FDA disagrees with the comments. While the rule's economic impacts may be significant, those impacts do not necessarily result in a taking. For example, the final rule does not require firms to terminate employees or to stop sponsoring events. In fact, the final rule expressly permits sponsorships in the corporate name. The concerns expressed by the comments are also speculative and, to the extent that they do occur, would result from decisions made by third parties rather than by FDA. The Fifth Amendment requires just compensation for a governmental taking of private property; it does not require compensation for the consequential damages resulting from the exercise of a lawful Government regulation on that property.

Indeed, as noted in the preamble to the 1995 proposed rule, courts have generally required either a physical invasion of the property or a denial of all economically beneficial or productive use of the property and examined the degree to which the governmental action serves the public good, the economic impact of that action, and whether the action has interfered with ''reasonable investment-backed expectations'' (60 FR 41314 at 41357 through 41358). The preamble to the 1995 proposed rule noted that deprivation of the most beneficial use of property does not constitute a taking and that Government regulation often involves adjustment of rights for the public good. If every Government regulation resulted in a taking, then the Government would be effectively required to ''regulate by purchase'' (60 FR 41314 at 41358 (citing *Andrus* v. *Allard*, 444 U.S. 51, 65 (1979)). Here, the agency is not directing retailers to terminate staff, taking revenue belonging to retailers, or ending sponsored events. It is only issuing regulations to reduce illegal cigarette and smokeless tobacco to young people and the appeal of such products to young people. Retailers would still receive revenues from legal sales to adults; sponsorships in the corporate name could occur.

Other cases support the notion that lawful regulatory action does not constitute a taking merely because the Government action diminishes the value of private property, reduces profits, or prevents the most beneficial use of property (see *Carlin Communications, Inc.* v. *Federal Communications Comm'n*, 837 F.2d 546, 557–558 n. 5 (2d Cir.), *cert. denied*, 488 U.S. 924 (1988) (FCC regulation of ''dial-a-porn'' services to protect minors did not constitute a taking); *Galloway Farms, Inc.* v. *United States*, 834 F.2d 998 (Fed. Cir. 1987) (trade embargo, while closing off certain markets, did not eliminate all economic value so no taking occurred); *Minnesota Ass'n of Health Care Facilities, Inc.* v. *Minnesota Dep't of Public Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985) (nursing home's decision to participate in Medicaid program was voluntary and so a statute pertaining to Medicaid rates did not constitute a taking); *Carruth* v. *United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (regulation affecting contaminated peanuts, while reducing their value, did not constitute a taking); *Warner-Lambert Co.* v. *Federal Trade Comm'n*, 562 F.2d 749, 759 n. 45 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (FTC order requiring corrective advertising did not constitute a taking)).

Furthermore, courts have generally declined to require compensation for the loss of contracts that could not be completed following the enactment of a new statute or regulation or action by the Government and have not required compensation for the loss of future or anticipated profits. In *Omnia Commercial Co.* v. *United States*, 261 U.S. 502 (1923), the Supreme Court had to decide whether the Government's acquisition of a steel company's entire production of steel plate constituted a taking of a firm's contract for a large quantity of steel plate from the same steel company. The Court wrote that, ''There are many laws and governmental

operations which injuriously affect the value of or destroy property—for example, restrictions upon the height or character of buildings, destruction of diseased cattle, trees, etc., to prevent contagion—but for which no remedy is afforded. Contracts in this respect do not differ from other kinds of property'' (*Id*. at pp. 508 through 509). The Court reviewed earlier decisions and stated that:

> The conclusion to be drawn * * * is, that for consequential loss or injury resulting from lawful governmental action, the law affords no remedy. The character of the power exercised is not material. * * * If, under any power, a contract or other property is *taken* for public use, the Government is liable; but, if injured or destroyed by lawful action, without a taking, the Government is not liable.

(*Id*. at p. 510)

The Court held that while the Government took the steel, it did not take the contract itself and that ''[f]rustration and appropriation are essentially different things'' (*Id*. at p. 513). (See *also Louisville & Nashville R.R. Co*. v. *Mottley*, 219 U.S. 467, 484 (1911); *NL Industries, Inc*. v. *United States*, 839 F.2d 1578, 1579 (Fed. Cir.), *cert. denied*, 488 U.S. 820 (1988) (''frustration of a business by loss of a customer was not a taking''); *Carruth*, 627 F.2d at 1081 (''[I]n cases where there has been no direct appropriation of property by governmental agencies, consequential damages resulting from the exercise of lawful regulations are not compensable takings within the purview of the Fifth Amendment'').)

Thus, FDA disagrees with the comments suggesting that the rule will result in a taking of jobs or future revenues associated with sponsored events.

(9) Several comments said that the 1995 proposed rule's restrictions on the use of trade names constitute a taking of trade names or the goodwill associated with a tradename or asserted that one has a ''right'' to use a brand name in any manner.

As discussed in section XI. of this document, the agency disagrees that any provision in this rule effects a taking of trademarks and goodwill.

XIV. Environmental Impact

In the Federal Register of August 11, 1995 (60 FR 41314), the preamble to the proposed rule stated that FDA had determined under § 25.24(a)(8), (a)(11), and (e)(6) that the proposed action was of a type that does not individually or cumulatively have a significant impact on the human environment. No new information or comments have been received that would affect the agency's previous determination that this action has no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

XV. Analysis of Impacts

A. Introduction and Summary

The Food and Drug Administration (FDA) has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of such rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any year. Section 205 of the Unfunded Mandates Reform Act also requires that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. The following analysis, in conjunction with the remainder of this preamble, demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes.

FDA published its preliminary economic analysis in the preamble to its 1995 proposed regulation. In response, the agency received thousands of comments raising economic issues or concerns. Representatives of affected industry sectors emphasized burdens in excess of those estimated in the preliminary economic analysis. Other comments stressed the considerable economic value of the expected public health benefits. Although few comments provided quantifiable data on projected economic impacts, whether benefits or burdens, a report prepared by the Barents Group and presented as Volume 11 of the Tobacco Institute submission provided a comprehensive critique of the methodology, assumptions, and cost estimates presented in FDA's preliminary economic analysis and developed alternative estimates of regulatory costs. Other comments addressed selected economic issues. FDA carefully examined and evaluated the reasoning and data presented in these comments, accepted those that were persuasive, and presents this revised analysis of the final rule.

In its preliminary analysis, FDA based the benefits of the 1995 proposed rule on a finding that compliance could help to achieve the Department's ''Healthy People 2000'' goal of reducing underage tobacco use by one-half. Comments received in response to the proposal have reinforced the agency's conviction that this goal can be realized, although it will require the active support and participation of State and local governments and civic and community organizations, as well as manufacturers and retail dispensers of tobacco products. In the Federal Register of January 19, 1996 (61 FR 1492), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a regulation governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. SAMHSA predicted that its rule would cut the rate of underage tobacco consumption by between one-tenth and one-third. FDA can not separately quantify the incremental benefits of the respective agency programs, due to the substantial interdependencies and uncertainties regarding future compliance with these rules; but finds that its final rule and the SAMHSA regulation are fully complementary and, working together, will produce results that would more than equal the sum of their independent efforts.

Each year, an estimated 1 million adolescents under the age of 18 begin to smoke cigarettes. The Centers for Disease Control and Prevention (CDC) estimate that approximately one in three of these adolescents will die of smoking-related diseases, and FDA has concluded that this projection provides the best estimate of the excess fatality rate. FDA finds that even overly conservative projections indicate that achieving the ''Healthy People 2000'' goal of reducing underage tobacco use by one-half would prevent well over

60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. The monetary value of these health benefits (at a 3 percent discount rate) is estimated to total $28 to $43 billion per year and includes $2.6 billion in medical cost savings, $900 million in productivity gains from reduced morbidity, and $24.6 to $39.7 billion per year in willingness-to-pay values for averting premature fatalities. (Because of the long periods involved, a 7 percent discount rate reduces the total benefits to about $9.2 to $10.4 billion per year). If the agency's goal were exceeded, these benefits would be even larger. Moreover, if even a fraction of the goal were achieved, the benefits would substantially outweigh the costs of the rule. As shown in Table 1c, halting the onset of smoking for only 1/20 of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from $2.8 to $4.3 billion a year. In addition, although FDA has not quantified the benefits of reducing the number of serious illnesses attributable to the use of smokeless tobacco by youngsters under the age of 18, the agency is convinced that these benefits also will be substantial.

TABLE 1c.—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES (UNDISCOUNTED LIVES AND LIFE-YEARS; 3% DISCOUNT RATE FOR MONETARY VALUES)[1]

Fraction of Teenage Cohort Deterred	Fewer Teenagers who will Smoke as Adults[3] (No.)	Smoking Related Deaths Averted (No.)	Life-Years Saved (No.)	Medical Savings ($bils.)	Morbidity-Related Productivity Savings ($bils.)	Mortality-Related Willingness-to-Pay		Total Benefits	
						Life-Yrs. Saved ($bils.)	Deaths Averted ($bils.)	Low ($bils.)	High ($bils.)
1/2[2]	250,000	60,200	905,300	2.6	0.9	24.6	39.7	28.1	43.2
1/3	167,000	40,100	603,600	1.8	0.6	16.4	26.4	18.7	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.8	15.9	11.2	17.3
1/10	50,000	12,000	181,100	0.5	0.2	4.9	7.9	5.6	8.6
1/20	25,000	6,000	90,500	0.3	0.1	2.5	4.0	2.8	4.3

[1] Totals may not add due to rounding.
[2] Estimate used in analysis.
[3] Assumes 50% of adolescents who are deterred from smoking continue to refrain as adults.

In its evaluation of the economic impact on industry, FDA also includes those costs that might be attributable to the SAMHSA program, as the rules of both agencies work collectively to reduce youth access to tobacco products. As a result, the overall estimated compliance costs of the rules range from $174 million to $187 million in one-time costs and from $149 million to $185 million in annual operating costs (see Table 2). Manufacturers of tobacco products will incur one-time costs ranging from $78 million to $91 million, primarily for removing prohibited point-of-sale promotional items and self-service displays, and for changing package labels. As the responsibility for removing the prohibited point-of-sale promotional and display items resides with the owner, manufacturers and retailers may ultimately share the costs of removal and replacement. FDA's cost estimates assume that manufacturers will pay for most removal and installation activities and retailers will pay for most replacement items. (If, in fact, retailers assume most removal responsibilities, the estimated manufacturer costs fall by about $47 million).

TABLE 2.—COSTS OF FDA AND SAMHSA REGULATIONS ($ mils.)[1]

Requirements By Sector	One-Time Costs	Annual Operating Costs
Tobacco Manufacturers	**78–91**	**2**
Point-of-Sale Advertising	30	
Self-Service Ban	40	
Label Changes	4–17	
Paperwork Requirements		1.2
Training	1.5	0.2
Readership Surveys	2	1
Retail Establishments	**96**	**78**
Training	34	20
I.D. Checks		43
Self-Service Ban	57	11
Point-of-Sale Advertising	5	
Vending Machines		3.5
Consumers		**41–50**
I.D. Checks		41–50
Government		**28–55**
States (SAMHSA)		25–50
FDA		3–5
TOTAL	**174–187**	**149–185**

[1] Assumes manufacturers remove prohibited retail display. If retailers bear full burden, manufacturer one-time costs fall by about $47 million and retailer one-time costs rise by about $17 million. Advertising restrictions are considered under distributional effects. Excludes costs of short-term resource dislocation and educational programs.

Retail establishments will incur an estimated $96 million in one-time costs. About $57 million of these costs are due to the self-service restriction, primarily for replacing display cases and other functional promotional items. (If retailers rather than manufacturers remove the prohibited point-of-sale advertising and display items, the estimated retailer costs rise by about $17 million). The retail sector will also incur about $78 million in annual costs. In addition to new labor costs attributable to the self-service restrictions, both the FDA and SAMHSA rules impose costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers, and for foregoing profits due to reduced vending machine sales. Consumers will bear costs of up to $50 million annually for incurring some delay in checkout lines. Finally, enforcement of these rules may cost the FDA from $3 million to $5 million per year and State governments from $25 million to $50 million per year for administering various SAMHSA enforcement programs.

FDA could not, however, quantify every regulatory cost. For example, the agency may require certain tobacco manufacturers to broadcast educational messages under the agency's notification process. Cost estimates for these activities will be developed in parallel with the program elements. In addition, a number of commercial sectors will experience costs for short-term dislocations of current business activities. Neither FDA nor any of the industry comments on the agency's proposal projected the magnitude of these costs, but they would be mitigated for those businesses that anticipate the adjustments in long-term business plans.

In addition to the costs described previously, the rule will create significant distributional and transitional effects. Some industry comments asserted that FDA had neglected the cost of lost sales revenues in its preliminary economic analysis and one industry study estimated these ''Illustrative Costs'' at from $1.3 billion to $3.3 billion per year. In fact, FDA had considered these sector-specific revenue reductions, but described the impacts as distributional effects, rather than as net societal costs. For example, any lost sales experienced by suppliers of advertising were considered distributional impacts, because dollars not spent on advertising will not be lost to the U.S. economy, but will be spent on other goods and services. As acknowledged by the authors of one of the economic impact analyses commissioned by the tobacco manufacturing industry:

* * * when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

Similarly, the anticipated slow but persistent decline in tobacco product sales revenues are not societal costs, because the dollars not spent on tobacco-related items will be spent on other goods or services.

Nevertheless, FDA is aware that many tobacco-related industry sectors will be adversely affected by this rule. Tobacco manufacturers and suppliers will face increasingly smaller sales, because reduced tobacco consumption by youth will lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues, however, will be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent. Also, if State and Federal excise tax rates on tobacco products remain at current levels, tax revenues would decrease slowly over time, falling by about $231 million and $196 million, respectively, by the 10th year following compliance with the regulation.

Tobacco manufacturers spent $6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent may be substantially altered to reflect the various ''text only''

restrictions or other prohibitions. If tobacco companies choose to reduce advertising and promotional activities due to the FDA restrictions, the sectors affected would include advertising agencies and communications media, owners of retail and outdoor advertising space, and recipients of corporate brand-name sponsorships (especially auto racing). These businesses would need to attract new revenues to maintain current levels of profitability. Similarly, vending machine operators will need to find substitute products to replace up to 3 percent of their sales revenues.

In summary, FDA finds that compliance with this rule will bring significant health benefits to the U.S. population. The rule will also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors. With regard to small businesses, many near-term impacts will be small or transitory, but some business will be adversely affected. For a small retail convenience store not currently complying with this rule, the additional first year costs could average $400. For those convenience stores that already check customer identification, these costs average $137, largely to relocate tobacco product displays. Moreover, the rule will not produce significant economic problems at the national level, as the long-term displacement within tobacco-related sectors will be offset by increased output in other areas. Thus, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current rule is the least burdensome and most cost-effective alternative that would meet the objectives of this rule.

B. Statement of Need for Action

The need for action stems from the agency's determination to ameliorate the enormous toll on the public health that is directly attributable to the consumption by adolescents of cigarettes and smokeless tobacco. According to the nation's most knowledgeable health experts, tobacco use is the most important preventable cause of morbidity and premature mortality in the United States, accounting each year for over 400,000 deaths (approximately 20 percent of all deaths). Moreover, these morbidity and mortality burdens do not spare middle aged adults—with the average smoking-related death responsible for the loss of up to 15 life-years.[268]

In its guidelines for the preparation of Economic Impact Analyses, OMB asks that Federal regulatory agencies determine whether a market failure exists and if so, whether that market failure could be resolved by measures other than Federal regulation. The basis for this request derives from standard economic welfare theory, which by assuming that each individual is the best judge of his/her own welfare, concludes that perfectly competitive private markets provide the most efficient use of societal resources. Accordingly, the lack of perfectly competitive private markets (market failure) is frequently used to justify the need for Government intervention. Common causes of such market failures include monopoly power, inadequate information, and market externalities or spillover effects.

While FDA agrees that various elements of market failure are relevant to the problem of teenage use and tobacco addiction, the agency also believes that this regulatory action would be justified even in the absence of a traditional market failure. As noted previously, the implications of the market failure logic are rooted in a basic premise of the standard economic welfare model—that each individual is the best judge of his/her own welfare. FDA, however, is convinced that this principle does not apply to children and adolescents. Even steadfast defenders of individual choice acknowledge the difficulty of applying the ''market failure'' criterion to non adults. Littlechild, for example, adds a footnote to the title of his chapter on ''Smoking and Market Failure''[269] to note that ''[t]he economic analysis of market failure deals with choice by adults.'' Although both Beales[270] and Viscusi find that young persons balance risks and rewards in making decisions on whether or not to smoke, Viscusi explains that:

[n]evertheless, there are some classes of choices that have major consequences, and for that reason society may wish to reserve the privilege of making these choices until a particular age is reached. These limits should, however, be set according to the age at which individuals are believed to be capable of making reasonable long-term decisions regarding their welfare, rather than some arbitrary date independent of the choice context. The emerging consensus of smoking restriction policies has focused age 18 as the minimum age for the purchase of cigarettes.[271]

FDA concludes, therefore, that even if some children do make rational choices, the agency's regulatory determinations must reflect the societal conviction that children under the age of legal consent cannot be assumed to act in their own best interest.[272]

In particular, FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. Section VI. of this document describes numerous studies on the shortcomings of the risk perceptions held by children. Health economist Victor R. Fuchs describes the typical sequence:

There is considerable evidence that the [time discount] rate falls as children mature. Infants and young children tend to live very much for the present; the prospect of something only a week in the future usually has little influence over their behavior. As children get older their time horizons lengthen, but once adult status is reached there seems to be little correlation between time discount and age.[273]

Thus, although most youngsters acknowledge the existence of tobacco-related health risks, the agency finds that the abridged time horizons of youth make them exceptionally vulnerable to the powerful imagery advanced through targeted industry advertising and promotional campaigns. In effect, these conditions constitute an implicit market failure not adequately remedied by existing government action.

Moreover, the agency does not view these results as inconsistent with the growing economic literature based on the Becker and Murphy models of ''rational addiction.''[274] Although several empirical studies have

[268] Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, pp. 1–2, April 28, 1994.

[269] Littlechild, S. C., ''Smoking and Market Failure,'' in ''Smoking and Society: Toward a More Balanced Assessment,'' edited by R. D. Tollison, Lexington Books, p. 271, 1986.

[270] Beales III, J. Howard, ''Advertising and the Determinants of Teenage Smoking Behavior,'' p. 44, 1993.

[271] Viscusi, W. K., ''Smoking: Making the Risky Decision,'' Oxford University Press, New York, p. 149, 1992.

[272] Goodin, R. E., ''No Smoking: The Ethical Issues,'' University of Chicago Press, pp. 30–32, 1989.

[273] Fuchs, V. R., ''How We Live,'' Harvard University Press, Cambridge, MA, pp. 228–229, 1983.+

[274] Becker, G. S., and K. M. Murphy, ''A Theory of Rational Addiction,'' Journal of Political Economy, vol. 96, No. 4, pp. 675–700, 1988.

demonstrated that, for the general population, cigarette consumption is ''rationally addictive'' in the sense that current consumption is affected by both past and future consumption,[275] Chaloupka notes that this ''rationality'' does not hold for younger or less educated persons, for whom past but not future consumption maintains a significant effect on current consumption. He concludes, ''[t]he strong effects of past consumption and weak effects of future consumption among younger or less educated individuals support the a priori expectation that these groups behave myopically.''[276]

FDA's justification of this regulation relies on the total costs associated with childhood addiction to tobacco, rather than on the external or spillover costs to nonusers. Nevertheless, a further market failure would exist if the use of tobacco imposed such costs on nonusers. Many studies have attempted to calculate the societal costs of smoking, but few have addressed these externalities. The most detailed research on the issue of whether smokers pay their own way is the 1991 study by Manning, et al.,[277] which develops estimates of the present value of the lifetime external costs attributable to smoking. This study examines differences in costs of collectively financed programs for smokers and nonsmokers, while simultaneously controlling for other personal characteristics that could affect these costs (e.g., age, sex, income, education, and other health habits, etc.). The authors found that nonsmokers subsidize smokers' medical care, but smokers (who die at earlier ages) subsidize nonsmokers' pensions. On balance, they calculated that, before accounting for excise taxes, smoking creates net external costs of about $0.15 per pack of cigarettes in 1986 dollars ($0.33 per pack adjusted to 1995 dollars by the medical services price index). While acknowledging that these estimates ignored external costs associated with lives lost due to passive smoking, perinatal deaths due to smoking during pregnancy, and deaths and injuries caused by smoking-related fires, the authors concluded that there is no net externality, because the sum of all smoking-related externalities is probably less than the added payments imposed on smokers through current Federal and State cigarette excise taxes. A Congressional Research Service Report to Congress concurred with the study's conclusion,[278] although many uncertainties remain regarding the potential magnitude of the omitted cost elements.

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the regulation include the costs that would be avoided by reducing the adverse health effects associated with the consumption of tobacco products. Most research on the costs of smoking-related illness has concentrated on the medical costs and productivity losses associated with the prevalence of death and illness in a given year. These prevalence-based studies typically measure three components: (1) The contribution of smoking to annual levels of illness and death, (2) the direct costs of providing extra medical care, and (3) the indirect costs, or earnings foregone due to smoking-related illness or death.[279]

In a recent statement, the former U.S. Office of Technology Assessment (OTA) declared that ''the greatest 'costs' of smoking are immeasurable insofar as they are related to dying prematurely and living with debilitating smoking-related chronic illness with attendant poor quality of life.'' Nonetheless, OTA calculated that in 1990 the national cost of smoking-related illness and death amounted to $68 billion and included $20.8 billion in direct health care costs, $6.9 billion in indirect morbidity costs, and $40.3 billion in lost future earnings from premature death.[280] More recently, the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at $50 billion.[281] Unfortunately, these prevalence-based studies do not answer many of the most important questions related to changes in regulatory policy, because they present the aggregate cost of smoking-related illness in a single year, rather than the lifetime cost of illness for an individual smoker. As noted in the 1992 Report of the Surgeon General, most prevalence-based studies fail to consider issues concerning ''the economic impact of decreased prevalence of cigarette smoking, the length of time before economic effects are realized, the economic benefits of not smoking, and a comparison of the lifetime illness costs of smokers with those of nonsmokers.''[282] In effect, although these studies are designed to measure the smoking-related draw on societal resources, they are not well-suited for analyzing the consequences of regulation-induced changes in smoking behavior.

2. FDA's Methodology

An alternative methodology, termed incidence-based research, compares the lifetime survival probabilities and expenditure patterns for smokers and nonsmokers. As this approach models the individual life-cycle consequences of tobacco consumption, FDA relied on these incidence-based studies for its original analysis of the proposed rule to value the beneficial effects of the rule over the lifetime of each new cohort of potential smokers. The methodology incorporates the following steps:

- A projection of the extent to which the rule will reduce the incidence, or the annual number, of new adolescent users of tobacco products;
- A projection of the extent to which the reduced rates of adolescent tobacco consumption will translate to reduced rates of lifetime tobacco consumption;
- A projection of the extent to which the reduced rates of lifetime tobacco consumption will decrease the number of premature deaths and lost life-years; and
- An exploration of various means of estimating the monetary value of the expected health improvements.

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[275] Becker, G. S., M. Grossman, and K. M. Murphy, ''An Empirical Analysis of Cigarette Addiction,'' *The American Economic Review*, vol. 84, No. 3, pp. 396–418, June 1994; Chaloupka, F., ''Rational Addictive Behavior and Cigarette Smoking,'' *Journal of Political Economy*, vol. 99, No. 4, pp. 722–742, 1991; Keeler, T. E., T. W. Hu, P. G. Barnett, and W. G. Manning, ''Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence,'' *Journal of Health Economics*, vol. 12, pp. 1–18, 1993.

[276] Chaloupka, F., ''Rational Addictive Behavior and Cigarette Smoking,'' *Journal of Political Economy*, vol. 99, No. 4, p. 740, 1991.

[277] Manning, W. G., E. B. Keeler, J. P. Newhouse, E. M. Sloss, and J. Wasserman, ''The Costs of Poor Health Habits, A RAND Study,'' Harvard University Press, Cambridge, MA, 1991.

[278] Gravelle, J. G., and D. Zimmerman, ''CRS Report for Congress: Cigarette Taxes to Fund Health Care Reform: An Economic Analysis,'' Congressional Research Service, p. 1, March 8, 1994.

[279] See ''Smoking and Health in the Americas: A 1992 Report of the Surgeon General in collaboration with the Pan American Health Organization,'' Department of Health and Human Services (DHHS), Public Health Service (PHS), CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), pp. 105–112, 1992, (hereinafter referred to as ''1992 SGR'') for a full summary of these methodologies and findings.

[280] Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, p. 2, April 28, 1994.

[281] ''Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993,'' in *Morbidity and Mortality Weekly Reports* (*MMWR*), CDC, DHHS, vol. 43, No. 26, pp. 469–472, July 8, 1994.

[282] 1992 SGR, p. 111.

The annual benefits of the 1995 proposed rule were measured as the present value of the lifetime benefits gained by those youngsters, who in the absence of the proposed regulation, would have become new smokers. Upon review of the public comments, FDA found none that would persuade the agency to revise its projections. In general, the relevant comments expressed no objection to the basic methodology or model, but some disputed the accuracy of the specific data estimates. The following paragraphs describe the FDA assumptions that underlie these benefit estimates and present the agency's response to the applicable public comments.

3. Reduced Incidence of New Young Smokers

FDA's preliminary analysis assumed that 1 million youngsters become new smokers each year. One trade association comment questioned this figure, asserting that the relevant studies included individuals over the age of 18. However, the 1985 National Health Interview Survey reported 1.08 million 20-year old smokers, and the Combined National Health Interview Surveys for 1987–1988 found that 92 percent of 20-year old smokers had started smoking by age 18. Taking 92 percent of 1.08 million yields 993,600 new underage smokers per year. This figure is supported by parallel estimates of the SAMHSA. Based on data from the 1994 National Household Survey on Drug Abuse, SAMHSA estimated that 1.29 million persons under age 20 became daily smokers in 1993, and that 1.1 million of these persons were under the age of 18. As a result, FDA retains confidence in its original estimate of 1 million new smokers per year.

The regulation targets youngsters by restricting youth access to tobacco products and by limiting advertising activities that affect adolescents. Several communities have demonstrated that access restrictions are extremely effective when vigorously applied at the local level. Woodridge, IL, for example, achieved a compliance rate of over 95 percent. Moreover, 2 years after that law was enacted, a survey of 12- to 14-year-old students indicated that overall smoking rates were down by over 50 percent (over 2/3 for regular smokers).[283]

Advertising and promotional restrictions will augment these efforts to limit the attractiveness of tobacco products to underage consumers. As discussed in detail in section VI. of this document, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, much of the relevant research indicates that advertising restrictions will reduce consumer demand. For example, according to the 1989 report of the Surgeon General, ''The most comprehensive review of both the direct and indirect mechanisms concluded that the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption.''[284] Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the United Kingdom Department of Health determined that, ''the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption.''[285] A detailed evaluation of the effects of advertising on youth consumption of tobacco products is provided in section VI. of this document.

In Northern California, 24 cities and unincorporated areas in 5 counties adopted local youth tobacco access ordinances that prohibit self-service merchandising and point-of-sale tobacco promotional products in retail stores. Survey measures of the impact of these ordinances by the Stop Tobacco Access for Minor Project (STAMP) found that, on average, tobacco sales to minors dropped by 40 to 80 percent.[286]

In its analysis of the 1995 proposed rule, FDA argued that, while quantitative estimates of the effectiveness of its regulation cannot be made with certainty, comprehensive programs designed to discourage youthful tobacco consumption could reasonably achieve the ''Healthy People 2000'' goal of halting the onset of smoking for at least half, or 500,000, of the 1,000,000 youngsters who presently start to smoke each year. In the Federal Register of January 19, 1996 (61 FR 1492) SAMHSA published a regulation governing a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. SAMHSA had originally estimated that its program would reduce tobacco consumption by youth and children by from one-third to two-thirds, but subsequently determined that reductions of between one-tenth and one-third would be ''more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion.''[287] While strongly supporting the objectives of the SAMHSA program, FDA finds that achieving the ''Healthy People 2000'' goal will demand a full arsenal of controls to complement and fortify the new State inspectional programs, including restrictions on industry advertising and promotions and quite possibly educational messages to counter the influence of ongoing marketing activities.

Numerous public comments to the 1995 proposal addressed the issue of the effectiveness of the regulation. Many argued that tobacco advertising does not increase tobacco use, or that the enforcement of existing or forthcoming State laws, alone, could accomplish reasonable goals. In contrast, many others supported a comprehensive regulation, contending that only vigorous enforcement of new restrictions would bring significant results. As outlined earlier in the preamble in this document, FDA has determined, based on a full examination of the evidence, that the combined effect of the regulations (restricting advertising and promotion, prohibiting self-service sales, providing new labeling information, and imposing age verification obligations) and educational programs will significantly diminish the allure as well as the access to tobacco products by youth. The agency acknowledges the imposing size of the required effort, but is confident that its goals are reasonable and presents regulatory benefits based on the presumption that the ''Healthy People 2000'' goals will be met.

[283] Jason, L. A., P. Y. Ji, M. D. Anes, and S. H. Birkhead, ''Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors,'' *The Journal of the Amercian Medical Association* (*JAMA*), vol. 266, No. 22, p. 3159, December 11, 1991.

[284] DHHS, ''Reducing the Health Consequences of Smoking: 25 Years of Progress,'' A Report of the Surgeon General, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, DHHS publication No. (CDC) 89–8411, p. 517, 1989 (the 1989 SGR).

[285] Leaney, K., ''Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence,'' Economics and Operational Research Division, Department of Health, London, p. 22, October 1992.

[286] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access to Minors Program (STAMP), Petaluma, CA, p. 4, November 3, 1994.

[287] 61 FR 1502, January 19, 1996.

FDA agrees, however, that these projections are uncertain and therefore also presents estimates of benefits at effectiveness levels that are considerably smaller. The agency conducted this exercise not because its estimates are excessively speculative or arbitrary, as suggested by one comment, but because sensitivity analyses are part of generally accepted ''best practice'' for the conduct of cost-benefit analysis and are recommended by OMB guidance. These results demonstrate that even if the rule were only modestly effective in reducing tobacco use, it yields justifiable benefits.

One comment urged the agency to demonstrate the effectiveness of tobacco marketing restrictions over and above those for access restrictions or public information campaigns. FDA is unable to forecast the independent results of each regulatory provision, due to the high degree of interdependence among the various requirements, but notes that SAMHSA concluded that its access restrictions, alone, would reduce underage tobacco consumption by one-tenth to one-third. If so, accomplishing the ''Healthy People 2000'' goal implies that the FDA rule would generate incremental tobacco use reductions of between 17 and 40 percent for youngsters under 18 years of age.

4. Reduced Number of Adult Smokers

The major beneficiaries of the rule are those individuals who would otherwise begin using tobacco early in life and who, accordingly, are unlikely to start using tobacco products as an adult. Evidence suggests that this percentage will be high, as over half of adult smokers had become daily cigarette smokers before the age of 18. Moreover, the 1994 Surgeon General's Report indicates that 82 percent of persons (aged 30 to 39) who ever smoked daily began to smoke before the age of 18. That report concludes that ''if adolescents can be kept tobacco-free, most will never start using tobacco.'' [288] Although some comments disagreed with that conclusion, FDA believes that the Surgeon General's Report is correct. Nonetheless, to account for the possibility that some would-be smokers who are prevented from smoking until they are age 18 may eventually start smoking as adults, FDA uses the more conservative assumption that these rules will lead to a tobacco free adult life for only one-half of the estimated 500,000 youngsters who will be deterred from starting to smoke each year. Accordingly, FDA calculates the annual benefits from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult. Further, in response to comments that challenge this estimate, FDA presents sensitivity analysis showing results using a wide range of alternative rates.

5. Lives Saved

Based largely on data from Peto, et al., who found that about half of all adolescents who continue to smoke regularly throughout their lives will eventually die from a smoking-related disease, [289] CDC estimates that about one in three adolescent smokers will die prematurely. [290] Although the CDC projection provides the best estimate of this excess fatality rate, it does not provide a distribution of the smoking-related fatalities over time. Consequently, FDA derived this distribution by comparing age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate are derived from the American Cancer Society's Cancer Prevention Study II, as shown in Table 3.

TABLE 3.—PROBABILITY OF SURVIVAL BY AGE, SEX, AND SMOKING STATUS
(Probabilities of a 17-year-old surviving to age shown)

Age (Years)	Male Neversmokers	Male All Smokers	Female Neversmokers	Female All Smokers
35	1	1	1	1
45	0.986	0.966	0.988	0.984
55	0.951	0.893	0.962	0.939
65	0.867	0.733	0.901	0.831
75	0.689	0.466	0.760	0.630
85	0.336	0.159	0.453	0.289

Source: Thomas Hodgson, ''Cigarette Smoking and Lifetime Medical Expenditures,'' *The Milbank Quarterly*, vol. 70, No. 1, 1992, p. 91. Based on data from the American Cancer Society's Cancer Prevention Study II.

FDA initially multiplied differences in the probabilities of death for smokers versus nonsmokers within each 10-year period by the number of smokers remaining at the start of each 10-year period. Assuming an equal number of males and females, the excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. FDA recognizes that this methodology probably understates the current risk of smoking, because it arbitrarily assumes that the smoking-related risks for females will continue to be smaller than for males, even though female smoking patterns are presently comparable to those of males. Nevertheless, FDA used this model to support its proposed regulation and maintains the calculation to demonstrate the robustness of the results. Moreover, because some comments suggested that these data may not account for all potentially confounding variables, such as alcohol consumption or other lifestyle differences, FDA further adjusted the mortality estimate to 24 percent to reflect findings by Manning et al., that such nontobacco versus tobacco lifestyle factors may account for 13 percent of excess medical care expenditures. Thus, the benefits projections presented below conservatively rely on the probabilities

[288] 1994 SGR, pp. 5 and 65.

[289] Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., ''Mortality from Smoking in Developing Countries, 1950–2000,'' Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

[290] Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, ''Trends in Cigarette Smoking in the United States: Projections to the Year 2000,'' *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, ''Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from national Vital Statistics,'' Oxford University Press, Oxford, 1994.

shown in Table 3, corrected by the 13 percent lifestyle influence adjustment. In sum, they indicate that achieving the ''Healthy People 2000'' performance goal will prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.

The economic assessment of health-related variables requires discounting the value of future events to make them commensurate with the value of present events. For this analysis, a 3 percent discount rate is used to calculate the present value of the projections. (This rate was recommended by the Panel on Cost-Effectiveness in Health and Medicine, a nonfederal multidisciplinary group of experts in cost-effectiveness analysis, convened by the Office of the Assistant Secretary for Health in 1993.[291] Since the Office of Management and Budget (OMB) Circular A–94 recommends the use of 7 percent as a base case, FDA presents summary estimates below for discount rates of both 3 percent and 7 percent.) On the assumption that it would be roughly 20 years for each year's cohort of new adults to reach the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that the present value of these benefits equate to 15,863 lives per year.

6. Life-Years Saved

The number of life-years that will be saved by preventing each year's cohort of 250,000 adolescents from acquiring a smoking addiction was calculated from the same age-specific survival differences between smokers and nonsmokers. In each 10-year life span, the number of years lived for each cohort of persons who would have been smokers but who were deterred was compared to the number of years that would have been lived by that same cohort if they had been smokers. The difference between these two measures is the life-years saved for that 10-year period.[292] Deducting the 13-percent lifestyle adjustment indicates that, over the full lifetime of each cohort, the regulations will gain an estimated 905,000 life-years, which translates to almost 4 years per smoker and 15 years per life saved.[293] The present value of these additional life-years equates to 211,391 life-years annually.

7. Monetized Benefits of Reduced Tobacco Use

There is no fully appropriate means of assigning a dollar figure to represent the attendant benefits of averting thousands of tobacco-induced illnesses and fatalities. However, to quantify important components of the expected economic gains, FDA developed estimates of the value of the reduced medical costs and the increased worker productivity that will result from fewer tobacco-related illnesses. In addition, since productivity measures do not adequately address the avoidance of premature death, FDA adopted a willingness-to-pay approach to value the benefits of reduced tobacco-related fatalities.

8. Reduced Medical Costs

On average, at any given age, smokers incur higher medical costs than nonsmokers. However, nonsmokers live longer and therefore continue to incur medical costs over more years. Several analysts have reported conflicting estimates of the net outcome of these factors, but the most recent research is the incidence-based study by Hodgson,[294] who found that lifetime medical costs for male smokers were 32 percent higher than for male neversmokers and lifetime medical costs for female smokers were 24 percent higher than for female neversmokers. Hodgson determined that the present value of the lifetime excess costs were about $9,400 in 1990 dollars (future costs discounted at 3 percent).[295] As noted earlier, the incidence-based study by Manning, et al., implies that about 13 percent of the excess medical costs were attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index for medical care raises the present value of Hodgson's excess medical cost per new smoker to $10,590 in 1994 dollars. Thus, those 1,000,000 young people under the age of 18, who currently become new smokers each year, are responsible for excess lifetime medical costs measured at a present value of $10.6 billion (1,000,000 x $10,590). Because FDA projects that achieving the ''Healthy People 2000'' goals will prevent 250,000 of these individuals from smoking as adults, the medical cost savings are estimated at $2.6 billion per year.

9. Reduced Morbidity Costs

An important cost of tobacco-related illness is the value of the economic output that is lost while individuals are unable to work. Thus, any future reduction in such lost work days contributes to the economic benefits of the regulation. Several studies have calculated prevalence-based estimates of U.S. productivity losses due to smoking-related morbidity, but FDA knows of no incidence-based estimates. Hodgson, however, has shown that, in certain situations, incidence measures can be derived from available prevalence measures. For example, he demonstrates that in a steady-state model the only difference between prevalence and incidence-based costs is due to discounting.[296] Accordingly, FDA has adopted Hodgson's method to develop a rough approximation of incidence-based costs from an available prevalence-based estimate of morbidity costs.

Rice, et al.,[297] found that lost wages due to tobacco-related work absences in the United States amounted to $9.3 billion in 1984. This equates to $12.3 billion in 1994 dollars when adjusted by the percentage change in average employee earnings since 1984. Although FDA does not have a precise estimate of the life-cycle timing of these morbidity effects, the relevant latency periods would certainly be shorter than for mortality effects. Thus, to account for the deferred manifestation of smoking-related morbidity effects, FDA assumed that they would occur over a time horizon equal to 80 percent of that previously measured for mortality effects. Although one comment mistakenly assumed that FDA had made no adjustment for lifestyle differentials between smokers and nonsmokers, in fact, these estimates were further

[291] Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, ''Cost-effectiveness in Health and Medicine,'' Oxford University Press, p. 232, 1996.

[292] For each 10-year age interval, the number of life-years is calculated as the number of people in each cohort (250,000) times the probability of surviving until the end of that age interval times 10 years of life, plus the number expected to die in that interval times an assumed 5 years of life.

[293] The calculation procedure probably understates total life-years saved, because it misses smoking related-fatalities that occur within the same 10-year age interval. However, because more of these misses involve fatalities that, if avoided, would add few life-years, the resulting 15-year average life-years saved may be high. FDA's benefit estimates, however, remain understated because they are based on total life-years saved, not average life-years saved.

[294] Hodgson, T. A., ''Cigarette Smoking and Lifetime Medical Expenditures,'' *The Milbank Quarterly*, vol. 70, No. 1, p. 97, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

[295] *Id*. (Using the average of the male and female totals).

[296] Hodgson, T. A., ''Annual Costs of Illness Versus Lifetime Costs of Illness and Implications of Structural Change,'' *Drug Information Journal*, vol. 22, No. 3, p. 329, 1988.

[297] Rice, D. P., et al., ''The Economic Costs of the Health Effects of Smoking, 1984,'' *The Milbank Quarterly*, vol. 64, No. 4, p. 526, 1986.

reduced by 13 percent to reflect the Manning, et al., findings. Finally, because the long-term decline in smoking prevalence has exceeded the growth in population, FDA reduced the incidence-based costs by another 20 percent. At a 3 percent discount rate, this methodology implies that the incidence-based cost of smoking-related morbidity, or the present value of the future costs to 1 year's cohort of 1,000,000 new smokers, is about $3.5 billion. Thus, the estimated annual morbidity-related savings associated with preventing 250,000 new youths per year from smoking as adults is estimated at about $879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB guidance advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Unfortunately, the specific willingness-to-pay of smokers is unknown, because institutional arrangements in the markets for medical care obscure direct measurement techniques.[298] Nevertheless, many studies have examined the public's willingness-to-pay to avoid other kinds of life-threatening risks, especially workplace and transportation hazards. An EPA-supported study[299] found that most empirical results support a range of $1.6 to $8.5 million (in 1986 dollars) per statistical life saved, which translates to $2.2 to $11.6 million in 1994 dollars. However, the uncertainty surrounding such estimates is substantial. Moreover, Viscusi has shown that smokers, on average, may be willing to accept greater risks than nonsmokers. For example, smokers may accept about one-half the average compensation paid to face on-the-job-injury risks.[300] FDA therefore has conservatively used $2.5 million per statistical life, which is towards the low end of the research findings, to estimate society's willingness-to-pay to avert a fatal smoking-related illness. Thus, the annual benefits of avoiding the discounted number of 15,863 premature fatalities would be $39.7 billion.

An alternative method of measuring willingness-to-pay is to calculate a value for each life-year saved. This approach is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age and is the traditional means of assessing the cost-effectiveness of medical interventions. Nevertheless, there have been few attempts to determine the appropriate value of a life-year saved. OMB suggests several methodologies, including annualizing with an appropriate discount rate the estimated value of a statistical life over the average expected life-years remaining. For example, at a 3-percent discount rate, a $2.5 million value per statistical life for an individual with 35 years of remaining life-expectancy converts to about $116,500 per life year. Since achieving the agency's goals were estimated to save 211,391 discounted life-years annually, this calculation yields annual benefits of $24.6 billion.

FDA notes that even these values understate the full value of the health impact, because they fail to quantify any reduction in either the adverse effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking. Moreover, these totals may not capture the heavy toll of psychic loss to surviving family members, or the corresponding economic losses among family members for the mental health care of grief-related depression and other conditions that often follow the premature death of middle aged adults.[301]

11. Reduced Fire Costs

Every year lighted tobacco products are responsible for starting fires which cause millions of dollars in property damage and thousands of casualties. In 1992, fires started by lighted tobacco products caused 1,075 deaths and $318 million in direct property damage.[302] A reduction in the number of smokers, and the corresponding number of cigarettes smoked, will result in a drop in the number of future fires. In the 1995 proposal, FDA estimated that if the number of fires falls by the same percentage as the expected reduction in cigarette sales, this implies present value savings of $203 million for the value of lives saved and $24 million for the value of averted property damage, totaling $227 million annually over a 40-year period.

One comment denied the existence of any association between fires and cigarette consumption. FDA acknowledges that the relationship may be nonlinear, but finds the asserted lack of a positive correlation implausible. This comment further stated that residential fires caused by smoking and deaths from residential fires caused by smoking decreased from 1983 to 1992 by 39 percent and 40 percent, respectively, or about 5.5 percent annually. Accounting for this trend would lower FDA's fire cost estimate to a present value savings of $145 million for the value of lives saved and $17 million for the value of averted property damage, totaling $162 million annually over a 40-year period. Even these estimated savings significantly underestimate the potential benefits, however, because they exclude both nonfatal injuries and the need for temporary housing.

12. Smokeless Tobacco

The Smokeless Tobacco Council, Inc., remarked that FDA had not attempted to measure the benefits that would result from the decreased use of smokeless tobacco products by underage youths. The introduction to the 1995 proposed regulation, however, explained that the use of smokeless tobacco causes severe health effects. While data are not available on age-specific differences in the probability of survival for smokeless tobacco users as compared to nonusers, the 1994 Surgeon General Report indicates that the ''primary health consequences during adolescence include leukoplakia, gum recession, nicotine addiction, and increased risk of becoming a cigarette smoker. Leukoplakia and/or gum recession occur in 40 to 60 percent of smokeless tobacco users.''[303] Oral leukoplakias have a 5-percent chance of becoming malignancies in 5 years.[304] Cancers of the nasal cavity, pharynx, larynx, esophagus, stomach, urinary tract and pancreas have also been linked to smokeless tobacco use.[305] Other effects include discoloration of teeth, periodontal disease and excessive tooth wear and decay.[306] One study of female snuff users showed that it increased one's risk of developing oral and

[298] Schelling, T. C., ''Economics and Cigarettes,'' *Preventive Medicine*, vol. 15, pp. 549–560, 1986.

[299] Fisher, A., L. G. Chestnut, and D. M. Violette, ''The Value of Reducing Risks of Death: A Note on New Evidence,'' *Journal of Policy Analysis and Management*, vol. 8, No. 1, pp. 88–100, 1989.

[300] Viscusi, W. K., ''Fatal Tradeoffs: Public and Private Responsibilities for Risk,'' Oxford University Press, p. 24, 1992.

[301] Harris, M., ''The Loss That is Forever The Lifelong Impact of the Early Death of a Mother or Father,'' Penguin Books, 1995.

[302] Miller, A. L., ''The U.S. Smoking-Material Fire Problem Through 1992: The Role of Lighted Tobacco Products in Fire,'' National Fire Protection Association, p. 2, 1994.

[303] 1994 SGR, p.39.

[304] *Id*.

[305] Goolsby, M. J., ''Smokeless Tobacco: The Health Consequences of Snuff and Chewing Tobacco'', *Nurse Practitioner*, vol. 17, No. 1, p. 31, January 1992.

[306] *Id*.

pharyngeal cancer between 1.5 to 4.2 times. [307]

If the provisions pertaining to smokeless tobacco are as effective as those pertaining to cigarettes, the rule will prevent about 36,500 youths from becoming adult users of smokeless tobacco. This projection assumes that the number of underage users will decrease by 50 percent and one-half of those youths will remain nonusers after reaching 18 years of age. The estimate also assumes that the ratio of new underage users to total underage users parallels that of cigarette users (i.e., approximately one-third) and that about 440,000 youths under the age of 18 are current users of smokeless tobacco products. [308]

Leukoplakia and/or gum recession are estimated to occur in 40 to 60 percent of smokeless users. [309] If even 50 percent of these cases were caused by smokeless tobacco use, the previous assumptions imply that these regulations will prevent from 7,300 to 11,000 cases of leukoplakia and/or gum recessions per year. Although FDA can not estimate the number of oral or other cancers prevented, the realized number will be substantial.

13. Summary of Benefits

The discussion above demonstrates the formidable magnitude of the economic benefits available from smoking reduction efforts. As described, FDA forecasts annual net medical cost savings of $2.6 billion and annual morbidity-related productivity savings of $900 million. From a willingness-to-pay perspective, the annual benefits of reduced smoking-related disease mortality range from $24.6 to $39.7 billion. As a result, the value of the annual disease-related benefits of achieving the ''Healthy People 2000'' goal is projected to range from $28.1 to $43.2 billion. (Following Hodgson, this analysis uses a 3-percent discount rate. A 7-percent rate reduces these benefits to a range of $9.2 to $10.4 billion). These totals do not include the benefits expected from fewer fires (over $160 million annually), reduced passive smoking, or infant death and morbidity associated with mothers' smoking. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates still yield impressive results. Table 1c of this section summarizes the disease-related health benefits and illustrates that youth deterrence rates as small as 1/20, which would prevent the adult addiction of at least 25,000 of each year's cohort of 1,000,000 new adolescent smokers, would provide annual benefit values measured in the billions of dollars. Moreover, the higher risk estimates suggested by Peto, et al., could significantly increase these values. In addition, while FDA could not quantify the benefits that will result from the projected decline in the use of smokeless tobacco, they would be considerable.

D. Regulatory Costs

A recently issued guideline for conducting economic analysis of Federal regulations, prepared under the auspices of OMB, states that:

[T]he preferred measure of cost is the ''opportunity cost'' of the resources used or the benefits foregone as a result of the regulatory action. Opportunity costs include, but are not limited to, private-sector compliance costs and government administrative costs. Opportunity costs also include losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time * * *. An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth. While transfers should not be included in the [Economic Analyses'] estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation. [310]

Accordingly, FDA finds that the final rule will impose new cost burdens on manufacturers, retailers, consumers, and Government regulators of tobacco products. In addition, certain industry sectors will experience lost sales and employment, but these revenue losses will be at least partly offset by gains to other sectors, as discussed in the ''Distributional Effects'' section of this document. [311] While a number of industry comments argued that the agency's preliminary analysis was deficient for not including these lost revenues in its cost-benefit assessment, FDA finds that the revenue losses suggested by these comments do not meet the previous definition of ''opportunity cost;'' because they fail to provide the changes in net costs that are necessary to estimate producer surplus, conventionally defined as sales minus variable costs. This rule will affect producer surplus in several industries and only net changes in these surplus' are social costs. Calculating such changes would require a multi-market model of economic changes over many years. Such general equilibrium models have not been used by Federal agencies for regulatory analyses, are not specifically recommended by the OMB guidance, and would be impractical to use, especially where major markets are dominated by few firms.

The most comprehensive critique of FDA's preliminary economic analysis was prepared by the Barents Group, economic consultants to the Tobacco Institute. While the Barents Group developed independent estimates of economic costs, in many instances its methodology was consistent with FDA's analysis of its 1995 proposal. Often, however, the Barents Group had access to more recent data, or to additional data provided by the affected industries. FDA's revised cost estimates rely extensively on these new data, but as described below, the agency's final cost estimates are far smaller than those presented by the Barents Group.

1. Number of Affected Retail Establishments

A critical variable underlying the agency's cost estimates is the number of retail outlets currently selling over-the-counter (OTC) tobacco products. A major confounding factor is that the U.S. Census publishes product line data only for establishments with payroll. For its original estimate of the number of retail establishments selling tobacco products, FDA relied on 1987 Census data to count the number of affected payroll establishments and very conservatively included every nonpayroll establishment in those categories that traditionally sell tobacco products (general merchandise stores, grocery stores, service stations, eating and drinking places, drug stores, and liquor stores). FDA estimated that the number of establishments selling tobacco products OTC included 275,000 payroll establishments and 215,000 nonpayroll establishments, for a total of 490,000 retail establishments. To account for all other business categories that might sell

[307] Winn, D. M., W. J. Blot, C. M. Shy, L. W. Pickle, A. Toledo, and J. F. Fraumeni, ''Snuff Dipping and Oral Cancer Among Women in the Southern United States,'' *The New England Journal of Medicine*, vol. 304, No. 13, pp. 745–749, Table 2, March 26, 1981.

[308] Estimates of youth smokeless usage vary. This projection relies on a conservative estimate of total youth (ages 12–17) usage calculated from data in the Statistical Abstract of the U.S. 1995, 115th edition, Tables 16 and 218.

[309] 1994 SGR, p.39.

[310] Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996. Prepared by interagency group convened by OMB and co-chaired by a Member of the Council of Economic Advisers.

[311] This analysis evaluates the regulation following the Kaldor-Hicks criteria for societal welfare maximization.

OTC tobacco products, FDA estimated a total upper bound range of 600,000 establishments. FDA did not know how many locations currently served by cigarette vending machines would convert to OTC operations following implementation of the regulation, but estimated the number at 100,000, raising the upper bound total to 700,000 future establishments.

FDA still has no definitive estimate of the number of retail outlets selling tobacco products. For their economic analysis, the Barents Group used 1992 U.S. Census estimates for the number of affected retail establishments with payroll, but adopted an alternative methodology to estimate the number of affected establishments without payroll. The Barents Group subdivided retail businesses into 10 categories: General merchandise stores, supermarket/grocery stores, convenience stores without gas, convenience stores with gas, gasoline service stations, eating places, drinking places, drug and proprietary stores, specialty tobacco stores, and miscellaneous retail stores. Within each category, the Barents Group assumed that the percentage of nonpayroll establishments selling tobacco products would be the same as the percentage of payroll establishments selling tobacco products. As a result, they concluded that the number of retail payroll establishments selling tobacco products OTC is approximately 283,000, and the number of retail nonpayroll establishments selling tobacco products OTC is about 107,000, for a total of 390,000 retail outlets. The Barents Group's subsequent calculations are less clear and not documented in their appendix on methodology. Noting that FDA had estimated an upper bound of 600,000 establishments selling OTC tobacco products, they assumed the existence of an additional 100,000 to 200,000 nonretail establishments, such as operations within manufacturing or service businesses, that sell OTC tobacco products. Finally, the Barents Group accepted FDA's estimate that about 100,000 current vending machine locations would convert to OTC sales for tobacco products and proposed total lower and upper bound estimates of from 500,000 to 700,000 establishments.

For this final economic analysis, FDA adopts the apparent mid-point of the Barents Group's forecast of the number of establishments that will sell tobacco products, or about 500,000 current establishments and a total of 600,000 future establishments. FDA estimates by business category are displayed in Table 4 and follow closely the methodology presented by the Barents Group, except for slight adjustments to eliminate nonstore outlets. Because Census data on the number of establishments without payroll were not reported separately for convenience stores, convenience stores with gas, or specialty tobacco stores, these outlets are counted with the higher level outlet categories.

2. Removing Self-Service and Other Prohibited Retail Displays

The 1995 proposed regulation restricted all point of purchase advertising to ''text only'' and banned the use of all self-service displays by requiring vendors to physically provide the regulated tobacco product to purchasers. In its original analysis, FDA explained that the proposed ban on self-service displays would affect many retail stores selling tobacco products, although shoplifting concerns had already caused a large number of these stores to place tobacco products in areas not directly accessible to customers. Those retailers that discontinued self-service displays typically modified their stores by either: (1) Placing tobacco products behind or above store cashiers or in locked cases located within close reach of store cashiers, (2) placing tobacco products behind only one or two checkout lines, similar to the ''cash only'' or ''less than 10 items'' lines commonly found in supermarkets, (3) dispensing tobacco products from a controlled area of the store, where store employees also conduct other administrative or customer-service tasks, or (4) installing a signaling system, whereby assigned store clerks bring requested tobacco products to individual checkout stations. Each store's physical configuration dictates the most cost-effective approach, but at least one regional survey found that retail outlets readily complied with comparable local ordinances without architectural remodeling or substantial refitting of checkout counters or store aisles. [312]

[312] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

TABLE 4.—ESTIMATED NUMBER OF ESTABLISHMENTS CURRENTLY SELLING TOBACCO PRODUCTS OVER-THE-COUNTER

Kind of Business	Number of Retail Establishments with Payroll	Percentage of Retail Establishments with Payroll Selling Tobacco Products	Number of Retail Establishments with Payroll Selling Tobacco Products	Total Number of Retail Establishments without Payroll	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products[j]	Estimated Total of Establishments Selling Tobacco Products Over-the-Counter[k]
	(1)	(2)	(3)	(4)	(5)	(6)
Retail Establishments:						
General Merchandise	34,606	35.01%	12,117	28,010 [f]	9,807	21,924
Supermarket/Grocery	126,785[a]	56.19%	71,240	97,061[g]	54,538	125,778
Convenience Stores	30,748	95.62%	29,400	– [h]	–	29,400
Convenience Stores with Gas	57,033[b]	91.02%	51,913	– [h]	–	51,913
Service Stations	71,336[c]	53.21%	37,958	14,248	7,581	45,539
Eating Places	377,760[d]	3.17%	11,992	96,538	3,065	15,057
Drinking Places	55,848	19.24%	10,745	27,733	5,336	16,081
Drug Stores	48,142	60.33%	29,046	3,031	1,829	30,875
Tobacco Stores	1,477	100.00%	1,477	– [h]	–	1,477
Miscellaneous Retail Stores	273,256[e]	9.15%	24,995	490,633[i]	44,879	69,874
Other Establishments	–	–	–	–	–	100,000
Total	1,076,991		280,883	757,254	127,035	507,918

(a) Category contains food stores (SIC 54) with payroll, excluding convenience food stores (SIC 541 pt) and convenience food/gasoline stores (SIC 541 pt).
(b) Category contains convenience food/gasoline stores (SIC 541 pt) and gasoline/convenience food stores (SIC 554 pt).
(c) Category excludes gasoline/convenience food stores (SIC 554 pt).
(d) Category contains eating and drinking places (SIC 58), excluding drinking places (SIC 5813).
(e) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596) and tobacco stores and stands (SIC 5993).
(f) 1992 Nonemployer Statistics Series only provides data on variety and miscellaneous general merchandise establishments without payroll.
(g) 1992 Nonemployer Statistics Series only provides data on grocery stores, retail bakeries, and other food stores without payroll.
(h) 1992 Nonemployer Statistics Series does not provide data on establishments without payroll for these categories.
(i) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596).
(j) Column (2) times Column (4).
(k) Column (3) plus Column (5).
Source: Columns (1)–(4) from U.S. Census of Retail Trade Merchandise Line Sales and Nonemployer Statistics Series; Columns (5) and (6) projections according to Barents Group LLC Appendix I methodology.

Because prevailing business practice is for tobacco manufacturers to assist and even pay for most product display equipment,[313] FDA had assumed that manufacturers would share with retailers any expense of relocating displays and that the majority of the costs would be to relocate self-service displays for cartons. FDA estimated one-time costs of $22 million to be shared by manufacturers and retailers and additional annual operating costs of $14 million to be incurred by retailers (all in 1994 dollars). In stark contrast, the Barents Group projected one-time costs of from $558 to $780 million in 1996 dollars ($520 to $728 million in current dollars), with 62 percent attributed to the replacement of display items by retailers and the remaining 38 percent to manufacturers due to ''time costs involved in removing banned display and promotional items, whether the work would be performed directly by a manufacturer's employee or subcontracted out to a display distributor.'' As explained below, FDA finds that many aspects of the Barents Group's estimates are seriously flawed. Nevertheless, the agency has adopted the basic framework of that analysis and its revised estimates reflect the Barents Group's methodology and data, unless specifically modified as discussed below.

a. *The Barents Group's methodology*. The Barents Group's cost projections were based on estimates of an average outlet cost for each of seven outlet categories. Each average outlet cost was multiplied by the total number of outlets of that category in the United States to produce national cost estimates. The actual outlet cost data were collected by A. T. Kearney, Inc., still another business consulting firm. The Barents Group explained that:

> [O]ur estimates are based on a compliance audit study conducted especially for this purpose by A. T. Kearney, Inc. A. T. Kearney performed an in-depth study of the actions and efforts that would be required of tobacco manufacturers' representatives, of point-of-sale display item distributors, and of tobacco retailers in order to bring stores into compliance with the proposed regulations. Detailed surveys were conducted of seven categories of retail outlets in five U.S. metropolitan areas, for a total of 88 retail outlets. Surveyors performed a detailed inventory of the many types of tobacco product displays and promotional materials which are currently found in stores. The surveyors noted which items would need to be modified or replaced.

A. T. Kearney reportedly completed a comprehensive on site compliance protocol checklist at 88 establishments randomly selected in 5 general regions of the United States. The individual display items were grouped into 41 discrete item categories and a lengthy discussion of the methodology and results are presented as a Technical Appendix to the Barents Group's comments.

b. *The Barents Groups's miscalculations*. To evaluate these results, FDA carefully reviewed the A. T. Kearney survey data and the Barents Group's extrapolation procedures and attempted to replicate the aggregate estimates. In doing so, numerous computational discrepancies were identified. For example, in calculating retailer time costs, the Barents Group intended to use an estimated retail employee wage of $9.51, but in fact used the estimated wage for a manufacturer's sales representative of $25.70. (See Appendix Table ''Initial Compliance Effort Costs per Retail Store.'') Also, the Barents Group's calculations relied on incorrectly transposed data for the average number of disposable displays per store and miscalculated compliance effort costs for five of the seven types of business. Further, A. T. Kearney reported that only one-third of the lighted signs and clocks would need to be replaced by retailers, but the Barents Group's calculations assumed that all would be replaced. Finally, A. T. Kearney reported that retailers would not replace most promotional posters, signs and displays, but the Barents Group's calculations assigned each $85 in replacement costs. Correcting these errors reduces the Barents Group's low and high cost estimates by $77 and $108 million, respectively.

Even more important, in aggregating the unit costs for ''Compliance Activity No. 19—Remove and replace interior newsstands and shopping basket racks and baskets and shopping carts,'' A. T. Kearney committed a major error that dominates the aggregated cost totals. In discussing the costs for this item, A. T. Kearney focused on the need to replace shopping basket racks, which ''* * * are free-standing units and contain about 20 shopping baskets, that also contain the name or logo of the cigarette manufacturer.'' Although it seems probable that the logos or brand names affixed to these items could be either removed or obscured, the survey data indicate that six supermarket/grocery stores, three convenience stores, two tobacco stores and one convenience store with gas would replace shopping basket racks. The detailed survey data for supermarket/grocery stores, however, reveal that one store supposedly possessed 71 racks, two stores 50 racks, and the remaining three stores 41, 32, and 10 racks, respectively. Even a casual review of these data suggests that individual hand-held shopping baskets rather than basket racks were counted. Indeed, an FDA contractor visited the five Washington, DC area outlets in which A. T. Kearney observed the largest number of racks and found scores of plastic hand-held baskets adorned with simple advertising stickers, but only a few basket racks.[314]

Although the advertising on these plastic baskets could easily be removed or covered, or new plastic baskets purchased quite inexpensively, the Barents Group's calculations inadvertently assumed that a distribution services contractor would be hired to remove each plastic hand-held shopping basket at a fee of $45 apiece and that a retailer would spend 30 minutes plus an additional $89 replacement fee for each plastic hand-held shopping basket in its possession. Thus, the estimated cost attributed to each hand-held basket was $138 and the cost for just the one outlet reporting 71 shopping baskets totaled $9,850. Extrapolating to each outlet category, the A. T. Kearney results implied that removing and replacing plastic hand-held baskets would cost, on average, over $1,300 for each supermarket/grocery store and $300 for each convenience store in the United States. Its projected costs for removing and replacing the hand-held shopping baskets in all supermarket/grocery stores in the United States ranged from $163 million to $229 million. For all outlet types, costs for these hand-held baskets were estimated at $194 to $271 million, or 43 percent of the national point-of-sale costs estimated by the Barents Group.

Based on site visits, FDA modified Kearney's field data for the correct number of shopping basket racks in the Washington, DC area establishments. Furthermore, FDA contractors determined that the hand-held shopping baskets could easily be modified by a marketing representative, who would take, at most, 5 minutes to affix new stickers on each basket or rack. For a rack of 20 baskets, this task was estimated to take a total of 105 minutes, plus about $42 for stickers. These adjustments reduce the Barents Group's estimated one-time costs by $180 to $252 million.

[313] *Id*.

[314] Buck, E., ''Site Visit Report,'' April 24, 1996.

c. *The Barents Group's extrapolation procedure*. The Barents Group contributed still another bias by their method of extrapolating these survey results to the assumed range of 500,000 to 700,000 retail establishments. A. T. Kearney surveyed stores in only seven business categories: General Merchandise, Supermarket/Grocery, Tobacco Specialty, Convenience Store without Gas, Convenience Store with Gas, Service Station, and Drug Store. To represent all affected outlets, the Barents Group apportioned the full upper and lower bounds for their estimated number of establishments (500,000 and 700,000) among 10 business categories ''based on the fractions they represent in the Census sample of with-payroll retail stores selling tobacco products.'' (Eating Places, Drinking Places, and Miscellaneous Retailers were added for this outlet allocation, but were assigned no costs because they are not ''* * * the types of retail outlets where the vast majority (more than 90 percent) of tobacco product sales occur and where promotional items are most prevalent.'' That is, the Barents Group used a proportional adjustment to raise each establishment category count so that the lower and upper bound totals sum to 500,000 and 700,000, respectively. The estimated number of establishments in each category was then multiplied by the average cost for each business category using data from the A. T. Kearney site visits.

The implications of these inappropriate establishment number extrapolations are considerable. For example, A. T. Kearney surveyed a sample of 10 outlets from its first business category—General Merchandise Stores. These 10 outlets, which include three K-Mart and two Wal-Mart stores, averaged over 84,000 square feet of space, with the smallest store measuring 40,000 square feet. The U.S. Census reports only 12,117 such establishments with payroll. The Barents Group's proportional adjustment automatically expanded this outlet type count to between 21,299 and 29,818. (See Barents Group's Appendix Table.) Thus, to generate a national estimate of costs, the Barents Group applied the cost per establishment for its sample of very large general merchandise stores to roughly double the number reported in the U.S. Census for such establishments with payroll. This methodology inappropriately bases the per outlet cost for thousands of small nonpayroll and nonretail outlets on the per outlet cost reported for very large general merchandise stores.

The identical problem holds for the Barents Group's projection of the A. T. Kearney survey sample of 27 Supermarket/Grocery stores. Although this sample includes a few moderately sized establishments (1 less than 1,000 square feet and 4 less than 5,000 square feet), 21 of the establishments exceed 10,000 square feet and the average sized facility is almost 35,000 square feet. Nevertheless, the Barents Group's apportionment procedure inflates the number of establishments in this category from the U.S. Census estimate of 71,240 with payroll to 125,222 and 175,311, on the dubious assumption that thousands of small nonpayroll or other nonretail establishments are best represented by the A. T. Kearney sample of mostly large supermarkets/grocery stores.

FDA's fundamental concern is not with the Barents Group's estimate of 500,000 to 700,000 affected establishments (although the upper bound of this estimate should be 600,000, because there would be no display relocation costs for the additional 100,000 outlets assumed to be established at existing vending machine locations), but with the allocation of the small establishments among the largest business categories surveyed by A. T. Kearney. To offset this bias, FDA reallocated the number of establishments in the business categories used to extrapolate the outlet cost estimates. As shown, in Table 5, FDA takes the number of establishments in the first two business categories—General Merchandise and Supermarket/Grocery stores—directly from the U.S. Census number of establishments with payroll, because there would be very few nonpayroll or nonretail establishments equivalent to those surveyed. For outlet extrapolation purposes, FDA assigns its estimated number of nonpayroll establishments in these two business categories to the Convenience Store category, on the assumption that this category is most representative of the small establishments excluded from the Census product line data. Although the Barents Group omitted all costs for Eating Places, Drinking Places, and Miscellaneous Retail Stores, FDA groups these outlets under Other Establishments and assumes certain minimal costs, as explained below. This redistribution of the establishment category groupings reduces the Barents Group's low cost estimate by $65 million and its high cost estimate by $170 million.

TABLE 5.—ESTIMATED NUMBER OF ESTABLISHMENTS REMOVING SELF-SERVICE AND OTHER PROHIBITED RETAIL DISPLAYS

Kind of Business	Number of Retail Establishments with Payroll Selling Tobacco Products Over-the-Counter	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products Over-the-Counter	Estimated Total Number of Establishments Selling Tobacco Products Over-the-Counter
A. T. Kearney Categories:			
General Merchandise	12,117	– (A)	12,117
Supermarket/Grocery	71,240	– (B)	71,240
Convenience Stores	29,400	64,345 (C)	93,745
Convenience Stores with Gas	51,913	– (D)	51,913
Service Stations	37,958	7,581	45,539
Drug Stores	29,046	1,829	30,875
Tobacco Stores	1,477	– (E)	1,477
Other Establishments	–	–	201,012 (F)
Total	233,151	73,755	507,918

(A) Variety and miscellaneous general merchandise stores are tallied as convenience stores.
(B) Food stores are tallied as convenience stores.

(C) This category includes food, variety, and miscellaneous general merchandise stores. The 1992 Nonemployer Statistics Series does not provide information about convenience stores without payroll.
(D) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(E) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(F) Includes retail establishments excluded from the Kearney field audit and other establishments selling tobacco products over-the-counter.

d. *Further modifications.* The Barents Group faulted FDA for not including costs for the removal of banned display items or for the replacement of banned point-of-sale promotional materials. Their estimates assumed that manufacturers alone would bear these costs, since the proposed regulation required that manufacturers remove all prohibited advertising displays. The final regulation, however, places this responsibility on the owners of the displays, which may frequently be the retail establishments. FDA cannot forecast the ultimate distribution of display ownership, but in view of current business practices, assumes that the manufacturer representatives will at least participate in the removal process. Nevertheless, this change in regulatory responsibility is likely to shift a greater share of the cost burden to retailers.

On the other hand, the Barents Group assumed that retailers alone would replace those promotional items having a utilitarian function, including display cases, signs, shopping carts or baskets, newspaper racks, ash trays, and clocks. FDA believes that this assumption is unfounded, because many retailers will modify rather than replace these items and many manufacturers will share the replacement burden with retailers. For example, one report describing the results of a local self-service ban indicated that, ''tobacco distributors and tobacco company sales representatives furnished behind-the-counter shelving and locking cases for tobacco products to retailers at no charge in order to assist retailers comply with self-service/vendor-assisted regulations.'' [315] Again, however, the future allocation of these costs among manufacturers and retailers is unknown. For its initial estimates, except as explained below, FDA maintains the Barents Group's assumptions that removal costs are primarily borne by the manufacturer and replacement costs by the retailer. In fact, both cost categories will be shared and the implications of these assumptions are illustrated below through sensitivity analysis.

In February 1996, economic consultants to FDA attempted to replicate the A. T. Kearney field audit in Boston (the Eastern Research Group, Inc. (ERG),) [316] and in Washington, DC (an independent contractor). While most observations of the number of affected display cases were reasonably consistent with the A. T. Kearney findings, the observed number of exterior and interior promotional materials deviated significantly from the A. T. Kearney audit data. One explanation may be that the seasonal items available at the end of November had been removed by the following February. As a result, FDA has not adjusted its calculations to account for these discrepancies (except for the cost of basket racks in the Washington, DC stores), but used certain insights from these visits to revise the Barents Group's unit cost assumptions, as follows:

(i) The agency rejects the Barents Group's assumption that retailers rather than manufacturers will bear the costs of replacing promotional unattached counter displays. Because many of these items will be moved to visible locations behind counters, it is far more likely that manufacturers, not retailers, would pay for replacements. For its revised estimate, therefore, FDA assumes that manufacturers will pay replacement costs for unattached counter displays. Although total costs are unchanged, this assumption increases the costs for manufacturers by $17 million and decreases the costs for retailers by an equal amount.

(ii) A. T. Kearney and the Barents Group contradict themselves on the cost of removing disposable display cases. A. T. Kearney describes these units as temporary displays ''frequently found in association with promotional offerings, sales, or seasonal themes,'' but assumes that retailers will replace them with permanent self-standing retail pack cases at $250 each. In contrast, the Barents Group calculations imply that a distribution services company will remove each display for a fee of $150 and retailers will replace each item for $50. FDA agrees with the Barents Group that retailers will not replace temporary units with permanent retail pack cases. Moreover, if a marketing representative can throw away free-standing ash trays filled with sand, as noted by A. T. Kearney, then a marketing representative can also dismantle and throw away disposable displays made of cardboard and plastic. FDA estimates, therefore, that instead of hiring a distribution services company, the manufacturer's representative will take no more than 15 minutes to remove each disposable unit, install a new unattached counter display and restock any excess inventory in a nonself-service area. This assumption decreases the estimated one-time costs by $7 million.

(iii) The A. T. Kearney cost-estimating methodology for the self-service ban implies that store modifications take place in a sequential pattern, with no allowances for economies of scale. For example, the outlet cost for hiring a distribution services contractor to relocate or replace display cases was calculated as a fixed multiple of the number of cases to be removed, even though many establishments must remove several display cases. This approach overstates costs by ignoring the significant scale economies achievable by performing all compliance activities at one time. Thus, FDA modified A. T. Kearney's distribution services costs for the removal, relocation and installation of small attached, retail pack, and carton self-service display cases by assuming that the first display unit in an outlet would be removed at a unit charge of $90, $150, or $185, respectively, but that each additional unit would be removed at one-half of these costs. For those stores with different sizes of display cases, the first unit was assumed to be the most expensive to remove (e.g., a carton display would be considered the first item when there is also a retail pack display or a small attached display). Adjusting for these scale economies reduces the estimated total costs by $15 million.

(iv) A. T. Kearney assumed that many promotional items, such as signs and clocks, would be removed by a distribution services company hired by the manufacturer. FDA's consultants, however, found that almost all of the promotional material observed could be easily removed or modified by retail personnel or marketing representatives.

[315] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

[316] ''ERG's Review of Docket Materials Concerning FDA's Proposed Regulations Covering Tobacco Products: Final Site Visit Report,'' Eastern Research Group, April 22, 1996.

For example, rather than needing a contractor to remove the lighted sign in one of the sampled outlets, ERG found that the front panel was easily removable and could be quickly replaced by an acceptable panel. Although a few signs may require substantial time to dismantle, most of these items will take just a few minutes to remove. To account for this range, FDA assumes that a manufacturer's representative will take 15 minutes to remove and dispose of the various exterior signs, banners, clocks and news stand displays, as well as the interior lighted signs and clocks, lowering total costs by $27 million.

(v) A. T. Kearney assumed that many display cases located in nonself-service areas would be removed and replaced, because of improper advertising. They assumed that the manufacturer would pay for the removal of the old case and the installation of the new case, but that the retailer would purchase the new display case. Contrary to this finding, FDA consultants found no sites in the Boston or Washington, DC regions where it was necessary to replace nonself-service displays. Because in each instance, all visible advertising could be altered or obscured, retailers would almost always opt to cover impermissible advertising rather than to purchase new display cases costing up to $300. Accordingly, FDA estimated that it would take 15 minutes and $5 worth of stickers to cover each small attached display; 25 minutes and $10 worth of stickers to cover each retail pack display; and 35 minutes and $15 worth of stickers to cover each carton display. This modification decreases total costs by $20 million.

(vi) Even though the A. T. Kearney audit identified a number of self-service display cases that did not fit in the nonself-service area but could be retrofitted with locks, the Barents Group did not include cost estimates for these items. FDA estimates that it would take 30 minutes of retailer time and cost about $10 for materials to add a lock to these display cases, increasing the total one-time costs by $1.5 million.

(vii) In its analysis of the 1995 proposed regulation, FDA acknowledged that the required reconfiguration of tobacco displays may also impose added labor costs for some purchase transactions, especially for those stores that move inventory to areas located away from employee work stations. On the assumption that the ban on self-service tobacco displays would require 10 seconds of additional labor time for 75 percent of all retail transactions involving cartons, FDA had estimated costs of about $14 million per year. Although a few comments indicated that the self-service ban would increase labor costs, the Barents Group did not include such costs in its assessment. Nevertheless, FDA believes that some establishments, particularly those selling a substantial number of cigarette cartons that could not be stored within easy reach of a checkout station, could experience increased annual labor costs. Thus, FDA recalculated its estimate based on the updated retail employee compensation rate of $9.51 suggested by the Barents Group and the new site visit data from the A. T. Kearney study, which imply that only about 40 percent of cigarette cartons are purchased at establishments that sell cigarette cartons from self-service areas. These adjustments project additional annual labor costs of about $10.9 million per year.[317]

Except for those adjustments, FDA used the information found in the A. T. Kearney field audit to develop its revised estimate. For comparison, the original Barents Group estimates of the number of establishments and one-time point-of-sale costs (corrected for miscalculations as described above) are shown in Table 6 and FDA estimates of one-time costs in Table 7. Detailed summaries of the FDA one-time cost estimates are presented in Table 8 and Table 9 and indicate that costs related to self-service display cases comprise 73 percent of the total, followed by 18 percent for promotional materials and 9 percent for nonself-service display cases. As explained above, these estimates assume that manufacturers will bear the cost of removing all promotional items and retailers will bear the cost of replacing most functional items. Because the regulation places the removal responsibility on owners of the materials, FDA does not know how these obligations will be divided. However, if retail outlets, rather than manufacturers, must remove these items, the overall cost to manufacturers falls by about $47 million and the cost to retailers increases by about $17 million. (Retail compensation rates are about one-third of manufacturer rates, according to the Barents Group data). The following discussion describes specific compliance costs for each outlet category.

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[317] Derived from assumption that 10 percent of carton transactions are for multiple (2) cartons, and that cartons constitute 85 percent of tobacco sales at supermarket/grocery stores, general merchandise stores, drug stores, and tobacco stores, and 10 percent of tobacco sales at other outlets. Tobacco sales data from 1992 Census of Retail Trade, pp. 3–31. Kearney site visits found that 80 percent of general merchandise stores, 33 percent of supermarket/grocery stores, 25 percent of convenience stores, 17 percent of service stations, 30 percent of drug stores, 42 percent of tobacco stores had self-service carton display cases.

TABLE 6.—BARENTS GROUP LLC ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS [1]

Kind of Business	Estimated Number of Establishments		Average Cost per Facility ($)	Estimated Point-of-Sale Costs (Lower)			Estimated Point-of-Sale Costs (Upper)		
	Lower	Upper		Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)	Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	21,299	29,818	1,067	13,268,172	9,449,404	22,717,576	18,575,066	13,228,900	31,803,966
Supermarket/Grocery	125,222	175,311	2,356	182,028,407	112,960,223	294,988,630	254,840,061	158,144,493	412,984,554
Convenience Stores	51,678	72,349	925	24,408,368	23,382,610	47,790,978	34,171,621	32,735,564	66,907,185
Convenience Stores with Gas	91,250	127,750	515	21,656,668	25,294,382	46,951,050	30,319,336	35,412,134	65,731,470
Service Stations	66,721	93,409	217	4,894,902	9,616,053	14,510,955	6,852,833	13,462,416	20,315,250
Drug Stores	51,056	71,478	167	4,472,540	4,054,323	8,526,863	6,261,520	5,676,020	11,937,541
Tobacco Stores	2,596	3,635	2,940	4,486,055	3,147,456	7,633,511	6,281,514	4,407,166	10,688,680
Total	409,822	573,750		255,215,112	187,904,451	443,119,563	357,301,952	263,066,694	620,368,645

[1] Totals may not add due to rounding.

TABLE 7.—FDA ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS

Kind of Business	Estimated Number of Establishments[1]	Average Cost Per Facility ($)	Estimated Point-of-Sale Costs[2]		
			Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	12,117	919	7,874,058	3,263,894	11,137,952
Supermarket/Grocery	71,240	810	32,655,560	25,067,316	57,722,876
Convenience Stores	93,745	364	12,271,061	21,879,370	34,150,431
Convenience Stores with Gas	51,913	213	1,397,066	9,644,359	11,041,425
Service Stations	45,539	122	2,560,164	2,974,000	5,534,164
Drug Stores	30,875	160	2,978,007	1,966,563	4,944,570
Tobacco Stores	1,477	2,175	2,165,591	1,046,163	3,211,753
Other Establishments	210,012	19	522,765	3,384,741	3,907,506
Total	507,918		62,424,273	69,226,404	131,650,677

[1] Number of establishments from Table 5.
[2] Totals may not add due to rounding.

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Promotional Materials:																
No. 3 Ext. Attached Signs	*	*	1.19	0	*	*	*	*	1.07	1	*	*	*	*	*	*
No. 4 Ext. Movable Sign Board	*	*	0.95	0	6.43	2	2.86	1	3.75	3	*	*	8.57	0	*	*
No. 5 Ext. Decal/Stickers	*	*	0.85	0	6.03	2	2.82	1	0.85	1	*	*	4.02	0	*	*
No. 6 Ext. Lighted Signs/Clocks	*	*	0.61	0	4.09	1	9.08	4	1.36	1	*	*	16.34	1	*	*
No. 7 Ext. Signs, Posters & Displays	*	*	0.38	0	1.93	1	1.33	1	*	*	*	*	1.43	0	*	*
No. 8 Ext. Movable Window Signs	*	*	0.95	0	10.44	3	2.14	1	1.61	1	*	*	.54	0	*	*
No. 9 Ext. Open/Closed Signs	*	*	0.43	0	2.20	1	*	*	*	*	0.59	0	0.98	0	0.59	3
No. 10 Ext. Signs on Gas Pumps	*	*	*	*	*	*	0.24	0	0.14	0	*	*	*	*	*	*
No. 11 Ext. News Stand Displays	*	*	7.42	1	*	*	*	*	*	*	*	*	*	*	*	*
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	*	*	0.80	0	3.57	2	1.07	1	*	*	0.54	0	*	*
No. 14 Signs, Posters & Banners	0.34	0	1.14	0	1.71	0	1.71	1	1.71	1	0.17	0	2.14	0	0.17	1
No. 15 Lgted. Signs, Clocks/Mach. Dev.	19.61	2	10.29	1	18.39	5	16.34	8	8.17	7	3.27	2	28.60	1	3.27	17
No. 16 Decals/Stickers	0.26	0	0.79	0	2.36	1	0.67	0	0.71	1	1.29	1	0.93	0	1.29	7
No. 17 Shelf Marker w/Adv.	0.60	0	0.44	0	2.14	1	1.49	1	1.83	2	0.37	0	0.96	0	0.37	2
No. 18 Shopper Aids	0.04	0	0.42	0	0.19	0	0.31	0	0.02	0	0.04	0	0.21	0	0.04	0
No. 19 News Racks, Shop. Bask., Carts	*	*	83.75	10	43.49	12	9.66	5	*	*	*	*	14.50	1	*	*
No. 20 Fl. St. Ash Trays, Waste Basket	*	*	3.30	0	*	*	9.89	5	*	*	*	*	24.71	1	*	*
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	*	*	0.48	0	0.71	0	1.18	1	*	*	1.93	0	*	*
Promotional Materials Subtotal:	20.85	2	112.92	14	100.67	28	62.82	30	23.47	19	5.73	4	106.39	5	5.73	29
Self-Service Display Cases:																
Small, Unattached																
No. 22 Space Available, Ads Removed	*	*	0.32	0	1.34	0	2.38	1	0.71	1	1.07	1	3.21	0	1.07	6
No. 23 Unit Must be Replaced	10.60	1	25.52	3	53.00	15	53.00	25	8.83	7	*	*	141.33	6	*	*
Small, Attached												*				
Removal and Installation/Relocation	13.50	1	65.00	8	*	*	10.00	5	*	*	9.00	6	*	*	9.00	46
No. 24 Unit Must be Replaced	10.00	1	55.56	7	*	*	*	*	*	*	*	*	*	*	*	*
No. 25 Space Available, Ads Removable	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Packs																
Removal and Installation	67.50	7	86.11	11	*	*	*	*	6.25	5	7.50	5	193.75	9		
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	0.79	0	0.29	0	*	*	0.88	0	*	*	*	*	0.66	0	*	*
No. 28 Unit Must Be Replaced	200.00	22	222.22	27	*	*	*	*	20.83	17	25.00	16	625.00	29	*	*
No. 29 Unit Modified w/Locking Doors	1.48	0	3.28	0	*	*	*	*	*	*	*	*	*	*	*	*

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Cartons																
Removal and Installation																
No. 40 Space Available, No Ads	166.50	18	65.09	8	46.25	13	*	*	15.42	13	37.00	23	262.08	12		
	*	*	0.26	0	*	*	*	*	*	*	*	*	*	*	*	*
No. 42 Unit Must Be Replaced	*	*	*	*	1.19	0	*	*	*	*	*	*	1.59	0	*	*
No. 43 Unit Modified w/Locking Doors	390.00	42	155.56	19	112.50	31	*	*	25.00	21	60.00	37	775.00	36	*	*
No. 44 Disposable, Replaced	35.41	4	3.83	0	*	*	*	*	3.69	3	8.85	6	11.07	1	*	*
Self-Service Subtotal:	*	*	2.09	0	*	*	*	*	4.70	4	*	*	37.62	2	*	*
	895.78	97	685.12	85	214.28	59	66.26	31	85.44	70	148.42	93	2,051.30	94	10.07	52
Non Self-Service Display Cases:																
Small, Unattached																
No. 45 Advertising Removable																
No. 46 Unit Must be Replaced	*	*	0.16	0	2.41	1	6.43	3	3.75	3	2.14	1	0.89	0	2.14	11
Small, Attached	*	*	*	*	26.50	7	47.11	22	*	*	*	*	13.25	1	*	*
No. 47 Advertising Removable																
No. 48 Unit Must be Replaced	*	*	1.27	0	3.75	1	4.52	2	2.86	2	1.50	1	2.14	0	1.50	8
Packs	*	*	*	*	8.57	2	*	*	0.95	1	*	*	*	*	*	*
No. 49 Advertising Removable																
No. 50 Unit Must be Replaced	*	*	0.40	0	1.07	0	0.48	0	0.36	0	1.71	1	0.18	0	*	*
Cartons	*	*	2.30	0	*	*	*	*	*	*	*	*	*	*	*	*
No. 51 Advertising Removable																
No. 52 Unit Must be Replaced	2.57	0	1.43	0	*	*	*	*	*	*	0.64	0	0.36	0	*	*
No. 53 Disposable, Replaced	*	*	6.66	1	*	*	*	*	*	*	*	*	*	*	*	*
Non-Self-Service Subtotal:	*	*	*	*	7.05	2	25.08	12	4.70	4	*	*	*	*	*	*
	2.57	0	12.22	2	49.35	14	83.61	39	12.61	10	6.00	4	16.82	1	3.64	19
TOTAL:	919.20	100	810.26	100	364.29	100	212.69	100	121.53	100	160.15	100	2,174.51	100	19.44	100

[1] Totals may not add due to rounding.

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Promotional Materials:										
No. 3 Ext. Attached Signs	*	85	*	*	49	*	*	*	134	0.1
No. 4 Ext. Movable Sign Board	*	68	602	148	171	*	13	*	1,002	0.8
No. 5 Ext. Decal/Stickers	*	60	565	146	39	*	6	*	816	0.6
No. 6 Ext. Lighted Signs/Clocks	*	43	383	471	62	*	24	*	984	0.7
No. 7 Ext. Signs, Posters & Displays	*	27	181	69	*	*	2	*	279	0.2
No. 8 Ext. Movable Window Signs	*	68	979	111	73	*	1	*	1,232	0.9
No. 9 Ext. Open/Closed Signs	*	31	206	*	*	18	1	118	375	0.3
No. 10 Ext. Signs on Gas Pumps	*	*	*	12	7	*	*	*	19	0
No. 11 Ext. News Stand Displays	*	529	*	*	*	*	*	*	529	0.4
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	75	185	49	*	1	*	310	0.2
No. 14 Signs, Posters & Banners	4	81	161	89	78	5	3	34	456	0.3
No. 15 Lgted. Signs, Clocks/Mach. Dev.	238	733	1,724	848	372	101	42	657	4,715	3.6
No. 16 Decals/Stickers	3	57	221	35	33	40	1	258	647	0.5
No. 17 Shelf Marker w/Adv.	7	31	201	77	83	12	1	75	488	0.4
No. 18 Shopper Aids	1	30	18	16	1	1	0	9	75	0.1
No. 19 News Racks, Shop. Bask., Carts	*	5,967	4,077	502	*	*	21	*	10,566	8
No. 20 Fl. St. Ash Trays, Waste Basket	*	235	*	513	*	*	37	*	784	0.6
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	45	37	54	*	3	*	139	0.1
Promotional Materials Subtotal:	253	8,044	9,437	3,261	1,069	177	157	1,151	23,549	17.9
Self Service Display Cases:										
Small, Unattached										
No. 22 Space Available, Ads Removed	*	23	125	124	33	33	5	215	557	0.4
No. 23 Unit Must be Replaced	128	1,818	4,968	2,751	402	*	209	*	10,277	7.8
Small, Attached										
Removal and Installation/Relocation	164	4,631	*	519	*	278	*	1,809	7,400	5.6
No. 24 Unit Must be Replaced	121	3,958	*	*	*	*	*	*	4,079	3.1
No. 25 Space Available, Ads Removable	*	*	*	*	*	*	*	*	*	*
Packs										
Removal and Installation	818	6,135	*	*	285	232	286	*	7,755	5.9
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	10	21	*	46	*	*	1	*	77	0.1
No. 28 Unit Must Be Replaced	2,423	15,831	*	*	949	772	923	*	20,898	15.9
No. 29 Unit Modified w/Locking Doors	18	234	*	*	*	*	*	*	251	0.2
Cartons										
Removal and Installation	2,017	4,637	4,336	*	702	1,142	387	*	13,222	10
No. 30 Space Available, No Ads	*	19	*	*	*	*	*	*	19	0
No. 31 Space Available, Ads Removable	*	*	111	*	*	*	2	*	114	0.1
No. 32 Unit Must Be Replaced	4,726	11,082	10,546	*	1,138	1,853	1,145	*	30,489	23.2
No. 33 Unit Modified w/Locking Doors	429	273	*	*	168	273	16	*	1,159	0.9
No. 34 Disposable, Replaced	*	149	*	*	214	*	56	*	419	0.3

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Self-Service Subtotal:	10,854	48,808	20,087	3,440	3,891	4,583	3,030	2,024	96,717	73.5
Non-Self-Service Display Cases:										
Small, Unattached										
No. 35 Advertising Removable	*	11	226	334	171	66	1	431	1,239	0.9
No. 36 Unit Must be Replaced	*	*	2,484	2,446	*	*	20	*	4,949	3.8
Small, Attached										
No. 37 Advertising Removable	*	90	351	235	130	46	3	301	1,157	0.9
No. 38 Unit Must be Replaced	*	*	803	*	43	*	*	*	847	0.6
Packs										
No. 39 Advertising Removable	*	28	100	25	16	53	0	*	223	0.2
No. 40 Unit Must be Replaced	*	164	*	*	*	*	*	*	164	0.1
Cartons										
No. 41 Advertising Removable	31	102	*	*	*	20	1	*	153	0.1
No. 42 Unit Must be Replaced	*	475	*	*	*	*	*	*	475	0.4
No. 43 Disposable, Replaced	*	*	661	1,302	214	*	*	*	2,177	1.7
Non-Self-Service Subtotal:	31	870	4,626	4,340	574	185	25	732	11,385	8.6
TOTAL:	11,138	57,723	34,150	11,041	5,534	4,945	3,212	3,908	131,651	100

[1] Totals may not add due to rounding.

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e. *General merchandise stores*. None of the general merchandise stores in the A. T. Kearney sample had exterior promotional materials and only a few had interior promotional materials. Eighty percent of the stores had only self-service displays, with carton displays more numerous than pack displays at these locations. The average per facility one-time costs estimated by FDA were $919. Overall, 97 percent of the outlet costs related to the replacement of self-service display cases, although in some general merchandise stores, tobacco products were stocked on shelves rather than in special display cases, which suggests that the costs for this business category may be overstated.

f. *Supermarket/grocery*. Unlike general merchandise stores, supermarkets had significant promotional materials. While both packs and cartons were sold at most locations, over 75 percent of the stores already had nonself-service display areas. FDA estimates per facility costs at $810. Self-service display case removal and replacement amount to 85 percent of the total cost, whereas promotional materials account for 14 percent. Commenting on the feasibility of the proposed FDA self-service ban, the Food Marketing Institute argued that most retail food stores do not have adequate space at checkout lines for tobacco products and rejected the practicability of alternative procedures. They suggested that the only option available to many food retailers would be to remodel and set-up a controlled area for the sale of tobacco products, costing up to $50,000 per store. The A. T. Kearney audit, however, found that a majority of supermarket/grocery stores have already installed nonself-service areas for tobacco products and would not need to reconfigure their stores. While some establishments will incur costs above the average, the A. T. Kearney site visit data suggest that most stores could comply by either moving inventory to nonself-service areas or by purchasing new displays that are compatible with existing store configurations.

g. *Convenience stores*. Stores in this category exhibited numerous interior and exterior promotional items. All of the convenience stores surveyed had nonself-service display cases and 50 percent had carton displays. FDA estimates per facility costs of $364. Costs for removing and replacing self-service display cases made up 59 percent of the total, while costs for promotional materials and nonself-service display cases were 28 percent and 14 percent, respectively.

The National Association of Convenience Stores (NACS) faulted FDA on its assumption that the main cost of the self-service ban would be to relocate tobacco product inventory, contending that their members would incur thousands of dollars in reconfiguration costs. According to NACS:

> [i]t is largely irrelevant that retailers already keep packs behind the counter. Many NACS members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales.

Based on an estimate from one member with a high volume of self-service cigarette sales, NACS suggested it could cost $4,320 and $10,120, respectively, to reconfigure a newer and older convenience store.

Based on other evidence, however, FDA does not believe that a large number of stores will be forced to undergo extensive modifications and finds that most convenience stores can adequately adapt space either behind or above checkout counters. As noted earlier, one regional survey reported that retail outlets readily complied with local self-service restrictions without architectural remodeling or substantial refitting of checkout counters or store aisles.[318] Space above counters is typically available for display cases either by suspending a case from the ceiling or by supporting a case on beams from the counter. In its survey, A. T. Kearney found at least some tobacco products sold from nonself-service space in every convenience store. Although it is possible that stores might incur added inventory handling costs if this space were smaller than optimal, FDA concludes that major reconfiguration would rarely be required and relies on the A. T. Kearney survey data, as adjusted, to project average costs for this sector.

h. *Convenience stores with gas*. Like convenience stores without gas, these establishments had numerous interior and exterior promotional materials. About 89 percent of the stores surveyed had nonself-service display cases. FDA estimates per facility costs of $213. Consistent with the findings of the Barents Group, the average outlet cost for this sector is about one-half that of convenience stores without gas.

In comments to the 1995 proposed rule, the Society of Independent Gasoline Marketers of America (SIGMA) did not present specific data on the cost to their members, but indicated that many members would be required to reconfigure their stores. They stated that:

> [m]any SIGMA members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. At a minimum, these members would have to install new cabinets to accommodate tobacco products behind the counter. Many members would have to enlarge the counter area to make room for the new cabinets.

In contrast, the A. T. Kearney field audit found few convenience stores with gas that have self-service displays, other than unattached promotional counter displays. Costs to remove or replace promotional counter displays will be borne primarily by manufacturers, not retailers. In sum, the costs for self-service display cases amount to about 31 percent of the total, promotional material 30 percent, and nonself-service display cases 39 percent.

i. *Service stations*. These establishments had both interior and exterior promotional material. Seventy-five percent of the locations surveyed had only nonself-service display cases and one-fourth had carton displays. FDA estimates the per facility cost at $122.

j. *Drug stores*. Drug store outlets had few exterior and interior promotional materials. As in general merchandise stores, tobacco products were stocked on shelves in some locations. Ninety percent of the stores surveyed by A. T. Kearney already had nonself-service displays and approximately 70 percent had carton displays. FDA estimated $160 cost per facility for this category of business. About 93 percent of the total one-time costs are for replacement of self-service display cases.

k. *Tobacco stores*. These stores had substantial promotional materials and multiple display cases. FDA estimates per facility costs of $2,175. About 94 percent of the costs are for self-service display cases, with promotional materials and nonself-service display cases dividing the remaining 6 percent. While not reflected in the cost totals, these establishments may choose to operate as ''adult only'' restricted areas to avoid replacing self-service display cases.

l. *Other establishments*. This category includes eating/drinking establishments and miscellaneous retail stores, which

[318] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

were excluded from the A. T. Kearney audit, plus the estimated 100,000 nonretail establishments that sell tobacco products OTC, such as hotels, factories and sporting facilities. Due to the low volume of tobacco product sales at these establishments, FDA assumed that only a small quantity of packs and no cartons would be sold. Lacking detailed data, FDA assigned costs of $19 per outlet, based on the costs of removing promotional materials and relocating and replacing small attached display cases, as reported for drug stores.

3. Label Changes

The final regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA estimated the compliance costs for printing new labels in its earlier analysis of the proposed regulation and has received no comments that improve those original estimates.

Approximately 933 varieties of cigarettes are currently produced in the United States.[319] FDA does not have information on the number of smokeless tobacco varieties, but assumes that the total number of cigarette and smokeless tobacco varieties is roughly 1,000. Because most varieties of cigarettes are packaged in both single packs and cartons, the total number of labels is assumed to number about 2,000.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach relied on information compiled by The Research Triangle Institute (RTI) for its report to FDA on the cost of changing food labels.[320] RTI reported a cost of about $700 for a 1-color change in a lithographic printing process. FDA multiplied this figure by 4 to account for a 2-color change on the actual warning labels and an additional 2 colors for modifications to the existing label to make room for the warning label. This calculation yielded incremental printing costs of about $2,800 per label, or $5.6 million for all 2,000 varieties of affected tobacco products. Adjusting this figure downward by RTI's methodology to account for the current frequency of label redesign predicts that the total one-time cost of completing these label changes within a 1-year compliance period would be approximately $4 million.

The second approach was to use cost information provided in the regulatory impact analysis of a roughly comparable Canadian regulation.[321] The Canadian Government estimated a cost of $30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are likewise sold in two sizes, but about 20 percent are also sold in flip top packages.[322] Canadian labels, however, are typically printed using a gravure method; which, according to RTI, is about 3.5 times as expensive as the lithography process used in the United States. Adjusting the Canadian estimate upward, to account for the larger number of cigarette and smokeless tobacco varieties in the United States; and downward, for the smaller number of packages per variety and the smaller cost of the lithography printing process, provides a $17 million estimate for the total cost of these label changes.

4. Educational Program

FDA may issue notification orders under section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360h(a)) to require manufacturers of cigarettes and smokeless tobacco products to fund consumer educational programs. While the precise details of these orders are still under development, these orders may involve the achievement of specific performance objectives by directing manufacturers to initiate informational programs designed to transmit messages that will reach the majority of young people. The 1995 proposed regulation directed manufacturers to spend at least $150 million annually on this program. While industry comments were critical, many other comments suggested that this figure was too low. One comment noted that $150 million is equivalent to about one week of pro-tobacco expenditures and another that the industry gained $221 million in profits from underage sales. Still another pointed out that the current dollar value of the informational advertising that was conducted under the Fairness Doctrine would amount to about $300 million per year. One study appears to indicate that 75 percent of adolescents aged 12 to 17 could have been reached in 1985 to 1986 with multiple messages at a cost of about $17 million a year.[323] FDA is still evaluating various types of informational programs, with respect to both effectiveness and practicality. Before a final decision is reached, the agency will determine the costs of selected alternatives.

5. Restricted Advertising and Promotional Activities

a. *Tobacco industry*. The determination of the societal costs attributable to the restrictions on tobacco product advertising and promotion is complex. While there is no doubt that individual manufacturers realize enhanced goodwill asset values from advertising programs, the industry has long held that advertising prompts brand-switching, but does not increase aggregate sales. Of course, if this were true, advertising would be unprofitable from the standpoint of the industry as a whole and reduced levels would increase rather than decrease aggregate industry profits. In addition, if the primary motivation for tobacco advertising is to promote brand-switching, then, as long as all firms are equally restricted from advertising, the above mentioned loss in goodwill value will be substantially reduced.

In its comments, the tobacco industry claimed that tobacco advertising and promotion have virtually no effect on youth consumption. Although FDA does not accept this claim, the agency does not consider the expected voluntary reduction in the consumption of tobacco products to be a societal cost. Although industry sales will fall, they will reflect new consumer preferences and consumer dollars no longer used on tobacco products will be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales are not net costs and the potential magnitude of this revenue transfer is discussed below under the heading of Distributional Effects. Moreover, as shown in that discussion, any short-term frictional or relocation impacts will be significantly moderated by the gradual phase-in of the economic effects.

b. *Advertising industries*. In its original analysis, FDA argued that advertising and promotional restrictions will impose no long term net costs on society. The Barents Group's study found that the various suppliers of

[319] "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes," Federal Trade Commission, 1994.

[320] French, M. T., D. M. Neighbors, L. K. Carswell, K. B. Heller, and G. L. McDougal, "Compliance Costs of Food Labeling Regulations," Final Report, RTI Project Number 233U–3972–02 DFR, January 1991.

[321] Department of National Health and Welfare, "Tobacco Products Control Regulations, amendment," *Canada Gazette*, Part II, vol. 127, No. 16, pp. 3277–3294, August 11, 1993.

[322] Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.

[323] Bauman, K. E., J. D. Brown, E. S. Bryan, L. A. Fisher, C. A. Padgett, and J. M. Sweeney, "Three Mass Media Campaigns to Prevent Adolescent Cigarette Smoking," *Preventive Medicine*, vol. 17, pp. 510–530, 1988.

industry advertising will incur substantial regulatory costs. It estimated that illustrative annual costs for this sector could reach $722 million to $2.17 billion, or up to one-half of its estimate of the total costs of the FDA proposal.

Upon review, FDA remains firmly convinced that its original position was correct. That is, from the standpoint of assessing societal costs and benefits, reduced revenues from tobacco advertising and promotional activities are not net costs and are appropriately considered a distributional impact. Indeed, FDA believes that a strong argument can be made that, even irrespective of health benefits, these advertising restrictions will decrease net societal costs by freeing productive resources for alternative uses. This does not imply that no individual business entities will be negatively impacted. Many of the companies that currently benefit from tobacco promotions (e.g., advertising agencies, publishers, sporting event promoters) will suffer lost revenues and those firms that specialize in those activities may lose a substantial part of their business. Nevertheless, from a societal perspective, these losses will be counterbalanced by an increase in demand for other consumption and investment goods, so that nontobacco-related entities will gain sales. Although overlooked in most industry comments, this result is acknowledged within the comments submitted for the Tobacco Institute by the Barents Group:

A key assumption in the simulations is that, when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

That report also reveals the underlying distributional nature of the impacts by explaining that its modeling incorporates the assumption that:

* * * in the long run economic losses in one sector of the economy will be redistributed to other sectors of the economy, i.e., winners and losers will generally balance out for the economy as a whole.

Further discussion of the impact of these revenue transfers is included below under the section on ''Distributional Effects.''

c. *Retail sector.* In addition to the previously estimated direct costs associated with the removal of prohibited point-of-purchase advertising, promotional restrictions will impact the retail sector because they will lead to a long-term decline in tobacco products sales and a potential fall in promotional allowances (slotting fees) from manufacturers. Once again, these impacts are not net societal costs, since reduced tobacco product sales will be counterbalanced by increased sales for other products or services; and smaller promotional allowances, if they occur, are gains to tobacco manufacturers that would be used for other purchases. Consequently, these impacts also are examined below under ''Distributional Effects.''

d. *Consumers.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. Firms engage in advertising to inform potential customers about their product (informative advertising) or to persuade customers that a product is desirable (persuasive advertising). According to the FTC's Bureau of Economics, the benefits of advertising derive from:

* * * its role in increasing the flow and reducing the cost of information to consumers * * * First, advertising provides information about product characteristics that enables consumers to make better choices among available goods * * * Second, theoretical arguments and empirical studies indicate that advertising increases new entry and price competition and hence reduces market power and prices in at least some industries * * *. Third, advertising facilitates the development of brand reputations. A reputation, in turn, gives a firm an incentive to provide products that are of consistently high quality, that live up to claims that are made for them, and that satisfy consumers. [324]

FDA has considered each of these issues. First, while agreeing that many forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that consumers will lose little utility from these particular advertising restrictions. The regulation does not prohibit factual, written advertising. Thus, the rule will not impede the dissemination of important information to most consumers. In its preliminary analysis, the agency concluded that, ''[w]hile imagery and promotional activities may be important determinants of consumer perceptions and sales, they typically provide little meaningful information on essential distinctions among competing tobacco products'' (60 FR 41314 at 41368).

One industry comment strongly opposed this position, arguing that advertising is important for product improvement and that past restrictions on the advertising of ''low tar'' products retarded product innovation. The crux of the argument is that color and/or imagery are prerequisites for disseminating relevant quality information and that, in its absence, consumers could not be adequately informed about the merits of new products. FDA, however, is not persuaded that manufacturers will be unable to convey vital information. The agency finds that true product improvements in this industry are rare, but where they exist, manufacturers could rely on traditional ads in adult-oriented publications and on ''text only'' advertising elsewhere. Moreover, FDA and other public health agencies would likely coordinate with companies in disseminating truly important consumer safety information.

The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, are less certain, as various empirical studies have reached conflicting conclusions. One industry comment insisted that FDA's regulation will deprive consumers of the benefits of competition, stating that, ''[u]ndoubtedly the clearest measure of consumer benefit is the effect of advertising on price.'' To support this view, the comment references several studies that demonstrate the ability of advertising to reduce product prices. The comment also contended that the ''[e]limination of advertising will predictably consolidate the market as marginal brands are abandoned and fewer brands are introduced'' and that, ''[o]ver time this can also reduce the number of players, as companies with dominant brands drive out others.''

FDA agrees that advertising can often lead to decreased product prices, but notes that the other industries referenced (e.g., eyeglasses and pharmaceuticals) are much more competitive than tobacco products. Moreover, economists have found that advertising can also serve as a barrier to entry in oligopolistic industries. One author, for example, determined that ready-to-eat breakfast foods companies used advertising programs to support brand proliferation strategies in order to dominate retail shelf space. [325] These programs helped to keep new firms out and prices high without necessarily

[324] Recommendations of the Staff of the Federal Trade Commission, ''Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices,'' Appendix A, pp. 3–4, March 1985.

[325] Sutton, J., ''Sunk Costs and Market Structure,'' The MIT Press, Cambridge, Massachusetts, pp. 229–247, 1991.

embodying improved quality. Thus, in certain circumstances, oligopolistic firms can use extensive advertising to create barriers for suppressing innovation and competition. FDA cannot determine whether tobacco advertising restrictions would ultimately increase or decrease product prices.

Finally, FTC's third point, which emphasizes the positive aspects of advertising in supporting brand reputations, is more relevant for long-lived items, such as consumer durables, where purchases are infrequent or personal experience is inadequate. Advertising is less likely to play a key role in assuring high quality levels for tobacco products, where consumer search costs are low and a brand's reputation for quality is tested by consumers every day. For these products, high quality will remain a prerequisite of commercial success irrespective of advertising strategies.

Other analysts suggest still other potential attributes of product advertising. For example, according to F. M. Scherer, author of a widely read text on industrial organization:

Advertising is art, and some of it is good art, with cultural or entertainment value in its own right. In addition, it can be argued that consumers derive pleasure from the image advertising imparts to products, above and beyond the satisfaction flowing in some organic sense from the physical attributes of the products. There is no simple case in logic for distinguishing between the utility people obtain from what they think they are getting and what they actually receive. As Galbraith observed, ''The New York housewife who was forced to do without Macy's advertising would have a sense of loss second only to that from doing without Macy's.'' [326]

Similarly, Becker and Murphy have argued that advertisements should be considered ''goods'' if people are willing to pay for them and as ''bads'' if people must be paid to accept them. [327] They explain that, in general, the more easily the advertisements can be ignored, the more likely it is that the ads themselves provide utility to consumers. Newspaper and magazine advertisements, for example, must provide positive consumer utility or they would be ignored by readers. This final rule allows such advertisements to continue, some in their current form, others in a text-only format. (In fact, industry outlays for newspaper and magazine advertisements have dropped sharply in recent years and currently constitute less than 5 percent of the industry's total advertising and promotion budget). [328] Conversely, the extraordinary growth in industry advertising and promotion has occurred in areas that are typically bundled with other products, or placed in prominent public settings that are difficult to ignore. Thus, there is considerable question about the contribution of these programs to consumer utility.

6. Training

a. *Retailers*. The final regulation does not explicitly require retail employees who sell tobacco products to be trained in checking customer I.D.'s. FDA understands, however, that some training is essential to effective performance. In its analysis of the proposed regulation, FDA estimated total annual costs of $10 million for employee training at retail outlets. This estimate assumed that an average of 12 employees per store at 467,000 retail stores (assuming 1/3 of 700,000 stores already conducted training) would receive 15 minutes of training at a compensation rate of $7.41/hour. The Barents Group commented that FDA's analysis did not account for many individual cost elements, resulting in a significant underestimate of total training costs. It estimated one-time training costs of $184 to $257 million and recurring annual training costs of $48 to $67 million.

Specifically, the Barents Group stated that FDA relied on outdated compensation data. FDA had obtained these data from a 1992 report prepared by Price Waterhouse for the Tobacco Institute, but agrees that more recent data are available and employs the suggested compensation rate of $9.51 for its revised estimate. The Barents Group also claimed that FDA failed to consider recurring training costs due to annual employee turnover and annual updating, focusing instead on one-time training costs only. This criticism is not valid. Table 2 of the original analysis (60 FR 41314 at 41360) clearly lists training costs for retail establishments as an annual operating cost and the text (60 FR 41314 at 41367) refers to a ''per year'' cost. Because employees would be trained when first hired, this estimate implied a 100 percent employee turnover rate.

To refine its analysis, however, FDA has disaggregated the cost elements. Although the Barents Group accepted FDA's preliminary estimate of 12 employees per retail store, FDA now believes that this figure is accurate only for retail stores with payroll. Stores without payroll constitute a significant percentage of the stores selling tobacco products and, on average, are much smaller. As explained above, FDA estimates that about 600,000 establishments will sell over-the-counter tobacco products, including the 100,000 that replace those vending machines that are removed. Table 10 presents the data that underlie FDA's revised estimates of the number of employees who will be trained. For existing retail establishments with payroll, FDA assumes that training will be needed for all employees in the affected outlets, except in General Merchandise and Supermarket/Grocery stores, where one-third of the employees will be trained. For establishments without payroll, nonretail establishments, and new establishments replacing vending machines, Census data on the number of employees is not available, but FDA assumes that an average of six employees will be trained. As shown in Table 10, these calculations indicate that training will be required for a total of 4.2 million workers.

The Barents Group further faulted FDA for underestimating the training time that would be required to educate retail sales clerks about recognizing proper forms of identification and handling related customer service problems. It assumed that 2 hours of training would be necessary. FDA, however, reviewed the time needed to present the training materials from several corporate entities and finds that they need not exceed one hour. For example, one large convenience store corporation uses a 45 minute training videotape that covers the sale of tobacco products, but also covers the sale of alcohol and possible inhalants, including means for recognizing inebriated or drugged individuals. Moreover, many establishments, especially small stores, will provide no formal training, but will provide instruction during the work day with minimal lost time. Thus, FDA believes that average costs are reasonably based on a 1-hour training program.

[326] Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2nd edition, Rand McNally College Publishing Co., Chicago, IL, p. 380, 1980.

[327] Becker, G. S., and K. M. Murphy, ''A Simple Theory of Advertising as a Good or Bad,'' *Quarterly Journal of Economics*, vol. 108, p. 941, November 1993.

[328] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, issued 1995.

TABLE 10.—NUMBER OF EMPLOYEES TO BE TRAINED

Kind of Business	Payroll Establishments				Nonpayroll Establishments		Total Employees Trained
	Establishments Selling Tobacco Products	Employees Per Store	Percent Trained	No. of Employees Trained	Establishments Selling Tobacco Products	No. of Employees Trained[1]	
General Merchandise	12,117	60.1	33%	242,593	9,807	58,842	301,435
Supermarket/Grocery	71,240	20.9	33%	497,253	54,538	327,228	824,481
Convenience Store/no gas	29,400	5.6	100%	164,718	---	---	164,718
Convience Store/gas	51,913	6.8	100%	353,868	---	---	353,868
Gas Station	37,958	6.0	100%	228,002	7,581	45,486	273,488
Eating Place	11,992	16.5	100%	198,212	3,065	18,390	216,602
Drinking Place	10,745	5.4	100%	58,498	5,336	32,016	90,514
Drug/Proprietary Store	29,046	12.2	100%	354,730	1,829	10,974	365,704
Specialty Tobacco	1,477	3.7	100%	5,530	---	---	5,530
Miscellaneous	24,995	5.2	100%	130,253	44,879	269,274	399,527
Retail Subtotal	**280,883**			**2,233,656**	**127,035**	**762,210**	**2,995,867**
Nonretail[2]							**600,000**
Converted Vending Machines[2]							**600,000**
Total							**4,195,867**

[1]Assumes 6 employees per establishment.
[2]Assumes 100,000 outlets with 6 employees to be trained.
Sources: Table 4 for description of establishment data; 1992 Census of Retail Trade, Subject Series: Establishment and Firm Size (Table 1) for employment data; FDA estimates for percent trained.

Adopting FDA's original estimate that about one-third of all affected establishments already provide employee training (also assumed by the Barents Group), implies one-time employee training costs of $26.6 million (4.2 million employees x 2/3 x $9.51). The Barents Group suggested, however, that even employees who currently receive training would need 5 extra minutes on the new regulations, which adds about $1.0 million to the cost estimate. Next, the Barents Group included costs for time spent by trainers, assuming that the training would be provided by an outside source. FDA believes that a more typical approach would have a store supervisor provide the training. Using $13.64 as the compensation rate for a retail manager, as suggested by the Barents Group, and adjusting for the assumed one-third current compliance rate in existing establishments, yields a one-time cost for trainer time of $6 million. Thus, FDA projects total one-time training costs of about $33.5 million.

In addition, FDA estimates that employee turnover, using the Barents Group suggested rate of 42 percent, will add annually recurring training costs of about $11.2 million. Also, new employees will receive I.D. check training as part of their initial orientation activities. Since stores may provide this to several new employees at once, using either written or video training materials, FDA estimates that retail managers, on average, would spend about 1 additional hour per year providing this training. This adds $6.0 million to the annual training costs. The Barents Group also recommended annual reinforcement training. An annual 10-minute reinforcement training period for employees of those establishments that do not already have a training program will cost about $2.9 million. In sum, these annual recurring training costs total about $20 million.

The Barents Group also assumed that retail managers would need extensive training to understand the new regulations. FDA estimated in its 1995 proposal that manufacturers' representatives would need about 8 hours of training on their new responsibilities and the Barents Group assumed that retail managers would need a similar duration of training. FDA rejects this estimate, however, as the final provisions affecting retailers are straight-forward and will be routinely communicated through traditional industry channels.

b. *Manufacturers representatives.* In its preliminary economic analysis, FDA estimated that 7,300 manufacturer representatives would be trained for 8 hours at a cost of $25.00 per hour. After noting FDA's ''undocumented'' cost estimate, the Barents Group proceeded to apply the identical number of training hours to their ''documented'' cost estimate of $25.70 per hour. They also suggested a 15 percent labor turnover premium, giving a total cost of $1.5 million. As the final rule eliminates the monitoring burden for these employees, this training cost should be correspondingly smaller. Nevertheless, these manufacturer employees will still need to determine the types of displays that remain permissible. FDA therefore accepts the $1.5 million cost estimate.

7. Access Restrictions

a. *Manufacturers.* Although voluntary decreases in the sale of consumer products do not impose long-term net societal costs, mandatory restraints on the access of consumers to desired products may imply economic costs. Economists typically measure producer-related inefficiencies attributable to product bans by calculating lost ''producers' surplus,'' which is a technical term for describing the difference between the amount a producer is paid for each unit of a good and the minimum amount the producer would accept to supply each unit, or the area between the price and supply curve. Data derived from Cummings, et al., indicate that youngsters under the age of 18 consume 316 million packs of cigarettes per year, leading to industry profits of $118 million.[329] On the assumption that the regulation would reduce teenage smoking by one-half, these profits would fall by about $59

[329]Cummings, K. M., T. Pechacek, and D. Shopland, ''The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State,'' *American Journal of Public Health*, vol. 84, No. 2, p. 301, February 1994, (derived by subtracting sales to 18-years-olds from the reported 516 million packs consumed).

million. However, because most of this profit stems from illegal sales to youths, FDA has not counted this figure as a societal cost.

b. *Consumers.* Consumer surplus is a concept that represents the amount by which the utility or enjoyment associated with a product exceeds the price charged for the product. Because it reflects the difference between the price the consumer is willing to pay and the actual market price, it is used by economists to measure consumer welfare losses imposed by product bans. However, FDA's rule imposes no access restrictions on adults, who will be free to consume tobacco products if they so desire. Thus, FDA has not included any value for lost consumer surplus in its estimate of the societal costs of these access restrictions.

8. I.D. Checks

a. *Retailers.* For the 1995 proposed regulation, FDA estimated that retail establishments would bear annual compliance costs of $28 million for consumer identification checks. This figure was derived by multiplying the estimated retail employee compensation rate by the extra time that might be needed to complete purchase transactions. The estimate measured the cost to retailers for either increasing the number of working hours of existing staff or for hiring new staff to handle the added workload. The Barents Group commented on numerous aspects of this compliance cost estimation, accepting several key FDA assumptions, but rejecting others in deriving its estimate of $142 million per year.

In its preliminary analysis, FDA estimated the number of tobacco product transactions for the 18 to 26 year-old age group based on data that reflected the tobacco consumption of cigarette smokers 5 to 6 years after high school [330] and the annual per capita consumption of smokeless tobacco. [331] The Barents Group faulted FDA for limiting these transactions to 18 to 26 year-olds, asserting that the standard practice for alcohol sales is to request identification for anyone who appears to be 30 years old or younger. The Barents Group calculations actually estimated compliance costs on the assumption that customers up to age 34 would be asked for identification, because some older consumers would appear to be only 30 years old.

FDA has not accepted this Barents Group assumption for several reasons. First, the legal age of purchase for alcohol in all 50 States is 21 years, whereas the rule for cigarettes and smokeless tobacco sets 18 as the legal age of purchase. This 3-year difference implies that comparable cigarette and smokeless identification checks would be expected only up through age 27. Also, the current policy and practice of many retail stores is to request identification from tobacco consumers only up to age 26. Requiring proof of age for anyone who appears younger than 26 years of age was also recommended by a working group of 26 State Attorneys General. [332] Finally, the Barents Group's use of age 34 to provide a margin of safety for identifying those under the age of 30 is illogical, since the FDA rule requires retail stores to identify consumers who are under the age of 26, not 30.

The Barents Group accepted the FDA assumption that an I.D. check would take an average of 10 seconds, but referenced a study by A. T. Kearney that found that the actual time needed to verify a photo I.D. for a tobacco product sale averaged 8.3 seconds. Because FDA has no better data, the agency adopts 8.3 seconds as the average time needed to conduct an I.D. check. The Barents Group further commented that FDA used outdated employee compensation data in its calculations. FDA's revised totals use the Barents Group's employee compensation estimate of $9.51/hour (1994 dollars) as the time value for retail sales employees.

FDA originally assumed that only 75 percent of all retail transactions for the 18 to 26 year-old age group would be extended due to I.D. checks. The Barents Group argued that the correct percentage should be 100 percent, as the rule would apply to all sales to the relevant age group. FDA continues to believe that this assumption leads to an over-estimate of the probable costs. First, not every moment of a clerk's time is effectively utilized and a few seconds more per transaction will not always result in lost labor productivity. Second, many smokers patronize the same retail store almost daily and are well-known to clerks. I.D. checks for these customers will take little extra time. Finally, many customers will take less time to produce an I.D., once they realize that identification checks have become routine. Nevertheless, FDA adopts the Barents Group's 100-percent assumption to assure a full accounting of the relevant costs.

One comment claimed that FDA failed to include the cost of hiring additional sales clerks. As noted above, the FDA calculation does reflect the cost of the additional labor time that might be needed. The Barents Group also inexplicably asserts that FDA failed to consider I.D. checking costs as annual costs, instead listing them as a one-time cost. Table 2 of the original analysis (60 FR 41314 at 41360), clearly lists the $28 million identification check cost as an annual operating cost and the accompanying text (60 FR 41314 at 41367) refers to the figure as a ''per year'' cost. The Barents Group further faulted FDA for not taking into account the cost of checking I.D.'s for those youths under age 18, who will still attempt to buy cigarettes. While a small percentage of underage smokers may opt for this course of action, few would return to complying outlets. Thus, FDA believes that any plausible estimate of the associated costs would be less than $1 million annually.

FDA originally estimated the number of tobacco product transactions for the 18 to 26 year-old age group at 2.2 billion, but has updated its estimate to 2.5 billion. [333] Also, the 80-percent current noncompliance rate that had been assumed for the 1995 proposal may be too high, as the Surgeon General estimated that minors are unable to make an OTC purchase of tobacco products about one-third of the time. [334] Nevertheless, FDA retains this assumption to calculate a cost to

[330] 1994 SGR, p. 85.

[331] U.S. Department of Commerce, *Statistical Abstract of the United States 1993*, 113th edition, p. 137, 1993; DHHS, Office of Inspector General, *Spit Tobacco and Youth; Additional Analysis*, June 1993.

[332] ''No Sale: Youth Tobacco and Responsible Retailing,'' Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.

[333] 1994 Population data for 18 to 26 year-olds from 1995 Statistical Abstract, Table 16. Cigarettes: Number of smokers for age group calculated from Table 217 (1993 data). Average packs/yr. and total packs/yr. for smokers aged 18 to 26 calculated from data in Table 20, 1994 SGR, p. 85. (Those smoking 1 to 5 cigarettes/day assumed to smoke 3, those smoking 20+ cigarettes/day assumed to smoke 25). The resulting number of packs smoked by 18 to 26 yr.-olds totals about 2.5 billion. If even 1 percent of these transactions were for cartons, this number falls to about 2.3 billion. Smokeless: Total units of smokeless products sold calculated from data in *Spit Tobacco and Youth: Additional Analysis*, Dept. of Health and Human Services, June 1993, Excise Tax calculations, Option 4; Units consumed by youths from the Institute of Medicine Report (the IOM Report) ''Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths'', p. 8. 1994, Usage data and total units (cans or pouches) consumed for age group for those aged 18 to 26 from ''Use of Smokeless Tobacco Among Adults-U.S., 1991'' in ''MMWR'', CDC, DHHS, volume 42, No. 14, p. 264, 1993. The number of containers sold for 18 to 26 yr. old age group totals about 0.2 billion.

[334] IOM Report, p. 202.

retailers for I.D. checks of $43 million per year (2.5 billion transactions x 8.3 seconds/transaction x $9.51/hour ÷ 3600 seconds/hour x 80 percent noncompliance rate). This revised estimate exceeds FDA's original $28 million figure, but remains far below the $142 million estimate of the Barents Group.

b. *Consumers.* The Barents Group also criticized FDA for not quantifying the costs to consumers for the extra time needed to undergo I.D. verifications. They estimated this cost at $282 million a year. FDA agrees that consumers would incur time costs and, for its revised estimates, adopts the analytical framework suggested by the Barents Group, which counts only the time lost by young customers. (The Barents Group suggests that older consumers also would experience delays, but FDA's estimates already account for the cost of additional clerk time that would offset longer checkout lines. Younger customers, however, must wait while their age is verified, even when additional checkout clerks are available.) To estimate the time cost, FDA applies the same methodology that was used to estimate the time cost for retail employees. That is, 2.5 billion transactions taking an extra 8.3 seconds each for the 18 to 26 year-old age group, adjusted for a 20 percent current compliance rate. The Barents Group used an average hourly private sector compensation rate ($15.13/hour) as the basis of its consumer time cost estimate, but FDA finds this average rate too high for young consumers and estimates a range of $9 to $11 per hour.[335] As a result, FDA's estimate of the cost to consumers for lost time cost amounts to between $41 and $50 million per year.

9. Vending Machines

In its comments on the costs of FDA's proposed vending machine ban, the Barents Group reports that automatic vending machine operators will lose $403 million in annual revenues. They then subtract an estimated $281 million offset for future over-the-counter sales (calculated by assuming an equal number of future packs sold and an $.80 price premium for vending machine packs) to project a net $122 million of regulatory costs to the retail sector. Although not acknowledged, this methodology implicitly assumes that a redistribution of revenues (from vending machine owners to over-the-counter sellers) does not generate added societal costs. Elsewhere, the Barents Group includes distributional impacts in cost totals. Nevertheless, even this $122 million estimate is far too high.

The fundamental problem is that changes in revenue, as discussed above, do not measure economic costs. The relevant economic measure of regulatory costs to an industry is the change in producer surplus that a firm makes from selling a good or service. Because producer surplus' are difficult to measure, accounting profits are sometimes used as a proxy. By examining only lost revenues, the Barents Group ignores the difference in the operating costs of the alternative sales channel, despite its recognition that ''[i]n general terms, the extra margin at vending machines reflects the costs to vending machine owners of operating these machines, in addition to a return on their labor effort and capital investments.'' In other words, the reason that cigarettes purchased from a vending machine are more expensive is that it costs more to sell a pack of cigarettes by vending machine. Consequently, if cigarette sales shift from more expensive-to-operate vending machines to OTC, the loss of industry profits is much smaller than the loss of industry revenues.

An approximate assessment of the net impact on retail profits requires a comparison of the pretax profit margins for vending machine operations as compared to OTC sales. The Barents Group cited survey results from the National Automatic Merchandising Association (NAMA) showing an average pretax profit margin of 3.8 percent in 1993 and 2.0 percent in 1992, for an average 2.9 percent for vending machine operations. Because cigarette vending machine sales have decreased in recent years, current profit margins might be even smaller. Coincidentally, the Barents Group reports that the estimated average industry profit margin for convenience stores is also 2.9 percent. If this rate applies to cigarette sales at convenience stores and if all lost vending machine cigarette sales were transferred to convenience stores, the net pretax cost to the industry would be $3.5 million, not $122 million ($403 million to $281 million) x 2.9 percent). Moreover, NAMA reports that over 50 percent of all vending machines are located in bars and taverns and many others in business establishments frequented only by adults. The final rule permits vending machines in those places where the owner can ensure that no young people under age 18 are present at any time. FDA does not know how many vending machines will be moved to restricted areas in compliance with this rule, but the number will further reduce this annual cost.

10. Readership Surveys

The Barents Group reported that 101 leading national magazines had advertisements for tobacco products in 1994. In addition, Barents obtained youth and adult readership data for 1994 from MediaMark Research, Inc. (MediaMark), for 41 of these 101 magazines. Applying the regulatory threshold of 2 million readers or 15 percent of total readership below the age of 18, Barents projected that advertisements in 32 of the 41 magazines (78 percent) would be restricted to ''text only'' by the proposed regulation. In comparison, FDA examined copyrighted youth and adult readership data from the Simmons Marketing Bureau, Inc. (Simmons), another major marketing research firm, and found that only 13 of the 27 magazines with tobacco ads (48 percent) had youth readership over the threshold. A comparison of youth readership levels from MediaMark and Simmons for magazines that had tobacco advertisements in 1992 is shown in Table 11.[336]

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[335] Data from the 1995 *Statistical Abstract of the United States*, Table 677 lists weekly earnings for full time wage and salary workers for the group ''16 to 24 year-olds'' in 1994. Table 682 lists median hourly earnings for workers paid hourly rates for the same group in 1994. Assuming a 40 percent increase for benefits, the compensation rates for these two tables for 16 to 24 year-olds are $9.98/hour and $7.87/hour, respectively.

Using these figures will result in a low estimate for the 18 to 26 year-old group because 25 and 26 year-olds earn more than 16 and 17 year-olds. Conversely, using a benefits/wage ratio of 40 percent for 18 to 26 year-olds will overstate the costs because lower paid workers (hourly and part-time workers, college students) are more likely to have less generous benefits packages (little or none of the following: paid vacation, sick leave, employer-paid health insurance). FDA increased the estimated compensation rates to $9 to $11/hour to assure it does not underestimate the true compensation rate.

[336] Tobacco industry spending on magazine advertising was calculated using tobacco advertising share data from Barents and advertising revenues from *Advertising Age*. Advertising revenue was unavailable for five small publications that accounted for less than one percent of tobacco magazine advertising spending in 1994. To estimate tobacco advertising expenditures in these five publications, FDA assumed total advertising revenues for each publication equal to $14,388, which is the lowest total revenue reported in *Advertising Age* for 1994.

TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated[1,2]	10.0	5,201	18.0	4,614	17.1
People[1,2]	9.8	3,020	7.8	2,465	8.0
TV Guide[1,2]	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade[2]	3.7	n/a	n/a	6,059	6.9
Cosmopolitan[1]	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly[2]	2.9	n/a	n/a	674	15.3
Better Homes & Gardens[1]	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour[1,2]	2.0	2,216	17.1	1,540	17.4
Rolling Stone[1,2]	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver[1]	1.6	1,465	18.3	n/a	n/a
Life[1]	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life[1]	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track[1]	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle[1,2]	1.0	1,369	19.7	959	18.5
Vogue[1,2]	1.0	2,237	18.0	1,300	17.4
Hot Rod[1]	0.8	2,295	28.0	n/a	n/a
Ebony[1]	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly[1]	0.7	1,037	15.1	n/a	n/a
Motor Trend[1]	0.7	1,393	22.1	n/a	n/a
Premiere[1]	0.7	617	25.8	n/a	n/a
Sport[1,2]	0.7	2,274	33.8	1,132	24.0
Elle[1]	0.6	819	17.8	409	14.4
Essence[1]	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet[1]	0.4	1,724	16.7	1,169	12.2
Popular Science[1,2]	0.4	1,906	20.8	874	16.1
Self[1]	0.4	786	16.2	n/a	n/a
Harper's Bazaar[1]	0.3	718	18.2	n/a	n/a
The Sporting News[1,2]	0.3	1,394	27.8	666	15.7
Cable Guide[1]	0.2	3,358	22.6	n/a	n/a
Ski[1,2]	0.0	827	26.4	584	24.9

[1]MediaMark youth readership exceeds regulatory threshold.
[2]Simmons youth readership exceeds regulatory threshold.
Source: Barents Group LLC Tables IV–1 and A–2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, ''The Ad Age 300,'' *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.