

## Commentary

# Research Opportunities Concerning Youth and the Family Smoking Prevention and Tobacco Control Act

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Enactment of the Family Smoking Prevention and Tobacco Control Act creates a number of research opportunities, some of which are mandated by the statute. The Act establishes Food and Drug Administration jurisdiction over tobacco and reestablishes the FDA regulations initially issued in 1996 concerning the sale of tobacco to minors. The public health value of enforcing restrictions on the sale of tobacco to minors is now well established, but many questions remain regarding the most efficient approach to enforcement. Evaluations are needed concerning the effectiveness of restrictions on the distribution of free samples, restrictions on advertising of cigarettes to youth, and enforcement of sales restrictions on Indian lands. The potential impact of raising the minimum age for tobacco sales to 21 years needs investigation. Legal and regulatory strategies to encourage tobacco manufacturers to take responsibility for keeping their products out of the hands of children need to be explored.

## Introduction

This paper considers potential research opportunities and challenges concerning aspects of the Family Smoking Prevention and Tobacco Control Act that pertain to youth. These involve various aspects of the sale and promotion of tobacco. Each section begins with a brief overview of the issue and a description of prior regulation. The relevant aspects of the Act will be outlined, followed by a list of bulleted ideas for potential research. The ideas and opinions expressed are those of the author.

## Retail Sales to Minors

### History of Regulation

Individual states have long regulated the sale of tobacco to minors, but such laws were rarely enforced until the 1990s (Jason, Ji, Anes, & Birkhead, 1991). The first federal regulation of such sales was through the Synar Amendment, which was enacted in 1992 but did not go into effect until the publication of the final rules in 1996 (Department of Health and Human Services, 1996). The regulations for the Synar Amendment were

coordinated with those issued by the Food and Drug Administration (FDA; FDA & Department of Health and Human Services, 1996). The Synar regulations require states to enact and enforce state laws that prohibit the distribution of tobacco products to minors. The 1996 FDA regulations made the sale of tobacco to minors under 18 years of age a federal offense for the first time. The FDA puts into effect a federal enforcement program that was distinct from the state enforcement of state laws. However, state and federal governments worked together to enforce the federal regulations as states were contracted to conduct enforcement inspections for the FDA (Natanblut, Mital, & Zeller, 2001). This joint effort was just getting started when the Supreme Court ruled that the FDA did not have jurisdiction over tobacco (*Food and Drug Administration et al. v. Brown & Williamson Tobacco Corp. et al.* 529 U.S. 120, 2000). The states have continued to enforce their laws under the Synar mandate with generally very good results in terms of the retailer compliance rates that states have measured (DiFranza & Dussault, 2005).

### What Is Known

The intent of youth access interventions is to reduce the number of young smokers by reducing the supply of tobacco to youth from commercial sources. Access interventions that do not reduce the commercial supply of tobacco to youth cannot reduce smoking. Research conducted since 1987 has clearly identified strategies that are and are not effective at reducing commercial availability (DiFranza, 2005a; DiFranza, Norwood, Garner, & Tye, 1987). As knowledge has accumulated, authorities have improved the effectiveness of their programs substantially, and this is reflected in increased merchant compliance with the law (Center for Substance Abuse Prevention, 2010) and declining rates of youth smoking across the United States and Australia (DiFranza, Savageau, & Fletcher, 2009; Tutt, Bauer, & DiFranza, 2009).

The earliest research on youth access established that merely banning the sale of tobacco to children by enacting laws was an ineffective strategy (DiFranza et al., 1987; Jason, Berk, Schnopp-Wyatt, & Talbot, 1999; Radecki & Zdunich, 1993). Subsequent trials demonstrated that strategies based on merchant education alone could elicit only partial or temporary improvements in

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merchants' compliance with the law (Altman, Foster, Rasenick-Douss, & Tye, 1989; Altman, Rasenick-Douss, Foster, & Tye, 1991). The first case reports of the implementation of active law enforcement using underage decoys indicated that this strategy could produce prompt and dramatic reductions in the number of young smokers (DiFranza, Carlson, & Caisse, 1992; Jason et al., 1991). These early case reports were followed by four controlled interventions of active enforcement conducted at the community level (Cummings, Hyland, Perla, & Giovino, 2003; Forster et al., 1998; Jason et al., 1999; Rigotti et al., 1997). Three of these studies demonstrated that active enforcement reduced adolescent smoking substantially. The authors of the only study that did not demonstrate an impact on youth smoking observed that the enforcement program had failed to reduce youths' access to cigarettes from commercial sources (Rigotti et al.). A subsequent literature review revealed that in every study in which a youth access intervention had failed to reduce adolescent smoking, there was either no evidence that the intervention had reduced youth access to commercial sources or there was evidence that the intervention had not reduced access (DiFranza, 2005b).

Reductions in youth tobacco use resulting from youth access interventions have been observed in at least 18 studies (Altman, Wheelis, McFarlane, Lee, & Fortmann, 1999; Chaloupka & Pacula, 1998; Dent & Biglan, 2004; DiFranza, 2002; DiFranza et al., 1992, 2009; Forster et al., 1998; Jason, Pokorny, & Schoeny, 2003; Levinson & Mickiewicz, 2007; Jason et al., 1991, 1999; Perla, 1999; Pokorny & Jason, 2003; Powell, Tauras, & Ross, 2003; Ross & Chaloupka, 2001; Staff, Bennett, & Angel, 2003; Staff et al., 1998; Tutt, Bauer, Edwards, & Cook, 2000; Tutt et al., 2009; Widome, Forster, Hannan, & Perry, 2007). There are no studies in which an impact on access was documented without a concomitant impact on youth smoking (DiFranza, 2005b). The literature is clear and consistent. Strategies that are ineffective in curtailing youth access to tobacco through commercial sources (such as relying solely on merchant education) are uniformly ineffective at reducing youth smoking. Conversely, strategies that effectively reduce youths' access to tobacco from commercial sources have been uniformly effective in reducing youth tobacco use (DiFranza, 2005b). The literature appears "mixed" in regard to effectiveness only when reviewers inexplicably mix studies of ineffective strategies that were abandoned years ago with those of current proven strategies and recommend throwing the baby out with the bath water (DiFranza, 2000; Fichtenberg & Glantz, 2002; Richardson et al., 2009; Stead & Lancaster, 2000).

National studies in the United States and Australia demonstrate that restricted access to tobacco has contributed to the historic reductions in youth smoking rates witnessed since the inception of youth access enforcement programs in these countries (DiFranza et al., 2009; Tutt et al., 2009). The only youth access strategy that has proven efficacy is proactive enforcement

involving the routine inspection of retailers through the use of test purchases conducted by decoys, resulting in financial penalties (DiFranza, 2005a). The FDA's intention to enforce its regulations using underage decoys is well grounded in public health science and legal precedent. The Synar initiative, with its requirement for routine inspections of merchants using test purchases, has resulted in marked improvement in merchant compliance with state laws in every state (Center for Substance Abuse Prevention, 2010). The observed improvement in merchant compliance has been linked to declining teen smoking in national surveys when controlled for other public health policies, such as taxation and clean indoor air regulations (DiFranza et al., 2009).

A major misconception in regard to youth access restrictions is that youths increase their attempts to purchase tobacco in response to restrictions, and social sources of tobacco expand to completely fill the void left by the removal of commercial sources (Castrucci, Gerlach, Kaufman, & Orleans, 2002; Friend, Carmona, Wilbur, & Levy, 2001; Ling, Landman, & Glantz, 2002). The scientific evidence soundly refutes both points. In Australia, enforcement resulted in a 75% decline in attempts by underage youth to purchase tobacco (Tutt et al., 2009). Since youths who buy cigarettes are more likely to supply other youths (Forster, Chen, Blaine, Perry, & Toomey, 2003), preventing them from purchasing cigarettes reduces the largest social source. By reducing the number of underage smokers, access restrictions also reduce the number of potential social sources. There is no evidence supporting the fear that black markets develop to provide youth with cigarettes (DiFranza & Coleman, 2001). For these reasons, youth access restrictions result in a net absolute decline in social sources.

Despite the success of the Synar program, additional attention from the FDA to the problem of illegal sales of tobacco to minors is welcome as there is room for improvement. Some states tolerate violation rates that are consistently three to four times higher than in other states (Center for Substance Abuse Prevention, 2010). Also, under the current Synar regulations, states need only to achieve a compliance rate of 80%, even though high-performing states like Florida and Maine have shown that merchant compliance rates can be maintained above 90% indefinitely (Center for Substance Abuse Prevention).

## What the Law Provides

The Family Smoking Prevention and Tobacco Control Act reenacts the original FDA regulations on tobacco sales to minors. These include a minimum age of 18 years, a requirement for age verification, and a restriction on the location of vending machines and self-service displays to locations where minors are not allowed. Table 1 indicates the fine structure for violations of the prohibition on providing tobacco to minors. This fine structure

**Table 1. Fine Structure For Violations of the Prohibition On the Provision of Tobacco to Minors**

	First offence	Second offence	Third offence	Fourth offence	Fifth offence
With approved training program	Warning	\$250	\$500	\$2,000	\$5,000
Without approved training program	\$250	\$500	\$1,000	\$2,000	\$5,000

is within the range of penalties that has proven to be effective in persuading retailers to obey the law. Many states have used license suspensions or the threat thereof as an effective tool (DiFranza, 2005a). The law does not provide for retailer licensing but does allow the FDA to issue “no tobacco sales” orders to retailers who violate the law.

The law provides that reliance on a forged government ID is a positive defense. This provision has been included in many local laws and has not been an obstacle to enforcement as the decoys never carry forged IDs.

### Research Opportunities

The FDA regulations regarding sales to minors are well formulated and well supported by the scientific literature. Research should continue to determine if there are more effective ways of curtailing the sale of tobacco to minors.

- Currently local, state, and federal governments bear the entire burden of ensuring that tobacco is sold in compliance with the law. Research is needed to determine if there are practical ways of shifting some of this burden onto the manufacturers that place tobacco products into commerce.
- It has been suggested that tobacco companies could be required to maintain control of their products through to the point of sale to prevent smuggling and the illegal sale to minors. This proposal would require manufacturers to limit the sale of their products to retailers that are official manufacturer-licensed distributors. Manufacturers would be required to inspect their own licensees and prohibit the sale of their product by those that repeatedly sell to minors. Legal research is needed to determine if state governments have the authority to enact such a requirement. Research is needed to identify licensing models that are used for sales, distribution, or repairs of other products to determine if tobacco dealership licensing by the manufacturers is feasible.
- Tobacco products are arguably the most widely available consumer product in terms of the number of outlets available. Research is needed to determine the feasibility of states passing laws to limit the number of tobacco outlets in a community as is routinely done with alcohol outlets and to determine the potential public health benefit of such a policy.
- Research is needed concerning the feasibility of states limiting tobacco sales to government-owned stores to ensure compliance with the law. Research is needed to determine if government-owned stores comply with alcohol sales restrictions better than privately owned stores.
- The FDA regulations sidestep the issue of licensing of retailers by providing that the FDA can issue an order to stop selling tobacco. However, the lack of a licensing system makes it time consuming to locate tobacco outlets for inspection purposes and makes it very difficult to ascertain to whom violation notices should be addressed. Research is needed to determine the potential impact of a federal tobacco retail license requirement. Considerations include the feasibility of this approach, the cost of implementing licensing nationally, and how much money federal licensing of retailers would save federal and state taxpayers by reducing inefficiencies in enforcement programs.
- The optimum frequency at which inspections should be conducted has not been determined (DiFranza, 2005a; Jason, Billows, Schnopp-Wyatt, & King, 1996). Some states such as Florida obtain excellent results through inspecting only 20% of retailers each year. Others try to inspect every retailer quarterly.

Smaller fines appear to require more frequent inspections. If inspections are too infrequent, the public health benefits of the law may not be achieved. If inspections are excessively frequent, taxpayer money is wasted. The FDA will be in the position to vary inspection frequencies from location to location and over time to determine the minimum inspection frequency that is compatible with achieving the highest rates of compliance. Research is needed to determine the most efficient approach to using state and federal resources for enforcement.

- Research is needed to determine the optimal balance between expenditures on merchant education versus enforcement to achieve the highest compliance rates. The FDA could vary the balance used in different states.
- Research is needed to determine if inspections conducted under the FDA protocols accurately simulate what happens when real underage smokers attempt to purchase tobacco (DiFranza, Savageau, & Bouchard, 2001). Research could be piggybacked onto official inspections to determine if a real underage smoker was able to purchase tobacco from the same clerk minutes after an FDA inspection. This would indicate whether FDA protocols need to be improved.
- Research is needed to determine how well community compliance rates reflect the availability of tobacco to youth living in the community (DiFranza & Coleman, 2001; Forster, Wolfson, Murray, Wagenaar, & Claxton, 1997). School surveys or focus groups could be conducted in selected communities before and after the implementation of FDA enforcement to answer this question. Prior research has established that adults buy tobacco for minors (Klonoff, Landrine, Lang, Alcaraz, & Figueroa-Moseley, 2001). While it is clear that enforcement programs have a beneficial effect on youth smoking rates despite the availability of social sources of tobacco, a greater impact might be achieved if further reductions in social sources could be achieved. Research is needed to determine if there are ways in which social sources of tobacco could be reduced.
- The FDA regulations provide only a warning for a first offense if a retailer has adopted a set of best practices regarding tobacco sales (Table 1). By examining the results of its compliance tests, the FDA would be in a position to determine what the recidivism rate is in response to a warning in comparison with that observed after the administration of a \$250 fine imposed in response to a first offense in the absence of best practices. This research could be performed by the FDA itself or in collaboration with academic researchers.
- Research is needed to determine if governments should institute a minimum age for clerks since underage clerks are known to sell to their friends (DiFranza & Coleman, 2001).
- Research is needed to determine if restrictions on cigarette pack size would be beneficial to public health. Would a prohibition on single pack sales reduce youth access? What would be the impact of an increase in the minimum pack size?
- A major obstacle to achieving 100% compliance is that clerks find it difficult to look at an ID and determine if it is legal to make a sale (Krevor, Capitman, Oblak, Cannon, & Ruwe, 2004; Levinson, Hendershott, & Byers, 2002). Research is needed to determine what features on licenses best help clerks to identify an underage customer.
- Research is needed concerning the impact of training on the performance of store clerks. Does it matter whether the training is done by the employer or the government?
- Do price discounts affect the availability of tobacco to minors?

## Raising the Minimum Age

### History of Regulation

After the Synar Regulation was adopted, about a dozen states that had no restriction on the sale of tobacco to minors established a minimum age of 18 years (DiFranza et al., 1987). Only three states have a minimum age of 19 years, the rest have 18 as the minimum age (Downey & Gardiner, 1996). Only states can raise the minimum age.

### What Is Known

There are no studies that have evaluated the effect of actually raising the minimum age as this has not occurred in the United States. The impact of raising the minimum age for tobacco sales to 21 years has been considered in models (Ahmad, 2005a, 2005b; Ahmad & Billimek, 2007). There are many arguments in favor of raising the minimum age, foremost of which is that most youth turn 18 while they are still a junior or a senior in high school, which allows these youths to legally purchase tobacco and supply their classmates (Crane, Dunn, & Cocoran, 2003). Retailers argue that having the same minimum age for alcohol, lottery tickets, and cigarettes would make it easier for them to train clerks. It would also eliminate the need to have three license designs under 18, 18–20, and 21 years and over.

### What the Law Provides

Section 104 requires a study of the effect of raising the minimum age but does not allow the FDA to raise this limit.

### Research Opportunities

- There are data on the effect of raising the minimum drinking age in all 50 states (Wagenaar & Wolfson, 1994). A review of the alcohol studies could provide a rationale for raising the minimum age for tobacco. Since the minimum age is relevant only if the law is enforced, experiences in countries that do not enforce their laws are not informative.
- Research is needed on the potential impact that raising the age restriction would have on uptake patterns through age 21 years.

## Holding Manufacturers Accountable For Underage Sales

### History of Regulation

None.

### What Is Known

Several authors have calculated the dollar value of cigarettes consumed by minors and have called for the government to confiscate the profits manufacturers' derive from the underage market as a way to discourage competition for the youth market (Cummings, Pechacek, & Shopland, 1994; DiFranza & Tye, 1990; Glantz, 1993). The proposed law would require the General Accounting Office (GAO) to study one such approach.

### What the Law Provides

Section 919 apportions user fees to manufacturers and importers according to overall market share. It requires the GAO to conduct a study to determine (a) brand preferences of minors, (b) the feasibility of reapportioning the user fees on the basis of market share among minors, and (c) the likely impact on the marketing of tobacco products to youth if user fees were apportioned according to youth market share.

### What Is Known

Published studies establish that (a) youth brand preferences do not match those of adults, (b) youth brand preference varies by region, and (c) brand preference is not an exact match for market share because youth cannot always afford their preferred brands (DiFranza, Eddy, Brown, Ryan, & Bogojavlensky, 1994; DiFranza et al., 1991b).

### Research Opportunities

- Research is needed to determine the best methods of determining youth market share.
- Youth market share could be assessed by asking youth the name of the brand of the cigarette that they last smoked (DiFranza et al., 1994). As youth brand preferences vary by region, a weighted nationally representative survey would be required to fairly apportion the youth market among manufacturers. Research is needed to track youth brand preference on a national and regional basis.
- Research is needed on the potential impact a reapportionment of user fees based on youth market share would have on youth marketing. One could start with an assumption that manufacturers will act in their own financial self-interest. The annual profit each manufacturer enjoys from the youth market can be estimated based on market share. If annual profits from underage consumption exceed the user fee, there would be no financial disincentive for manufacturers to change their current practices. Given the size of the user fees, it seems likely that there would be a disincentive to pursuing the youth market when only short-term gains are considered. Because adult brand preferences are often established during adolescence, tobacco manufacturers have a long-term incentive to attract underage smokers to their brands. A more sophisticated analysis would have to factor in the long-term profits that are realized by establishing brand preference during adolescence (DiFranza & Tye, 1990).

## Free Sampling of Cigarettes and Smokeless Tobacco

### History of Regulation

All states prohibit the distribution of free samples to minors. Many states and municipalities prohibit the distribution of free samples entirely and do not make exceptions for adults.

### What Is Known

When free sampling of adults has been allowed, there has been very poor compliance with the prohibition of distribution to minors. Historically, youth have had little difficulty obtaining free samples when they are available.

### What the Law Provides

Title I, Bill Section 102 prohibits the distribution of free samples of cigarettes, smokeless, or tobacco but provides for a limited exception for smokeless tobacco in Section 919 that allows for the distribution of free samples of smokeless tobacco to adults under very restricted circumstances.

### Research Opportunities

Research is needed to determine if the proposed regulations adequately protect minors. Compliance testing with minors should be conducted to determine if they are able to obtain free samples. Youth surveys could ask if subjects have received free samples since the regulations went into effect.

## Enforcement on Indian Territory

### History of Regulation

There are no existing regulations specific to Indian territory.

### What Is Known

No studies have been published regarding the adequacy of enforcement on Indian lands. In some states, enforcement programs have covered tribal territories but not in others. To the extent that the tribes have prevented or neglected enforcement, Indian youth are being deprived of the proven public health benefits of this intervention.

### What the Law Provides

Section 102 requires the Secretary of the Department of Health and Human Services to ensure that the provisions of this Act are enforced with respect to the United States and Indian tribes.

### Research Opportunities

A research opportunity would be to conduct compliance testing in Indian stores or to survey Indian youth to determine if they report purchasing tobacco from stores. Results could be compared with areas of the state exclusive of Indian territory.

## Restriction on the Advertising of Menthol Cigarettes to Minors

### History of Regulation

The Federal Trade Commission considers advertising of cigarettes to minors to be an unfair trade practice as reflected in their decision regarding Joe Camel and a few prior decisions ([Federal Trade Commission, 1997](#)). It might be possible to prosecute companies for soliciting illegal sales but that would have to be proved on a case-by-case basis. The companies agreed to limited restrictions on their ability to advertise to children as part of the Master Settlement Agreement but that is a negotiated agreement with the states and not a regulation ([National Association of Attorneys General, 1989](#)). Violations are handled through civil litigation, not through prosecution.

### What Is Known

Efforts in other countries to prohibit advertising have been circumvented by the tobacco companies through the exploitation

of loopholes, such as advertising in imported publications and by using tobacco brand logos and colors on other products and services. Ongoing vigilance and rapid reactions will be the price of imposing restrictions on the advertising of tobacco.

### What the Law Provides

Title I, Bill Section 103 provides that the Secretary shall publish an action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth. The action plan shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

### Research Opportunities

The research question is whether the proposed restrictions are adequate to protect minors and minority youth from tobacco advertising. This can be assessed through ongoing monitoring.

- Exposure of youth to advertising can be monitored in a number of ways. Youth could be shown masked advertisements to see if they recognize them as was done with the Joe Camel ads ([DiFranza et al., 1991a](#)).
- Youth could be asked to identify their favorite tobacco ads ([Kaufman et al., 2002](#)). If they have favorite ads, it demonstrates that they are exposed to them. Over time, there should be fewer and fewer youth with favorite ads.
- Youth could be asked if they own any tobacco branded articles or if they are aware of any events sponsored by tobacco companies.
- Research could address how many millions of youth are exposed to tobacco ads in magazines each year.
- Youth could be asked to name the brands of tobacco that they see advertised most frequently.
- Youth surveys could be conducted to determine which brands of tobacco they feel are targeted at youth.
- Youth could perform neighborhood surveys to determine their exposure to tobacco advertising.
- Youth groups could be asked to identify possible violations of the regulations.
- In England, they found that the proportion of youth who felt that smoking was “macho” declined sharply after that particular advertising theme was banned ([Charlton, 1984](#)). Youth opinion surveys could be conducted before and after the implementation of the regulations to determine if youth harbor false beliefs about tobacco that are transmitted to them through advertising.

An important question is whether generic packaging is required to protect youth.

- Youth could be shown different cigarette packs and asked if they think the packs are attractive.
- Youth could be asked to identify the brand personality based on the package design and advertisements.

## Discussion

The passage of the Family Smoking Prevention and Tobacco Control Act provides a number of research opportunities and challenges. Some of these can be best addressed by the FDA, some by researchers in the public sector, and some by a collaboration between the FDA and academic researchers.

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## Declaration of Interests

None declared.

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