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January 19, 2012

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments in Docket No. FDA-2011-N-0467

To Whom It May Concern:

The undersigned organizations hereby submit these comments in response to the advance notice of proposed rulemaking published by the FDA in Docket No. FDA-2011-N-0467 dealing with non-face-to-face sale and distribution of tobacco products and the advertising, promotion and marketing of tobacco products and the advertising, promotion and marketing used to promote the sales of tobacco products through non-face-to-face sales.

Section 906(d)(4)(A)(i) of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) requires the Secretary to promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution to minors. Section 906(d)(4)(A)(ii) requires the Secretary to issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and consumer.

FDA's notice seeks comments and "information about how non-face-to-face sale and distribution practices for cigarettes and smokeless tobacco have changed or will change in light of the Prevent All Cigarette Trafficking (PACT) Act and its implementing regulations and about the advertising, promotion and marketing of tobacco products sold or distributed through non-face-to-face transactions in light of technological innovations that make possible new channels of communication."

I. General Comments

Non-face-to-face sale and distribution of tobacco products may undermine effective tobacco control policies in two ways: by facilitating evasion of age verification requirements and by facilitating evasion of state and federal excise taxes.¹ The FSPTCA gives FDA authority to impose restrictions on the sale and distribution of tobacco products. Sec. 906(d)(1). Under this authority, the FDA could promulgate rules limiting or prohibiting non-face-to-face purchases.² Non-face-to-face transactions should be permitted if and only if it can be shown that they can be made consistent with promotion of the important policies that promote effective age verification and the enforcement of state and federal excise tax provisions.

Preventing underage users from experimenting with and becoming addicted to tobacco products is a prime objective of the FSPTCA and federal, state and local public health policy. The importance of such prevention is evident from the fact that nearly everyone who becomes addicted to tobacco products begins usage before reaching majority.³ FSPTCA, Sec. 2 (4). Millions of smokers become addicted to cigarettes while they still believe they are only experimenting with smoking. Despite reductions in youth tobacco usage, the rate of youth tobacco usage remains disturbingly high. More than 7% of eighth graders, 13% of tenth graders and 19% of twelfth graders have smoked cigarettes in the last 30 days.⁴

One of the principal tools for preventing youth access is an efficient program of age verification. Development of a program for effective age verification in face-to-face transactions has been a priority in tobacco control programs for many years. We applaud FDA's efforts to make needed improvements in age verification programs. The potential for evasion of age verification requirements is much greater where tobacco products are sold in non-face-to-face transactions. It is far more difficult to determine that age verification requirements have been met when the contact between customer and seller is not face-to-face. For this reason, the FSPTCA prohibited the sale of tobacco products in vending machines except in adult-only facilities.⁵ The rapid development of the internet and other forms of electronic communication,

¹ Mislabeled packages shipped from abroad could evade both state and federal excise taxes. See, e.g., Figure 1, www.cigarettespub.com, advertising "Purchasing duty free cigarettes products means not having to pay any duties on the products, including excise tax, state and *federal* taxes." (emphasis added) (Accessed Nov. 30, 2011)

² A prohibition on remote sales is not only authorized by the statute, but would also be consistent with international tobacco control norms. Guidance promulgated by the Conference of Parties under the Framework Convention on Tobacco Control recommends that such a ban be adopted by Parties. World Health Organization Framework Convention on Tobacco Control (FCTC), Article 13, Article 13 Guidelines paragraphs 18-21.

³ Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Mental Health: national findings. US Department of Health and Human Services. Available at <http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8results.pdf>.

⁴ Johnston, LD, et al., *Monitoring the Future national survey results on drug use, 1975-2010*, Volume I: Secondary school students, Ann Arbor: Institute for Social Research, The University of Michigan, 2011.

⁵ 21 C.F.R. 1140.16(c).

however, greatly increased the difficulty of implementing an effective program of age verification. Thus, it is unquestionable that one of the primary concerns in dealing with the sale of tobacco products in non-face-to-face transactions is the potential for evasion of age verification requirements.

A second issue of at least equal importance is the use of non-face-to-face transactions to evade state and federal taxation. Because a portion of the total cost of tobacco products—especially cigarettes—is taxes, tax evasion has an impact on the selling price of cigarettes. As shown in more detail below, a carton of Marlboros costs \$95 in New York but is being advertised on the internet for \$25.⁶ It is well-established that the price of tobacco products is a major factor in determining the level of consumption.⁷ Moreover, price differentials have an even greater impact on youth smoking rates than on adult smoking rates.⁸ The ability of internet sellers to evade payment of state excise taxes on tobacco products has a substantial effect on both youth smoking and smoking by adults. The availability of cigarettes on the internet not only makes cheap cigarettes available through purchases from internet sellers, but also depresses the price level in face-to-face sales by sellers who must compete with internet sites. Internet sellers based in locations where it is more difficult for federal and state officials to enforce the law (such as Indian reservations or in foreign countries) have posed a particularly difficult problem. Such sellers have frequently advertised their products—falsely—as being immune from taxation and continue to do so even after the enactment of the PACT Act.⁹ Unfortunately, however, such sellers have often been able to sell their products without paying the applicable taxes.

Federal and state governments have attempted to prevent tax evasion by remote sellers. In 2005, the State of New York, with the participation of the federal Bureau of Alcohol, Tobacco and Firearms (ATF) negotiated voluntary agreements with the major credit card companies under which the companies agreed not to permit use of their cards for the purchase of tobacco products.¹⁰ In 2005 and 2006, the attorneys general of many states reached agreements with the major common carriers under which the carriers agreed not to transport cigarettes.¹¹ The

⁶ See, Figure 2, www.buycigarettes4cheap.com (Accessed Dec. 1, 2011).

⁷ Chaloupka, FJ, Straif, K, & Leon, ME, “Effectiveness of tax and price policies in tobacco control,” *Tobacco Control*, doi: 10.1136/tc.2010.039982, published online November 29, 2010.

⁸ Ding, A, Youth Are More Sensitive to Price Changes in Cigarettes than Adults; *Yale Journal of Biology and Medicine* 76 (2003), pp. 115-24

⁹ See, e.g., Figure 3, www.buycigarettes4cheap.com. “We are exempt from all state taxing agencies because we are based on a Sovereign Native American Territory.” (Accessed Nov. 30, 2011).

¹⁰ Office of the New York State Attorney General. State AGs and ATF Announce Initiative with Credit Card companies to Prevent Illegal Internet Cigarette Sales. http://www.ag.ny.gov/media_center/2005/mak/mar17b_05.html. (Accessed Nov. 30, 2011)

¹¹ Attorney General of the State of New York Health Care Bureau. In the Matter of Federal Express Corporation and FedEx Ground Package Systems, Inc.: Assurance of Compliance, Feb. 2006; Attorney General of

agreements by the carriers did not prevent remote sellers from delivering their products, however, since the United States Postal Service (“USPS”) refused to agree not to deliver tobacco products purchased in remote sales and because remote sellers could still find alternative means of delivery, including using their own vehicles.

In 2010, the Prevent All Cigarette Trafficking (PACT) Act became law. P.L. 111-54; 124 Stat. 1087. The PACT Act was designed to strengthen the enforcement of both age verification requirements and state tax laws with regard to remote sales. The PACT Act contained the following provisions:

- Prohibited delivery of cigarettes and smokeless tobacco to consumers by the USPS;
- Required internet and other remote sellers to comply with all State, local, tribal and other laws—including tax laws--applicable to cigarettes and smokeless tobacco in the state in which such products are delivered;
- Required periodic reporting by remote sellers to states to which delivery sales are made;
- Required remote sellers to verify the age of buyers through the use of commercially-available databases to ensure that the purchasers were of legal age in the state of delivery;
- Required use of a method of delivery of cigarettes and smokeless tobacco that included verification of the age and identification of the person accepting delivery;
- Directed the Attorney General of the United States to create and distribute a list of delivery sellers of cigarettes and smokeless tobacco that are not in compliance with the PACT Act.

Remote sellers of tobacco products challenged the legality of the PACT Act in several jurisdictions. In *Musser’s Inc. v. U.S.*, (E.D.Pa., No. 10-4355, Sept. 26, 2011), the US District Court for the Eastern District of Pennsylvania denied a preliminary injunction against enforcement of the PACT Act and held that the plaintiff was unlikely to prevail on the merits of its challenge to the non-mailability provision or its challenge to the provision requiring internet and other remote sellers to comply with State tax law. In *Red Earth v. U.S.*, 657 F. 3d 138 (2d Cir. 2011) the Second Circuit affirmed a ruling by the district court that the plaintiff was unlikely to prevail in its challenge to the non-mailability provision. However, the Second Circuit left in effect a ruling by the district court staying the provision of the PACT Act that required remote sellers to comply with all State tax laws, finding that it was likely that in some situations internet sellers could not be required to comply with State tax law because of lack of sufficient

the State of New York Health Care Bureau. In the Matter of DHL Holdings USA, Inc. and DHL Express, (USA), Inc.: Assurance of Discontinuance, July, 2005; Attorney General of the State of New York Health Care Bureau. In the Matter of United Parcel Service: Assurance of Discontinuance, October, 2005.
http://www.ag.ny.gov/media_center/2005/oct/9tiupsaodfinal.oct.pdf. (Accessed Nov. 30, 2011)

connection with the delivery state. In a third case, *Gordon v. Holder*, 2011 US Dist. LEXIS 139210, (D.D.C. 2011) the US District Court for the District of Columbia upheld the non-mailability provisions of the PACT Act but granted a preliminary injunction against the enforcement of the provisions requiring internet and other remote sellers to comply with State tax law. . As a result of these conflicting decisions, the potential effectiveness of the PACT Act remains an open question. Key provisions remain under challenge and a stay of the provisions requiring remote sellers to comply with state tax laws remains in effect. Moreover, as noted below, there are questions as to whether the provisions of the PACT Act are being effectively enforced and whether some remote sellers have found ways to weaken its impact by setting up their own delivery mechanisms. Some websites openly brag about their intention and ability to avoid compliance with the PACT Act.¹² Some sellers have also developed their own delivery mechanisms and there are open questions regarding their compliance with the youth access provisions of the PACT Act. To our knowledge, there is no evidence that law enforcement officials have taken the steps necessary to track compliance or penalize offenders.

Non-face-to-face sales present a serious challenge both to effective enforcement of age verification requirements and to effective enforcement of state tax laws. As a result, remote sales threaten two of the most important pillars of tobacco control policy. Section 906(d)(4) gives FDA authority to regulate sales in such transactions. FDA should consider what steps would be necessary to ensure (1) that effective age verification requirements are imposed in such transactions and (2) that state taxes are effectively collected on all such sales. The collection of state taxes is not just a revenue issue: as previous studies have demonstrated, collection of taxes affects the level of youth sales. Moreover, FDA should coordinate with other federal agencies to ensure that provisions of the PACT Act are being effectively enforced. FDA might consider requiring non-face-to-face sellers of tobacco products to agree to comply with all federal and state tax laws, to implement effective age verification measures, and to submit to regular inspections of their books and records as a condition of being permitted to sell such products. However, unless FDA can develop and implement regulations that ensure in practice that remote sales undermine neither the age verification requirements nor the enforcement of state tax law, such sales should be prohibited.

II. Answers to Specific Questions

A. Non-face-to-face sale and distribution of tobacco products.

1. *Other than direct mail, catalog, and internet sales, what types of non-face-to-face sales and distribution methods are used to sell or distribute tobacco products to consumers?*

¹² See, e.g., Figure 4, www.nativeblend.net (Accessed Nov. 30, 2011).

Vending machine sales are still permitted in adult-only facilities. In addition, some remote sellers take orders by telephone.¹³

2. *Do the non-face-to-face sales and distribution methods differ depending on the type of tobacco product being sold (i.e., cigarettes, smokeless tobacco, or other products “made or derived from tobacco” subject to the Tobacco Control Act)? If so, how?*

The State and ATF agreements with credit card companies are applicable only to cigarettes. Moreover, the PACT Act banned the shipment of cigarettes and smokeless tobacco through the USPS but did not cover other tobacco products.¹⁴

Some websites specialize in cigarettes, others in non-cigarette products, but many sell a wide range of tobacco products. Since the PACT Act did not cover tobacco products other than cigarettes and smokeless tobacco, some websites that had principally sold cigarettes have been promoting products they call little cigars that are all but indistinguishable from cigarettes and are marketed as being similar to cigarettes but at a much lower price.¹⁵

3. *What are the methods used by minors to acquire tobacco products through a non-face-to-face exchange?*

Numerous studies have shown that underage consumers can easily buy tobacco products online with no effective age verification. These studies are enumerated and described in the well-documented comments filed in this docket by Rebecca Williams, Kurt Ribisl, and Catherine Jo of the University of North Carolina (hereinafter referred to as “Comments of Dr. Williams”). In our opinion the findings summarized in these comments raise serious concerns that require effective action by the FDA.

4. *Since the enactment of the PACT Act, have minors found alternative methods to purchase and/or acquire cigarettes or smokeless tobacco products by a means other than a face-to-face exchange? If so, what are they?*

A national telephone survey of 500 adolescents conducted in March 2010 showed that 60% of those surveyed believed that it would be either “easy” or “very easy” for minors to buy tobacco products on the internet.¹⁶ Cigarettes remain easily accessible from internet sites, many

¹³ See, e.g., Figure 5, www.AllOfOurButts.com (Accessed Nov. 30, 2011).

¹⁴ Some websites that previously sold cigarettes now promote products denominated as “little cigars,” which are virtually indistinguishable from cigarettes. See, e.g., Figure 6, www.cigarettesexpress.com (Accessed Nov. 30, 2011).

¹⁵ See, e.g., Figure 6, www.cigarettesexpress.com (Accessed Nov. 30, 2011)

¹⁶ International Communications Research Teen Excel Study; National telephone survey of 500 children aged 12-17 conducted March 4-8, 2010.

of which are based in other countries. Hundreds of sites accessible on the internet still offer cigarettes for sale to customers in the United States, usually at prices far below those available in face-to-face transactions. According to Dr. Williams's comments, in 2011 there are at least 413 English-language websites selling cigarettes, of which 51% were located overseas. Many of the websites based abroad sell cigarettes manufactured in Europe under familiar US trademarks.¹⁷ Most of these websites focused on shipping cigarettes to customers in the United States. Studies referenced in Dr. Williams's comments indicate that it is not difficult for underage customers to purchase and obtain delivery of tobacco products without providing appropriate proof of age. These findings indicate that evasion of age verification requirements in remote sales remains a serious concern even after enactment of the PACT Act. The evidence is sufficient to warrant FDA undertaking its own investigation to determine whether, after the PACT Act, it remains easy to evade age verification requirements. Such an investigation can be done utilizing established methods for attempting to purchase and obtain delivery of tobacco products without providing appropriate proof of age.

5. *What are the current technologies, procedures, or other methods used to ensure that the purchaser of a tobacco product through a non-face-to-face exchange is an adult, including age and ID verification?*

The comments submitted by Dr. Williams provide a summary of the different methods currently used by various vendors to accomplish age verification. It is apparent from the information provided that the large majority of vendors use methods that are ineffective to accomplish this purpose. The pretense that these methods actually prevent sales to underage buyers is worse than having no protection at all.

a. *How effective are these methods at preventing minors' access to tobacco products through a non-face-to-face exchange?*

Numerous studies cited in Dr. Williams's comments demonstrate that minors can and do purchase cigarettes on the internet with little difficulty and that age verification protocols applicable to such transactions are ineffective in preventing such sales.

The comments submitted by Dr. Williams detail the results of a recently conducted study designed to investigate the ease with which minors can bypass online age verification programs used by the major tobacco company brand marketing websites allegedly to prevent youth access. The websites studied were not sites on which cigarettes could actually be purchased.

The results of the study indicate that participants were able to bypass the age verification programs used by R.J. Reynolds in 42% of their attempts. The websites sponsored by Philip Morris and Lorillard, in which subjects were required to provide driver's license numbers that

¹⁷ See, e.g., Figure 7, www.smokerjim.net (Accessed Nov. 30, 2011).

were evidently verified against databases, fared significantly better. However, the protocol for the study prohibited the subjects from using driver's license images found on Google and Yahoo search engines that would have allowed them to gain access to the websites. Dr. Williams's comments note that "the participants overwhelmingly said that not only could they easily gain access to their parents' IDs for use in bypassing online age verification, but they had no qualms about doing so." Moreover, similar studies conducted by Dr. Williams and her associates for alcohol vendors indicate that programs in which buyers were allegedly required to provide age verification upon delivery of the product were ineffective because the deliverers often did not actually require any such proof.

These results indicate that even the age verification programs presumed to be the most rigorous are easy to circumvent. The age verification programs utilized by internet sellers are typically considerably less sophisticated and are likely even less effective. Furthermore, while the FDA has established a nationwide system to monitor compliance with age verification requirements in face-to-face sales, no comparable system exists to monitor remote sales. Moreover, since many remote sellers are not licensed and many are or claim to be located outside the jurisdiction of state law enforcement officials, establishing effective compliance mechanisms remains a serious challenge.

b. *If these methods are not effective, which other technologies, procedures, or methods would work more effectively to prevent minors' access to tobacco products through a non-face-to-face exchange?*

Although improved enforcement of delivery restrictions and the use of "challenge questions" (as outlined in Dr. Williams's comments) might improve compliance somewhat, it is very questionable whether any age verification programs are capable of preventing widespread evasion of minimum age purchase requirements in non-face-to-face transactions. It is essential that the efficacy of age verification strategies be tested in actual use. FDA should require all remote sellers (including manufacturers) to provide documentation demonstrating that cigarettes and smokeless tobacco products are not being delivered to youth. Moreover, it should conduct its own independent investigations, in conjunction with the states, to identify violations and to develop an enforcement strategy. We strongly recommend that FDA undertake its own investigation to determine the efficacy of such programs. Such investigations should not place artificial limitations on strategies used to evade age verification. If these investigations reveal that such programs do not effectively eliminate a large share of purchases by underage users, FDA should give serious consideration to banning non-face-to-face sales of tobacco products. Whatever dubious benefits such sales may provide are likely strongly outweighed by the increased access they provide to tobacco products for underage purchasers.

d.¹⁸ *Is requiring an adult (whether or not the person who placed an order) to sign for the delivery of tobacco products adequate to ensure that tobacco product purchased through non-face-to-face exchange are not delivered minors? Or, is it necessary to require that the products be delivered only to the person who ordered them? Are there other requirements that could be placed on the delivery of tobacco products to prevent their delivery to minors?*

Any program requiring an adult signature for delivery of tobacco products would be ineffective if not rigorously enforced. FDA should devise methods to study compliance with delivery requirements. No requirement for adult signature should be presumed to be effective in the absence of evidence that a program requiring such a signature is actually being enforced. We also believe that the cigarettes should only be delivered to the adult who placed the order to minimize the risk that a youth will place an order and get a consenting adult to sign for them.

6. *What payment methods are used for the sale of tobacco products through non-face-to-face exchanges? Do these payment methods differ depending on the type of tobacco product purchased? If so, how?*

Dr. Williams's recent study indicates that, despite the state agreements with credit card companies, 82% of the 200 most popular online cigarette vendors in 2011 claimed to accept credit cards, a substantial increase over levels that had prevailed following the ATF prohibition on the use of credit cards.¹⁹ The widespread advertising of the availability of payment by major credit card indicates that the agreements negotiated by the States with major credit card companies (referenced supra, at note 10) may not be working. Substantial percentages reported accepting money orders, Western Union, bank transfers and other payment methods. We recommend that FDA conduct its own investigation to determine what payment methods are actually accepted in practice.

7. *To what extent are tobacco products sold through non-face-to-face exchange sold at substantially lower prices than the same types of tobacco products sold through a face-to-face exchange? Do the price differences vary depending on the type of tobacco product purchased? If so, how?*

There are dramatic differences in the prices charged for cigarettes purchased on the internet compared to those sold in face-to-face transactions. Prior to the enactment of the PACT Act, most internet sellers did not charge state excise tax and aggressively advertised this fact to potential buyers. For buyers in high-tax states, this difference amounts to a very high percentage of the total selling price. Some foreign internet sellers also evaded federal excise taxes as well. The result was that cigarettes could be purchased on the internet at prices far lower than those

¹⁸ The undersigned submit no response to question 5.c.

¹⁹ See, e.g., Figure 8, <http://www.cigarettes-outlet.com> (Accessed Nov. 30, 2011).

offered in face-to-face transactions. As noted above, the availability of cheap cigarettes on the internet nullifies one of the most effective tobacco control strategies: the use of taxation to discourage the purchase of tobacco products. Most of these sales were illegal under the Jenkins Act, 15 U.S.C. §§ 375-78, but the Jenkins Act was rarely enforced and was not an effective deterrent. The PACT Act amended the Jenkins Act to enhance the enforceability of these prohibitions.

The enactment of the PACT Act was designed to prevent such tax evasion. However, the injunction issued by the federal district court and affirmed by the Second Circuit in the *Red Earth* and *Gordon* cases and continued claims by sellers on tribal lands that they cannot constitutionally be required to collect state excise taxes for delivery sales makes leaves open the question whether the PACT Act will in fact be effective to accomplish this goal. The PACT Act will succeed only if the Postal Service effectively enforces its provisions and it is not clear that such enforcement has yet been made effective.²⁰

Moreover, shipment of tobacco products from foreign countries continues largely to evade detection. In the wake of the PACT Act it appears that many internet sellers have now located in other countries, where they continue to ship cigarettes to consumers in the United States while evading state and federal taxes. Some websites appear to have stopped selling cigarettes because of the ban on shipment of cigarettes through the US Postal Service,²¹ but anecdotal reports indicate that a considerable number of such shipments continue to get through. FDA should coordinate with other federal agencies, including the US Postal Service, to ensure that the most effective measures are introduced to ensure compliance.

FDA should use its primary role in tobacco regulatory policy to facilitate coordination of efforts by all federal agencies involved in the enforcement of the PACT Act. Coordination of the efforts of the US Immigration and Customs Enforcement (ICE), the US Postal Service and the ATF will be necessary for effective enforcement of the PACT Act.

8. *What means are used to deliver tobacco products sold to consumers through non-face-to-face transactions?*

Subsequent to the agreements of the major common carriers not to deliver cigarettes, the major form of delivery was through the USPS. Enactment of the PACT Act made delivery of cigarettes by the USPS illegal and all challenges to the validity of this provision have been dismissed. As noted above, although the prohibition has prompted some internet sellers to discontinue sales, anecdotal reports indicate that deliveries of tobacco products may continue to be made through the Postal Service in spite of the prohibition. As the leading agency for the development of tobacco control policy, FDA should take an active role in ensuring that the US

²⁰ Anecdotal reports indicate that packages containing cigarettes and smokeless tobacco continue to be delivered through the Postal Service.

²¹ See Figure 9, www.cheapcigarettesworld.com, announcing a temporary suspension of sales because of a Postal Service audit. (Accessed Nov, 30, 2011)

Postal Service and other agencies with responsibilities relevant to law enforcement with regard to non-face-to-face sales such as ATF and ICE are coordinating their efforts effectively.

We also understand that many shipments of cigarettes from internet sellers located abroad are being delivered to US customers by the USPS Existing procedures to identify shipments of cigarettes and interdict them before they are delivered to US customers appear to be ineffective. In its capacity as the lead federal agency with regard to tobacco control programs, FDA should work with the Postal Service to develop procedures that ensure that such shipments do not get through.

We also understand anecdotally that a number of internet sellers located on Indian reservations are in the process of developing independent delivery networks designed to permit them to continue to make delivery sales without relying on delivery by common carriers or the US Postal Service. For example, one internet seller advertises “BEAT the PACT Act. Get Cheap Cigarettes and Tobacco with NO STATE TAXES. NO REPORTS to Anyone EVER. Cigarettes DELIVERED directly to your door.”²² (Emphasis in original) It claims that its selling device, an alleged “cigarette buyers club,” is “legally IMMUNE to reporting requirements.” (Emphasis in original). At least some of these sellers also take the position that they are not subject to any requirement to collect state excise tax. One internet seller advertises “Tax Free Cigarettes delivered the same day of purchase”²³ and an affiliated site brags, “We do not collect sales tax. Nor do we report tax or customer information to any government agency or other entity.”²⁴ FDA should effectively monitor efforts of such sellers to create independent delivery networks in order to prevent such schemes from undermining federal tobacco control policy and ensure that appropriate law enforcement actions are taken in response to such challenges. FDA should consult with the Department of Justice about the appropriateness of using mail fraud statutes to prosecute sellers who misrepresent their alleged immunity from tax and reporting obligations.

9. *What strategies, if any, are used by tobacco product manufacturers to ensure that their tobacco products are not sold or distributed to minors through non-face-to-face exchanges by parties other than the manufacturer?*

We do not have information on such strategies. At a minimum FDA should require all remote sellers to provide it with information on the strategies they use, along with documented evidence that is satisfactory to FDA that such strategies are universally applied and that independently validates whether and to what extent they are effective.

²² See Figure 10, www.nativeblend.net (Accessed Nov. 30, 2011).

²³ See Figure 11, www.totalsmokes.com (Accessed Dec. 1, 2011).

²⁴ See Figure 12, www.nativeamericancigarettes.com (Accessed Dec. 1, 2011)

- a. *Do tobacco product manufacturers verify the effectiveness of these strategies? If so, how?*

Current remote sellers do not provide such information. FDA should require them to provide FDA documentation of all remote sales as well as information on how they verify the age of the buyer and the age of the person to whom the cigarettes are delivered. The sellers should be required to provide this information in a manner to allow the FDA to run independent checks to verify the information. In addition, FDA and the states with which it has contracted should be required to run their own independent checks just as they do for face-to-face sales.

- b. *Are there any data available to verify the effectiveness of these strategies? If so, what are they?*

Currently remote sellers do not provide such data but should be required to do so. Given the substantial information about the ineffectiveness of strategies pursued by internet vendors that is summarized in the comments submitted in this docket by Dr. Ribisl, there is solid evidence that the tobacco product manufacturers' and sellers' strategies to prevent such sales or such deliveries cannot be considered effective.

10. *How can FDA most effectively partner with other Federal agencies and State, local, territorial and tribal governments to prevent the sale and distribution of tobacco products to minors through non-face-to-face transactions?*

As noted above, it is important for FDA to recognize that there is no compliance program in effect for remote sales comparable to FDA's compliance program for non-remote sales. The evidence related to non-remote sales is clear: in the absence of rigorous, sustained compliance efforts, violations of the law inevitably increase.²⁵ The failure to police non-face-to-face transactions and ensure that age verification requirements are being met and state taxes collected as required by federal law will undermine federal tobacco control policy. As the lead agency charged with development and implementation of federal tobacco control policy, FDA should act to ensure that there is, at a minimum, a comprehensive enforce plan governing remote sales and appropriate coordination among the efforts of various instrumentalities of the federal government charged with enforcing the provisions of the PACT Act to ensure that the Act is effectively enforced. This will involve regular contact and coordination with the ATF, ICE, and the USPS and critical evaluation of the success of their efforts.

It is also important for FDA to coordinate with state officials charged with collecting state excise tax on delivery sales. In doing so, FDA should recognize that evasion of state tax laws not only deprive states of revenues, but also that the availability of tobacco products at prices that do not reflect payment of such taxes seriously undermines federal tobacco control

²⁵ No Sale: Youth, Tobacco and Responsible Retailing, Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors, Findings and Recommendations of a Working group of State Attorneys General, December 1994.

policy. Effective enforcement of state excise tax laws is a priority not only for the States, but for the implementation of federal tobacco control policy as well. FDA can coordinate its activities with state law enforcement officials in developing sting operations both with regard to age verification and tax collection. FDA is already cooperating with State officials with regard to age verification in retail face-to-face transactions. It is necessary to extend this cooperation to non-face-to-face transactions as well. As recommended elsewhere in these comments, FDA investigation should involve sting operations designed to be a realistic test of the ability of minors to purchase cigarettes in remote transactions and to document the procedures used for delivery and payment. In addition, remote sellers should be required to maintain and make available to FDA all sales and delivery records. Drs. Ribisl and Williams have done extensive work researching and documenting remote sales. We recommend that FDA make use of their expertise in fashioning an implementation plan.

B. Advertising, Promotion and Marketing of Tobacco Products

11. What forms of advertising, promotion, and marketing are used to promote the sale of tobacco products through non-face-to-face exchanges?

The major tobacco companies have a substantial presence on the internet.²⁶ Spending by the major tobacco companies on internet marketing and company websites has increased dramatically. According to the FTC, spending on such promotional activities for cigarettes and smokeless tobacco rose from \$125,000 in 1998 to \$17.8 million in 2008, the latest year for which figures are available.²⁷ The current figure is not available and is likely far higher. Although federal law bars advertisements for cigarettes and smokeless tobacco on communications media regulated by the Federal Communications Commission (FCC), the FCC has not taken action with regard to tobacco advertising on the internet. Since 93% of youth and young adults use the internet and more than half go online daily, this channel of communication is potentially an important avenue of communication to the youth market. Moreover, 73% of teenagers and 83% of young adults use social networking sites.²⁸

In recent years, all the major tobacco companies have launched websites for the major tobacco brands. These websites not only show current products, but also provide an array of entertainment features such as games, contests, popular music, videos, interviews, and other

²⁶ See Campaign for Tobacco-Free Kids, *Tobacco Product Marketing on the Internet*, http://www.tobaccofreekids.org/facts_issues/fact_sheets/policies/internet/.

²⁷ U.S. Federal Trade Commission (FTC), *Cigarette Report for 2007 and 2008*, 2011, <http://www.ftc.gov/os/2011/07/110729cigarettereport.pdf>. See also, FTC, *Smokeless Tobacco Report for 2007 and 2008*, 2011, <http://www.ftc.gov/os/2011/07/110729smokelesstobaccoreport.pdf>. Data for top 5 manufacturers only.

²⁸ Lenhart, A., et al., *Social Media and Young Adults*, Pew Internet Project, Feb. 3, 2010. <http://www.pewinternet.org/~media/Files/Reports/2010/PIP>

content. As noted above in response to questions 3 through 5, access to these websites is theoretically restricted to adults, but age verification varies from company to company.

The comments of Dr. Williams provide detailed information on advertising and promotion of non-face-to-face sales of tobacco products. These comments demonstrate the many new channels of communication available to online sellers and the unique advantages enjoyed by sellers who have an electronic link with their customer base. Internet vendors have a greatly enhanced ability to communicate directly with their customers by email, obtain large amounts of information from them, and encourage peer-to-peer communications. Dr. Williams's research indicates that half the internet cigarette vendors offered mechanisms for customers to refer friends to their sites and 21% of vendors included social media sharing links.

Dr. Williams's comments include data from a 2004 CDC study showing that 34.1% of middle school students and 39.2% of high school students reported seeing advertisements for tobacco products on the internet.²⁹ That percentage is probably much higher today.

In addition to internet promotions directly operated by internet sellers and by major tobacco companies, numerous social network sites promoting various brands are available. Pages have been established on Facebook for numerous tobacco products, including most of the brands of the major tobacco companies. Moreover, pro-tobacco videos are widely available in videos on YouTube.³⁰ A recent study by the Minnesota Department of Health found that 17.1% of middle school students and 26.3% of high school students have seen videos or clips showing smoking on YouTube or similar sites and that 17.4% of middle school students and 20.2% of high school students have seen Facebook pages or groups for tobacco products.³¹ Tobacco manufacturers should be required to provide information to the FDA stating whether they directly or indirectly have any connection or in any way support these websites and social

²⁹ Centers for Disease Control and Prevention. Tobacco use, access, and exposure to tobacco in media among middle and high school students—United States 2004. *Morbidity and Mortality Weekly Report* 2005;54:297-301.

³⁰ Freeman, B & Chapman, S, "Is 'YouTube' telling or selling you something? Tobacco content on the YouTube video-sharing website," *Tobacco Control* 16:207-10, 2007. Forsyth, SR & Malone RE, "'I'll be your cigarette--light me up and get on with it': examining smoking imagery on YouTube," *Nicotine & Tobacco Research* 12(8):810-6, August 2010. Elkin, L & Thomson, G, "The extent of YouTube videos with smoking and smokefree words," *The New Zealand Medical Journal* 123(1311):93-4, March 19, 2010. Elkin, L, Thomson, G, & Wilson N, "Connecting world youth with tobacco brands: YouTube and the internet policy vacuum on Web 2.0," *Tobacco Control* 19(5):361-6, October 2010. Kim, K, Paek, HJ, & Lynn, J, "A content analysis of smoking fetish videos on YouTube: regulatory implications for tobacco control," *Health Communication* 25(2):97-106, March 2010. See also, Center for Media Education (CME), *Youth Access to Alcohol and Tobacco Web Marketing: The Filtering and Rating Debate*, October 1999, and prior CME reports. See also, Hong T & Cody MJ, "Presence of Pro-Tobacco Messages on the Web," *Journal of Health Communication* 7(4):273-307, July-Sept 2002.

³¹ Minnesota Department of Health, *Teens and Tobacco in Minnesota, 2011 Update, Results from the Minnesota Youth Tobacco and Asthma Survey, December, 2011*
<http://www.health.state.mn.us.divs/chs/tobacco/FullReport2011.pdf>.

network postings or whether, as owners of the trademarks for their brands, they have taken action to prevent the unauthorized use of their trademarks.

FDA should conduct regular inspections that include underage youth to determine the ease of their access to these online promotions of cigarettes to determine the extent to which such promotion reaches an underage audience and promote attempts by minors to buy cigarettes electronically. Moreover, FDA should expand its investigation to determine the extent to which tobacco companies are involved in the creation of websites and other social network sites associated with particular brands and the extent to which such websites are accessed by minors. Tobacco manufacturers should be required to verify that they have no involvement in and do not authorize any such websites and to document the actions they have taken to prevent others from using their trademarks.

12. How are the Internet, e-mail, direct mail, telephone, smartphones, and other communication technologies used to direct tobacco product advertising, marketing and promotion messages to specific recipients?

Detailed information on the use of these technologies to promote tobacco products is not available to the public. FDA should require the tobacco manufacturers to provide FDA with the information in its possession. Such technologies are widely used by the underage population and systematic study by the FDA of how such technologies are being used is relevant in formulating appropriate regulatory policy. The promotional programs utilized by the major tobacco companies through their brand marketing websites and described by Dr. Williams in her response to this question are likely to appeal to adolescents. FDA should regularly monitor these websites to ensure that they are not misused.

13. What technologies, procedures or other methods are currently used by the tobacco industry (including, but not limited to, manufacturers, importers, distributors, and retailers) to restrict or minimize a minor's exposure to the forms of advertising, promotion, and marketing of tobacco products described in questions 11 and 12?

As indicated by Dr. Williams's comments, internet cigarette vendors have not widely implemented effective age verification procedures to restrict or minimize the exposure of minors to advertising, sale, and intense promotion of tobacco products. FDA should conduct its own investigation to determine the exposure of minors to such promotional efforts and take the regulatory steps necessary to prevent such promotion from reaching youth. FDA should require tobacco manufacturers to provide it with detailed information about what they are doing and what their marketing and research departments have developed and what information developed by others they possess or are aware of. In developing such a program, FDA should make use of information developed by the promotional and market research departments of the tobacco companies themselves. If, as expected, such an inquiry concludes that the availability and promotion of tobacco products in non-face-to-face transactions contributes to tobacco usage by

minors, FDA should determine whether the implementation of an effective tobacco control program can be accomplished without requiring that all sales of tobacco products be made in face-to-face transactions.

14. Given the rapid growth of social media (e.g., Facebook, Twitter, YouTube, etc.), how can minors' exposure to tobacco product advertising, promotion and marketing through these types of media be restricted or minimized?

Given the availability of these media, their popularity with adolescents, and the tobacco industry's long history of innovative strategies of marketing its products to a youth audience, FDA should first develop a strategy for monitoring youth exposure to tobacco product advertising, promotion and marketing in these and other media and, based on careful analysis of its findings, develop appropriate regulations to ensure that the industry is not marketing its products to youth. FDA should also require tobacco manufacturers to report what they know about communications on social media, what actions they are taking to communicate on social media, what measures they are taking to prevent youth access from promotional messages on social media, and what evidence they have concerning the effectiveness of these measures.

Sincerely,

American Academy of Family Physicians

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Association of State and Territorial Health Officials

Campaign for Tobacco-Free Kids

Legacy