

**COMMENT ON THE NEED FOR FDA TO ELIMINATE THE EXEMPTION
FOR INTERNET SALES OF DEEMED PRODUCTS TO YOUTH**

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We were troubled to find that the FDA buried in the Paperwork Reduction Act of 1995 section of the proposed deeming rule (79 FR 23142 at p. 23184) a gigantic exemption to its minimum age and identification restrictions for covered tobacco products: internet sales. **This exemption should be removed and replaced with appropriate auditable rules for ensuring face-to-face delivery of tobacco products that are ordered over the internet.**

In addition to extending the agency’s tobacco authority to cover additional products, including e-cigarettes and cigarillos popular among young people, FDA also proposed restrictions requiring retailers to verify by means of photographic identification that buyers of tobacco products are at least 18 years of age. With much fanfare, FDA touted these new proposed rules as a way “to prevent sales to underage youth” and to “reduce the public health burden of tobacco use on the American public, including youth.” (FDA press release, April 24, 2014) However, the proposed rule includes an exception for “mail-order sales” which are permitted without the age verification requirements set forth in proposed section 1140.14(b)(2)(i) for newly covered tobacco products and which are also an exception to the age verification requirements and “direct, face-to-face exchange” requirements set forth in sections 1140.14(a)(2)(i) and 1140.14(a)(3) for cigarettes and smokeless tobacco.

FDA states that the goal of the proposed minimum age and identification restrictions is to “reduce youth initiation of tobacco use, thereby reducing the number of people who suffer from tobacco-related illnesses and death” (FR 23160). However, this goal cannot be achieved if FDA does not restrict internet sales of newly covered products such as e-cigarettes which are aggressively marketed and sold online to youth.

Proposed sections 1140.14(a)(3) and (b)(3) would prohibit retailers from using any “electronic or mechanic device (such as a vending machine)” (FR 23204). Explaining its reasoning for this, FDA states that “because the proposed rule would prohibit retailers from selling covered tobacco products to individuals without verifying that they are at least 18 years of age, FDA believes *it would not be logical* to allow such individuals to purchase such products from vending machines or other mechanical devices.” (emphasis added, FR 23178) Nevertheless, FDA defies logic and allows such individuals to easily purchase these products via the Internet without face-to-face exchanges and without sufficient age verification.

Although FDA is deafeningly silent about Internet sales in the sections of the proposed rule where vending machine sales are discussed (FR 23160-162, 23178, 23204), it sneaks in a brief note in the “Paperwork Reduction Act of 1995” section that “this prohibition on sales from electronic or mechanical devices is *not intended to impact the sale of any tobacco product via the Internet*” (emphasis added, FR 23184).

The seemingly contradictory messages found in the proposed rule have created confusion, leading major news media to interpret the proposed rule differently, with the NY Times initially reporting that internet sales would be prohibited by the proposed rule (<http://www.nytimes.com/2014/04/24/health/fda-will-propose-new-regulations-for-e-cigarettes.html?emc=eta1>), and the Washington Post reporting that internet sales would be allowed under the proposed rule (http://www.washingtonpost.com/national/health-science/fda-outlines-plan-to-regulate-e-cigarettes/2014/04/23/4e7c8684-ca39-11e3-93eb-6c0037dde2ad_story.html).

The dirty little secret is found in existing section 1140.16(c)(2)(i) which provides that although retailers may not sell tobacco products in vending machines or self-service displays because these products may only be sold in a “direct, face-to-face exchange between the retailer and the consumer,” (section 1140.16(c)), “mail-order sales” are a permitted method of sale and an explicit exception. FDA explicitly preserves this exception in the proposed rule in sections 1140.14(a)(2)(i) and 1140.14(b)(2)(i).

Although originally FDA proposed to prohibit mail-order sales, in its final rule published on August 28, 1996, FDA relented and made an except for mail-order sales in response to comments from customers in rural and “isolated areas” such as prisons that eliminating mail-order sales would eliminate a convenient source of cancer sticks for them (61 FR 44396 at p. 44459, <http://www.gpo.gov/fdsys/pkg/FR-1996-08-28/pdf/X96-10828.pdf>) and that there was “inadequate evidence demonstrating that young people use mail-order sales” because, among other reasons, that are not “patient enough to wait several weeks to obtain tobacco products.” (FR 44458, 44459)

Things have changed a bit in the nearly 20 years since FDA enacted this rule, and the Sears-Roebuck catalog has been replaced by the Internet as the predominant way people, especially young people, buy merchandise. And while patience may be a virtue, Amazon Prime guarantees two-day delivery, and gives students this service for free for the first six-months. Nevertheless, FDA’s reasoning for not prohibiting mail-order sales in 1996 apparently reflects their current “thinking” as well, since FDA refers to this rationale in its “Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” published in August 2013 (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm>, at page 20, footnote 32).

Internet and social media marketing of tobacco products, including the more recent addition of e-cigarettes and other new products, is exploding, causing Internet sales of e-cigarettes and other tobacco products to skyrocket. (Herzog, B., & Gerberi, J.

(2013). *Equity research: E-Cigs revolutionizing the tobacco industry*. New York: Wells Fargo Securities.)

The Internet serves as a significant means of acquiring these products, and is likely the predominant means of purchase for young people, where age verification is virtually non-existent or meaningless. An American Journal of Public Health study reported that almost 20% of cigarette-selling websites do not say sales to minors are prohibited, more than half require only that the buyer say they are of legal age (e.g., by clicking a button that says “I am over age 18”), another 15% require only that the buyer types in their date of birth, and only 7% require any driver’s license information. (Ribisl, K, et al., “Are the Sales Practices of Internet Cigarette Vendors Good Enough to Prevent Sales to Minors?,” *AJPH* 2002; 92(6):940-41).

Attorneys general from at least 15 states have conducted Internet stings and found that children as young as 9 years old were able to purchase cigarettes easily, with a New York sting operation finding that 24 of 26 websites sold to kids under 18. (Unger, JB, et al., “Are adolescents attempting to buy cigarettes on the Internet,” *Tobacco Control* 2001; 10:360-63 [citing Sherer, R, “States crack down on Web tobacco sales,” *The Christian Science Monitor*, Nov. 8, 2000 and ABC News, “Getting smokes online: Children buying cigarette with click of mouse,” March 6, 2001.]

A JAMA study found that more than 96% of minors aged 15-16 were able to find an Internet cigarette vendor and place an order in less than 25 minutes, with most completing the order in seven minutes. (Jensen, JA, et al., “Availability of tobacco to youth via the Internet,” *JAMA* 291(15):1837, April 21, 2004.)

A study of 101 Internet websites selling tobacco products in California found that none of them complied with the California state laws regarding age and ID verification to stop sales to kids. (Williams, RS, et al., “Internet cigarette vendors’ lack of compliance with a California state law designed to prevent tobacco sales to minors,” *Archives of Pediatrics and Adolescent Medicine* 2006; 160:988-989.)

In a recent survey of popular e-cigarette manufacturers reported by the staff of several U.S. Congressional leaders, seven of the nine surveyed companies sell their products online, and there was wide variation in the use of age-verification to limit access to their websites and to purchase their products, with three companies allowing access to their sites without any age verification or confirmation at all, and three companies requiring buyers to merely click a button verifying that they are at least 18 years old. (Durbin, R., Waxman, H., Harkin, T et al. *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*. April 14, 2014. Available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Report-E-Cigarettes-Youth-Marketing-Gateway-To-Addiction-2014-4-14.pdf>).

The National Youth Tobacco Survey includes a question asking respondents if they’ve bought tobacco products online in the past 30 days. In 2012, about 85,000 teens

(.2% of the 42.4 million 10-19 year-olds in the U.S.) reported buying cigarettes, cigars, and smokeless tobacco online in the past month. (That's 1 million kids buying tobacco products online in 2012.)

Because of expanding use of the internet and aggressive internet marketing of e-cigarettes, that number is almost certainly much larger today.

FDA's exception for internet sales in its newly proposed restrictions supposedly aimed at preventing youth sales demonstrates either a complete misunderstanding of youth purchasing behavior, or a cynical bowing to industry pressures to leave this lucrative source of e-cigarette and other tobacco product sales intact.

The FDA needs to remove this loophole from its final rule and, instead, require that internet sales of all tobacco products be subject to the same-face-to-face verification that the FDA proposes for all other sellers.

To do this, the FDA should require that all internet sales require a that vendors obtain a certified receipt (at the vendor's expense) from the delivery agency that indicates:

1. The company providing the product and the nature of the products supplied.
2. The addressee receiving the product.
3. The person who signed for the product.
4. The person who delivered the product.
5. The specific form of identification that was used by the delivery agent to verify the age of the recipient.

This receipt would then be returned to the vendor (at the vendor's expense) and the vendor required to maintain these records, together with sales records, for a period of 5 years where they could be inspected and audited by the FDA and other law enforcement officials (such as state attorneys general).

If this process is deemed too burdensome, the FDA could, of course, simply ban internet sales.