Decreasing youth tobacco use is a significant public health priority. In the U.S., nearly one in 15 middle school students and one in four high school students were current tobacco users in 2012, and 5.6 million youth aged under 18 years today are projected to die prematurely from smoking-related disease. The Family Smoking Prevention and Tobacco Control Act (FSPTCA), signed into law on June 22, 2009, amended the Federal Food Drug and Cosmetic Act (FD&C Act) to provide the U.S. Food and Drug Administration (FDA) with the authority to regulate the manufacturing, distribution, and marketing of tobacco products to protect public health. In writing the Act, Congress recognized the critical importance of adolescent tobacco use in propagating the tobacco use epidemic, noting that “the use of tobacco products by the Nation’s children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults” and “virtually all new users of tobacco products are under the minimum legal age to purchase such products.”

The protection of adolescents is also reflected in the standard that the FDA must use in the regulation of tobacco products. Unlike the “safe and effective” standard used to regulate drugs and devices, the FDA is required to use a population health standard to regulate tobacco products. This standard requires the FDA, in making regulatory decisions, to assess not only the impacts on current tobacco product users but also those on never users and former users. One of the earliest regulatory actions of the FDA was the issuance of a final rule restricting the sale and distribution of cigarettes and smokeless tobacco. This rule, intended to protect children and adolescents, set a minimum age of purchase; restricted the sale of non-face-to-face purchases; and prohibited the sale of single cigarettes; free samples of cigarettes (and restricted free samples of smokeless tobacco); tobacco brand name sponsorship of sporting, cultural, and musical events; and the sale or distribution of non-tobacco items with tobacco brands or logos.

In February 2014, the FDA also launched its first youth tobacco prevention campaign, “The Real Cost.” This campaign targets at-risk youth aged 12–17 years who are susceptible to smoking or already experimenting with cigarettes. The objective of the campaign is to educate these at-risk youth about the harmful effects of tobacco use in order to build awareness, change attitudes and beliefs, alter behavioral intent, and ultimately reduce current smoking among adolescents. Additional campaigns are planned, including one aimed at rural smokeless tobacco users, a multicultural campaign, and a campaign aimed at the lesbian, gay, bisexual, and transgender communities.

FDA and CDC Partnership to Enhance Youth Tobacco Surveillance

Monitoring and assessing tobacco use and the factors that influence use among youth will help inform effective programs, policies, and regulations for tobacco use prevention and control. In order to inform and monitor the impact of the FDA’s efforts and assess progress toward achieving one of its core public health goals, preventing youth tobacco use, the FDA entered into a partnership with the CDC to expand the National Youth Tobacco Survey (NYTS). The NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use and its correlates. The CDC, the lead public health surveillance agency in the U.S., has conducted the NYTS on a regular basis since 1999. These data have been used to inform and evaluate the CDC’s National Comprehensive Tobacco Control Program, inform progress toward achieving Healthy People 2020 goals related to tobacco and youth, provide data to inform the USDHHS’s
Tobacco Control Strategic Action Plan, and provide national benchmark data for state-level Youth Tobacco Surveys and comparison with the international community through the Global Youth Tobacco Survey.

In collaboration with the CDC, the FDA identified the need for comprehensive, annual data on tobacco use among youth to help inform and evaluate the impacts of FDA tobacco regulatory activities. In order to minimize unnecessary duplication and redundancy, the FDA and CDC are collaborating to leverage this surveillance system for our nation’s public health goals by moving to annual surveys. The annual fielding has resulted in the ability to timely identify emerging trends, such as the increased use of electronic cigarettes (e-cigarettes) observed between 2011 and 2012.1

In 2012, the FDA and CDC introduced questions to the survey specifically related to FDA’s regulatory authority, including more detailed information on the use of non-conventional (e.g., e-cigarettes, hookah) tobacco products, curiosity about cigarettes, cigars, and smokeless tobacco, tobacco dependence symptoms, quitting intentions and behaviors around all tobacco products, harm perceptions of conventional and non-conventional products, and awareness and perception of product warning labels. The studies presented in this supplement reflect a focus on these questions of particular relevance to informing federal tobacco product regulation.

**Highlights from the Supplement**

The findings reported in this supplement highlight the changing landscape of tobacco product use among U.S. adolescents in middle and high school. The majority of middle and high school current tobacco users report past 30-day use of more than one product. This high degree of polytobacco use has important implications for the likelihood of maintaining tobacco use into adulthood. Apelberg et al.2 examined the prevalence of four symptoms of tobacco dependence in adolescent tobacco users and found that polytobacco use was one of the most consistent predictors of reported symptoms, after controlling for frequency of use, age at first use, and demographic factors. Apelberg and colleagues4 also report results consistent with a growing body of evidence that symptoms of tobacco dependence can arise even among recent-onset and intermittent adolescent users. Among adolescent cigarette, cigar, and smokeless tobacco users, more than half reported at least one symptom of tobacco dependence, representing 2 million middle and high school students. Significant differences in symptom reporting were found when comparing those who used on as few as 3–5 days compared with 1–2 days in the past month. These findings highlight the need for tobacco prevention efforts aimed both at non-users and experimenters in order to prevent tobacco use.

The findings presented in this supplement also point to the growing concern surrounding the use of non-cigarette tobacco products. Presently, the FDA has regulatory authority over cigarettes, smokeless tobacco, and roll-your-own tobacco. In April 2014, the FDA issued a proposed rule to extend its authority over all other tobacco products, including cigars, hookah, and e-cigarettes. Cigars are the second most widely used tobacco product among youth and, among certain subgroups (e.g., female non-Hispanic blacks), is more prevalent than cigarette smoking. Corey et al.5 report on the high burden of cigar use among U.S. youth in 2012, finding that the inclusion of cigar brand names on the survey questions may have improved ascertainment of cigar smoking. In addition, Portnoy and colleagues6 report that about one in five adolescents who had never used tobacco products were curious about the use of cigars, a predictor of future susceptibility, experimentation, and regular use.

Recent studies conducted using the NYTS have raised public health concerns about the increase in e-cigarette use in youth7 and the high degree of dual use with cigarette smoking.8 Wang et al.8 build on this work by characterizing patterns of e-cigarette use in the context of other non-conventional products and highlight the widespread awareness of e-cigarettes among youth. Ambrose and colleagues10 examined perceptions about the harm of e-cigarettes, finding that one in three students perceived these products as less harmful than conventional cigarettes and a significant association between ever use of e-cigarettes and lower perceptions of risk. The authors also found that youth who perceive the harmfulness of conventional cigarettes as dose-dependent were more likely to perceive e-cigarettes as less harmful, which may make them susceptible to future e-cigarette experimentation and use, either alone or in conjunction with cigarettes. Wang et al.9 also found a high degree of awareness of hookah among youth and prevalence of ever and current hookah use that exceeded both e-cigarettes and conventional smokeless products. Tworek and colleagues11 found that hookah users were the least likely to intend to quit tobacco and make a past year quit attempt among all tobacco product users, which may suggest a lack of awareness of the harmfulness of these products among youth.

The FDA’s tobacco regulatory authority includes authority over the marketing and labeling of tobacco products, including tobacco product warning labels. In this supplement, Tessman et al.12 find that youth
continue to be exposed to tobacco promotions, including direct mail coupons, which serve both as a source of marketing and price discounting. Exposure to tobacco marketing has consistently been associated with youth susceptibility, and, in Portnoy and colleagues’ study, was found to be associated with curiosity to use cigarettes, cigars, and smokeless tobacco. Finally, Johnson et al. report on youth exposure to cigarette and smokeless tobacco product warning labels, finding that less than half of adolescents who saw a pack reported high exposure to the warnings and less than one third who saw a warning reported that it made them think a lot about health risks. These findings are consistent with the widely held belief that current warning labels are not as effective as they could be and that strengthening the warning labels would benefit public health.

Conclusions
The FD&C Act provides the FDA with important new regulatory tools to reduce the toll of tobacco use in the U.S., which can complement recommended tobacco control efforts at the local, state, and national level. Given that the overwhelming majority of adult tobacco users began using as youth, preventing youth tobacco use remains a major public health priority. The FDA and CDC are collaborating to leverage the NYTS to meet the nation’s public health goals by collecting national data on tobacco susceptibility, experimentation, and use among middle and high school students, along with the factors that influence use, such as exposure to tobacco marketing and health warnings, harm perceptions, and symptoms of tobacco dependence. The studies presented in this supplement highlight areas of particular relevance to the FDA’s regulatory authority and add to the evidence base to inform tobacco regulatory science and tobacco control efforts nationwide.

Publication of this article was supported by the U.S. Food and Drug Administration, Center for Tobacco Products.

The authors thank Rebecca Bunnell, Catherine Corey, Corinne Husten, and Brian King for their thoughtful review and comments.

No financial disclosures were reported by the authors of this paper.

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