Report to Congress

on the

Study on Raising the Minimum Age to Purchase Tobacco Products

Department of Health and Human Services
Food and Drug Administration

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Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize the Food and Drug Administration (FDA or the Agency) to regulate the manufacture, marketing, distribution, and sale of regulated tobacco products and protect the public from the harmful effects of tobacco product use. The Tobacco Control Act was enacted in 2009 and required the Agency to establish the Center for Tobacco Products (CTP or the Center) to implement the new law. The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco as well as the authority to regulate additional tobacco products by issuing a regulation. The Tobacco Control Act also obligated FDA to convene an expert panel to study the public health implications of raising the minimum age to purchase tobacco products. The Agency contracted with the Institute of Medicine (IOM) in 2013 to convene a committee to examine existing literature on tobacco use initiation and to use modeling and other methods as appropriate, to predict the likely public health outcomes of raising the minimum age to purchase tobacco products to 21 years and 25 years. The Committee was empanelled on February 4, and April 10, 2014, with 13 experts in public health law, epidemiology relating to tobacco use and risks, adolescent and young adult development, risk behaviors and perceptions, public health policy and practice, and public policy modeling. IOM released a report to FDA and the public in March 2015. This report provides a summary and discussion of the results of that expert panel, pursuant to the requirements of Section 104(1) and (2) of the Tobacco Control Act.

Table of Contents

Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to regulate the manufacture, marketing, distribution, and sale of regulated tobacco products and protect the public from the harmful effects of tobacco product use. The Tobacco Control Act was enacted by Congress in 2009 and required FDA to establish the Center for Tobacco Products (CTP or the Center) to implement the new law. The law required FDA to regulate tobacco within a different context than the one used to regulate other products in FDA, such as pharmaceuticals and medical devices, because tobacco is inherently harmful when used as intended. This new context is one that takes into consideration the impact of tobacco products on the health of the public as a whole, including users and nonusers, which has been referred to as the "public health standard." In addition, the law required FDA to re-issue, with certain exceptions, the "1996 Rule" (21 CFR Part 1140), which includes, among other important provisions, a minimum age of 18 years old to purchase cigarettes and smokeless tobacco products. Other areas of the law outline FDA's authority to regulate new products as well as those products currently on the market.

The Tobacco Control Act also requires FDA to report to Congress on various aspects of its work at specific intervals. This report addresses the requirement in Section 104 (1) and (2) of the Tobacco Control Act.

Section 104 (1) and (2) states:

The Secretary of Health and Human Services shall—

(1) convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products; and

(2) not later than 5 years after the date of enactment of this Act, submit a report to the Congress on the results of such study.[1]

In response to the this requirement, the Agency contracted with the Institute of Medicine (IOM) to convene an expert panel to study the public health implications of raising the minimum age to purchase tobacco products. This report is a summary and discussion of the IOM study, which IOM published on March 12, 2015, and is available at http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx.

Public Health Significance

There is more than 50 years of research demonstrating that tobacco products are dangerous and that use of these products causes serious health issues such as cancer, heart disease, lung diseases, premature births and other conditions. Cigarettes alone kill more than 480,000 Americans every year.[2] The use of these products is especially dangerous for children due to the impact of nicotine and smoke exposure on their growth and development as well as the risk that

[1] Family Smoking Prevention and Tobacco Control Act, Section 104(1) and (2).

[2] The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General 2014

many may become long-terms users due to the addictiveness of the products. Research has found that virtually all new users of tobacco products are under the age of 30. Youth generally start buying tobacco products as they become more regular users. Fifty-four percent of smokers, who ever had smoked daily, started smoking daily before age 18, 85 percent before age 21, and 97 percent before age 26.[3] Thus restricting access during this critical transition period has the potential to reduce the prevalence of daily use.[4]

Congress has acknowledged that the lack of legal and regulatory authority by the federal government and states prior to enactment of the Tobacco Control Act contributed to the adverse public health and societal issues created by tobacco use. This was especially evident in the increased use of traditional (cigarettes) and novel (electronic cigarettes, hookah, etc.) tobacco products by young people.

In recent years, a greater proportion of first cigarette use is occurring among young adults.[5,6] In addition, older adolescence and young adulthood is often the time of transition to daily use. Because of this continued initiation in young adulthood, the prevalence of tobacco use is highest among young adults (compared to adolescents and older adults).

The 2014 Report of the Surgeon General on the Health Consequences of Smoking, predicted that, at the current rate of smoking, 5.6 million Americans currently under the age of 18 will die prematurely from a smoking-related illness. The report also acknowledged that since the first Surgeon General's Report on tobacco in 1964, more than 20 million Americans have died from smoking-related illnesses.[7] While smoking rates have declined,[8] estimates of premature deaths associated with smoking have increased because of additional diseases found to be causally related to smoking. Smoking-related illnesses affect not only people who smoke, but also those exposed to second-hand smoke.[9] In addition to the issue of tobacco smoke exposure, young people are at an additional risk due to nicotine exposure. The literature demonstrates that exposure to nicotine has an adverse effect on the brain during adolescence, a critical time of development. This has lifelong implications.[10]

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[3] Institute of Medicine. (2014). Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products. Retrieved on March 25, 2015 from http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx

[4] DiFranza JR, Savageau JA, Fletcher KE. Enforcement of underage sales laws as a predictor of daily smoking among adolescents – a national study. BMC Public Health. 2009; 9:107.

[5] Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2004 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2005. http://media.samhsa.gov/data/NSDUH/2k4nsduh/2k4tabs/Sect4seTabs1to50.htm#tab4.25d. Accessed January 5, 2016.

[6] Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality; 2015. http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf. Accessed January 5, 2016.

[7] The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General 2014

[8] Ibid.

[9] Ibid.

[10] Ibid.

The Tobacco Control Act provides FDA with broad authority to regulate the manufacture, sale, and distribution of regulated tobacco products. However, the law also includes some limitations on the agency's authority. This includes provisions prohibiting FDA from banning face-to-face sales of any tobacco product by a specific category of retail outlets, as well as those that prevent FDA from raising the minimum age of sale of tobacco products above 18 years of age.[11]

Institute of Medicine Study Process

In August 2013, the Agency contracted with the Institute of Medicine (IOM) to convene a committee to:

1. examine existing literature on tobacco use initiation; and
2. use modeling and other methods, as appropriate, to predict the likely public health outcomes of raising the minimum age for purchase of tobacco products to 21 years and 25 years.

IOM is a part of the National Academies, which includes the National Academies of Sciences, the National Academy of Engineering, and the National Research Council. These groups comprise a 140 year old institution that has provided objective and scientific opinions and advice to the nation in various capacities. The members of the National Academies organizations are professionals in various scientific fields, who are called upon to provide their expertise to objectively answer rigorous scientific questions. The primary financial sponsors of the National Academies research are federal agencies, states, and foundations. The National Academies have processes in place to ensure that financial sponsors of a National Academies study have no influence on the study process and the results.

When studies are commissioned by agencies, IOM employs the National Academies' four-stage study process, which includes: Defining the Study, Committee Selection Approval, Committee Work (public meetings, information gathering, deliberations, and drafting the report), and Report Review. This is a standard format for all studies conducted by any organization within the National Academies.

The IOM Committee on the Public Health Implications of Raising the Minimum Age for Purchasing Tobacco Products was assembled to address these tasks and was comprised of experts in public health law, epidemiology relating to tobacco use and risks, adolescent and young adult development, risk behaviors and perceptions, public health policy and practice, and public policy modeling. For approximately a year and a half, this group examined the tasks above within the context of the body of literature that includes current youth access laws and enforcement policies in states and localities.

Summary of IOM's Findings

The review and evaluation by IOM yielded seven conclusions, which were provided in the Summary of the Report. It did not issue any recommendations to the Agency.

[11] FD&C Act, Section 906(d)(3)(ii).

Conclusion 1: Increasing the minimum age of legal access to tobacco products will likely prevent or delay initiation of tobacco use by adolescents and young adults.[12]

The Committee based this conclusion on the scientific evidence regarding the increased vulnerability to nicotine addiction by adolescent and young adults that use tobacco products due to the immature biology of the brain during this stage of life. As a person ages and the brain matures, there is a diminishing effect of the addictive properties of nicotine; therefore, a person that is older at the time of initiation[13] is less likely to become addicted after initiation.

Conclusion 2: Although changes in the minimum age of legal access to tobacco products will directly pertain to individuals who are age 18 or older, the largest proportionate reduction in the initiation of tobacco use will likely occur among adolescents of ages 15 to 17 years.[14]

Conclusion 3: The impact of raising the minimum age of legal access to tobacco products to 21 on the initiation of tobacco use will likely be substantially higher than raising it to 19, but the added effect of raising the minimum age beyond 21 to age 25 will likely be considerably smaller.[15]

The premise for the Committee's Conclusions 2 and 3 is their finding that access to tobacco products is primarily based on social networks. Adolescents are less likely to have peers and associates over the age of 21.[16]

A further restriction to age 25 would increase the impact more as they are even less likely to have adults aged 25 in their social networks.[17] Using these social constructs, the Committee concluded that the higher the minimum legal age, the greatest effect would be on initiation rates for adolescents aged 15 to 17 years. However, significant reductions in use would also be seen among younger adolescents and among young adults aged 18-21.

Conclusion 4: Based on the modeling, raising the minimum age of legal access to tobacco products, particularly to ages 21 and 25, will likely lead to substantial reductions in smoking prevalence.[18]

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[12] Institute of Medicine. (2014). Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products. Retrieved on March 25, 2015 from http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx

[13] Initiation is defined as having smoked 100 cigarettes. This definition is taken from the National Health Interview Survey (NHIS).

[14] Institute of Medicine. (2014). Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products. Retrieved on March 25, 2015 from http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx

[15] Ibid.

[16] Ibid.

[17] Ibid.

[18] Ibid.

The Committee used two tobacco simulation models to illustrate Conclusion 4: SimSmoke and the Cancer Intervention and Surveillance Modeling Network (CISNET) smoking population model. Although the models have different assumptions; the results are similar and show the same trajectory. With the current federal minimum legal age of 18, both models predict a reduction in smoking prevalence between 2015 and 2100 in the United States. The models further predict that raising the minimum legal age to 19 years, 21 years, or 25 years will reduce prevalence still further due to greater reductions in initiation. Both models estimate that raising the minimum legal age will lead to greater decreases in smoking prevalence *above and beyond the current expected continued decreases in prevalence* as follows[19]:

Minimum Legal Age of Access	**Expected Additional Decrease in Smoking Prevalence**
19 years	3%
21 years	12%
25 years	16%

Conclusion 5: Based on the modeling, raising the minimum age of legal access to tobacco products will likely lead to substantial reductions in smoking-related mortality.[20]

The modeling analysis by the Committee suggests that raising the minimum legal age could lead to remarkable reductions in smoking-attributed death and disability over time, and that these impacts would be more immediate for younger generations (those born 2000-2019), as they would be impacted by the change in minimum legal age most immediately. The models took into consideration the total number of years of life lost (YLL) as well as the number of deaths averted by birth cohorts. The CISNET Yale Lung Cancer Model was used in concert with the CISNET smoking population model to further illustrate the number of lung cancer deaths that would be averted at each minimum legal age interval.[21] The total number of deaths saved would be greater with a higher minimum age, but that incremental increase is greater going from age 18 to age 21. For example, the cumulative number of deaths prevented (from the more conservative model) when the minimum age is increased from 18 to 21 is 250,000; increasing from 21-25 adds another 80,000 additional deaths prevented.

Conclusion 6: Based on a review of the literature, raising the minimum age of legal access to tobacco products will likely immediately improve the health of adolescents and young adults by reducing the number of those with smoking-caused diminished health status. As the initial birth cohorts affected by the policy change age into adulthood, the benefits of the reductions of the intermediate and long-term adverse health effects will also begin to manifest. Raising the minimum age of legal access to tobacco products will also likely reduce exposure to secondhand

[19] Ibid.
[20] Ibid.
[21] Ibid.

smoke and the prevalence of other tobacco products, further reducing their associated adverse health effects, both immediately and over time.[22]

Conclusion 7: Based on a review of the literature and on the modeling, an increase in the minimum age of legal access to tobacco products will likely improve maternal, fetal, and infant outcomes by reducing the likelihood of maternal and paternal smoking.[23]

In Conclusions 6 and 7, the Committee noted that as this generation matures into adulthood, the likelihood that they will begin smoking will be reduced if the minimum legal age of access is increased. This reduction in smoking initiation will lead to improved health outcomes over time. A generation of fewer smokers, who will become parents, naturally leads to improved health outcomes for pregnant women, infants, and children, particularly those who would be at risk for cigarette smoke exposure directly or via secondhand delivery.[24] The SimSmoke model was used to predict the effects of raising the minimum legal age on the incidence of pre-term births, low birth-weight, and SIDS. These data demonstrate that with an increase of the minimum legal age, immediate reductions in pre-term births, low birth-weight, and SIDS would be realized.

An increase in the minimum legal age will likely prevent or delay initiation by youth and young adults, which would lead to a reduction in the prevalence of tobacco use in general. A reduction in the prevalence of tobacco use contributes to immediate population health benefits, especially for those that would have used tobacco or would have been exposed to the smoke. Those that would benefit most from a change in the minimum legal age are those adolescents who would have initiated smoking well before 18 years of age.[25] Some of the known adverse health effects due to cigarette smoking include nicotine addiction, respiratory and cardiac problems, as well as multiple forms of cancer. Delayed initiation of tobacco use would delay the onset of any immediate health effects until later in life, which would allow individuals to be healthier during their most active and productive years of life. This would reduce lost productivity in the workforce due to smoking-related illnesses as well as contribute to a reduction in health care costs for smoking-related illnesses.

Conclusion

Adolescents are particularly vulnerable to the adverse health effects of tobacco use, including nicotine exposure, which often leads to nicotine addiction and long-term use of tobacco products. This has life-long implications, including development of preventable and chronic smoking-related illnesses, which cause suffering and reduced productivity due to illness and premature death.

In lieu of federal action, states and localities have begun to explore and enact changes in their laws regarding the minimum legal age to purchase tobacco products. Since the passage of the Tobacco Control Act, ten states have either raised the minimum legal age of purchase for

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[22] Ibid.
[23] Ibid.
[24] Ibid.
[25] Ibid.

tobacco entirely or have local laws that raise the age to either 19 or 21. The findings of this IOM report will be useful to federal, state, and local policy makers that have the authority to raise the minimum legal age of purchase of tobacco products to reduce tobacco use initiation by America's youth.

APPENDIX A

COMMITTEE ON THE PUBLIC HEALTH IMPLICATIONS OF RAISING THE MINIMUM AGE FOR PURCHASING TOBACCO PRODUCTS

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