SMOKELESS TOBACCO

Among youth, males are far more likely to use smokeless tobacco than females.

630,000
High school and middle school past 30-day smokeless tobacco users in 2020

Most forms of smokeless tobacco use causes precancerous oral lesions, oral, esophageal, and pancreatic cancer.

Smokeless tobacco comes in many flavors that are popular among youth.

Products contain a variety of nicotine strengths. Youth use of nicotine in any form is unsafe.

NEW ORAL NICOTINE PRODUCTS

Oral nicotine pouches and lozenges are a new category of tobacco product that come in many flavors and are increasing in popularity. The products are still derived from tobacco and contain nicotine, but due to the absence of tobacco leaf, the Food and Drug Administration does not classify it as a smokeless tobacco product. Some of these products also claim to use synthetic nicotine, which has not yet been regulated by the FDA and in the meantime remain on the market.

13% of 15-24 year olds surveyed in Fall 2020 were past 30-day users of pouches.
BACKGROUND

There are four general types of smokeless tobacco available in the United States: chew, snuff, snus, and dissolvable tobacco. New oral nicotine pouches and lozenges are a new category of tobacco product that come in many flavors and are increasing in popularity. The products are still derived from tobacco and contain nicotine, but due to the absence of tobacco leaf, the Food and Drug Administration does not classify it as a smokeless tobacco product. Some of these products also claim to use synthetic nicotine, which has not yet been regulated by the FDA.

- **Chewing tobacco** [“chew”] is available in loose leaves, plugs, or twists of tobacco, and is placed between the cheek and gum or teeth. Examples of chewing tobacco include Red Man and Levi Garrett.¹ ²

- **Snuff** is finely ground tobacco packaged in cans or pouches, which can be sold dry (powdered form that is sniffed) or moist [placed between the lower lip or cheek and gum] and is sometimes used in teabag-like pouches.¹ Popular brands of moist snuff are Copenhagen and Skoal.¹

- **Snus**, a product that originated in Sweden, is moist snuff that comes packaged in small pouches and is often flavored. This product does not produce excess saliva like other forms of smokeless tobacco, making it spit-less. Separate from American snus, Swedish Snus are produced pursuant to a voluntary standard designed to reduce contaminants and nitrosamine levels [the “Gothiatek” standard]. The FDA reviewed some of these Swedish Snus products and permitted their sale in the U.S. and authorized them as modified risk tobacco products. The eight Swedish Match USA, Inc. snus smokeless tobacco products sold under the “General” brand name are permitted to be marketed with the claim, “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”³ By allowing them to be sold, FDA concluded that the manufacturer demonstrated that the products will benefit the health of the population as a whole. By allowing the modified risk claims, FDA determined that the manufacturer’s reduced risk claims were substantiated. Not all snus products have gone through FDA review, and no other snus products have been granted modified risk marketing orders.³

- **Dissolvable tobacco** is another spit-less, frequently flavored tobacco product that is finely milled and dissolves orally. Ariva and Stonewall are some of the dissolvable products on the market.⁴
Tobacco companies recognize that cigarette smoking is decreasing and have invested significantly in smoke-free nicotine delivery products to “maintain a market of users addicted to nicotine as a lifestyle product.”

New oral nicotine products, often called Modern Oral Nicotine by the tobacco industry, have been emerging among big tobacco companies (e.g. RJ Reynolds, Swedish Match, and British American Tobacco). These typically come in the form of pouches but can come in other forms like dissolvable tablets.

These products are advertised as “tobacco-free” or “tobacco leaf-free,” with frequent emphasis on how they can be used anywhere with no need for batteries or additional devices. They also come in a variety of flavors and different nicotine strengths.

The products are still derived from tobacco and contain nicotine, which is harmful to young people in any form, but due to the absence of tobacco leaf, the Food and Drug Administration does not classify it as a smokeless tobacco product.

Although these new oral nicotine products may have lower health risks than combusted tobacco, they have not been reviewed by FDA’s Center for Tobacco Products (CTP). Further, none of these products are approved for smoking cessation by FDA’s Center for Drug Research and Evaluation (CDER) and there is a lack of evidence that they can be used as such. Oral nicotine products have the potential to appeal to youth and young adults due to their wide array of flavors and their ability to be used discreetly.

Oral nicotine pouches and lozenges — a new category of tobacco product that includes brands such as Zyn, On! and Velo that come in many flavors proven to appeal to youth — are increasing in popularity. According to Nielsen sales data reported in an industry news article, Zyn nicotine pouch dollar sales in convenience stores increased 470% in the first half of 2020. Truth Initiative has also observed a concerning number of young people reporting use of oral nicotine products. For example, Truth Initiative tracking shows that 13% of 15-24 year olds surveyed in Fall 2020 were past 30-day users of pouches. Enrollees in This is Quitting, a text message quit vaping program for young people from Truth Initiative, are also reporting use of nicotine pouches when they sign up for the quit program.

While official data on youth use do not yet exist because they are not included in national surveys, Truth Initiative has submitted recommendations that federal agencies include oral nicotine pouches and lozenges like Zyn, On! and Velo in future surveys.
PATTERNS OF USE IN THE U.S.

In 2018, there were 8 million (2.9%) past 30-day smokeless tobacco users age 12 or older in the U.S. The prevalence of smokeless tobacco use among adolescents and adults has been relatively stable since 2002.

YOUTH

In 2020, there were 630,000 high school and middle school past 30-day smokeless tobacco users. The prevalence of past 30-day smokeless tobacco use was 3.1% among high schoolers and 1.2% among middle school students.

Among youth, males are far more likely to use smokeless tobacco than females. A greater proportion of white Americans use smokeless tobacco compared to any other ethnic group.

Flavored smokeless tobacco products are particularly popular among youth. In 2019, the prevalence of flavored smokeless tobacco use among past 30-day smokeless tobacco users was 42.3% among middle school students and 49.8% among high school students.

In 2019, among middle and high school students who were past 30-day users of smokeless tobacco, 34.1% used the product on 20 or more days in the past 30 days.

YOUNG ADULTS & ADULTS

Younger adults use smokeless tobacco at higher rates than older adults:

- Respondents in the 2019 MMWR reported that “every day” or “someday” use of smokeless tobacco at 2.4% in adults overall, but 2.2% in 18-24 year olds, 3.2% in 25-44 year olds, 2.5% in 45-64 year olds, and 1.2% in 65 years and older.

Among adults, smokeless tobacco use is most common among Whites compared to other race/ethnicities.

There are considerable regional differences in adult smokeless tobacco use.

- Smokeless tobacco use is most common in the Midwest (3.1%) and the South (3%) and is less common in the West (1.9%) and the Northeast (1.1%) among adults who reported “every day” or “someday” use.

- The states with the highest rate of smokeless tobacco use among adults are Wyoming (9.8%), West Virginia (8.5%), Arkansas (7.8%), Montana (7.7%), Kentucky (7.4%), and Mississippi (7.2%).
There are high concentrations of smokeless tobacco use in certain industries and occupations.

Among working U.S. adults, smokeless tobacco use is highest in mining (14.3%), utilities (8.2%), and agriculture, forestry, fishing, and hunting (7.3%) industries, as well as occupations involving installation, maintenance, and repair (9.6%), and construction and extraction (9.0%).

Use of smokeless tobacco is also prevalent in military populations

In 2011, the Department of Defense determined that 12.8% of military personnel were current smokeless tobacco users.

Use of most types of smokeless tobacco causes precancerous oral lesions, oral, esophageal, and pancreatic cancer. The risk of cancer of the oral cavity, esophagus, and pancreas is lower for smokeless tobacco users than for smokers.

It is likely that the stimulating effects of nicotine may increase cardiovascular risk.

Youth use of nicotine in any form is unsafe. Nicotine use during adolescence can disrupt the formation of brain circuits that control attention, learning, and susceptibility to addiction. Early age of nicotine use and pleasurable initial experiences are correlated with daily use and lifetime nicotine dependence.

Harms from smokeless tobacco products vary by product type, given that levels of nicotine and toxicants vary significantly across different types of smokeless products. However, smokeless tobacco use, while harmful, can be less harmful than cigarette smoking. After reviewing health and behavioral data, the FDA determined that Swedish Match’s General brand snus smokeless tobacco products were “appropriate for the protection of public health.” Those products have also received an order from FDA allowing them to be marketed as modified risk tobacco products with the claim “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” To receive such an order, manufacturers must demonstrate that such claims are accurate and not misleading and would benefit public health.

Switching completely from smoking cigarettes to using the least harmful forms of tobacco may result in lower health risks to individuals. For example, evidence from Sweden indicates that increased prevalence of Swedish snus use from 1976 to 2002 was correlated with reductions in cigarette smoking prevalence and faster reductions in rates of lung cancer and heart attack than seen in similar countries examined over the same period. As of 2012, lung cancer was the leading cause of cancer death among men in all European countries except Sweden.
MARKETING IN THE U.S.

- The five major U.S. manufacturers of smokeless tobacco products spent a total of $658.5 million on advertising and promotion of their products in 2018, a decrease from $718.3 million the year prior.\textsuperscript{31}
- Promotional allowances and price discounts to retailers or wholesalers accounted for 62.8% of 2018 spending.\textsuperscript{33}
- Expenditures for sports and sporting events were $2 million in 2018, a decrease from as high as $26.6 million in 1998.\textsuperscript{3}
- Some cigarette companies advertise that smokeless tobacco can be used in places where tobacco smoking is not allowed.\textsuperscript{34}

POLICY IN THE U.S.

YOUTH ACCESS

The 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) gave the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products, including smokeless tobacco. Provisions in that law pertaining to smokeless tobacco include:

- Establishing a federal nationwide minimum age of 18 for smokeless tobacco sales. (In December 2019, the United States adopted a law raising the federal minimum age of sale of all tobacco products to 21, effective immediately.)
- Requiring retailers to verify age by photographic identification for all over-the-counter tobacco sales.\textsuperscript{35}
  - The FSPTCA required FDA to issue regulations to establish age verification requirements for the Internet and other non-face-to-face purchase of any tobacco products. However, FDA has yet to implement this set of regulations.\textsuperscript{35,36}
- Prohibiting name brand sponsorship of sporting or other cultural events for cigarettes and smokeless tobacco.
- Requiring retailers to keep smokeless tobacco products behind the counter.
- Prohibiting vending machines in most locations and requires smokeless tobacco sales in stores to be conducted in a face-to-face transaction.
- Prohibiting free samples of smokeless tobacco, except in adult-only facilities.
- Prohibiting free gifts with purchase, other than tobacco products (no branded t-shirts or hats).
- Prohibits marketing products with modified risk claims without an order from FDA.
- Continues the prohibition of smokeless tobacco advertising on radio and television, originally established by the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) of 1986.
Further, the Prevent All Cigarette Trafficking (PACT) Act prohibits the mailing of smokeless tobacco through the U.S. Postal Service and requires internet and mail-order retailers to comply with age verification requirements and pay appropriate federal and state taxes.

SMOKELESS TOBACCO AND SPORTS

There is association between smokeless tobacco and sports, which affects young people.

In 2016, to break the cultural association between sports — particularly baseball — with smokeless tobacco, the state of California banned the use of smokeless tobacco in all its professional baseball stadiums.

Over half (16 of 30) of Major League Baseball stadiums are completely tobacco-free. California and several localities including Boston, MA, Chicago, IL, King County, WA, Milwaukee, WI, New York, NY, Phoenix, AZ, St. Louis, MO, St. Petersburg, FL and Washington, DC all have passed laws banning tobacco use at all sports venues. In 2016, Major League Baseball and its players’ union prohibited the use of smokeless tobacco by new players entering the MLB. The ban does not apply to current players who have at least one day of major league service. Smokeless tobacco has been banned in the minor leagues since 1993.

FLAVORED SMOKELESS TOBACCO

Currently there are no federal laws or regulations restricting the manufacture of flavored smokeless tobacco products. In March 2018, FDA issued an advance notice of proposed rulemaking to request public comment to better understand the role that flavors in tobacco products play in attracting youth, as well as the role they may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. However, as of October 2020, no proposed rules regarding flavored smokeless tobacco products have been issued by the FDA.

As of September 30, 2020, California, Massachusetts, and several localities in Colorado, Illinois, Minnesota, New York, and Rhode Island have instituted some form of a ban on the sale of at least some flavored tobacco, including flavored smokeless tobacco.

TOBACCO PRODUCT STANDARD FOR NNN LEVELS

In 2017, the FDA proposed a tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products of 1.0 microgram of NNN per gram of tobacco. NNN is a potent carcinogen found in smokeless tobacco products and is a major contributor of the increased risk of cancer associated with smokeless tobacco product use. However, as of October 2020, FDA has not issued a final rule regarding a tobacco product standard for NNN levels in smokeless tobacco products.
**WARNING LABELS**

- The FSPTCA required larger and more visible text warnings for smokeless tobacco products and their advertising. On a rotating basis, smokeless manufacturers must include the following four warnings on all smokeless tobacco packages and advertisements:
  - WARNING: This product can cause mouth cancer
  - WARNING: This product can cause gum disease and tooth loss
  - WARNING: This product is not a safe alternative to cigarettes
  - WARNING: Smokeless tobacco is addictive

- FDA’s final “deeming” regulation further required the following warning to be included on all tobacco products:
  - WARNING: This product contains nicotine. Nicotine is an addictive chemical.

**TAXES**

- The Children’s Health Insurance Program Reauthorization Act (CHIPRA) of 2009 increased the federal excise taxes on chewing tobacco from $0.195 per pound to $0.5033 per pound and snuff from $0.585 per pound to $1.51 per pound.

**ACTION NEEDED: SMOKELESS TOBACCO**

Truth Initiative is dedicated to achieving a culture where all youth and young adults reject tobacco. As we actively pursue our vision of a future where tobacco is a thing of the past, we support the following policies with regard to smokeless tobacco:

- **FDA must issue product standards eliminating flavors from all tobacco products.** Truth Initiative has long supported the removal of flavors in cigarettes, cigars and smokeless tobacco. We know that flavors have overwhelmingly been used to attract youth and those who have not previously used nicotine or tobacco. We strongly support removing all flavored smokeless tobacco from the market including mint and menthol, as well as any “concept” flavors or other ambiguously named or packaged products that are flavored. We support a permanent ban on flavored tobacco unless a manufacturer can demonstrate three things to the FDA: 1) that a particular flavor helps current tobacco users to switch completely to a substantially less hazardous product, 2) the flavor will not lead non-tobacco users, such as youth, to start, and 3) the flavor itself does not increase the risk of harm from using the product.

- **FDA must clarify the regulatory status of products claiming to use synthetic nicotine and make that decision clear to the public, consumers, manufacturers, and retailers.**

- **FDA must restrict smokeless tobacco marketing so that it does not target or appeal to youth.**
FDA must prohibit and aggressively enforce internet and other non-face-to-face sales of all tobacco products, including smokeless tobacco.

State and local jurisdictions should require smokeless tobacco be subject to tobacco-free laws and policies. Truth Initiative actively supports tobacco-free college campuses and tobacco free sports venues.

Tax smokeless products at the highest level. Federal, state, and local tax-writing authorities should set the highest possible taxes on all tobacco products, including smokeless tobacco, to discourage youth use.

Enforce the idea that smokeless tobacco is not a quit-smoking tool. While smokers may try to use smokeless tobacco products to switch completely away from cigarette smoking and other combustible products, smokeless tobacco products are NOT cessation products, and are not approved by FDA as such. Federal agencies such as the FDA and National Institutes of Health must redouble all efforts to develop nicotine cessation interventions for the millions of tobacco users across the country. Additionally, the Centers for Medicaid and Medicare Services and insurance companies should make quitting services and interventions available for all those addicted to nicotine — whether from smokeless tobacco or combustible tobacco products — with no barriers to treatment.

STATE AND LOCAL ACTION NEEDED

States and local communities are often the incubators of strong tobacco control policies. They have an important role to play when it comes to protecting youth from smokeless tobacco as well. Some examples include:

Licensing: Requiring all smokeless tobacco vendors to be licensed and registered with the state or local (where allowed) government. Licensing, besides being an important way to keep track of who is selling tobacco products, can also be a tool to limit the density and location (i.e. not near schools) of tobacco retailers. For more information on the importance of tobacco retail licenses please see our Point of Sale Policy Resource.

Flavor Restrictions: Many local jurisdictions have taken action to restrict or prohibit the sale of flavored tobacco products. Truth Initiative supports such actions because they limit the availability of such highly appealing tobacco products for youth.

Federal agencies such as the FDA and National Institutes of Health must redouble all efforts to develop nicotine cessation interventions for the millions of tobacco users across the country.
TRUTH INITIATIVE’S AFFILIATED PUBLICATIONS


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