

TOBACCO POLICY WITHOUT BLOWING SMOKE

Robert A. Howard III†

I. Introduction.....	117
II. Health Controversy.....	120
A. United States versus Swedish Snus	120
B. Tobacco Control Advocates.....	122
C. Harm Reduction Advocates	123
D. Synthesis – Proper Tobacco Health Policy.....	125
III. Agriculture.....	127
A. Snus as a Possible Boom for American Agriculture.....	127
1. Agricultural Employment.....	128
2. Maintaining Family Farms	130
B. Increased American Tobacco Agriculture Benefits Developing Nations	132
IV. Taxes and Public Spending	133
V. FDA and Modified Risk Tobacco Products	135
A. FDA Abuse and the Tobacco Control Act in Practice.....	136
1. FDA as Modified Risk Tobacco Product Deniers.....	136
i. Cigarettes Compared to Snus	138
2. FDA Overreach	139
i. Proper FDA Action	140
VI. Conclusion.....	141

I. INTRODUCTION

Tobacco regulation, legislation, and policy has been made with good intentions but without complete understanding. When thinking about tobacco, the discourse has become ideological. While health is clearly an important issue, other areas should be viewed to determine tobacco policy. Tobacco regulation, legislation, and policy ought to be determined, not only by health concerns, but also by viewing the many areas in which tobacco has an impact: agriculture, taxes,

† Robert A. Howard III has his undergraduate degree in history from Grand View University and his J.D. from Drake University Law School. He currently works in-house at Creative Risk Solutions in Waukee, Iowa. Howard enjoys spending time with his wife, Lumea, and four children: Benedict, Ignatius, Genevieve, and Augustine.

trade, and business. An in-depth look, based on recent scientific knowledge should be utilized when determining policy for tobacco.¹

The mistrust of tobacco companies is well earned, as these companies have traditionally deceived the public in the past.² Tobacco companies appear to have a history of misleading the public on the health risks, addictiveness, effectiveness of various treatments, and their ability to make less addictive products.³ While this may all be true, it is important when making policy decisions to not commit the same sin of deception in regulating tobacco. Tobacco companies are not basing their future policy on cigarettes,⁴ neither should the United States.

The position of this Note is tobacco regulation must be based on the most up-to-date scientific understanding. Different forms of tobacco should be treated differently when they are, in fact, different. Dealing in half-truths and refusing to provide the public with the most accurate statements based on scientific research, regarding tobacco was inexcusable by the tobacco companies. It is even more inexcusable in United States' regulation, legislation, and policy on tobacco. The United States' handling of tobacco regulation cannot be based on "two wrongs make a right." Instead, the United States should consider viewing current information on alternate forms of tobacco that will likely mitigate the harms of tobacco.

One alternate form of tobacco, and the focus of this Note, is snus (pronounced "snōōs").⁵ "Snus is a smokeless and spitless upper-lip tobacco product that originated in Sweden."⁶

Snus is a form of smokeless tobacco but is distinguishable from other types of smokeless tobacco that have been sold in the U.S. for decades. The primary

1. Lorna Schrefler & Jacques Pelkmans, *Better Use of Science for Better EU Regulation*, 5 EUR. J. RISK REG. 314, 317-18 (2014) (stating that the current EU regulations [like the United States' regulations but more stringent] on snus contradict current scientific knowledge).

2. Kathleen H. Dachille & Jacqueline M. McNamara, "Safer" Tobacco Products: *Reducing Harm or Giving False Hope?*, 11 J. HEALTH CARE L. & POL'Y 1, 4 (2008).

3. *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 233 (2d Cir. 1999); *see also United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 32 (D. D.C. 2006).

4. David Carrig, *Philip Morris Says its New Year's Resolution is to Give up Cigarettes*, USA TODAY (Jan. 3, 2018), <https://perma.cc/6C98-HEA9>.

5. *Welcome to GeneralSnus.com*, GEN. SNUS, [https:// perma.cc/GH4D-JU32](https://perma.cc/GH4D-JU32) (archived Jan. 29, 2019).

6. *Id.*

traditional types of U.S. smokeless tobacco are chewing tobacco and dry or moist snuff. They are primarily used orally and require spitting.⁷

The indication that Swedish snus is healthier than other forms of tobacco use comes from what has been called the Swedish Experience:

It is most likely that the Swedish Experience can be explained by the unique form of tobacco use among Swedish men, which largely takes the form of snus. Total tobacco consumption is about equal in comparable countries, but Swedish men smoke substantially less. The proportion of daily smokers is currently 10 percent among men, the lowest in Europe. To this must be added that 18 percent of men use snus. Thus, the use of snus among Swedish men is more common than smoking. The positive effect of this phenomenon is a very low frequency of tobacco-related illnesses among Swedish men and low smoking-related mortality rates. This unique situation is documented in a large number of epidemiological studies, which, inter alia, note that Sweden shows the lowest risk of lung cancer among industrial countries. Although the use of snus is not without negative health effects, research results have shown that health risks are substantially lower for the use of snus compared with smoking.⁸

While there are multiple forms of new nicotine delivery products, snus allows tobacco, thus agriculture, to still play a role while mitigating many of the risks commonly associated with traditional forms of tobacco that people in the United States may be more familiar with.⁹

Snus manufacturers cannot currently update their warning labels as a safer alternative to smoking.¹⁰ The first section of this Note will discuss the health debate on snus as a harm mitigation substance. Second, this Note will examine snus's impact on areas of agriculture, both foreign and domestic. Third, this Note will

7. Lindsey C. Dastrup & Jacqueline M. McNamara, Comment, *Current Issues in Tobacco Regulation, Litigation, and Policy: Tobacco Control and Snus: Time to Take a Stand*, 11 J. HEALTH CARE L. & POL'Y 127, 161 (2008).

8. *The Swedish Experience*, SWEDISH MATCH, <https://perma.cc/MA3E-RK8L> (archived Jan. 29, 2019).

9. See Zhiwei Liu, et al., *Tobacco Use, Oral Health, and Risk of Parkinson's Disease*, 185 AM. J. EPIDEMIOLOGY 538, 538 (2017); Marzieh Araghi, et al., *Use of Moist Oral Snuff (snus) and Pancreatic Cancer: Pooled Analysis of Nine Prospective Observational Studies*, 141 INT'L J. CANCER 687 (2017); Lars Ramström et al., *Patterns of Smoking and Snus Use in Sweden: Implications for Public Health*, 133 INT'L J. ENVTL. RES & PUB. HEALTH (2016); Robert Nilsson, *Use of Rodent Data for Cancer Risk Assessment of Smokeless Tobacco in the Regulatory Context*, 88 REG. TOXICOLOGY PHARMACOLOGY 338, 338 (2017).

10. Alexandra Sifferlin, *FDA Panel Votes Against Smokeless Tobacco Safety Claims*, TIME (Apr. 10, 2015), <https://perma.cc/7Y4E-8EGW>.

explore the taxes, public spending, and economic impact of tobacco. This Note will then review current issues involving snus, the current Food and Drug Administration (FDA) position, and legislation, which would treat snus differently than traditional tobacco. Additionally, reasonable and equitable policy recommendations will be made throughout this analysis based on current scientific understandings, examination of the many areas which tobacco touches, and utilization of current law. The focus is to create a more well-rounded discussion on snus, as opposed to just health, to best determine policy on tobacco in general and snus, specifically.

II. HEALTH CONTROVERSY

Health is the largest policy consideration when discussing tobacco. Health is also the only policy consideration for many tobacco policy advocates.¹¹ The breadth of discussion ranges from outright banning tobacco consumption to a heated debate over allowing harm-reducing methods, such as snus, to be promoted.¹² However, some real concerns are raised by the public, in which many are suspicious of all forms of tobacco. One of the most serious concerns is the possibility that, as opposed to replacing and being harm-reducing, snus could be used to supplement smoking and create more harm or even make tobacco users out of those who would otherwise have not.¹³

To deal with such concerns, looking at current research is key to making proper policy. To do so, one must look at the evidence and arguments of both sides of the issue. Harm-reduction appears to be a goal of all in the health policy consideration of snus. However, other arguments exist which support harm-reduction while being more concerned with existential reasons.¹⁴

A. *United States versus Swedish Snus*

Concerns over snus being used as a supplement, as opposed to a replacement, for smoking are legitimate. Increased tobacco use would likely raise smoking-related illness costs, which are currently in excess of \$300 billion.¹⁵ Even if it were true that snus is no more effective than nicotine gum and patches,¹⁶ items that are

11. Dastrup & McNamara, *supra* note 7, at 127-28.

12. *Id.* at 142.

13. *Id.* at 138-39.

14. See generally Wendy E. Parmet, *Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes*, 70 U. MIAMI L. REV. 879 (2016).

15. *Economic Trends in Tobacco*, CTRS. DISEASE CONTROL & PREVENTION, <https://perma.cc/2ZR7-6MCL>, (archived Jan. 29, 2019).

16. Dastrup & McNamara, *supra* note 7, at 142.

healthier, regardless of the degree, and take the place of the less healthy alternative are a net gain each time they are used as an alternative. The lost productivity at work by smokers taking breaks to engage in smoking¹⁷ would likely receive some mitigation as the smoker's desire for nicotine would be satiated.

If the nicotine received in snus is significantly lower than with cigarettes, snus will not be an appropriate replacement, as the nicotine craving will not be satisfied. Since snus appears to cause less harm than cigarettes,¹⁸ using it as a supplement to cigarettes, instead of a replacement, does undermine the harm-reducing potential. United States companies' promotion of snus as a supplement rather than a replacement¹⁹ was supported in a study comparing United States snus with that from Sweden. The nicotine levels were considerably lower in the United States snus, where the Swedish snus has nicotine levels similar to that found in a cigarette.²⁰

Additionally, Swedish snus is created by being treated with steam to kill bacteria, packaged, and refrigerated, as opposed to fire-cured and fermented like United States smokeless tobacco.²¹ This makes the Swedish snus have "significantly lower levels of cancer-causing tobacco-specific nitrosamines (TSNAs) than other forms of smokeless tobacco."²²

Should United States tobacco companies wish to claim the benefits of snus, gain more lenient handling of their snus by the FDA, and regain the trust of the American consumer, they must bring United States snus into greater conformity with Swedish snus.

If the differences between the United States snus and Swedish snus are not reconciled, the FDA could, and should, only allow Swedish snus expansion in marketing under its ability to review modified risk tobacco products.²³ The FDA should also require United States snus to market as a different product, a restriction

17. Jayson DeMers, *Can You Fire Employees Who Smoke?*, FORBES (July 30, 2014), <https://perma.cc/HVT2-SWRM>.

18. See Liu, et al., *supra* note 9, at 538; Araghi, et al., *supra* note 9, at 687; Ramström et al., *supra* note 9; Nilsson, *supra* note 9, at 338.

19. Micah L. Berman, *Current Issues in Tobacco Regulation, Litigation, and Policy: Symposium: "Safer" Tobacco Products: Reducing Harm or Giving False Hope? Tobacco Litigation Without the Smoke? Cigarette Companies in the Smokeless Tobacco Industry*, 11 J. HEALTH CARE L. & POL'Y 7, 15 (2008) (discussing Philip Morris promoting its snus brand free with purchase of cigarettes).

20. Andrew B. Seidenberge et al., *Characteristics of "American Snus" and Swedish Snus Products for Sale in Massachusetts, USA*, 20 NICOTINE & TOBACCO RES. 262, 263-64 (Dec. 21, 2016).

21. Dastrup & McNamara, *supra* note 7, at 129.

22. *Id.*

23. 21 U.S.C. § 387 (2018).

that should prove constitutional, as the restriction on commercial speech will have the compelling governmental interest of stopping consumer confusion and is no more extensive than calling two things that are produced differently and have different levels of chemicals different items.²⁴

B. Tobacco Control Advocates

Snus is not without risks. All tobacco has health draw backs. According to the National Cancer Institute, “[t]here is no safe form of tobacco.”²⁵ Both smokers and snus users have an increased risk of type 2 diabetes.²⁶ Snus use also creates an increased risk of prostate cancer.²⁷ While these risks are certainly substantial, it is also true that snus use is less harmful than smoking and other forms of smokeless tobacco.²⁸

The debate has now moved to determining if snus will replace smoking and allow for the harm reduction to occur.²⁹ Some have argued since harm reduction is not assured, snus should be discouraged and possibly out-right banned.³⁰ Taking such action is basing policy on Greek fables. One can appreciate Aesop’s fable of *The Frogs Who Wanted a King*, in which the frogs receive a king (a log) from Jupiter, the frogs complain to Jupiter, and receive a new king (a stork) who eats them.³¹ Likewise, the concern appears to be that we have received the current policy through our representatives.³² The tobacco control advocates worry any change to the status quo may cause more harm, like the stork in the story.³³ While sage advice, this is poor policy making, especially when one considers snus is deemed less harmful by the current majority of scientific studies.³⁴ The devil you know mentality might be acceptable, however, unlike with Jupiter, in this case, one

24. See *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 534 (6th Cir. 2012); see also *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 562 (1980).

25. *Smokeless Tobacco and Cancer*, NAT’L CANCER INST., <https://perma.cc/JH6M-YDKG> (archived Jan. 29, 2019).

26. Sofia Carlsson et al., *Smokeless Tobacco (snus) is Associated with an Increased Risk of Type 2 Diabetes: Results from Five Pooled Cohorts*, 28 J. INTERNAL MED. 398, 398 (2017).

27. Kathryn M. Wilson et al., *Snus Use, Smoking and Survival among Prostate Cancer Patients*, 139 INT’L J. CANCER 2753, 2753 (2016).

28. Dastrup & McNamara, *supra* note 7, at 129.

29. See generally *id.*

30. *Id.* at 143.

31. Rob John, *Aesop’s Fables: The Frogs Who Wanted a King*, BRIT. BROADCASTING CORP., <http://perma.cc/88Q8-RVTJ> (archived Jan. 28, 2019).

32. See Dastrup & McNamara, *supra* note 7, at 140.

33. See *id.*

34. *Id.* at 129-33.

knows the new devil, if implemented properly, is dramatically superior for health.³⁵ Therefore, the question should not be if but instead, how?

C. Harm Reduction Advocates

The alleged increased risk of prostate cancer associated with snus has been challenged by another, more recent and cumulative, study.³⁶ Indeed, while there are critiques of the Swedish studies, when it comes to snus use,³⁷ current studies continue to show a correlation that users of snus are less likely to take up smoking.³⁸ This correlation has a mitigating effect on one of the implementation fears of the Tobacco Control Advocates.³⁹ In fact, rodent studies of the management of smokeless tobacco products have rarely been based on scientifically sound risk assessment, due to the majority of attention being given to the outstandingly higher hazards associated with smoking.⁴⁰ While this indicates that more studies of smokeless tobacco are necessary, it also indicates a bias in the scientific study of tobacco to treat all forms of tobacco alike.

While the risk factors of snus are arguably less than those associated with smoking, there is actual harm in doing nothing, or maintaining the status quo, which Tobacco Control Advocate appears to support by not utilizing new tools for the future. Abstinence only policies, when it comes to tobacco, have not been effective for some time, specifically since about 1992.⁴¹ While smoking rates continue to fall,⁴² smokeless tobacco rates have steadily increased, among males, since 2005.⁴³ This trend is likely due to anti-smoking laws passed in many states and higher taxes on smoking tobacco.⁴⁴ One could interpret the trend of smoking

35. See Liu, et al., *supra* note 9, at 538; Araghi, et al., *supra* note 9, at 687; Ramström et al. 9, *supra* note 9; Nilsson, *supra* note 9, at 338.

36. Wilson et al., *supra* note 27, at 2753; *but see* Araghi, et al., *supra* note 9, at 687.

37. See generally, Dastrup & McNamara, *supra* note 7.

38. Ramström et al., *supra* note 9.

39. *Id.*

40. Nilsson, *supra* note 9, at 338 (“epidemiological data and molecular biomarkers demonstrate that rodent bioassays with tobacco specific nitrosamines (TSNA) overestimate cancer risk from snus by more than one order of magnitude”).

41. Robert Rabin, *Reexamining the Pathways to Reduction in Tobacco-Related Disease*, 15 THEORETICAL INQUIRIES L. 507, 510 (2014).

42. *Smoking and Tobacco Use: Current Cigarette Smoking Among Adults in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/LWF7-W9E5> (archived Apr. 2, 2019).

43. *Id.*

44. Press Release, Ctrs. for Disease Control & Prevention, Smoking is Down but Almost 38 Million American Adults Still Smoke (Jan. 18, 2018), <https://perma.cc/MT9F-KBTZ> (“A 10% increase in price has been estimated to reduce overall cigarette consumption by 3-5%.”)

use decreasing as oral tobacco use increasing because smokers' increased openness to the use of oral tobacco. At the very least, more people are using oral tobacco than in the past.⁴⁵ Additional research needs to be done to determine if there is an overlap between those quitting smoking and those taking up oral tobacco. Loosening the restrictions on snus and differentiating it from smoked tobaccos and other smokeless tobaccos, creating an incentive for those using oral tobacco to switch to snus, and possibly encourage those changing from smoked to smokeless tobacco as well could further increase the trend to oral tobacco.

Many people in the United States enjoy tobacco.⁴⁶ While some may be upset and find tobacco distasteful, it is questionable if "the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences."⁴⁷ One would imagine this is especially true when the lawful product, snus, is arguably less harmful.

A legitimate critique of most tobacco legislation is that it is paternalistic, by "restrict[ing] the autonomy of an individual for that individual's own good."⁴⁸ The difference between snus and common paternalistic critiques on tobacco is that snus does not deny its harms, but instead highlights its harm reduction.⁴⁹ In the past, tobacco companies have been secretive about the harm of their products.⁵⁰ It has been argued that such restrictions on information could constitute a denial of human rights.⁵¹ The basic argument of liberty, in its different forms, is a fundamental, and less concrete argument in the tobacco harm reduction debate. However, it is clearly a strong one which the Tobacco Control Advocates will need

The consequence, intended or otherwise, appears to be that many of those people are moving to smokeless tobacco).

45. *Smoking & Tobacco Use: Smokeless Tobacco Use in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/6PEE-R6TZ> (archived Apr. 2, 2019).

46. *Smoking & Tobacco Use: Data and Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/Y4S6-ND7P> (archived Jan. 29, 2019). More than 40 million people according to the Center for Disease Control.

47. See *R.J. Reynolds Tobacco Co. v. FDA*, 696 F. 3d 1205, 1218 n. (D.C. Cir. 2012), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F. 3d 18, 22-23 (D.C. Cir. 2014).

48. Parmet, *supra* note 14, at 892 (arguing that a critique of paternalism works as a rhetorical device to undermine the nature of such laws as illegitimate).

49. Jim Solyst, *Toward a Comprehensive Policy on Nicotine Delivery Products and Harm Reduction*, 67 *FOOD DRUG L. J.* 393, 393 (2012) ("several tobacco companies will be submitting applications to FDA to have their smokeless nicotine products be characterized as modified risk tobacco products").

50. Dachille & McNamra, *supra* note 2, at 4.

51. David Sweanor & Rachel C. Grunberger, *Current Issues in Tobacco Regulation, Litigation, and Policy: Symposium: The Basis of a Comprehensive Regulatory Policy for Reduced Harm Tobacco Products*, 11 *J. HEALTH CARE L. & POL'Y* 83, 90 (2008).

to advance. Requiring tobacco companies to inform the public about their product likely does not rise to the level of paternalism or a restriction on liberty;⁵² however, not allowing tobacco companies to honestly describe their product may create a stronger case.⁵³

D. Synthesis – Proper Tobacco Health Policy

Snus is held by both the Tobacco Control Advocates and the Harm Reduction Advocates to be less of a health risk than smoked tobacco.⁵⁴ As such, debate must shift from if we should use it to how it should be used. Tobacco regulation, in the health industry, must have a focus “on pragmatic measures aimed at reducing death, injury, and disease, rather than simply imposing moral judgments on the actions of others.”⁵⁵

It is evident that people are dying.⁵⁶ Doing nothing is not an acceptable answer. One can determine with relative certainty that a complete outlaw of tobacco would not stop its use but merely create an illicit market.⁵⁷ An example would be alcohol prohibition, which created a larger problem through an illicit market, than the one attempting to be solved. Abstinence-only campaigns have outlived their usefulness and are no longer supported by science.⁵⁸

While the science supports the harm reducing effects of snus, it is important to keep Tobacco Control Advocates in the conversation. Tobacco Control Advocates distrust of tobacco companies is well warranted.⁵⁹ Tobacco Control Advocates bring important concerns to the discussion that need to be dealt with in forming a proper policy for tobacco, including the concern over having snus replace smoked tobacco and the fear that those who would not have used tobacco may use snus.⁶⁰

However, the fear of new users choosing snus may be a liberty issue. Current levels of tobacco education need to be adhered to, but additional information on snus allows for a more informed decision. Hiding information from the public

52. Parmet, *supra* note 14, at 892.

53. Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 534-35 (6th Cir. 2012); *see also* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557, 562 (1980).

54. Dastrup & McNamara, *supra* note 7, at 132-35.

55. Sweanor & Grunberger, *supra* note 51, at 85.

56. *Smoking & Tobacco Use: Data and Statistics*, *supra* note 46.

57. Tony Newman, *Why Not Prohibit Smoking?*, CNN, <https://perma.cc/NL28-JBMC> (archived Jan. 28, 2019).

58. Rabin, *supra* note 41, at 512-13; *see also* Sweanor & Grunberger, *supra* note 51, at 90.

59. Dachille & McNamara, *supra* note 2, at 4.

60. Dastrup & McNamara, *supra* note 7, at 138-39.

appears anti-democratic and paternalistic. A consumer, like an electorate, ought to be well-informed. Even without this information, smokeless tobaccos, like snus, are already being used at greater frequency than in the past.⁶¹

Additional steps should be taken to assure that if snus were to receive different handling by the FDA as a harm reduction measure, it would be used as a replacement and not a supplement. As outlined above, United States and Swedish snus must adhere to specific standards of identity.⁶² As with new drugs and fruit juice, snus should also have a standard of identity which clearly mandates the way in which it is produced to be considered snus.⁶³ Therefore, the FDA can ensure it will only loosen snus regulations based on qualities which allow for harm reduction. Additionally, “nudging” should be used to direct people towards snus, the only de-regulated form of tobacco:

A nudge, as we will use the term, is any aspect of the choice architecture that alters people’s behavior in a predictable way without forbidding any options or significantly changing their economic incentives. To count as a mere nudge, the intervention must be easy and cheap to avoid. Nudges are not mandates. Putting fruit at eye level counts as a nudge. Banning junk food does not.⁶⁴

Relaxed rules for snus marketing and product labeling, allow snus producers to give truthful information about snus as a harm-reducing alternative. Thus, having greater freedom than alternatives will allow consumers to make better decisions. However, this change will not force consumers to purchase snus. In regards to snus, the nudge is even less burdensome than described above since the nudge with snus is coming from greater freedom in the industry, without requiring greater restrictions on other tobacco products.

Humans should be allowed to make their own decisions, as they currently are, with a reduction in regulation on snus to nudge them to a healthier, though by no means completely healthy, alternative. Harm Reduction Advocates, Tobacco Control Advocates, tobacco companies, and consumers, need to be involved in an ongoing discussion about tobacco policy. However, the policy should be dictated by the most current scientific knowledge. Tobacco companies need to act in good faith and so does the government when making such policy.

61. *Smoking & Tobacco Use: Smokeless Tobacco Use in the United States*, *supra* note 45.

62. As with new drugs and fruit juice, *see* 21 C.F.R. § 310.201 (2019), snus should also have a standard of identity which clearly mandates the way in which it is produced to be considered snus 21 C.F.R. § 73.250 (2019).

63. *See* 21 C.F.R. § 73.250; 21 C.F.R. § 310.201.

64. RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* 6 (2008) (ebook).

III. AGRICULTURE

While health and liberty concerns may be the most important aspect when dealing with tobacco policy, a broad perspective must be taken as tobacco policy impacts many areas—especially agriculture. During the height of the tobacco litigation that occurred in the 1990s, there was a fear that such action would dramatically affect the agricultural industry in a negative way.⁶⁵ Such fears have proved prophetic. Tobacco farms have decreased from 93,530 farms in 1997, to 10,014 farms in 2012.⁶⁶ In the same time frame, the number of pounds of tobacco produced has dropped from 1,744,192,909 pounds to 766,609,252 pounds.⁶⁷ However, these trends do appear to be leveling off. In the early 2000s, and again in the early 2010s, the farm value of domestic leaf tobacco used in cigarettes dropped significantly.⁶⁸

A. Snus as a Possible Boom for American Agriculture

Farmers have felt the double whammy impact of selling reduced amounts of tobacco for less money.⁶⁹ Since the mid-2000s, there has been a steady increase in smokeless tobacco.⁷⁰ This smokeless tobacco increase shows an available and expanding market for tobacco producers.⁷¹ While restoring previous levels of tobacco production is unlikely, greater tobacco production and price is possible.⁷²

65. Jamey Pregon, Note, *Casualties of the War on Tobacco: Can Farmers Survive the Anti-Tobacco Onslaught?*, 3 DRAKE J. AGRIC. L. 465, 494 (1998).

66. NAT'L AGRIC. STATISTICS SERV., 2012 CENSUS OF AGRICULTURE SUMMARY AND STATE DATA, VOL. 1 PART 51 9 (2014), <https://perma.cc/YZB6-3PQF> (with a significant decrease in white and women principal owners, with only a slight increase in Hispanic principal owners).

67. *Id.* at 8.

68. THE TAX BURDEN ON TOBACCO, FED'N OF TAX ADM'RS VOLUME 49 2 (2014), <https://perma.cc/2J8R-9DC4>.

69. Pregon, *supra* note 65, at 486.

70. *Smoking & Tobacco Use: Data and Statistics*, *supra* note 46.

71. See Adrienne B. Mejia & Pamela M. Ling, *Tobacco Industry Consumer Research on Smokeless Tobacco Users and Product Development*, 100 AM. J. PUBLIC HEALTH 78, 84-87 (2010); *Global Smokeless Tobacco Market 2018-2023: Easy Availability and Low Prices to Drive the Smokeless Tobacco Market Growth*, CISION PR NEWswire (Sept. 6, 2018), <https://perma.cc/8DCT-UKWS>.

72. See *Area of Harvested Tobacco Worldwide from 1980 to 2017 (in Hectares)*, STATISTA, <https://www.statista.com/statistics/261192/global-area-of-harvested-tobacco-since-1980/> (last visited February 4, 2018) (showing slight decline in the amount of tobacco harvested between 1980 and present day); *Tobacco Market Size, Share & Analysis Report by Type (Cigarettes, Smoking Tobacco, Smokeless Tobacco, Cigars & Cigarillos), by Region (U.S., Canada, U.K., China), and Segment Forecasts, 2012-2021*, GRAND VIEW RESEARCH (July

Due to the United States having higher standards of regulations and requirements on labor, environment, and quality, it is positioned well for a new tobacco marketing environment.⁷³

While price is still the single most critical factor in determining competitiveness, today's buying segment is looking more at "value," which of course includes both price and quality of leaf but also some intangible factors referred to as social responsibility. Today's tobacco companies are being challenged on many fronts given the health risks associated with their products along with the general public's perception of the industry. In response to critics, tobacco companies are attempting (or perhaps being regulated) to be more transparent about their products and focusing on issues of their contract growers such as child labor and various environmental issues.⁷⁴

In addition to social responsibility issues, "U.S. tobacco is in demand worldwide for its flavor, with more than half sold abroad and added to cheaper, lesser quality foreign tobacco as a flavoring agent."⁷⁵ With both quality and social responsibility demands helping the American tobacco farmer, an increased demand in less harmful oral tobaccos could benefit both American tobacco farmers and American consumers.

1. Agricultural Employment

One of the social responsibility areas in which tobacco farmers worldwide are critiqued on is their use of labor. A sixteen-year-old tobacco worker stated "the hardest of all the crops we've worked in [is tobacco]. You get tired. It takes the energy out of you. You get sick, but then you have to go right back to the tobacco the next day."⁷⁶ A cooperative effort between the University of Kentucky, the University of Tennessee, Virginia Tech, and NC State University has resulted in a

2018), <https://perma.cc/5Y9P-G5E3> (showing projected growth in the global market for tobacco through 2021).

73. See BOB PEARCE ET AL., BURLEY AND DARK TOBACCO PRODUCTION GUIDE 2-3, <https://perma.cc/CH7K-7HWT> (archived Jan. 28, 2019) ("But this highly regulated tobacco product market will result in changes in the composition and types of tobacco products which will require closer scrutiny by tobacco companies on how the leaf they purchase is produced.").

74. *Id.* at 2.

75. Associated Press, *For Tobacco Growers, Farming a Family Affair*, NEWS4JAX (July 3, 2015), <https://perma.cc/U9F2-B2T7>.

76. Reid Maki, *American 12-Year-Olds Can't Buy Cigarettes. Why Can They Work in Tobacco Fields?*, THE GUARDIAN (June 28, 2018), <https://www.theguardian.com/commentisfree/2018/jun/28/tobacco-field-workers-cigarettes-work>.

guide to advise tobacco farmers exactly how to avoid some health-related labor issues:

Green tobacco sickness is a type of nicotine poisoning resulting from contact with wet tobacco, particularly when workers' clothing becomes saturated. Symptoms vary but may include nausea, vomiting, dizziness, headache, weakness, and cramping. Saturated clothing should be removed, the skin washed with soap and water, and dry clothing provided. Although the illness is not life-threatening and will normally resolve itself in a few days, medical care should be provided, since other factors might be involved, especially if symptoms are severe. Preventing green tobacco sickness means waiting until leaves are dry before harvesting or wearing a rain suit when working in wet tobacco.⁷⁷

A renewed interest in tobacco agriculture should help workers in the field. Clearly the answer is not making the field more restrictive, harder to be profitable, or ultimately ending and closing the field through regulation. This will not benefit those that hire or that determine such work is beneficial to them and desire agricultural employment. The following statistics illustrate why labor is so important to the tobacco industry:

According to the Census of Agriculture, on an average tobacco farm 18% of total revenue, which represent 24% of total expenses, are paid out in wages to workers. Labor share of revenue in other crops that are common in the area range from only 3% in the case of soybean to 13% for hay. Thus, the labor share of revenue in tobacco is between roughly 1.5 and 6 times greater than other common crops in the region. Combined with the fact that Dark tobacco farms also have larger total revenue than other crops, this means that an acre of a tobacco farm can provide jobs to a substantially larger number of workers than an acre of land used for other crops.⁷⁸

Dark tobacco is also likely to continue as a field dependent on labor because it has mechanized less than other fields due to the labor-intensive care required for its production.⁷⁹ While tobacco agricultural workers in the United States are relatively better off than some of their counterparts due to various regulations,⁸⁰

77. PEARCE ET AL., *supra* note 73.

78. Letter from Jose Luis Murillo, Vice President Regulatory Affairs, Altria, to Div. of Dockets Mgmt., Food and Drug Admin. (July 10, 2017), <https://perma.cc/8333-HZ4M>.

79. *Id.*

80. *Migrant and Seasonal Agricultural Worker Protection Act*, U.S. DEP'T OF LABOR, <https://perma.cc/587S-LLZ4>. While one may assume regulations aren't always followed, the mere fact that they exist, along with the many workers' rights organizations in the United States, present substantially better conditions than many parts of the world.

the industry itself is interested in training farmers on sustainability “improving conditions on the farm, yields and livelihoods.”⁸¹ While this program doesn’t currently cover all Swedish Match’s raw tobacco first and second tier suppliers, they hope to have all their raw tobacco for cigars included by 2020.⁸² As of 2017, it appears Swedish Match includes in their supplier contracts that suppliers must ensure ethical workplace and labor practices.⁸³ Supplier contracts usually covering social responsibility, quality, and price are present in over 90% of tobacco growing contracts in the United States.⁸⁴ While additional oversight by the government or another third party, along with transparency may still be required the foundations for proper quality control, social responsibility control, and fair pricing already exist and are developed by the industry itself.

2. Maintaining Family Farms

Snus producers and their suppliers are committed to utilizing American tobacco.⁸⁵ In 2007, tobacco generated nearly \$1.27 billion in revenue for producers.⁸⁶ Dark (air and fire cured) tobacco primarily used in oral tobaccos, makes up the smallest percentage of the United States tobacco production with the highest price per pound.⁸⁷ Dark tobacco production is essentially limited to Kentucky, Tennessee, and Virginia.⁸⁸ However, other forms of tobacco can be produced in other areas, from Pennsylvania to Iowa.⁸⁹

81. *Eliminate Child Labor*, SWEDISH MATCH, <https://perma.cc/97S6-Q9Y7> (archived Jan. 29, 2019); *see also* SWEDISH MATCH, SUPPLIER CODE OF CONDUCT (June 2017), <https://perma.cc/ME5W-HPAU> (outlining specifically what Swedish Match expects in labor, workplace, ethical and environmental practices from itself and its suppliers).

82. SWEDISH MATCH, OUR APPROACH TO SUSTAINABILITY AND SUSTAINABILITY STRATEGY 35, <https://perma.cc/K7NX-YJ2Y> (archived April 3, 2019) (first tier suppliers are suppliers which Swedish Match directly buys from, second tier are those suppliers of their suppliers and usually includes farmers, both tiers are included in the “Sustainable Tobacco Programme”).

83. SWEDISH MATCH, *supra* note 82.

84. INTERNAL REVENUE SERV., FARMERS (ATG) CHAPTER TEN – TOBACCO 5-6 (May 2011), <https://perma.cc/CZ3L-GVR5>.

85. *See* Letter from Gerry Roertry, Jr., Vice President, Gen. Counsel & Sec’y, Swedish Match, to Div. of Dockets Mgmt., Food & Drug Admin. (July 10, 2017) (on file with author); *see also* Letter from Jose Luis Murillo, *supra* note 78.

86. INTERNAL REVENUE SERV., *supra* note 84, at 4.

87. *Id.* at 5.

88. *Id.*

89. Roger Riley, *Ringgold County Family Raising Tobacco in Iowa*, WHO TV (Sept. 24, 2015), <http://perma.cc/43EE-PUJX>.

One commenter to the FDA puts the importance of the family tobacco farm into perspective:

My first tobacco crop was grown in the summer of 1982 for the Future Farmers of America. That tobacco crop helped pay for my college education at Murray State. Now, nearly 35 years later, my own son is an agriculture major at Southern Illinois University. Tobacco is my livelihood and is what helps to support my family. My wife owns one of two small grocery stores in Cadiz, and some of her business comes from the migrant employees who are working in the tobacco fields. . . . The other operations on the farm would not be enough to sustain the family business. Over the years, when my grandfather and father were running the farm, they had other crops. If it was a bad season for corn or beans, they always had tobacco to help make ends meet. . . . Currently, we have 100 acres of dark tobacco. This year, we plan on increasing that amount. In the past, we have had 20 employees lined up to help with the labor, and have plans to increase that number this year. Those employees contribute significantly to the Cadiz economy when they shop at local businesses like my wife's grocery store.⁹⁰

The family tobacco farm not only sustains families through generations, but also supports local, rural workers and economies. Snus and other oral tobaccos have allowed dark tobacco to continue as a stable and profitable revenue source for family farms.⁹¹ This stands in contrast to other forms of tobacco such as burley used for cigarettes, which have become less profitable due to current regulations and changes in consumer demands.⁹² While the tobacco production industry is important for maintaining generational stability in agriculture, employment, and rural business, it is also has the potential for future growth.

Substantial research is being done to determine the viability of tobacco in pharmaceuticals and biofuels.⁹³ As a biofuel additive, tobacco shows possible benefits over corn-based ethanol, though more research is needed.⁹⁴ An advantage that tobacco has over other non-food biofuel crops is that there would be little need

90. *Comment from Bob Lawrence*, REGULATIONS.GOV (Mar. 21, 2017), <https://www.regulations.gov/document?D=FDA-2016-N-2527-0282>.

91. Letter from Jose Luis Murillo, *supra* note 78.

92. Tonya S. Grace, *Dark-fired Main Reason Tobacco Holding on in West Kentucky*, KY. NEW ERA (Apr. 14, 2012), <https://perma.cc/L4ZQ-EE7P>.

93. *Id.*

94. Lindsey Hoshaw, *Tobacco Gets a Makeover as New Source for Biofuel*, KQED (Jun. 3, 2014), <https://perma.cc/FN7Z-45DE>. Benefits include being a non-food source of biofuel, multiple yearly harvests, decreased production time/costs, and occupies less acres of land.

to develop new land for production because of the large amount of land already used for tobacco production.⁹⁵

B. Increased American Tobacco Agriculture Benefits Developing Nations

While deregulation and the end of subsidies affected tobacco farmers negatively, the deregulation also appears to have made United States tobacco farmers more competitive on the international field.⁹⁶ The United States is the fourth largest producer of tobacco, behind China, India, and Brazil.⁹⁷ Over the past forty-five years, tobacco farming has shifted from high- to low- and middle-income countries.⁹⁸ Increased demand for tobacco, particularly more socially responsible and higher quality tobacco, would create incentives for high-income countries like the United States to re-enter the market.

Farmers in poorer nations may be taken advantage of by tobacco companies who negotiate poor credit terms for farmers in those nations.⁹⁹ In fact, “farming tobacco is not prosperous for most smallholder farmers” world-wide.¹⁰⁰ Cultivation of tobacco raises public health challenges such as, “including health hazards for farmers, environmental degradation and child labor issues.”¹⁰¹

A goal of the World Health Organization is to have farmers in less developed nations find “economically viable alternatives to tobacco production as a way to prevent possible adverse social and economic impacts on populations whose livelihoods depend on tobacco production.”¹⁰² Such an attempt of allowing low income nations to focus on alternative, more lucrative crops, has been attempted in Kenya with the growth of bamboo, which had mixed results.¹⁰³ A move towards high-income nation tobacco production gives middle and low-income nations a larger incentive to move towards such programs.

While many people may not look at the reinvigoration of tobacco in agriculture as a positive, it is important to remember farmers, and those they

95. Tina Casey, *Tobacco Goes from Dark Side Villain to Biofuel Hero*, CLEAN TECHNICA (Feb. 25, 2012), <https://perma.cc/N5YQ-GN3H>.

96. Nathan Bomey, *Thousands of Farmers Stopped Growing Tobacco After Deregulation Payouts*, USA TODAY (Sept. 2, 2015), <https://perma.cc/PV72-R8TJ>.

97. *Smoking & Tobacco Use: Tobacco-Related Spending*, CTRS. FOR DISEASE CONTROL & PREVENTION <https://perma.cc/2ZR7-6MCL> (archived Jan. 29, 2019).

98. *Growing*, TOBACCO ATLAS, <https://perma.cc/QH6S-V847> (archived Jan. 29, 2019).

99. *Id.*

100. *Id.*

101. *Id.*

102. WORLD HEALTH ORG., ECONOMICALLY SUSTAINABLE ALTERNATIVES TO TOBACCO GROWING (IN RELATION TO ARTICLES 17 AND 18 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL) 8 (July 17, 2012), <https://perma.cc/T3JP-HRS5>.

103. *Growing*, *supra* note 98.

employ, do look at tobacco agriculture as a positive over other alternatives. Pragmatic policy considerations require one to improve the current situation, while not destroying the opportunity farmers and their employees choose. Once a more sustainable tobacco agriculture sector exists, pragmatic policy considerations may demand more from the sector.

IV. TAXES AND PUBLIC SPENDING

Federal taxation on tobacco began in 1864, near the end of the American Civil War.¹⁰⁴ In 1921, Iowa was the first state to tax tobacco products.¹⁰⁵ In 2014, states and the federal government generated billions of dollars from tobacco product taxes—federal taxes on tobacco totaled \$14,352,669,000 and state taxes generated a total of \$18,152,040,000.¹⁰⁶

Clearly tobacco makes up a significant portion of federal and state revenue each year. However, much of that revenue is spent due to the health costs associated with tobacco use equaling more than \$300 billion a year.¹⁰⁷ Nearly \$170 billion is spent for direct medical care, 60% (\$102 billion) of which can be attributable to spending paid by public programs.¹⁰⁸ An estimated “\$5.6 billion in lost productivity due to secondhand smoke exposure” exists.¹⁰⁹ It is important to note, each replacement of snus by smokers would directly lessen all costs associated with secondhand smoke (since there is no secondhand smoke involved with the use of snus), not just merely productivity time.

Currently, snus and other non-cigarette tobacco is taxed less than cigarettes in the vast majority of states.¹¹⁰ However, there are calls for making non-cigarette tobacco tax rates equal to those of cigarettes.¹¹¹ The policy rationale for such a move is that because tobacco is unhealthy, one must reduce its use, and the tax would increase state revenues.¹¹² This rationale is indicative of the Tobacco

104. THE TAX BURDEN ON TOBACCO, *supra* note 68, at 4.

105. *Id.*

106. *Id.*

107. *Economic Trends in Tobacco*, *supra* note 15.

108. Xin Xu, et al., *Annual Healthcare Spending Attributable to Cigarette Smoking*, 48 AM. J PREVENTATIVE MED. 326, 326 (2015).

109. *Economic Trends in Tobacco*, *supra* note 15.

110. See ANN BOONN, CAMPAIGN FOR TOBACCO-FREE KIDS, STATE EXCISE TAX RATES FOR NON-CIGARETTE TOBACCO PRODUCTS, CAMPAIGN FOR TOBACCO-FREE KIDS 1 (2018), <https://perma.cc/FT9T-3KGP>; see also ANN BOONN, CAMPAIGN FOR TOBACCO-FREE KIDS, STATE CIGARETTE EXCISE TAX RATES & RANKINGS (2018), <https://perma.cc/DUQ4-TX5S>.

111. TOBACCO CONTROL LEGAL CONSORTIUM, STATE TAXATION OF NON-CIGARETTE TOBACCO PRODUCTS 5 (2012), <https://perma.cc/C9JQ-RC55>.

112. *Id.*

Control Advocates' thought process.¹¹³ Proper tax policy for tobacco deserves a nuanced understanding of tobacco. As many of the differences between snus and cigarettes are blatant, rather than nuanced, one wonders whether Tobacco Control Advocates are unable to see the difference or incapable due to their own ideology?

Consider this comparison of cigarettes and smokeless tobacco products:

Cigarettes are extremely effective nicotine delivery devices that are engineered to readily provide the user with rapidly delivered nicotine, thus maximizing the addicting and toxic effects of the drug, as well as delivering extremely toxic and carcinogenic additional chemicals. Smokeless tobacco products such as moist snuff appear to use buffering agents, tobacco cutting techniques, and various additives to control their rate of nicotine release, and thereby provide a diverse range of products—from slowly-releasing “starter” products to rapidly-releasing maintenance products.¹¹⁴

Tobacco Control Advocates' policy of increased taxes for non-cigarette tobacco would likely undercut their purported goal.¹¹⁵ Equalizing the taxes, thus the price, of snus and cigarettes would deter choosing the so-called healthier option. In fact, such a policy may cause some of the approximately eight million snus users to “switch to or back to more risky products like combustible cigarettes, thus increasing the risk to public health.”¹¹⁶

Reasonable tax policy on snus, and other non-cigarette tobacco, will better achieve goals of states and the federal government. Public spending has increased because tobacco harms have outpaced state revenue from tobacco products.¹¹⁷ The focus should not be on increased revenue but decreased public spending.

As the risks associated with cigarettes are substantially lower than with snus,¹¹⁸ public spending will decrease from increased snus use and decreased cigarette use. Likewise, reasonable tobacco tax policies, at the state and federal level, would recognize that different tobacco and nicotine delivery systems have different public health effects, and require different levels of public funding. Equitable tobacco tax policy requires the harm and public cost be proportional to

113. See *id.* at 1. Tobacco Control Advocates recognition of snus as significantly superior regarding health, but unwillingness to use such a tool due to it being tobacco.

114. Jack E. Henningfield & John Slade, *Tobacco-Dependence Medications: Public Health and Regulatory Issues*, 53 FOOD & DRUG L. J. 73, 82 (1998).

115. Except for raised state revenue. See generally, Letter from Jose Luis Murillo, *supra* note 78.

116. *Id.*

117. See Xu, et al., *supra* note 108, at 326; THE TAX BURDEN ON TOBACCO, *supra* note 68, at 4; *Economic Trends in Tobacco*, *supra* note 15.

118. Letter from Jose Luis Murillo, *supra* note 78.

the tax levied.¹¹⁹ While categories should not be so narrow as to create a different policy for each brand and its individualized product, it certainly should not be so broad as to treat substantially different products the same merely because they derive from the same genus of plant.

V. FDA AND MODIFIED RISK TOBACCO PRODUCTS

The FDA was given authority to determine labeling and advertising requirements of tobacco products claiming risk mitigation properties.¹²⁰ However, the FDA was not allowed to ban tobacco¹²¹ and tobacco manufacturers could submit to some exceptions of the rule as modified risk tobacco products.¹²² To market as a modified risk product an application must demonstrate that when used by consumers it will “significantly reduce harm and risk of tobacco-related disease” and “benefit the health of the population as a whole taking into account . . . users” and those that “do not currently use tobacco products.”¹²³ Should the Secretary of Health and Human Services determine that the previous requirements are shown, then “the Secretary shall . . . issue an order that a modified risk product may be commercially marketed. . . .”¹²⁴

Such determinations must be based on scientific evidence from both the applicant and that, as well as other information, made available to the Secretary.¹²⁵ The Secretary must also take into account health risks to individuals, the likelihood that users who would have quit tobacco will switch to the product, whether new users of tobacco will use the product, compare the risks and benefits of the applicant product with approved smoking cessation products, and comments, data, and information from interested parties.¹²⁶ Additional conditions are placed on

119. TRUTH INITIATIVE, ACTION NEEDED: TOBACCO TAXES 1 (Jan. 2019), <https://perma.cc/2VEG-GYRU>.

120. 21 U.S.C. § 387a (2018); Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

121. 21 U.S.C. § 387g(d)(3)(A) (2018).

122. 21 U.S.C. § 387k (2018).

123. 21 U.S.C. § 387k(g)(1)(A)-(B); *see also* 21 U.S.C. § 387k(d) (outlining the documentation required in an application to demonstrate the requirements of 21 U.S.C. § 387k(g)(1)(A)-(B)).

124. 21 U.S.C. § 387k(g)(1) (emphasis added) (the Secretary must refer to the Tobacco Products Scientific Advisory Committee any applications that are submitted. 21 U.S.C. § 387k(f)).

125. 21 U.S.C. § 387k(g)(3).

126. 21 U.S.C. § 387k(g)(4).

what sort of marketing and label disclosure the modified risk tobacco may or may not use, with discretion given to the Secretary and other requirements.¹²⁷

Assuming the above requirements are met, and the Secretary allows a modified risk tobacco product to alter their warning label or marketing, there are additional safeguards in place. One safeguard requires the applicant to annually submit postmarked surveillance and studies in order to determine the impact “on consumer perception, behavior, and health.”¹²⁸

The applicant must notify and submit for approval the protocol for the surveillance for it to meet the necessary protection of the public health standard.¹²⁹ The modified risk tobacco application shall be revoked after an informal hearing if any of the previous findings not be present in the future, information in the application was later found to be untrue, representations are not true in the future, the reduced risk or exposure is no longer valid, the applicant fails to conduct or submit post market surveillance and studies, or the specific label and marketing instruction are met.¹³⁰

A. FDA Abuse and the Tobacco Control Act in Practice

The FDA was given broad authority over tobacco products.¹³¹ The FDA was also required, if certain criteria were met, to allow changes to the marketing and labeling of tobacco products found to reduce harm or the risk of tobacco-related disease.¹³² It must not outlaw tobacco products, nor interfere with tobacco agriculture or anything related to production outside of “activities by a manufacturer affecting production.”¹³³ To date, the FDA’s following of such guidelines has been questionable.

1. FDA as Modified Risk Tobacco Product Deniers

The Family Smoking Prevention and Tobacco Control Act was signed into law on June 22, 2009 by President Barack Obama.¹³⁴ As of May 24, 2017, thirty-five applications have been reviewed with zero receiving a Modified Risk Order

127. See 21 U.S.C. § 387k(h).

128. 21 U.S.C. § 387k(i)(1).

129. 21 U.S.C. § 387k(i)(2).

130. See 21 U.S.C. § 387k(j).

131. See 21 U.S.C. § 387a (2018).

132. See generally 21 U.S.C. § 387k(g).

133. 21 U.S.C. § 387g(d)(3)(A) (2018); 21 U.S.C. §§ 387a(c)(2)(A), (C).

134. *Family Smoking Prevention and Tobacco Control Act – An Overview*, FDA, <https://perma.cc/TJ48-TZ6B> (archived Jan. 29, 2019); Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

from the FDA.¹³⁵ Swedish Match North America, Inc., maker of General Snus, applied for eight of their snus products to be Modified Risk Tobacco Products.¹³⁶

All products requested two changes to labeling and advertising of the products. The first, requesting “WARNING: This product can cause mouth cancer” be omitted from their packaging.¹³⁷ The second, “WARNING: This product is not a safe alternative to cigarettes” be replaced by “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”¹³⁸ All applications were denied with a response from the FDA.¹³⁹

The FDA’s position was that without the mouth cancer warning, it would indicate that “General Snus products *cannot* cause mouth cancer.”¹⁴⁰ The FDA also asserts that, “the totality of scientific evidence supports the statement that smokeless tobacco products in general and these products in particular ‘can cause mouth cancer’ and the proposed modified risk claim is not substantiated.”¹⁴¹ While this is a disputable statement by the FDA,¹⁴² the more egregious denial is that of snus’s comparison with cigarettes.

The FDA concluded there was evidence to support “[g]eneral snus products, as actually used by consumers in Sweden and Norway, as compared to smoking cigarettes may substantially reduce the risk of *some*, but not all, tobacco-related diseases to individual tobacco users.”¹⁴³ However, they ultimately found the evidence didn’t support significantly lower health risks when compared to cigarettes, tobacco use behavior and impacts on the population as a whole, likelihood of product use, and consumer comprehension.¹⁴⁴

135. *Modified Risk Tobacco Products*, FDA, <https://perma.cc/4LFX-D64S> (archived Jan. 29, 2019). There are currently two applications under scientific review, one for “Camel Snus,” the other, for “IQOS system with Marlboro Heatsticks”.

136. *M RTP Application Actions (Orders, Denials, and Responses)*, FDA, <https://perma.cc/845V-7B3J> (archived Jan. 29, 2019).

137. Letter from Benjamin J. Apelberg, Acting Dir., Food & Drug Admin. Ctr. for Tobacco Prod., to Gerard Roerty, Vice President, Swedish Match N. Am. (Dec. 14, 2016), <https://perma.cc/MUW3-FWZD>.

138. *Id.*

139. *M RTP Application Actions (Orders, Denials, and Responses)*, *supra* note 136.

140. Letter from Benjamin J. Apelberg, *supra* note 137.

141. *Id.*

142. ENVIRON INT’L CORP., REVIEW OF THE SCIENTIFIC LITERATURE ON SNUS (SWEDISH MOIST SNUFF) vii (July 2013), <https://perma.cc/E9YP-CBRS> (“The use of Swedish snus is not associated with oral cancer or cancer of any part of the respiratory tract. At this time, the health risks known to be associated with chronic use of Swedish snus are benign, snus-induced lesions in some snus users, and acute, reversible cardiovascular effects such as an increase in blood pressure and heart rate, most likely due to nicotine”).

143. Letter from Benjamin J. Apelberg, *supra* note 137.

144. *Id.*

i. Cigarettes Compared to Snus

The FDA's main issue with the claim that snus is better for consumers than cigarettes is that General snus doesn't lower all health risks of cigarettes—it has the same negative nicotine health impacts as cigarettes, and while some users will completely switch, some users will use both.¹⁴⁵ The FDA concedes there would be health benefits to those who completely switch from cigarettes to snus, but cannot approve snus as no conclusion can be drawn for those that may use both.¹⁴⁶

It is a patently absurd policy for the FDA to sacrifice the health benefits of those that would quit smoking because others may use both cigarettes and snus. This thinking contradicts one of the specific purposes of the Tobacco Control Act (TCA) “to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products.”¹⁴⁷ While effective oversight is necessary, it must be flexible to promote less harmful tobacco products. This reasoning fails to do so.

The specified nicotine levels present in both cigarettes and snus extracted during use are comparable, and occasionally overlap, with levels extracted during use of nicotine gum.¹⁴⁸ While no tobacco product is safe, snus is shown to have less health risks associated with tobacco use as evidenced below:

This comprehensive review of the published scientific literature confirms the lack of serious adverse health effects associated with Swedish snus. The use of Swedish snus is clearly not associated with lung cancer, oral cancer, or incident IHD or MI, and stroke. The most likely health risks associated with chronic use of Swedish snus appear to be acute, reversible increases in heart rate and blood pressure likely due to nicotine, and a characteristic, reversible lesion in the mouth of snus users. There is no evidence that snus is associated with other mouth and gum diseases. Several adverse pregnancy outcomes are also clearly associated with use of snus during pregnancy. Overall, there is very little evidence that current use levels of snus in Sweden are associated with any significant long-term health effects, and ongoing research is hoped to provide additional information to resolve remaining areas of uncertainty.

145. CONRAD J. CHOINIERE, FOOD & DRUG ADMIN., MODIFIED RISK TOBACCO PRODUCT (MRTP) APPLICATION – TECHNICAL PROJECT LEAD (TPL) REVIEW 22-23 (2016), <https://perma.cc/Z86J-3JSH>.

146. *Id.* at 24.

147. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 § 3(4), 123 Stat. 1776 (2009).

148. Helena Digard et al., *Determination of Nicotine Absorption from Multiple Tobacco Products and Nicotine Gum*, 15 NICOTINE & TOBACCO RES. 255, 255 (2012), <https://perma.cc/YU9A-MDQ7>.

The areas of more important public health significance where the available evidence has not yet reached the level of “definitive” for a lack of association, and thus firm conclusions cannot yet be drawn, include the relationship between Swedish snus use and possible weight gain issues, metabolic syndrome and diabetes, hypertension, and fatal myocardial infarction.¹⁴⁹

While there is evidence snus may not be as appealing to cigarette smokers as cigarettes,¹⁵⁰ that is beside the point. If snus is healthier, switching to snus will benefit those smokers who change. Having a Modified Risk Tobacco Product that notifies potential consumers of a healthier alternative might make snus more appealing to those not ready to quit tobacco but wanting to quit smoking. This action would meet one of the purposes of the TCA ensuring that consumers are better informed.¹⁵¹

2. FDA Overreach

The FDA has denied most snus advertising changes thus far and have also moved to limit snus production.¹⁵² The FDA has proposed a rule that limiting the amount of N-nitrosornicotine (NNN) in smokeless tobacco, including snus, to not exceed 1.0 microgram per gram.¹⁵³ The FDA believes this will benefit quality of life- years gained due to oral cancer mortality.¹⁵⁴ While, the oral damage by snus is questionable,¹⁵⁵ the proposed rule is problematic on other grounds.

The FDA is prohibited from outlawing smokeless tobacco products.¹⁵⁶ The levels required by the proposed FDA standard would make “it impossible to grow and cure it [dark tobacco] to meet the proposed 1 ppm NNN ceiling on a consistent, on-going basis.”¹⁵⁷ Average NNN levels range from 0.3 ppm to 5.0 ppm when Dark tobacco leaves come from tobacco farmers.¹⁵⁸ As the Dark tobacco is, on average, already above the standards set by the FDA when it comes from the farm,¹⁵⁹ the

149. ENVIRON INT’L CORP., *SUPRA* NOTE 142, AT VII.

150. CHOINIERE, *supra* note 145, at 24.

151. Pub. L. No. 111-31 § 3(6), 123 Stat. 1776, 1782.

152. Letter from Benjamin J. Apelberg, *supra* note 137; *MRTP Application Actions (Orders, Denials, and Responses)*, *supra* note 136.

153. FOOD & DRUG ADMIN., TOBACCO PRODUCT STANDARD FOR N-NITROSONORNICOTINE LEVEL IN FINISHED SMOKELESS TOBACCO PRODUCTS 9 (Jan. 2017), <https://perma.cc/3BAH-PZUE>.

154. *Id.* at 11.

155. ENVIRON INT’L CORP., *supra* note 142, at vii.

156. 21 U.S.C. § 387g(d)(3)(A) (2018).

157. Letter from Jose Luis Murillo, *supra* note 78.

158. *Id.*

159. *Id.*

FDA would have to regulate the production at the tobacco farm level. This is particularly problematic, as the FDA specifically lacks the ability to do this.¹⁶⁰

i. Proper FDA Action

The purpose of the TCA was to provide “new and flexible enforcement” and “oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.”¹⁶¹ To date, the FDA has been inflexible and has not assisted in the industry’s efforts to promote less harmful tobacco products. Additionally, they have not allowed consumers to be better informed, as they should under the TCA.¹⁶² One of the most important purposes of the TCA was “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.”¹⁶³

Allowing snus to be considered a Modified Risk Tobacco Product and notifying the public of the known health differences between snus and cigarettes and its health impacts in general would better further the goals of the TCA. As adolescents are more prone to engage in risky behavior, notice of snus being a healthier option is unlikely to impact underage decision making in utilizing snus.¹⁶⁴ In fact, disapproval of oral tobacco remained relatively unchanged among 8th and 10th graders, while perceived risk has declined since 2004, and use of snus had declined since 2012.¹⁶⁵ The reasons for adolescent and children tobacco use is related to image, social, and peer reasons, not health.¹⁶⁶ On the other hand, adults

160. 21 U.S.C. § 387a(c)(2)(A), (B) (2018).

161. Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, § 3(4), 123 Stat. 1776 (2009).

162. Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31 § 3(6), 123 Stat. 1776; Letter from Benjamin J. Apelberg, *supra* note 137.; *M RTP Application Actions (Orders, Denials, and Responses)*, *supra* note 136.

163. Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31 § 3(7), 123 Stat. 1776.

164. *See* LAURENCE STEINBERG, ADOLESCENT DECISION-MAKING AND WHETHER STANDARDIZED PACKAGING WOULD REDUCE UNDERAGE SMOKING, 2.3-2.4 (Aug. 25, 2016), <https://perma.cc/8E9D-KRXG>.

165. LLOYD D. JOHNSTON ET. AL., 2015 OVERVIEW KEY FINDINGS ON ADOLESCENT DRUG USE, NAT’L INST. ON DRUG ABUSE 41 (2016), <https://perma.cc/5QKN-RAQY>.

166. BONNIE L. HALPERN-FELSHER, ET AL., *ADOLESCENTS’ AND YOUNG ADULTS’ PERCEPTIONS OF TOBACCO USE: A REVIEW AND CRITIQUE OF THE CURRENT LITERATURE*, in *ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION* 478, 484-85, Appendix E-8 (2007) (ebook), <https://perma.cc/Qz42-STV2>.

do care about health, as the majority polled said they want to quit¹⁶⁷, and cited health as the reason for quitting.¹⁶⁸

Snus is just one option among many. The TCA should meet all the requirements outlined in the law, while keeping in mind its purpose. Adult consumers of tobacco should be fully informed and have access to the most tools possible should they decide to quit tobacco or change nicotine delivery product. The FDA should be vigorous, but flexible, in implementing the Tobacco Control Act to make sure that narrow reading does not interfere with the broad purpose of the Act.

VI. CONCLUSION

Tobacco Control Advocates must realize that snus, among other alternative forms of nicotine delivery, can assist in saving lives by giving people an alternative to cigarettes. Harm reduction Advocates still need Tobacco Control Advocates' healthy suspicion of tobacco, and proper implementation of the Tobacco Control Act can assist in breaching the gap between the two groups. Tax policy on tobacco products should be equitable. Equitable tax policy looks to the impact that each product has on society and taxes it accordingly. Thus, tobacco policy has an impact that goes beyond health.

The tobacco farmer depends on the cash crop for continued support of family farms. Additionally, American tobacco and the American tobacco farmers are well positioned for competing in the world economy. Supporting American tobacco farms is an investment in growing more sustainable, beneficial crops, and in the future with possible advancements in pharmaceuticals and biofuels coming from tobacco.

The tobacco issue has too long created ideologues more concerned with fighting "big tobacco" than finding proper public policy to better serve the people of the United States. The comments from Tobacco Control Advocates and the FDA, who are unable to move forward on snus due to claimed unknown impacts, rings hollow. The inaction of these organizations is reminiscent of constant questioning of the science on the health impacts of smoking by the tobacco companies fifty years ago.¹⁶⁹ While one can appreciate the long battle which Tobacco Control Advocates have had fighting the misinformation of tobacco

167. Frank Newport, *Most U.S. Smokers Want to Quit, Have Tried Multiple Times*, GALLUP NEWS (July 31, 2013), <https://perma.cc/TJ8A-9FPN>.

168. *Id.*

169. See generally Letter from Gerry Roertry, *supra* note 85 (response available at Letter from Benjamin J. Apelberg, *supra* note 137; Dastrup & McNamara, *supra* note 7; Cf. WORLD HEALTH ORG., TOBACCO EXPLAINED: THE TRUTH ABOUT THE TOBACCO INDUSTRY . . . IN ITS OWN WORDS, <https://perma.cc/G8MR-W3EL> (archived Jan. 29, 2019).

companies and their denial of current science on the health implications of their product, they would be wise to remember that “[w]hoever fights with monsters should see to it that he does not become one himself.”¹⁷⁰

170. FRIEDRICH NIETZSCHE, *BEYOND GOOD AND EVIL* 69 (2002).