UNIVERSAL LEAF TOBACCO COMPANY, INC.

August 2, 2022

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **Docket No. FDA-2021-N-1309 (87 Fed. Reg. 26396-26451, May 4, 2022)—Universal Comments on "Tobacco Product Standard for Characterizing Flavors in Cigars"**

I. INTRODUCTION

Universal Leaf Tobacco Company, Inc., ("ULT") on behalf of itself and its subsidiaries (collectively referred to herein as "Universal"), appreciates the opportunity to submit these comments to the Food and Drug Administration ("FDA" or "Agency") on the proposed rule entitled *Tobacco Product Standard for Characterizing Flavors in Cigars* ("Proposed Rule") issued on May 4, 2022.

Universal, headquartered in Richmond, Virginia, is the world's leading tobacco leaf supplier. Universal conducts its business in 30 countries spanning five continents, employs over 25,000 full-time and seasonal workers, and contracts with nearly 200,000 farmers. Through ULT and its subsidiary Lancaster Leaf Tobacco Company, Universal procures and processes dark air-cured and burley tobacco for manufacturers of, among other products, flavored cigars. Universal is a tobacco intermediary (i.e. a facility that receives, processes, blends, and stores leaf tobacco) between tobacco farmers and tobacco product manufacturers. Universal's processing facilities also meet the definition of a "Tobacco Warehouse" under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") and are therefore exempt from regulation under the Food, Drug, and Cosmetic Act ("FD&C Act").[1]

[1] Family Smoking Prevention and Tobacco Control Act § 901(c)(2), 21 U.S.C. § 387 (2011).

On May 4, 2022, the FDA issued the Proposed Rule to prohibit all characterizing flavors in cigars, including premium cigars.[2] Simultaneously, the Agency released the Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and the Unfunded Mandates Reform Act Analysis (collectively referred to herein as "Regulatory Impact Analysis").[3]

The Proposed Rule and accompanying Regulatory Impact Analysis solicit comments on the data and assumptions made by FDA in estimating the benefits and costs of the proposed ban. In this comment, Universal intends to provide the Agency direction and guidance to several of these outstanding questions. In doing so, our findings conclude there are considerable unknowns regarding the impact this regulation will have on America's farmers, rural agricultural communities, local governments, and public health due to the substantive and procedural insufficiencies in the Agency's due diligence efforts prior to submitting the Proposed Rule. We therefore believe FDA is inadequately positioned to make an informed decision based on the information provided and suggest a number of alternative regulatory options available to the Agency moving forward.

II. CONTROLLING LEGISLATIVE & REGULATORY AUTHORITY

Introduction. In promulgating a tobacco product standard, FDA must operate within a number of procedural and substantive guardrails to ensure due process is respected and certain considerations are made. In this case, FDA must follow the requirements of: (1) the Tobacco Control Act, (2) Executive Orders 12866 and 13563, (3) the Regulatory Flexibility Act, and (4) the Unfunded Mandates Reform Act of 1995.

Family Smoking Prevention and Tobacco Control Act. In 2009, Congress passed the Tobacco Control Act authorizing FDA to, among other powers, promulgate new tobacco product standards when the Health and Human Services Secretary ("Secretary") determines that a standard is appropriate for the protection of public health.[4] In doing so, Congress also expressly prohibited the Agency from banning certain tobacco products altogether and placed a number of substantive and procedural restrictions on the Agency's ability to promulgate such rules.[5] These statutory restrictions on FDA reflect the stated intent of Congress in making tobacco products safer while still preserving an adult consumer's right to choose to use them.[6]

In determining whether a product standard is appropriate for the protection of public health, the Tobacco Control Act requires the Secretary to make certain substantive considerations, including: (1) the risks and benefits to the population as a whole, (2) the impact on cessation, and (3) the impact on initiation.[7] Additional considerations by the Secretary must also include the technical achievability of compliance with the standard and information concerning the

[2] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396-26451 (proposed May 4, 2022).
[3] Food and Drug Administration, *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* (2022). Available at https://www.fda.gov/media/158013/download (last visited July 26, 2022).
[4] Family Smoking Prevention and Tobacco Control Act § 907(a)(3)(A).
[5] *Id.* at § 907(d)(3)(A).
[6] *Id.* at § 3(7).
[7] *Id.* at § 907(a)(3)(B).

countervailing effects of the tobacco product standard on public health, such as the creation of an illicit market.[8]

The Tobacco Control Act also mandates certain procedural requirements in the promulgation of a tobacco product standard. The notice of proposed rulemaking must specifically seek input from certain interested parties, including the Secretary of Agriculture and those stakeholders that may comment on "structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco".[9] In addition, the effective date must not take effect before the one year anniversary of the rule's publication date, unless the Secretary determines that an earlier effective date is necessary for the protection of public health. In making that determination, the Secretary must consider a timeline that minimizes economic loss to, and disruption of, domestic and international trade. Furthermore, if the Secretary determines that a product standard can only be met by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of such product standard must be at least two years after date of publication of the final regulation.[10]

Executive Orders 12866 and 13563. In 1993, President Clinton issued Executive Order 12866 with the intent to design a regulatory system that (1) advances policies without imposing unacceptable or unreasonable costs on society, (2) recognizes the private sector and private markets as the best engine for economic growth, (3) respects the role of state, local, and tribal governments, and (4) becomes increasingly effective, consistent, sensible, and understandable.[11] Specifically, the Executive Order requires agencies to adhere to certain principles in promulgating regulations, including the following relevant requirements:

(1) *Consideration of Viable Alternatives*: Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior such as user fees or marketable permits, or choosing to not regulate altogether.
(2) *Cost-Effective Method*: When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve such an objective. In so doing, agencies should select among those approaches that maximize net benefits—including potential economic, environmental, public health and safety, and other advantages such as distributive impacts and equity.
(3) *Cost/Benefit Analysis*: Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.
(4) *Evidence-Based Regulation*: Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

[8] *Id.* at § 907(b).
[9] *Id.* at § 907(c)(2)(C)-(D).
[10] *Id*. at § 907(d)(2).
[11] Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993).

(5) *Impact on State, Local, & Tribal Entities*: Agencies shall seek the views and assess the effects of federal regulations on state, local, and tribal governments, including the availability of resources to carry out those mandates.
(6) *Tailored*: Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), taking into account the cost of cumulative regulations.[12]

The Executive Order charges the Office of Information and Regulatory Affairs ("OIRA") under the Office of Management and Budget ("OMB") with coordinating a review of agency rulemaking to confirm that regulations are consistent with applicable law, the President's priorities, and the aforementioned set of principles. OIRA must also ensure that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. Thus, for rules deemed a "significant regulatory action", agencies must provide OIRA an assessment of the projected benefits, anticipated costs, and why the planned regulatory action is preferable to the identified potential alternatives.[13] The Executive Order also requires each agency to provide the public with meaningful participation in the regulatory process at this stage. Specifically, "before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation".[14]

In 2011, President Obama issued Executive Order 13563—Improving Regulation and Regulatory Review—to supplement and reaffirm the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.[15] This Executive Order reiterates the need for agencies to adopt regulation only upon a reasoned determination that its benefits justify its cost, tailor regulations to impose the least burden on society, and select the regulatory approach that maximizes net benefits—including economic, environmental, and public health and safety. It emphasizes the need to consider qualitative impacts, including equity, human dignity, fairness, and distributive effects. Agencies should also "endeavor to provide the public with an opportunity to participate in the regulatory process" and "seek the view of those who are likely to be affected" prior to issuing a notice of proposed rulemaking.[16]

Regulatory Flexibility Act. In 1980, Congress passed the Regulatory Flexibility Act stating, "Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public".[17] Congress was concerned that laws and regulations designed for application to large scale entities were being applied uniformly to small businesses, small organizations, and small governmental jurisdictions, even though the problems that gave rise to government action may not have been caused by those smaller entities.

[12] *Id*.
[13] *Id*.
[14] *Id*.
[15] Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).
[16] *Id*.
[17] Regulatory Flexibility Act § 2(a)(1), 5 U.S.C. §§ 601-612 (1980).

It was the purpose of the act to establish as a principle of regulatory issuance that agencies should, consistent with objectives of the rule and of applicable statutes, fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their ultimate decision.[18]

Agencies are thus required to provide an Initial Regulatory Flexibility Analysis that includes a statement of the rule's need, a succinct statement of the objectives, an estimate of the number of small entities to which the proposed rule will apply, a description of the compliance requirements, and an identification of all duplicate or conflicting rules.[19] They are then required to submit a Final Regulatory Flexibility Analysis ensuring the applicable agency considers the public comments and viable alternatives to minimize the impact on these small entities. This Act also intends to ensure that small entities have been given an opportunity to participate in the rulemaking process.[20]

Unfunded Mandates Reform Act of 1995. Lastly, the Unfunded Mandates Reform Act intends for each agency to assess the effects of the regulatory action on state, local, and tribal governments, and the private sector.[21] It requires that prior to issuing a notice of proposed rulemaking for any "significant regulatory action" and prior to issuing any such final rule, an agency must publish a written statement, including:

(1) *Cost/Benefits Analysis*: A qualitative and quantitative assessment of the anticipated costs and benefits of the federal mandate, including the costs and benefits to state, local, and tribal governments or the private sector, as well as the effect of the federal mandate on health, safety, and environment.
(2) *Disproportionate Budgetary Impacts*: Estimates by the agency of any disproportionate budgetary effects of the federal mandate upon any particular regions of the nation or particular state, local, or tribal governments, urban or rural, or other types of communities, or particular segments of the private sector.
(3) *U.S. Economic Impact*: Estimates by the agency of the effect on the national economy, such as the effect on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness of American goods and services.[22]

The Act furthermore requires an agency to identify and consider a reasonable number of regulatory alternatives. From those alternatives, the agency must select the least burdensome that achieves the objectives of the rule or provide an explanation why such an option was not preferable.[23]

[18] *Id*. at § 2(b).
[19] *Id*. at § 603.
[20] *Id*. at § 609.
[21] Unfunded Mandates Reform Act of 1995 §201, 2 U.S.C. § 1531-1538 (1995).
[22] *Id*. at § 202.
[23] *Id*. at § 205(a).

III. INSUFFICIENCIES OF THE PROPOSED RULE

Introduction. As required by the aforementioned legislation and regulations, FDA must submit specific information within a Preliminary Regulatory Impact Analysis, an Initial Regulatory Flexibility Analysis, and an Unfunded Mandates Reform Act Analysis when promulgating a proposed rule the Agency considers a "significant regulatory action". These studies must include a comprehensive cost/benefit analysis and consideration of the effects on particular small entities and vulnerable communities. In constructing these analyses, FDA must also provide the public with an opportunity to participate and seek the view of those who are likely to be affected prior to issuing a notice of proposed rulemaking.[24] FDA did not satisfy such requirements mandated by federal legislation and regulation. Specifically, this section explains the substantive and procedural insufficiencies of the Regulatory Impact Analysis conducted by FDA in promulgating the Proposed Rule.

Substantive Insufficiencies. FDA's Regulatory Impact Analysis concludes that the Agency "do[es] not predict that the proposed rule will have a substantial impact on tobacco farmers".[25] This 134-page document reaches this conclusion in a two-page investigation into the impact a ban on characterizing flavors in cigars will have on the demand for tobacco leaf, citing only one reference.[26] Furthermore, as explained below, this is an inadequate source as it is missing critical data. From this effort, it can be concluded that FDA spent considerable resources in understanding the economic benefits of the Proposed Rule, but did not extend the same consideration to the potential costs, specifically those to agriculture and farmers.

Procedural Insufficiencies. There are also concerns in the method in which FDA collected the data used in constructing the Regulatory Impact Analysis through OIRA. In an effort to inform FDA of the importance of including agriculture in their economic considerations, Universal requested a meeting with OIRA. Upon accepting the request and scheduling the date/time, Universal received notice of the meeting's cancellation mere hours prior to the scheduled meeting (see Appendix A). Universal was the only organization from the agricultural sector to request a meeting with OIRA. Of the 15 representatives that spoke with OIRA, none specifically focused on the economic impact the Proposed Rule would likely have on agriculture.[27] While Universal does not manufacture a tobacco product for retail sale, we chose to engage with OIRA because no other business is as closely aligned to the interests of the famers as Universal. As such, Universal was in a unique position to explain the impacts the Proposed Rule could have on farmers and agricultural communities prior to the Agency issuing the notice.

Conclusion. The federally required Regulatory Impact Analysis is designed to ensure an agency takes into consideration, *inter alia*, the impact of a significant regulatory action on economic growth, job creation, international competitiveness, distributive burden, equity, small entities, and state, local, and tribal jurisdictions. The required OIRA review for significant regulatory actions further ensures affected stakeholders have notice and opportunity to comment

[24] Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).
[25] *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* at pages 72-73.
[26] *Id*.
[27] Office of Information and Regulatory Affairs, *OIRA Conclusion of EO 12866 Regulatory Review of RIN: 0910-AI28* (2022). Available at: https://www.reginfo.gov/public/do/eoDetails?rrid=227361 (last visited July 26, 2022).

prior to issuing a proposed rule. Executive Order 12866 specifically states, "Before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation".[28]

It is axiomatic that the purpose of the notice and comment period required by the Administrative Procedure Act is for stakeholders to provide FDA with technical information as to better inform the Agency's decision to proceed or amend a proposed rule. However, it does not absolve the Agency from its statutory and regulatory obligations to seek out reasonably obtainable scientific, technical, and economic information concerning the need for, and consequences of, the intended regulation prior to issuing a notice of proposed rulemaking.[29] In this case, FDA spent negligible amount of resources seeking to understand how the proposed ban on characterizing flavors in cigars will affect agriculture in the United States. FDA's brief economic analysis makes no effort to calculate a reduction in leaf demand, assign a value to this reduction, or include this number in the final evaluation of costs.[30] Furthermore, FDA actively chose not to engage the only stakeholder in the agricultural sector that requested a meeting during the OIRA review process.

The remainder of this comment intends to (1) expand upon and supplement FDA's understanding of the impact on domestic tobacco leaf requirements, (2) introduce FDA to the wider economic impacts not considered by the Agency, and (3) suggest reasonable alternatives to a total ban of characterizing flavors in cigars.

IV. SUPPLEMENTAL REGULATORY IMPACT CONSIDERATIONS

Introduction. The Regulatory Impact Analysis acknowledges the Proposed Rule could affect the demand for domestically grown tobacco leaf. While FDA concludes that any impact will not be substantial, the Agency requests comments "on the potential indirect impacts the proposed rule might have on farmers of cigar type tobacco."[31] This section intends to fulfill this request by supplementing the Agency's assumptions and delineating the risk the Proposed Rule poses to leaf tobacco markets.

U.S. Tobacco Leaf Production Estimates. Tobacco leaf used in the production of cigars is categorized into three classes: filler (Class 4), binder (Class 5), and wrapper (Class 6).[32] Cigar filler is the tobacco that forms the core or inner part of a cigar. Cigar binder is the portion of a tobacco leaf rolled around the filler of a cigar to bind or hold it together and form the first covering. Wrapper is the portion of a tobacco leaf forming the outer covering of a cigar and is typically the highest value of the three classes.[33] Table 1 presents the production of these cigar class tobaccos in the United States over the past five years as estimated by the Regulatory Impact Analysis with data derived from the U.S. Department of Agriculture ("USDA") National Agricultural Statistics Service ("NASS").[34]

[28] Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993).
[29] *Id*.
[30] *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* at pages 72-73.
[31] *Id*. at 73.
[32] 7 C.F.R. § 30.31.
[33] 7 C.F.R. § 30.14-30.16.
[34] U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats*, (2021). Available at https://quickstats.nass.usda.gov/ (last visited July 26, 2022).

Table 1: U.S. Tobacco and Cigar Tobacco Production, 2013-2017 (lbs.)[35]

	2013	2014	2015	2016	2017
All Tobacco	724,266,000	876,689,000	719,563,000	628,720,000	710,161,000
Class 4-6	8,573,000	9,313,000	8,718,000	3,840,000	4,320,000

Unfortunately, this data and the subsequent assumptions are incorrect due to insufficiencies in the NASS Quick Stats data. FDA chose the 2013-2017 data range because it was the most recent reporting of Cigar Class 4-6 production by NASS. However, NASS reports production and value numbers for Type 41, a cigar filler variety grown in Pennsylvania, through 2021.[36] Clearly, there is cigar tobacco being produced in the United States that is not captured by the NASS cigar category. Furthermore, as seen in Table 2, it appears the NASS cigar category is solely comprised of this Type 41 between 2016 and 2017. This leaves FDA's understanding of the total cigar tobacco production in the United States as one type of filler produced in Pennsylvania, excluding all wrapper tobacco, binder tobacco, and other types of filler grown throughout the country.

Table 2: NASS Data on U.S. Production of All Cigar Tobacco and Type 41 (lbs.), 2016-2021[37]

Year	All Cigar (Class 4-6)	Type 41
2016	3,840,000	3,840,000
2017	4,320,000	4,320,000
2018	0	5,520,000
2019	0	5,500,000
2020	0	5,520,000
2021	0	6,250,000

As the USDA NASS is generally the authority for agricultural production in the United States, it is difficult to estimate the volumes of domestically-grown cigar tobacco without a larger, comprehensive study. However, the state-by-state Agricultural Census in 2017 gives some insight into these numbers. Connecticut[38], Massachusetts[39], Pennsylvania[40], and Wisconsin[41] are four tobacco-growing states that produce tobacco predominantly for the cigar market. Table 3 summarizes the size of tobacco production in those states in 2017.

[35] *Id*.
[36] *Id*.
[37] *Id*.
[38] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, Connecticut State and County Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_State_Level/Connecticut/ (last visited July 26, 2022).
[39] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, Massachusetts State and County Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_State_Level/Massachusetts/ (last visited July 26, 2022).
[40] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, Pennsylvania State and County Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_State_Level/Pennsylvania/ (last visited July 26, 2022).
[41] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, Wisconsin State and County Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_State_Level/Wisconsin/ (last visited July 26, 2022).

Table 3: 2017 Agricultural Census Tobacco Production (CT, MA, PA, WI)

States	Farms	Acres	Production (lbs.)	Production ($)
Connecticut	46	2,204	3,868,124	$26,817,000
Massachusetts	15	461	727,960	$5,733,000
Pennsylvania	812	7,476	17,431,368	$35,994,000
Wisconsin	108	478	983,963	$1,667,000
Total	981	10,619	23,011,415	$70,211,000

Conclusion. The Proposed Rule suggests eliminating a substantial portion of the cigar market in the United States. FDA acknowledges this will affect demand for domestically grown tobacco leaf, but concludes any effect will be negligible based on insufficient data. Table 3 does not suggest an all-encompassing estimate of cigar type production in the United States as Kentucky, Virginia, and Tennessee are also large producers of these tobaccos. However, this low estimate of 23 million pounds is already more than five times greater than the estimate included in FDA's Regulatory Impact Analysis.[42] It can be concluded from this section that FDA is not properly informed by the research in the Regulatory Impact Analysis regarding agriculture to make a well-informed decision in advancing the Proposed Rule. Especially when considering the risk to rural economies, farmers, and vulnerable populations as expanded upon below.

V. ADDITIONAL REGULATORY IMPACT CONSIDERATIONS

Introduction. The previous section explains the insufficiencies in the data FDA collected to understand how the Proposed Rule will impact demand for American-grown tobacco. However, no such data can truly quantify the economic and social impacts the Proposed Rule will have on American farms and rural communities. The following section introduces FDA to these additional considerations, including: (1) the impact on the economy of the United States, (2) the impact on American farmers and their workers, (3) the impact on the stability of underserved rural communities, and (4) the impact on small entities, including businesses and governmental jurisdictions.

(1) Impact on the Economy of the United States

Introduction. Tobacco continues to be a critically important crop in the United States. In 2021, American farmers grew 478 million pounds of tobacco leaf across 219,000 acres with farm level receipts of $1.026 billion.[43] Tobacco is produced in 18 states with most being grown in (ranked by production) North Carolina, Kentucky, Virginia, Tennessee, Georgia, South Carolina, and Pennsylvania. This section highlights the role tobacco plays and the larger risk the Proposed Rule poses to the overall economy of the United States.

[42] *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* at page 72.
[43] U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021) Available at: https://quickstats.nass.usda.gov/ (last visited July 26, 2022).

State of U.S. Tobacco Growing. The Regulatory Impact Analysis notes a decline in overall tobacco-growing farms and volumes to suggest the importance of tobacco in agriculture is waning.[44] However, the Agency overlooks two important issues related to tobacco volumes in the United States. First, as seen in Table 4 below, there have been two rather significant declines in volumes over the past five years, both due to global market factors.

Table 4. U.S. Leaf Tobacco Production (1,000 lbs), 2016-2020[45]

State	2016	2017	2018	2019	2020	5-Year Average
Georgia	28,350	26,250	23,750	18,900	19,276	22,805
Kentucky	136,280	183,300	134,370	123,390	107,235	127,129
North Carolina	331,800	360,040	251,925	234,700	184,127	250,895
Pennsylvania	20,460	18,990	17,400	14,300	13,440	16,600
South Carolina	24,700	25,200	22,140	15,770	8,400	18,630
Tennessee	35,690	43,000	39,610	30,490	29,380	34,956
Virginia	51,440	53,381	44,046	30,406	27,555	39,499
TOTAL	628,720	710,161	533,241	467,956	389,413	510,514

Beginning in 2017, the United States and China began a trade dispute culminating in import duties placed on tobacco leaf entering China in 2018 and 2019. Between 2017 and 2020, leaf exports to China dropped from 18,774,623 pounds worth $162,297,021 to 138,651 pounds valued at $1,144,890.[46] Secondly, the COVID-19 pandemic put stress on supply chains around the world, especially agriculture, resulting in non-market driven declines in production across the board starting in 2020.[47]

Specific to the cigar market, the demand for cigar type tobaccos in the United States have actually increased in recent years. For example, the production of Type 41, a Pennsylvania-grown cigar filler tobacco, has increased by 63% since 2016 as seen in Table 2.

Furthermore, FDA's economic analysis chose not to assign an economic value to the sale of leaf tobacco. The Agricultural Census provided by the USDA, summarized in Table 5 below, shows the sale value of tobacco leaf from the top tobacco-growing states and the 10-year average. The chart indicates that while acreage and production have declined over the years, the efficiency of farms and quality of the U.S. crop has led to 10-year stability in the overall market.

[44] *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* at page 72.
[45] U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: https://quickstats.nass.usda.gov/ (last visited July 26, 2022).
[46] TMA, *U.S. Trade Barometer: Exports of Leaf Tobacco*, (December 2017, December 2020).
[47] U.S. Department of Agriculture, Economic Research Service, *Rural America at a Glance* (2021). Available at: https://www.ers.usda.gov/publications/pub-details/?pubid=102575 (last visited July 26, 2022).

Table 5: Agricultural Census Summary of Tobacco Leaf Sales, 2007-2017[48]

State	2007	2012	2017	10-Year Average
North Carolina	$549,636,000	$732,772,000	$731,657,000	$671,355,000
Kentucky	$314,151,000	$356,603,000	$351,234,000	$340,662,667
Virginia	$68,073,000	$100,901,000	$107,620,000	$92,198,000
Tennessee	$70,634,000	$108,224,000	$99,431,000	$92,763,000
Georgia	$56,978,000	$39,656,000	$52,676,000	$49,770,000
South Carolina	$73,026,000	$47,984,000	$46,939,000	$55,983,000
Pennsylvania	$28,156,000	$40,379,000	$35,994,000	$34,843,000
US Total	$1,268,114,000	$1,491,208,000	$1,474,376,000	$1,411,232,667

Economic Impact of Tobacco-Growing. Dr. Blake Brown, Hugh C. Kiger Professor of Agriculture and Resource Economics at NC State University, conducted a high-level study to examine the impact of tobacco growing on the economy of the United States (see Appendix B).[49] The following is a summary of these results, given in terms of direct, indirect, and induced changes with each broken down to changes in employment, labor income, and value-added.

IMPLAN Analysis. IMPLAN is used for the input-output analysis of the economic impacts of tobacco farming. A change in one sector of the economy has multiple impacts in many different associated sectors. IMPLAN divides the impacts of changes in a sector's output into direct, indirect, and induced effects. The direct effects are for a given change in the industry sector in question. For example, if all tobacco production in the U.S. ceases, farm level revenues will decline by $1.026 billion. Indirect effects are the impacts due to changes in business-to-business transactions of the industry in question with other businesses. For example, if tobacco farms have reduced output, then fertilizer expenditures (and fertilizer industry output) are reduced. Induced effects stem from changes in household spending when the employees in the affected industry have changes in their labor income due to changes in the affected industry. For example, if tobacco farming revenues are reduced then farmers and their employees have less household income to spend which has negative effects on the economy. The sum of direct, indirect, and induced impacts is the total impact on economic output. IMPLAN further divides these three types of impacts into the impact on employment, labor income, and value-added. Employment is the reduction in the number of jobs due to the change in the affected industry. Labor income is thereby reduced. Value-added is defined as the difference in industry output (revenues) and expenditures on intermediate inputs for production in the sector in question.

Direct Impacts. Based on 2021 tobacco production, complete elimination of tobacco farming would reduce output by $1.026 billion. This exogenous change is imposed on the economy and the resulting impacts traced throughout the economy. Such a change could be brought about suddenly by changes in tobacco policy and regulations. Employment in tobacco farming would

[48] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/index.php (last visited July 26, 2022).
[49] Brown, Blake. "Economic Impact of U.S. Tobacco Farming." Analysis completed with IMPLAN. July 25, 2022.

fall by 15,569 jobs. To state it otherwise, employment in tobacco farming in 2021 is estimated by IMPLAN to be 15,569 and all this would be lost. Consequently, labor income in tobacco farming, all of it, would fall by $380 million. Value added to the economy by the tobacco farm sector would all be lost equaling $520 million. The sum of labor income lost plus value-added by tobacco farming plus the cost of intermediate goods purchased for tobacco production equal the direct output loss of $1.026 billion.

Indirect and Induced Impacts. Lost indirect output to the economy is estimated to be $828 million. This loss in output is due to a reduction in business that tobacco farms do with supporting and affiliated businesses. For example, tobacco farms will purchase no fertilizer or seeds. As a consequence, those businesses will lose 5,032 jobs and labor income paid by these businesses will decrease by $262 million. Additionally, these affiliated and supporting industries will reduce the value they add to Gross Domestic Product by $414 million. The induced impact is a reduction in output of $952 million. This is a result of people working in tobacco farming having less household income to spend.

Impacts on Affiliated Industries. The indirect and induced effects of the loss of tobacco farming affect a wide range of business and industry sectors as seen in Table 6.

Table 6: Impact on Output from Related Industries

Industry	Impact on Economic Output
Other Real Estate	($167,864,348.01)
Support Activities for Agriculture and Forestry	($110,154,484.84)
Owner-Occupied Dwellings	($74,816,869.77)
Pesticide and other Agricultural Chemical Manufacturing	($64,451,852.11)
Wholesale: Other Non-Durable Goods Merchant Wholesalers	($55,887,569.54)
Monetary Authorities and Depository Credit Intermediation	($43,097,467.24)
Hospitals	($41,831,978.64)
Petroleum Refineries	($36,473,673.64)
Insurance Carriers, Except Direct Life	($33,580,555.08)
Management of Companies and Enterprises	($27,865,941.38)

Interestingly, “Other Real Estate” is the affiliated category that is most affected by the elimination of tobacco farming with output in Other Real Estate falling by $168 million. Other Real Estate includes lessors of non-residential building and operations of residential property managers. Pesticide and other agricultural chemical manufacturing decreases by $64 million. Petroleum refineries are negatively impacted by $36 million. Hospitals experience a reduction in economic output of $42 million.

Total Impacts. The total impact on the economy with a loss of tobacco farming is $2.8 billion. This includes a reduction in employment of 25,701 jobs, a reduction in labor income of $944 million, and a reduction in value-added of $1.467 billion.

Table 7: Impact of Loss of Tobacco Farming on the U.S. Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(15,549)	($380,983,130)	($520,206,497)	($1,025,874,000)
Indirect	(5,032)	($262,123,176)	($413,623,092)	($828,609,026)
Induced	(5,120)	($300,862,962)	($533,647,757)	($951,936,707)
Total	**(25,701)**	**($943,969,267)**	**($1,467,477,346)**	**($2,806,419,733)**

Conclusion. America's tobacco-growing operations directly support 15,549 jobs paying $380,983,130 in labor income and support a total of 25,701 jobs paying nearly one billion dollars in labor income throughout the agricultural sector. Though it is difficult to precisely quantify the amount of cigar type tobacco produced in the United States and the percentage that will be affected by the Proposed Rule, every dollar lost in the sale of tobacco leaf on the farm accounts for $1.78 lost to the larger U.S. economy.

(2) <u>Impact on American Farmers and Workers</u>

Introduction. FDA's Proposed Rule will have the greatest direct impact on America's farmers and their workers, yet they are not considered in FDA's Regulatory Impact Analysis. According to the last Agricultural Census conducted by the USDA, there are 6,237 tobacco-growing farms in the United States.[50] In 2021, these farmers grew 478 million pounds of tobacco leaf across 219,000 acres with farm level receipts of $1.026 billion.[51] Of course, the biggest risk the Proposed Rule poses to the farm is lost revenue. Beyond the loss of this revenue, however, the sale of tobacco also plays an irreplaceable role on the farm in supplying the capital necessary to invest in the infrastructure supporting the cultivation of other crops and compliance with increasing regulations.

Tobacco-Growing Farms in the United States. Small family farms play a key role in tobacco production in the United States. As seen in Table 8, 98.8% of tobacco-growing farms in the top producing states are family/individually owned, partnerships, or held in family-controlled corporations.[52] Therefore, only 1.2%, or 71 farms, are organized as corporate entities outside of family control.

[50] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/index.php (last visited July 26, 2022).
[51] U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: https://quickstats.nass.usda.gov/ (last visited July 26, 2022).
[52] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/index.php (last visited July 26, 2022).

Table 8: Tobacco-Growing Farm Ownership in Top Tobacco Producing States, 2017[53]

State	Family/Individual	Partnership	Corp/Family Held	Corp/Other
North Carolina	897	184	185	29
Kentucky	2,249	272	74	20
Virginia	244	25	31	6
Tennessee	505	67	19	7
Georgia	71	20	7	8
South Carolina	83	28	5	1
Pennsylvania	746	39	27	0
Total	4,795	635	348	71

Alternatives to Tobacco Growing. Tobacco is considered a "cash crop" as it generates more revenue per acre than most other crops in the United States; this is particularly true for cigar type tobacco. Tobacco producers rely on this income to support the production of other crops and to invest in the overall farm. A study of Universal's contracted operations found 100% of farmers producing cigar type tobacco also cultivate a wide variety of complementary crops, the highest among them being corn, soybeans, and wheat in 2021.

Figure 1: Percentage of Crops Grown by Universal Farmers in the United States, 2021[54]

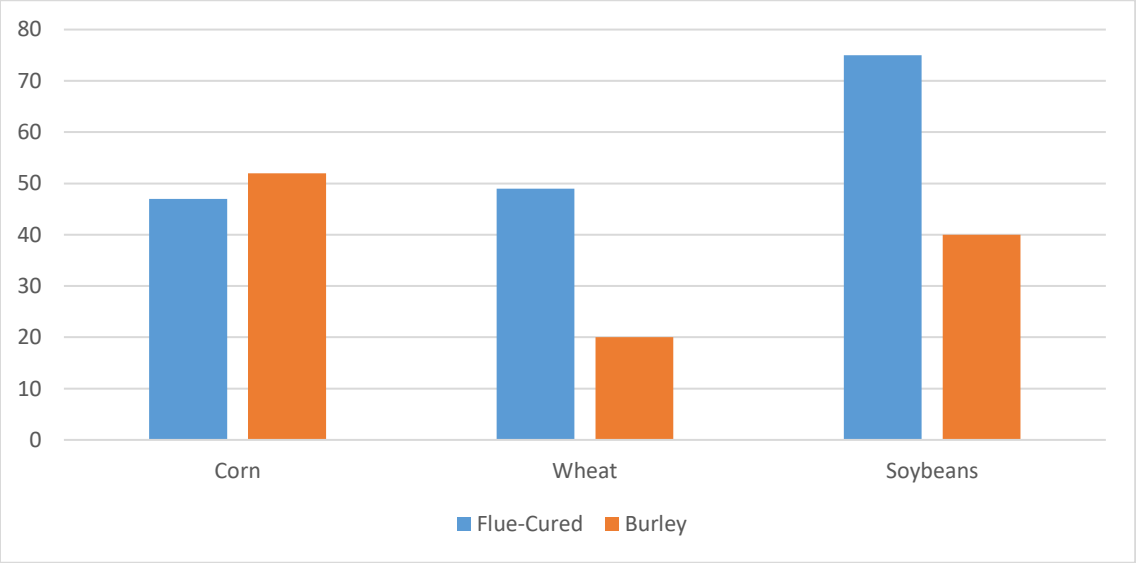
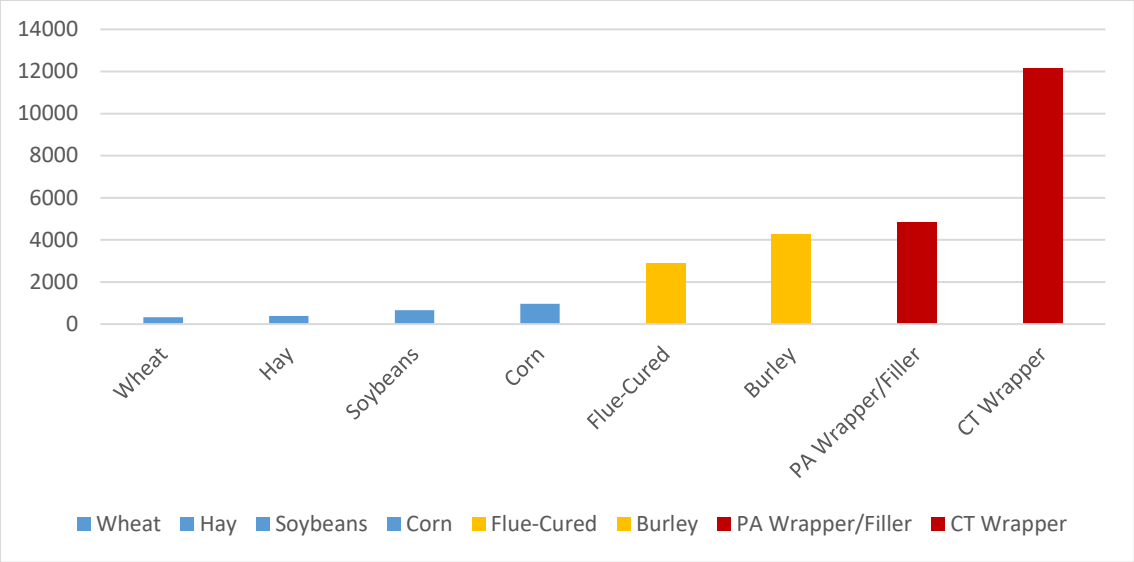


Figure 2 below shows 2021 crop revenue per acre in the sale of tobacco as compared to those of corn, wheat, soybeans, and hay.

[53] *Id.*
[54] Based on Universal Contracted Farmers (2021).

Figure 2: Comparison of Crop Revenue per Acre, 2021[55]



As Figure 2 represents, a loss of one acre of Connecticut wrapper tobacco requires a farmer to grow an additional 38 acres of wheat, 32 acres of hay, 18 acres of soybeans, or 12 acres of corn for grain. As cropland is limited on the farm, most growers do not have enough land to replace tobacco by simply growing more of another crop of significantly lower value per acre.

In a similar proposed product standard, FDA suggests that "some tobacco growers have switched to hemp production as it uses the same equipment and many of the same growing techniques as tobacco".[56] While the cultivation of hemp does share some similarities with tobacco, existing agronomic technology, markets, and federal regulations currently make hemp an ill-suited alternative. First, labor costs are significantly high for hemp compared to tobacco—which is already one of the most labor-intensive crops in the United States. Hemp seeds must be planted by hand rather than using the mechanical planters often used in tobacco. Additionally, no herbicide has been approved for the production of hemp, requiring weeds to be pulled manually. One of the largest obstacles to a farm's reliance on hemp is the instability of the unregulated cannabidiol ("CBD") market. The 2018 Farm Bill legalized the production of hemp and gave regulatory authority to FDA over products containing cannabis or cannabis-derived compounds, including CBD.[57] Since 2018, FDA has approved only one product, a medical grade drug for the treatment of seizures, that contains CBD.[58] The instability of the market has ultimately led to the instability in pricing of hemp, thus creating great risk to the farmer in dedicating acreage to such a crop. This risk is exasperated as regulations surrounding banking and crop insurance currently remain in their nascent phases.

[55] U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: https://quickstats.nass.usda.gov/ (last visited July 26, 2022).
[56] *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 201.
[57] Food & Drug Administration, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (2021). Available at: https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (last visited July 26, 2022).
[58] *Id*.

Conclusion. Tobacco has been, and remains, an unparalleled cash crop on farms in this nation. In 2021, American farms grew 478 million pounds of tobacco across 219,000 acres valued at $1.026 billion. The vast majority of these farms are small, family held businesses that directly employ 15,549 workers on the farm and support 25,701 jobs across the agricultural sector. Tobacco's revenues may be up to 30 times greater than those complementary crops grown alongside tobacco or in the off-season, meaning there is no economically viable alternative to tobacco on the farm. As North Carolina's Commissioner of Agriculture, Steve Troxler, commented to FDA:

> *Given the fluctuations of commodity markets, tobacco provides financial stability for many of these farms to remain in production. Without the profitability offered from tobacco, many would not be able to stay in business (see Appendix C).*[59]

Tobacco revenues support grower investment in the farm that makes the production of other crops economically feasible. It also supports farmer investment in compliance with regulatory requirements of, among other things, the Clean Water Act and the Chesapeake Bay Watershed Agreement. Certain emerging agricultural crops, such as hemp, may prove to be an option over the next decade as the market and federal/state regulations continue to mature, but are insufficient as they exist today. Such an impact on the farm should be considered and studied prior to issuing a final regulation.

(3) <u>Impact on Underserved Rural Communities</u>

Introduction. FDA states its public health equity objective is advanced by addressing how flavored cigars disproportionately affect vulnerable populations.[60] The Agency defines the term "vulnerable populations" to include those "with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions or substance use disorders."[61]

In fact, FDA is required to include a consideration of vulnerable populations in its Regulatory Impact Analysis. The Unfunded Mandates Reform Act requires FDA to include estimates of any disproportionate budgetary effects of a federal mandate upon any particular regions of the nation or particular state, local, or tribal governments, urban or rural, or other types of communities.[62] The Agency is also required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among vulnerable populations and other population subgroups.[63] In selecting among available regulatory alternatives, Executive Orders 12866 and 13563 require an agency choose the option likely to maximize net benefits, including distributive impacts and equity.[64]

[59] Statement by North Carolina Agricultural Commission Steve Troxler, North Carolina Department of Agriculture and Consumer Services (2022).
[60] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26396.
[61] *Tobacco Product Standard for Characterizing Flavors in Cigars Preliminary Regulatory Impact Analysis* at page 15.
[62] Unfunded Mandates Reform Act of 1995 §202(a)(3)(B).
[63] Family Smoking Prevention and Tobacco Control Act § 907(b).
[64] Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993) and Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).

In the Proposed Rule and Regulatory Impact Analysis, FDA spends considerable time discussing the impact on racial and ethnic populations, individuals who identify as LGBT+, those pregnant or trying to become pregnant, youth, and those with behavioral health conditions or substance use disorders. However, FDA does not include in its analysis the impact on an extremely relevant portion of the "vulnerable population"—underserved rural communities. Therefore, this section of our comment intends to supplement FDA's conspicuously absent exploration into the impact this Proposed Rule will have on underserved rural populations and communities intrinsically tied to agriculture.

Understanding Rural Populations. The Department of Agriculture defines "rural" or "non-metro" to include some combination of (1) open countryside, (2) rural towns with a population of fewer than 2,500, and (3) urban areas with populations ranging between 2,500-49,999 that are not part of larger labor market areas.[65] In 2020, approximately 47 million people, 14% of the population, lived in rural areas in the United States.[66] A typical rural county contained less than 10% of the population of a typical urban county in 2020—23,000 people compared with 245,000.[67] According to the USDA, "Residents who live in smaller and more isolated rural settings often face greater difficulties accessing provisions and services or commuting to work, among other economic development challenges. These factors may affect their resiliency to and recovery from shocks, such as the COVID-19 pandemic."[68] As seen in Table 9, persistent poverty and unemployment are a disproportionately high in non-metro counties, with 15.2% in persistent poverty as compared to 4.5% of metro counties.[69]

Table 9: Populations Statistics for Counties by Persistent Poverty, 2010-2020[70]

	Number of Counties	Population	Population Per County	Population Change (#)	Population Change (%)
Non-Metro	1,976	46,005,635	23,282	-287,771	-0.6
Persistent Poverty	301	5,742,693	19,079	-345,491	-5.7
Not-Persistent Poverty	1,675	40,262,942	24,038	57,720	0.1
Metro	1,166	285,443,646	244,806	22,991,514	8.8
Persistent Poverty	52	11,689,533	224,799	639,584	5.8
Not-Persistent Poverty	1,114	273,754,113	245,740	22,351,930	8.9
United States	3,142	105,490	105,490	22,703,743	7.4

[65] U.S. Department of Agriculture, Economic Research Service, *What is Rural?* (2021). Available at: https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/ (last visited July 26, 2022).
[66] U.S. Department of Agriculture, Economic Research Service, *Rural America at a Glance* (2021). Available at: https://www.ers.usda.gov/publications/pub-details/?pubid=102575 (last visited July 26, 2022).
[67] *Id*.
[68] *Id*.
[69] *Id*.
[70] *Id*.

Impact on Rural Communities. America's rural communities are fundamentally tied to agriculture. Approximately 22.4% of non-metro areas are dependent on the agricultural sector, and, as expected, the vast majority of farms are situated in rural areas.[71] As delineated above, the loss of tobacco volumes resulting from a ban on flavored cigars will have a ripple effect throughout the agricultural sector and therefore rural communities.

Impact on Amish/Mennonite Community. There is a specific rural community this Proposed Rule will disproportionally affect that has yet to be considered by FDA: the Amish and Mennonites. Those in the Amish and Mennonite communities revere agriculture and grow much of the cigar tobaccos produced in Pennsylvania, Maryland, and Wisconsin. These growers face many restrictions on the farm due to their faith, including no electricity, cars, mechanical farming equipment, or government subsidies such as the 2005 Tobacco Transition Payment Program.[72] As a result, these communities are limited in employment opportunities. Those who are not in agriculture typically join the construction industry or produce what is known as "Amish Furniture".[73] A significant loss of tobacco volumes, especially high-valued cigar tobacco, could be devastating to these communities as there are very limited alternatives for revenue.

Conclusion. The Proposed Rule will have a significant impact on rural economies, with a disproportionate impact on the Amish and Mennonite communities. The FDA must first understand and study this wider impact prior to issuing its final rule.

(4) <u>Impact on Small Entities (including Businesses and Governmental Jurisdictions)</u>

Introduction. The Regulatory Flexibility Act requires agencies to provide an Initial Regulatory Flexibility Analysis that includes an estimate of the number of small entities to which the proposed rule will apply and consider alternatives to minimize the rule's impact on them.[74] The Act includes in their consideration governmental jurisdictions and small businesses. A "small governmental jurisdiction" is defined in the Act to mean any locality with a population of less than 50,000.[75] The Small Business Administration considers a tobacco farm a "small business" concern if it has annually receipts of less than $2.25 million.[76] Currently, FDA's Regulatory Impact Analysis does not include an estimate of the small entities in the agricultural sector likely to be impacted by the Proposed Rule, specifically tobacco-growing farms and small governmental jurisdictions.

Small Tobacco-Growing Farms. According to the USDA, family farms remain a key part of United States' agriculture making up 98% of all farms and providing 88% of production.[77] Most farms are small family farms that operate almost half of U.S. farmland and generate approximately 21% of production.[78] As seen in Table 8 above, 98.8% of tobacco-growing farms are family

[71] U.S. Department of Agriculture, Economic Research Service, *County Typology Codes* (2015). Available at: https://www.ers.usda.gov/data-products/county-typology-codes/ (last visited July 26, 2022).
[72] Lancaster PA, *Amish and the Plain People* (2022). Available at: https://lancasterpa.com/amish/ (last visited July 26, 2022).
[73] *Id*.
[74] Regulatory Flexibility Act § 603(a).
[75] Regulatory Flexibility Act § 601(5).
[76] U.S. Small Business Administration, *Table of Small Business Size Standards* (2017). Available at: https://www.sba.gov/sites/default/files/2022-07/Table%20of%20Size%20Standards_Effective%20July%2014%202022_Final-508.pdf (last visited July 28, 2022).
[77] U.S Department of Agriculture, Economic Research Service, *A Look at America's Family Farms* (2021). Available at: https://www.usda.gov/media/blog/2020/01/23/look-americas-family-farms (last visited July 26, 2022).
[78] *Id*.

controlled. As of 2017, there were 6,237 tobacco-growing farms in the United States, and, as defined above, they will be greatly affected by the Proposed Rule in a number of ways.[79]

Small Governmental Jurisdictions. As delineated in the previous sections, rural communities are tied to the well-being of the agricultural economy with 22.4% of all non-metro areas dependent on the agricultural sector.[80] By definition, the governments of these rural communities are considered small governmental jurisdictions by the Regulatory Flexibility Act. The Proposed Rule will likely impact these localities in a number of ways, including loss of tax revenue from impacted farms and retail sales. Furthermore, the burden of enforcement and compliance with the Proposed Rule will ultimately be placed on these small governmental bodies. This includes not only the enforcement at the retail level, but the likely increase to illicit trade that will result from a ban on flavored cigars.

Conclusion. FDA is required in its analysis to take into consideration the small businesses and governmental jurisdictions impacted by the Proposed Rule. The Regulatory Impact Analysis at it is currently written overlooks the rural localities and farming operations, including the underrepresented Amish and Mennonite communities, that supply tobacco leaf to the U.S. cigar market and should be considered prior to the Agency moving forward with rulemaking.

VI. ALTERNATIVES & RECOMMENDATIONS

Introduction. In promulgating a rule, Executive Orders 12866 and 13563 require agencies to consider viable alternatives to direct regulation, including the alternative of not regulating altogether.[81] When choosing among the identified options, agencies should select among those approaches that maximize net benefits—including potential economic, environmental, public health and safety, and other advantages such as distributive impacts and equity.[82]

The agency must also tailor its regulations to impose the least burden on society, including individuals, businesses, and other entities. The Unfunded Mandates Reform Act likewise requires an agency to identify and consider a reasonable number of regulatory alternatives.[83] From those, the agency should select the most cost-effective or least burdensome alternative that achieves the objectives of the rule.

The following section recommends two alternatives to the Proposed Rule that meets the expectations and obligations required from FDA while imposing a far less burden on society as a whole. We also make three suggestions for amendments to the Proposed Rule regarding the extension of the effective date, exemptions of certain cigar products, and the definition of "characterizing flavors".

[79] U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Dat*a (2017). Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/index.php (last visited July 26, 2022).
[80] U.S. Department of Agriculture, Economic Research Service, *County Typology Codes* (2015). Available at: https://www.ers.usda.gov/data-products/county-typology-codes/ (last visited July 26, 2022).
[81] Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993) and Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).
[82] *Id*.
[83] Unfunded Mandates Reform Act of 1995 §205(a).

Agency Objectives. FDA states the intended purpose of the proposed regulation is to reduce the tobacco-related harm associated with flavored cigar use and mitigate tobacco-related health disparities by advancing health equity. To achieve these objectives, FDA suggests a total ban on the sale of flavored cigars.

Like the FDA, Universal and our customers are committed to eliminating youth use of tobacco products. Our customers' youth access prevention policies have contributed to the percentage of youth use of cigars dropping to a historic low. A blanket ban on flavored cigars, however, will only put unnecessary stress on America's agricultural economy, farmers, state and local governments, and vulnerable communities, including a disproportionate effect on rural populations and small entities. Small businesses and individuals are already burdened by supply chain disruptions, labor shortages, and unparalleled inflation. Additionally, state and local governments will be left to ultimately enforce this rule with less revenue and increased compliance costs from the rise of an illicit market.

The health and equity objectives of FDA and economic well-being of America's agricultural sector are not mutually exclusive. The following proposed alternatives explore two regulatory approaches FDA can take to achieve its objectives while mitigating the harm to agriculture.

Proposed Alternative 1. Universal believes the best means to achieve FDA's health objectives is to establish a well-regulated, legal market for flavored cigars. According to the 2020 National Youth Tobacco Survey, high school usage of cigars fell from 11.6% to 5.0% between 2011 and 2020.[84] This was the result of joint government and industry efforts to curb youth use of tobacco products. Continuing this targeted reduction of these products lessens the harm caused by the Proposed Rule's immediate reduction in tobacco leaf and allows the agricultural sector to gradually shift reliance away from the crop. If the Agency were to harness the regulatory tools already at their disposal to ensure a well-regulated, legal market—such as advertisement restrictions, education opportunities, and promulgating the rule to increase the legal age of purchase to 21—FDA could achieve greater health equity and reduced overall flavored cigar use while minimizing negative externalities (such as the risk of an illicit market).

Proposed Alternative 2. Should the FDA ultimately determine the only means to achieve their stated objectives is to move forward with a total ban on flavored cigars, there are options to achieve a less harmful transition. Universal recommends FDA, in coordination with the Secretary of Agriculture, establish a commission of stakeholders to review and study a flavored cigar ban's impact on the entities discussed in this comment, including farmers, state and local governments, vulnerable rural communities, and other small entities. This has not been part of FDA's study on flavored cigars.

This commission should consist of government representatives from the Center for Tobacco Products and the USDA, as well as their counterparts in the seven top tobacco-growing states—Georgia, Kentucky, North Carolina, Pennsylvania, South Carolina, Tennessee, and

[84] Gentzke AS, Creamer M, Cullen KA, et al. *Vital Signs: Tobacco Product Use Among Middle and High School Students—United States*, 2011-2018. MMWR Morb Mortal Wkly Rep 2019; 68: 157-164.

Virginia. It should also include industry and association representatives from the tobacco grower associations, farm worker labor unions, tobacco leaf suppliers, Farm Bureau, Agribusiness Council, and uniquely impacted state, local, and tribal governments. The group should be charged with: (1) conducting a comprehensive study to fully understand the impact a ban on flavored cigars will have on the agricultural sector, (2) conducting an economic development study to determine alternative or complimentary crops to tobacco, and (3) suggesting a strategy to mitigate the negative externalities of the Proposed Rule as derived from these studies.

As the mission of the work group requires technical expertise in agriculture, we suggest the USDA leads this effort. These studies and recommendations would then be included in the Secretary of Agriculture's input when the FDA restarts the rulemaking process as required by the Tobacco Control Act.[85] Ultimately, Universal believes that understanding the full economic impact on the agricultural sector is a necessary prerequisite to advancing the Proposed Rule, and FDA should refrain from issuing a final rule until it has completed this due diligence.

Extension of the Effective Date. The effective date in the Proposed Rule allows manufacturers one year after the date of publication to comply with the prohibition of characterizing flavors in cigars. In the Proposed Rule, the FDA requests information regarding the technical achievability of compliance with the standard, including from tobacco growers.[86] The Tobacco Control Act typically requires the effective date of a product standard to not take effect before one year after the date of the rule's publication, unless the Secretary determines that an earlier effective date is necessary for the protection of public health.[87] However, it also stipulates that a product standard which can only be met by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer must have an effective date of at least two years after date of publication of the final regulation.[88]

All tobacco products are made from the specific, propriety recipe of each tobacco product manufacturer. These recipes consist of decisions regarding ratios of tobacco types, varieties, stalk positions, country of origin, etc. and are what differentiate between cigar brands. Should adult consumers switch from flavored cigars to non-flavored products, there could be a shift in tobacco leaf demand. Meeting this new demand could require a substantial change to the type and methods of farming of domestically grown tobacco and require the effective date of the Proposed Rule to be at least two years after date of publication of the final regulation.

The Tobacco Control Act requires FDA to solicit comments on how to draft the product standard so as not to advantage foreign-grown tobacco over domestically grown tobacco.[89] It is important to note that tobacco leaf suppliers, like Universal, typically contract with farmers on an annual basis. Should the Proposed Rule result in a shift of tobacco requirements during the season, suppliers may be forced to meet market requirements by importing foreign-grown tobacco. The

[85] Family Smoking Prevention and Tobacco Control Act § 907(c)(2)(D).
[86] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26438.
[87] Family Smoking Prevention and Tobacco Control Act § 907(d)(2).
[88] *Id*.
[89] Family Smoking Prevention and Tobacco Control Act § 907(c)(2)(C).

Agency should therefore structure the rule so as to avoid this result by extending the effective date to at least two years.

Ultimately, should FDA decide the only means to achieve their stated objectives is to move forward with a total ban on flavored cigars, the Agency should conduct a study on how the ban would impact domestic leaf demand as suggested in Proposed Alternative 2. Regardless of that decision, FDA should extend the effective date to a minimum of two years to ensure the agency does not run afoul of the procedural restrictions in the Tobacco Control Act or advantage foreign-grown tobacco.

Exemption for Premium Cigars. FDA's proposed product standard would apply to all cigars rather than a subset, but the Agency requests comment on the scope of the rule.[90] As written, the Proposed Rule's definition of cigar is defined broadly to include both mass-manufactured cigars as well as premium cigars.

On July 5, 2022, a U.S. District Judge in Washington, D.C. ruled in *Cigar Association v. U.S. Food and Drug Administration* that the Agency's decision to regulate premium cigars identically as other tobacco products under the Tobacco Control Act was "arbitrary" and "capricious" as FDA ignored relevant information regarding the health risks of premium cigar usage.[91] When cigars—including premium—were among the tobacco products that the FDA could regulate via the 2016 Deeming Rule, the FDA examined and denied the plaintiff's request to exempt premium cigars from the final rule.[92] The plaintiffs argued that the FDA's requirements for cigar makers to register their products annually and provide ingredient lists for each product, and requiring all products be submitted for laboratory testing, were impractical for handmade, premium cigars.[93] The plaintiffs also cited studies that showed that young people were unlikely to use premium cigars, that premium cigar use was not frequent like other tobacco products, and that infrequent cigar use is not associated with increased mortality.[94] As FDA's authority over regulating premium cigars is in question, the Agency should, at a minimum, refrain from including these products in this proposed product standard.

Clarification of Characterizing Flavor. FDA's Proposed Rule refrains from clearly defining "characterizing flavors" and subsequently which products will be affected by this rule. This not only makes enforcement of the product standard by FDA difficult, but also makes it challenging for the industry to comply and gauge the impacts on businesses. The Final Rule should provide a clear definition of "characterizing flavors", including examples to ensure consistent enforcement.

VII. CONCLUSIONS

In this comment, we have endeavored to expand FDA's understanding of tobacco's significance in agriculture and on the American farm. FDA's exclusion of a sector that could experience significant economic impact—disproportionately incurred by small, family farms

[90] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. at 26434.
[91] *Cigar Association of America v. U.S. Food and Drug Administration*, U.S. District Court, District of Columbia, No. 16-cv-01460.
[92] *Id*.
[93] *Id*.
[94] *Id*.

located within underserved rural communities—from consideration in the Regulatory Impact Analysis is an abdication of the Agency's due diligence responsibilities under the statutes and regulations designed to ensure such entities are protected. This notice and comment period is intended for stakeholders to provide FDA with specific, technical information as to better inform the Agency's decision to proceed or amend the Proposed Rule. It is not intended to absolve the Agency of its obligations to seek out reasonably obtainable scientific, technical, and economic information. Considering this, we have not provided FDA an exhaustive study into how this Proposed Rule will impact the agricultural sector. For example, this comment only briefly touches upon the Proposed Rule's likely contribution to the rise in illicit trade and reduction in state/local tax revenues. Instead, we intended to simply expand upon what FDA has acknowledged and introduce the Agency to additional considerations yet to be thoroughly explored.

Universal would like to thank the Food and Drug Administration for its attention and consideration of this comment to the proposed product standard. It is a vastly complex issue with many more questions for the Agency to address. In conclusion, we respectfully recommend FDA consider either of the aforementioned alternatives designed to advance the Agency's objectives while mitigating the harm to agricultural communities.

Sincerely,

Benjamin Dessart
Director, External Affairs
Universal Leaf Tobacco Company, Inc.

APPENDIX A

Universal
UNIVERSAL CORPORATION

April 26, 2022

Dominic Mancini
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

Dear Acting Administrator Mancini,

We are writing today to inform you of what Universal considers an unacceptable disregard for process by the White House Office of Information and Regulatory Affairs. As you know, the FDA is considering two tobacco product standards intended to (1) ban menthol in cigarettes and (2) ban characterizing flavors in cigars. If adopted, these product standards could have a significant economic impact on not only tobacco product manufacturers, but also agricultural suppliers such as Universal, our contracted farmers, and the rural communities in which we serve.

Our intention was to fulfil the spirit of the Administrative Procedures Act by sharing the attached presentation with your office. Our meeting request was accepted several weeks ago and was posted publicly on the OIRA Rulemaking Dashboard. However, upon accepting our request and scheduling the date/time yourselves, we received notice the morning of the meeting of its cancellation. **Universal was the only organization from the agricultural sector to request a meeting with OIRA.** Our company does not manufacturer a tobacco product for retail sale, yet we chose to engage with the government because no other business is as closely aligned to the famers and growers of tobacco leaf. As such, Universal is in a position to offer your office and the FDA unique insight into the economic impacts these product standards could have on farmers, agricultural communities, and, ultimately, the pocketbooks of every American.

We consider the decision to actively disregard our nuanced perspective to be a disservice to the public, and we are concerned the FDA is subsequently not positioned to make a well-informed decision based on the economic information provided by OIRA. As such, we request you enter the attached presentation into the record and share the relevant information with the FDA prior to their submission of the proposed product standards.

We are happy to discuss with you further and welcome any questions you may have.

Sincerely,

Benjamin Dessart
Director, External Affairs

APPENDIX B

Economic Impact of Tobacco Farming

Blake Brown, Hugh C. Kiger Professor
July 25, 2022

This study examines the impact on the US, North Carolina and Kentucky economies should tobacco farming cease to exist. Farm level receipts from tobacco leaf were $1.026 billion in 2021. This was produced on 219,000 acres with 478 million pounds produced. North Carolina produced about one half of US tobacco with farm level receipts of $505 million. Kentucky, the second largest tobacco producing state, farm level receipts were $269 million. Tobacco is produced in 19 states with most being produced in (ranked by production) NC, KY, VA, TN, GA, SC and PA. Over 90 percent of US tobacco production is used in cigarette production in the US or exported for cigarette production globally.

IMPLAN

IMPLAN is used for the input-output analysis of the economic impacts of tobacco farming. A change in one sector of the economy has multiple impacts in many different associated sectors. IMPLAN divides the impacts of changes in a sector's output into direct, indirect and induced effects. The direct effects are for a given change in the industry sector in question. For example, if all tobacco production in the US ceases, farm level revenues will decline by $1.025 billion. Indirect effects are the impacts due to changes in business-to-business transactions of the industry in question with other businesses. For example, if tobacco farms have reduced output, then fertilizer expenditures (and fertilizer industry output) go down. Induced effects stem from changes in household spending when the employees in the affected industry have changes in their labor income due to changes in the affected industry. For example, if tobacco farming revenues are reduced then farmers and their employees have less household income to spend which has negative effects on the economy. The sum of direct, indirect and induced impacts is the total impact on economic output. IMPLAN further divides these three types of impacts into the impact on employment, labor income and value-added. Employment is the reduction in the number of jobs due to the change in the affected industry. Labor income is thereby reduced. Value added is defined as the difference in industry output (revenues) and expenditures on intermediate inputs for production in the sector in question.

RESULTS

The question posed by this study is "What are the economic impacts of eliminating tobacco farming in the United States?" This can also be interpreted as the economic impact that tobacco farming has on the U.S. economy. The results are given in terms of direct, indirect and induced changes with each broken down to changes in employment, labor income and value-added. Results for the US economy from such a change as well as changes in the economies of the two largest tobacco producing states, NC and KY, are given in Tables 1-3. The total impact on the economy of a loss of tobacco farming is $2.8 billion (Table 1). This means that $1 generated at the farm level by tobacco production generates an additional $1.78 in the general economy. As a result of the elimination of tobacco farming, reductions occur in employment of 25,701 jobs, labor income of $944 million and value-added of $1.467 billion.

Direct Impacts

Based on 2021 tobacco production, complete elimination of tobacco farming would reduce output by $1.025 billion. This exogenous change is imposed on the economy and the resulting impacts traced

throughout the economy. Such a change could be brought about suddenly by changes in tobacco policy and regulations. Employment in tobacco farming would fall by 15,569. To state it otherwise employment in tobacco farming in 2021 is estimated by IMPLAN to be 15,569 and all this would be lost. Consequently, labor income in tobacco farming, all of it, would fall by $380 million. Value added to the economy by the tobacco farm sector would all be lost equaling $520 million. The sum of labor income lost plus value-added by tobacco farming plus the cost of intermediate goods purchased for tobacco production equal the direct output loss of $1.025 billion.

Indirect and Induced Impacts

Lost indirect output to the economy is estimated to be $828 million. This loss in output is due a reduction in business that tobacco farms do with supporting and affiliated businesses. For example, tobacco farms will purchase no fertilizer, seed or chemicals. As a consequence, those businesses will lose 5,032 jobs and labor income paid by these businesses will decrease by $262 million. Additionally, these affiliated and supporting industries will reduce the value they add to Gross Domestic Product by $414 million. The induced impact is a reduction in output of $952 million. This is result of people working in tobacco farming having less household income to spend.

Impacts on Affiliated Industries

The indirect and induced effects of the loss of tobacco farming affect a wide range of business and industry sectors (Table 4). Interestingly, “Other Real Estate” is the affiliated category that is most affected by the elimination of tobacco farming with output in Other Real Estate falling by $168 million. Other Real Estate includes lessors of non-residential building, operations of residential property managers. Pesticide and other agricultural chemical manufacturing decreases by $64 million. Petroleum refineries are negatively impacted by $36 million. Hospitals experience a reduction in economic output of $42 million.

Geographical Impacts

Tables 2 and 3 give the impacts on the NC and KY economies. North Carolina produces almost 50 percent of US tobacco revenues at the farm level with Kentucky producing 26 percent of farm level receipts. NC loses $505 million in farm level receipts and Kentucky loses $269 million. Consequently 4,422 jobs in tobacco farming are lost in NC and 6,109 in KY. The total reduction in economic output is $1.057 billion in NC and $457 million in KY. Employment losses from direct, indirect and induced impacts total 8,250 in NC and 7,578 in KY.

Tax Impacts

Federal, state, county and municipal taxes collected decrease due to elimination of tobacco farming. At the US level $280 million in taxes are lost. This includes losses in county, state and federal taxes of $7, $49 and $202 million, respectively. North Carolina alone accounts for losses of county taxes of $3 million, state taxes of $14 million, and federal taxes of $71 million. This impact will be highest in rural counties that produce the most tobacco.

Table 1. Impact of Loss of Tobacco Farming on the US Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(15,549)	($380,983,130)	($520,206,497)	($1,025,874,000)
Indirect	(5,032)	($262,123,176)	($413,623,092)	($828,609,026)
Induced	(5,120)	($300,862,962)	($533,647,757)	($951,936,707)
Total	**(25,701)**	**($943,969,267)**	**($1,467,477,346)**	**($2,806,419,733)**

Table 2. Impact of Loss of Tobacco Farming on the North Carolina Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(4422)	($179,220,794)	($203,546,743)	($504,800,000)
Indirect	(2397)	($102,781,040)	($166,450,565)	($326,333,991)
Induced	(1431)	($69,447,617)	($129,972,558)	($226,208,661)
Total	**(8250)**	**($351,449,450)**	**($499,969,867)**	**($1,057,342,652)**

Table 3. Impact of Loss of Tobacco Farming on the Kentucky Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(6109)	($134,055,249)	($174,094,932)	($269,268,000)
Indirect	(702)	($27,303,419)	($38,238,104)	($72,697,792)
Induced	(768)	($35,924,347)	($63,715,813)	($114,824,724)
Total	**(7578)**	**($197,283,015)**	**($276,048,848)**	**($456,790,516)**

Table 4. Impact on Output from Related Industries

Industry	Impact on Economic Output
Other real estate	($167,864,348.01)
Support activities for agriculture and forestry	($110,154,484.84)
Owner-occupied dwellings	($74,816,869.77)
Pesticide and other agricultural chemical manufacturing	($64,451,852.11)
Wholesale - Other nondurable goods merchant wholesalers	($55,887,569.54)
Monetary authorities and depository credit intermediation	($43,097,467.24)
Hospitals	($41,831,978.64)
Petroleum refineries	($36,473,673.64)
Insurance carriers, except direct life	($33,580,555.08)
Management of companies and enterprises	($27,865,941.38)

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APPENDIX C

Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services

July 22, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: Docket ID FDA-2021-N-1349

Dear Dr.Califf:

I am writing to express my concern about the negative impacts a menthol cigarette ban would have on the agricultural economy in North Carolina. Specifically, that a highly traceable, compliant and quality U.S. produced tobacco utilized in domestic manufacturing would be replaced by an increased illicit trade centered around mentholated cigarettes. These products would not be held to the same high standards regarding production and manufacturing that currently exists in the marketplace.

As a North Carolina native, raised in Browns Summit, I am proud that agriculture has been and continues to be the foundation of our state's economy. Today, agriculture and agribusiness contribute $92.9 billion annually to our state's economy, or almost 16% of the gross state product. This leading economic driver also employees over 15% of the state's workforce through 668,000 jobs.

I have worked hard as the founder, owner and operator of Troxler Farms to build a successful business. Drawing from that experience, I have been elected to serve five terms as North Carolina Commissioner of Agriculture since 2005 and understand the challenges farmers face daily.

I have dedicated my life to preserving, promoting and developing North Carolina agriculture and agribusiness to ensure we can continue to provide food, fiber and fuel for our state, nation and world. I believe the success of agriculture is paramount to our national security and I want to ensure North Carolina farmers can continue to meet the needs of consumers domestically and abroad.

While our famers produce a diversity of crops and livestock, no discussion of North Carolina agriculture would be complete without including the significance of tobacco to our state. Every stage of tobacco production takes place in North Carolina, from farming and harvesting to

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processing, manufacturing and packaging. In fact, our state has been one of the centers of the U.S. tobacco industry for well over 100 years. The crop remains just as significant today.

Tobacco is vitally important to North Carolina's agricultural sector and broader state economy. North Carolina leads the nation in the production and sale of flue-cured tobacco. Nearly 80% of the flue-cured tobacco grown tobacco in the U.S. and half of the total U.S. tobacco crop originates in fields across our state. The total production value of tobacco in North Carolina in 2021 was $504.8 million with 252.4 million pounds harvested.

Money generated from the sale of tobacco trickles down through the economy, especially in rural North Carolina, supporting families and small business across the state. I can tell you that tobacco money has put many rural young people through higher education, including my own two sons.

As the global state of agriculture continues to transition, the tobacco industry faces new challenges at home and abroad. International tariffs, unpredictable extreme weather, a decline in the number of adult smokers, competition from foreign tobacco growers and the COVID-19 pandemic's disruption to rural farm operations and manufacturing all threaten the industry, and as a result, the state's revenue from tobacco production.

Tobacco is not the only crop grown on a "tobacco farm." These farms also grow sweet potatoes, soybeans, corn, cotton, cucumbers, and other commodities in addition to many having livestock operations. These farms produce tobacco that is the most traceable, compliantly produced tobacco in the world. Through Good Agricultural Practices, including a third-party verification process, tobacco grown in the US is held to certification standards that are often more stringent than state or federal laws regarding crop production, environmental stewardship and labor.

Given the fluctuations of commodity markets, tobacco provides financial stability for many of these farms to remain in production. Without the profitability offered from tobacco, many would not be able to stay in business. If the FDA was to ban menthol cigarettes, we are concerned that the impacts on the farm level could lead to many farming operations in our state ceasing to exist.

Even with all these challenges and uncertainties, farmers and industry representatives I talk with share a strong, common concern about the effort to ban menthol cigarettes. While I am not a scientist, I would expect any such ban by the FDA would need to be supported by scientific evidence. Much of this scientific support seems to be unclear, and the stated rationale has been to protect youth from smoking, which I believe has already been addressed by the Federal Tobacco 21 legislation. I also believe that adults are capable of making their own decisions regarding the use of a legal product.

I strongly support keeping our young people from smoking, as does the entire grower community. In fact, the use of traditional tobacco products, such as cigarettes, has been in decline for years and is at an all-time low among youth as noted in a report from the Centers for Disease Control and Prevention indicating that from 2011 to 2021, the percentage of middle school students who reported using cigarettes in the past 30 days decreased from 4.3% to 1%, and the percentage of high school students who reported smoking cigarettes in the past 30 days decreased from 15.8% to 1.9%.

It seems that measures such as the Federal Tobacco 21 legislation are addressing the concern regarding youth smoking. A menthol ban based on youth usage seems misguided and could cause significant damage to North Carolina's economy, farmers, and manufacturers.

The devastating economic consequences of a menthol ban are easy to predict and include significant job losses across North Carolina and the nation from farms to convenience stores. Further negative economic impact will be seen through reduced tax revenues ($240 million in NC alone) from tobacco products and reduced payments to states under the tobacco settlement agreements. Less obvious are the unintended consequences that removing menthol cigarettes from the market could trigger including expansion of an illegal cigarette market and organized crime activity.

Tobacco grown and manufactured in the United States is traceable, compliant and highly regulated – this higher standard also leads it to be the most expensive tobacco produced and sold in the world. An illicit market would utilize foreign tobacco that is not produced in compliance to the same high standards regarding crop production practices, environmental stewardship or human rights. This includes subjecting the public to illegal pesticide residues as well as a product that may be grown and/or manufactured under child, forced or unregulated labor. Additionally, FDA through statute has regulatory authority over domestic cigarette production; this oversight for public health would be lost through expansion of an illicit market.

While I am confident that North Carolinians will continue to uphold the state's reputation of being the world's most compliant and best leaf tobacco, I urge you to advocate for these hardworking farmers, families, manufacturers, and employees by opposing an economically devastating menthol ban.

Thank you for your attention to this critical matter and for all that you do on behalf of America's agricultural community.

Sincerely,

Steven W. Troxler
Commissioner