



September 22, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Regarding: Docket No. FDA-2017-D-3001: Modified Risk Tobacco Product Applications for IQOS Heating Systems

Dear Dr. Gottlieb:

The Tobacco Growers Association of North Carolina (TGANC) appreciates the opportunity to provide comments in support of the Modified Risk Tobacco Product Applications submitted by Philip Morris International (PMI) for its new heated tobacco product, IQOS.

TGANC represents approximately 2,200 tobacco farm families in North Carolina. We are the largest flue-cure tobacco producing state, generating approximately 400+ million pounds of leaf during a growing season on 180,000 acres. On average, tobacco farms in our state employ approximately 15-20 employees at peak periods. This equals roughly 30,000 – 45,000 individuals who rely on tobacco production to support themselves and their families on North Carolina farms.

In June, TGANC leadership had the opportunity to visit Philip Morris International's R&D facility and meet with their executives to discuss farm specific issues and the new IQOS product. PMI has made substantial investments into reduced risk products, including heat not burn products, and we were pleased they agreed to meet with us to discuss positive changes in the industry. That is why we are excited to comment today.

Tobacco is an important part of American history. Tobacco was native to the continent when European explorers and settlers were arriving during the 1600s in Jamestown. For the early colonists, this crop was the initial form of currency and the first vital export. Importantly, tobacco helped fund America's fight for independence. Since that time, tobacco has proven again and again its economic value and reliability generating capital for communities and tax revenue for government at all levels.

Tobacco farm families are an important part of our communities. We are proud small business owners who create jobs and support many others via various forms of taxes and much charitable donation. Many of the world renown universities and hospitals in NC and other locations across the county are a

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direct result of the American tobacco farmer and the commerce we generate. We are proud of our heritage.

As farmer's we don't regularly engage in the various aspects of the health debates that so often reference tobacco products primarily because there are many diverse opinions and widely varying conclusions about risks and consequences. We do, however, strongly support adult consumers' rights to make educated decisions about legal consumer products. We also support scientific research and new discoveries that achieve solutions to many expressed concerns and improve consumer products.

Now that FDA has assumed the regulatory authority of tobacco related products, we watch closely the actions the Agency is considering that could create economic impact on the farmers in our country. Some of this action could be adverse while other actions might generate opportunity. The tobacco crop in our state accounts annually for nearly \$1 billion directly to the farm sector and many times that when considering the multiplier effect throughout the economy. I hope you can appreciate the substantial economic importance this crop means to tens of thousands of people directly and indirectly involved in tobacco production.

The ability for U.S. tobacco farm families to maintain financial stability and success in the future depends heavily on our recognition of market forces, and leadership in adapting, and bringing innovation in our industry. If we fail to lead in these areas then the value of our farm sector will be completely transferred to offshore nations growing tobacco that we compete against every day. It is critical that all of us work together to make certain the United States never becomes a total importer of leaf tobacco. Especially when we know we grow the best premium leaf on the planet, at the highest standards and in compliance with a robust regulatory regime.

As we observe, develop and implement technology and innovation both on the farm and in the industry at large, we recognize there are amazing new opportunities for the future. One of these developments is the Philip Morris International- IQOS products that were recently launched in certain European and Asian markets. It is our understanding that a key factor in the consumer preference of this product is that it uses high quality, premium flavor styled tobacco like we grow in the US. If this expectation is accurate then the United States farmer is well situated to be the best source provider for future industry procurement volumes and specific needs, and we are excited about this possibility

If we accept the fact that some adults will always use tobacco in some legally marketed form, and in working to protect against the potential proliferation of illegitimate tobacco products in the hands of consumers, then all of us should be working towards and supporting new innovations that better serve the consumer driven market. Actions taken by FDA will either help bolster our rural economies or contribute to its continuing decline.

The Tobacco Growers Association of North Carolina urges FDA to approve applications of PMI's - IQOS product and other Modified Risk Tobacco Products, especially those that contain natural tobacco leaf. PMI's - IQOS product heats tobacco rather than burning it and a number of companies are developing similar technologies. Any delays in approving these products, including PMI's, will hinder the marketplace, and could potentially mean U.S. growers produce and sell less tobacco as these types of delivery devices are becoming increasingly available and demanded in other countries.

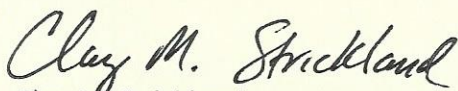
As was emphasized in an earlier paragraph, but deserves repeating, U.S. tobacco is of the highest quality and flavor and our tobacco is grown to the highest industry standards. Nowhere else in the world do we believe tobacco farmers register their crop, acres and cultural practices with the various governmental agencies such as USDA, NRCS, OSHA and State Departments of Agriculture. Our farmers use only approved crop protection agents with regards to fertilizer and crop protection agents, which includes licensed applicators and adhering to strict EPA approved labels. Our farms must also pass rigorous Department of Labor inspections, protocols and unannounced audits and investigations to confirm and improve compliance with labor laws and worker protections. Safer workers = safer tobacco. We make and maintain records and documentation to the point of exhaustion because it is required by law and because we wish to distinguish ourselves from tobacco farmers in other parts of the world. In addition, we are confident that a high percentage of our farmers hold college degrees and have great commitment to conservation and stewardship of the land and environment.

Please give your full consideration to these many points as you lead the government review in allowing these products to come onto the market in the U.S. We urge you to work towards an expedited FDA approval. Any favorable conclusion should result in immediate economic opportunity for American farmers.

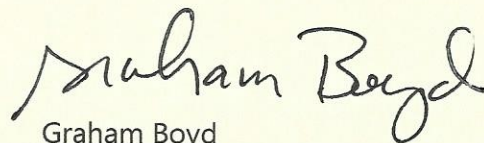
We have seen first-hand that new products, like IQOS, have the potential to reduce risks or harm from tobacco use by eliminating combustion and smoke; factors confirmed by numerous scientific studies to be one of the main causes of tobacco-related death and disease. We want to emphasize our belief that consumers have the right to enjoy all tobacco product options and we believe the tobacco in these products (whether liquid or in leaf format) should come from the United States farmers.

We appreciate your time and thank you for your prompt review and approval of PMI's applications.

Sincerely,



Clay M. Strickland
President



Graham Boyd
Executive Vice President

CC:

The Honorable Richard Burr
The Honorable Thom Tillis
The Honorable G.K. Butterfield
The Honorable George Holding
The Honorable Walter Jones, Jr.
The Honorable David Price
The Honorable Virginia Foxx
The Honorable Mark Walker

The Honorable David Rouzer
The Honorable Richard Hudson
The Honorable Robert Pittenger
The Honorable Patrick McHenry
The Honorable Mark Meadows
The Honorable Alma Adams
The Honorable Ted Budd
The Honorable Steve Troxler, Commissioner