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July 16, 2020

Mr. Mitch Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Bluetooth Technology in Tobacco Products

Dear Director Zeller:

There are indications that the Food and Drug Administration (FDA) may, in the near future, be required to assess the implications for public health of the use of Bluetooth technology in certain tobacco products. For example, Philip Morris International (PMI) announced in April that it has submitted a supplemental Premarket Tobacco Product Application (PMTA) for its IQOS 3 product.¹ This product, as marketed in other countries, features Bluetooth technology.² According to news reports, JUUL Labs will submit a PMTA for a Bluetooth-enabled ENDS device, which it already sells in the UK and Canada.³

Since it is likely that FDA will soon conduct PMTA review of tobacco products with Bluetooth technology, the undersigned organizations urge the FDA to carefully examine the evidence, critically assess any claimed benefits of a Bluetooth-enabled device, and rigorously

¹ Philip Morris International Inc., *2020 First-Quarter Results*, (Apr. 21, 2020), <https://www.businesswire.com/news/home/20200421005431/en/Philip-Morris-International-Reports-2020-First-Quarter-Reported>.

² The lack of transparency in the PMTA process makes it difficult to confirm that the product for which the supplemental PMTA was filed is the same as those sold in other countries with Bluetooth technology. In addition, the version of IQOS that FDA authorized includes microcontrollers and firmware, but FDA has not made public to what extent the Bluetooth technology is currently activated through these features. See FDA, Technical Project Lead Review, Marlboro Heatsticks (IQOS), at 17, 29, 91 (“The Holder and Charger contain microcontrollers and firmware....”), <https://www.fda.gov/media/124247/download>.

³ Richard Craver, *Juul plans to include Bluetooth device-locking technology with FDA regulatory application*, Winston-Salem Journal (Feb. 26, 2020), https://www.journalnow.com/business/juul-plans-to-include-bluetooth-device-locking-technology-with-fda-regulatory-application/article_eb4797cd-db62-5130-a46f-d86ecd846eeb.html.

determine the risk of significant harm to public health of introducing that technology to tobacco products. In our view, those risks are so significant that FDA should conclude that tobacco industry applications for products with this technology do not meet the statutory public health standard for the marketing of new tobacco products.

Bluetooth-enabled technology in tobacco products is of significant concern because it gives tobacco companies unlimited access to user data and raises substantial privacy concerns.⁴ Through this technology, tobacco companies will have the ability to utilize user data for marketing, prolong and enhance a user's addiction by controlling puff-by-puff nicotine delivery, and collect data on usage patterns of all users. Tobacco companies will also be able to monitor the use of flavors and other product modifications that attract and maintain users to prevent quitting.

In addition, based upon news reports, there are features available through this technology that enhance social interaction capabilities and the appeal of tobacco products that, based on prior experience, are likely to be attractive to youth and increase youth initiation and addiction to Bluetooth-enabled products. It is critical that FDA's review of PMTAs for products with Bluetooth technology properly consider all public health risks, but given the long history of how tobacco companies have always used technological change to enhance their profits over public health, sustain and facilitate addiction, and undermine public health goals, and based upon what is known about the potential of this technology thus far, there is strong reason to conclude that allowing the tobacco industry to market and control products with Bluetooth-enabled features in devices will not protect the public health.

Tobacco companies have a long history of product "innovation" calculated to attract and addict youth. The tobacco industry also has a long history of claiming to care about the health of tobacco users and claiming that its newest products are designed to reduce the harm to existing users. Those claims have always later proven to be false. The tobacco industry has proven by its repeated past actions that its claims that it prioritizes the health of its customers are nothing more than smokescreens for continuing to promote the use of its products without regard to their health consequences. This industry's past actions make clear it cannot be trusted with the type of

⁴ In general, FDA should not authorize any tobacco products that are integrated with technology that allows tobacco companies to collect data on consumer use of the product, because of significant privacy concerns raised by the collection of private health data and the inability of the user to control the personal information that is collected and utilized. Simply, tobacco companies cannot be trusted to utilize user data in any way that benefits public health. As explained in this letter, this concern is heightened with Bluetooth technology, which allows tobacco companies to monitor user data and influence user behavior in ways that are harmful to public health.

information and control that it will obtain if allowed to market products with Bluetooth technology.

The myriad of kid-friendly flavored tobacco products, crush pods in cigarette filters, sleek, concealable, flavored e-cigarettes, and heated tobacco products with high-tech designs provide ample evidence that tobacco companies are well aware that novel features create interest and curiosity among youth and encourage them to try these products. It is undeniable that the current epidemic of e-cigarette use among teens is largely the result of the extraordinary youth appeal of JUUL, with its sleek design that resembles a USB flash-drive. The addition of Bluetooth technology to tobacco products, which would give tobacco companies access to user data, facilitate social interactions, and add game features is just another industry “innovation” likely to attract yet more young people to highly addictive tobacco products, with little public health benefit.

Moreover, because of these risks, FDA should require a complete PMTA for any modification to a tobacco product that adds Bluetooth technology to a product for which a PMTA has already been granted. A supplemental PMTA is not appropriate for such a modification because the addition of Bluetooth technology is a significant product change that is likely to affect initiation and user behavior, has strong youth appeal and raises real privacy concerns.

I. Bluetooth Technology in Tobacco Products.

Tobacco companies have introduced tobacco products that feature communication and app technology in the U.S. market since at least 2011.⁵ As a result of FDA’s delay in issuing a Deeming Rule to regulate e-cigarettes, and its further delay in enforcing premarket review requirements,⁶ some Bluetooth-enabled tobacco products were sold in the U.S. market without

⁵ In addition to the products mentioned in this section, other Bluetooth-enabled products are described in Yvonne Staal et al., *New Tobacco and Tobacco-Related Products: Early Detection of Product Development, Marketing Strategies, and Consumer Interest*, 4 J. of Med. Internet Rsch. Pub. Health Surveillance e55 (2018), <http://europepmc.org/article/PMC/5996176>. See e.g., Smokio, Stanford University, Research Into the Impact of Tobacco Advertising, [smokio_2014, http://tobacco.stanford.edu/tobacco_main/videolist_ecigs.php](http://tobacco.stanford.edu/tobacco_main/videolist_ecigs.php) (Smokio, a Bluetooth connected device that advertises its ability to track a user’s usage, intensity of smoke, and location).

⁶ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements of Tobacco Products (Deeming Rule), 81 Fed. Reg. 28,974, 29,014 (May 10, 2016); see generally, *Am. Acad. of Pediatrics v. FDA*, 379 F.Supp.3d 461 (D. Md.) and 399 F.Supp.3d 479 (D. Md. 2019), *appeal dismissed sub nom In re Cigar Association of America*, No. 19-2130, 2020 WL 2116554 (4th Cir. May 4, 2020).

having submitted a PMTA. Consequently, the effect of these technologies on public health has not previously been examined by FDA. As discussed below, current features examined in Bluetooth-enabled tobacco products would give tobacco companies unconstrained access to private user data without constraints with how they use this data. Patents associated with tobacco products using Bluetooth technology reveal the vast capabilities of Bluetooth-enabled devices that raise additional serious concerns about the abuse liability of these products in the hands of the tobacco industry and their potential to harm public health. The potential of this technology to increase youth initiation and enhance user addiction also cannot be ignored, especially given the history of the tobacco industry and the fact that they have always put profits above the health of smokers.

Early marketing of Bluetooth-enabled tobacco products also described the addition of Bluetooth as a trendy design feature. In 2011, blu introduced its Smart Pack e-cigarette.⁷ blu boasted that its Smart Pack's technology features would make the e-cigarette experience more "interactive and enjoyable."⁸ Subsequently, in 2015 and 2016, Reynolds introduced VUSE devices that included Bluetooth technology. Reynolds described its new device as "sleek and sophisticated" and noted that "it is tapping into the emerging trend of 'The Internet of Things,' seamlessly connecting everyday physical devices to the world of smartphones, computers and tablets."⁹

Specifically, blu's Smart Pack included features that alerted users if other blu users or retailers selling blu were nearby, provided automatic re-ordering when cartridge supply ran low, and promised longer lasting battery life and flavor.¹⁰ blu noted that its built-in ID technology could instantly detect and notify a user when a fellow blu user or a blu retail location is within a 50-foot range – "creating all types of new possibilities for social interaction among like-minded people."¹¹ blu also said that it planned to add future enhancements to its product that would integrate with social media, identify locations that allow use of the product, and allow the Smart

⁷ blu Cigs, *e-Cigarettes Get Social, Last Longer, and Re-order Themselves With New "Smart Pack"* From blu Cigs, PR Newswire (Sep. 7, 2011), <http://www.prnewswire.com/news-releases/e-cigarettes-get-social-last-longer-and-re-order-themselves-with-new-smart-pack-from-blu-cigs-129367173.html>.

⁸ *Id.*

⁹ Zacks Equity Research, *Reynolds Offers Bluetooth-Enabled e-Cigarette: Vuse FOB*, (Mar. 3, 2016), <https://www.zacks.com/stock/news/209402/reynolds-offers-bluetooth-enabled-ecigarette-vuse-fob>; RJ Reynolds Vapor Company, *VUSE FOB™ with Bluetooth® technology offers innovative, new vapor experience*, R.J. Reynolds Vapor (Mar. 2, 2016), https://s2.q4cdn.com/129460998/files/doc_news/2016/2016-01-VUSE-FOB-with-Bluetooth-technology-offers-innov-new-vapor-exp.pdf.

¹⁰ blu Cigs, *supra* note 7.

¹¹ *Id.* See also, blu, *blu Cigs - Jason Healy Introduces Smart Electronic Cigarette*, YouTube, (Feb. 23, 2012), <https://www.youtube.com/watch?v=TzIlunVeUas>.

Packs to “monitor how much people are smoking and report back to them — or to their doctors.”¹² Reynolds’ devices with Bluetooth technology, VUSE Connect Solo and VUSE FOB,¹³ included Bluetooth technology to connect to a smartphone app, allowing users to monitor battery power and cartridge usage, as well as lock the device.¹⁴ IQOS models with Bluetooth connectivity sold in other countries have a corresponding app that notifies users about errors or heating status, locates the device, shows nearby retailers selling IQOS and HeatSticks, allows HeatStick purchases directly through the app, and can connect users to IQOS customer support for help with the device or app.¹⁵

JUUL’s Bluetooth-enabled device, the C1 model, which is available in the UK and Canada, includes Bluetooth connectivity to a smartphone app. The app features facial recognition tools and allows users to locate misplaced devices and lock the device if it is not near the user’s phone, using GPS.¹⁶ It also collects data on device diagnostics and errors.¹⁷ Previous descriptions of the app said that it could track daily, weekly, or monthly number of puffs, but the C1 product description on the Canada JUUL website currently states, “The “Usage Monitor” in the JUUL app is no longer available.”¹⁸

Although the existing features in tobacco products with Bluetooth technology already give tobacco companies vast access to user data, a review of patent applications indicates that Bluetooth-enabled tobacco products could have far more expansive and intrusive capabilities. For example, JUUL patent applications show that the company has the capability to add more features to its devices, including “multiplayer games controlled by moving the vape or taking a puff” and recommendations for “flavors, offer deals, or [to] connect users to friends or social

¹² Joshua Brustein, *A Social Networking Device for Smokers*, The New York Times (May 10, 2011), <http://www.nytimes.com/2011/05/11/technology/11smoke.html>.

¹³ blu Cigs, *supra* note 7.

¹⁴ *VUSE Connect Solo Power Unit*, Convenience Store News, <https://csnews.com/vuse-connect-solo-power-unit> (last accessed July 16, 2020); RJ Reynolds Vapor Company, *VUSE App*, <https://apprecs.com/ios/998622008/vuse-app> (last accessed May 21, 2020).

¹⁵ *Understanding the IQOS Connect App*, Heat180 (Aug. 13, 2019), <https://heat180.com/understanding-the-iqos-connect-app/>.

¹⁶ Craver, *supra* note 3; Alice Hancock, *Juul launches ecigarettes that monitor users’ vaping*, Financial Times (Aug. 4, 2019), <https://www.ft.com/content/a66e527a-b505-11e9-bec9-fdcab53d6959>; JUUL Labs, Inc., *JUUL*, Google Play, https://play.google.com/store/apps/details?id=com.juullabs.app&hl=en_US.

¹⁷ Craver, *supra* note 3.

¹⁸ Juul Labs, Inc., *JUUL C1 Device*, <https://www.juul.ca/en-CA/shop/devices/juul-c1> (last accessed May 21, 2020).

networks” based on data gathered “on everything from users’ preferred temperature and particle-size settings to their socioeconomic status.”¹⁹

According to the patent application filed by JUUL Labs in June 2019, “Apparatuses that include dosing (dose) control may include internal logic (circuitry and/or programming, including application-specific integrated circuit (ASIC) logic) for controlling dosing and/or **may communicate with an external processor (via a wireless communication link) that performs all or some of the dose control.**”²⁰ The devices “may be configured to facilitate social interaction” and “may be configured to share usage information with others, such as third parties, e.g., health care providers, including doctors, etc. for better prescription and administration of medical treatment. A vaporizer and/or vaporizer system may also be configured to communicate with non-medical third parties (e.g., friends, colleagues, etc.), and **with unknown third parties (making some or all information publicly available).** In some implementations, the vaporizers described herein, either by themselves or in communication with one or more communications devices that are part of a vaporizer system, **may identify and provide information about the operation, status or user input from the vaporizer to a public or private network.**”²¹

What this means is that JUUL, a tobacco company with a track record of playing a leading role in the creation of the youth e-cigarette epidemic²² and whose profit depends on promoting the use of its addictive products, would have the capacity to obtain personal health information about an individual’s addiction and use of its addictive products with absolutely no legal constraints on how or for what purpose it uses that information. In addition to the potential for JUUL to use this information for purposes contrary to the best interests of the consumer and the public at large, this raises serious privacy issues and the potential that it could sell the data or that the data could be hacked or misused.

As mentioned, the JUUL patent application also describes “one or more interactive games for use by the user and/or multiple users of different (or the same) vaporizers, including multi-player games that may be used with multiple different vaporizers” that are tied to the use of the device. Location and GPS capability could provide users knowledge about “proximity to

¹⁹ Alice Hines, *Vape King Juul Wants Everyone to Chill Out*, Bloomberg Businessweek (Aug. 1, 2018), <https://www.bloomberg.com/news/articles/2018-08-01/juul-is-trying-everything-to-prove-it-can-regulate-itself>.

²⁰ JUUL Labs, Inc., *Devices and Methods for Cessation of Nicotine Addiction*, U.S. Patent Application No. 16/453110, filed June 26, 2019, , <https://patents.google.com/patent/US20190387796A1/en?q=20190387796> (emphasis added).

²¹ *Id.* (emphasis added).

²² For instance, then-FDA Commissioner Scott Gottlieb stated, “There’s no question the Juul product drove a lot of the youth use.” Julia Belluz, *Scott Gottlieb’s last word as FDA chief: Juul drove a youth addiction crisis*, Vox (Apr. 5, 2019), <https://www.vox.com/science-and-health/2019/4/5/18287073/vaping-juul-fda-scott-gottlieb>.

one or more of: other users (known or unknown users, specified or unspecified users, etc.), retailers, specific locations (lounges, clubs, vaporizer-friendly locations), etc.,” but it also allows for others to determine and receive the location of the user, by “access[ing] GPS information from another device in communication with the vaporizer as part of a vaporizer system.”^{23,24,25}

The Bluetooth technology in tobacco products not only allows users’ devices to transfer information to tobacco companies but would also enable tobacco companies to communicate back to the devices. This could mean that tobacco companies could send prompts to users, as well as software upgrades that could, for instance, modify how the device works or enable different features that were not reviewed by FDA in the original application, which could ultimately change the health risks of the products.

This two-way communication is not just theoretical. Philip Morris USA was granted a patent in 2014 for an “electrically heated smoking system,” demonstrating that the company has considered such interaction functionality for various purposes including “for downloading software from the host to the system; for downloading information from the host to the system...for uploading information from the system to the host; and for registering the system with the host.”²⁶ In this description, the “system” refers to the “electrically heated smoking

²³ *Id.*

²⁴ If JUUL submits a PMTA for a product with technology that is the subject of a patent application, FDA should require the submission of all patent information, since the patent application provides valuable information as to whether the product, with its technology and communication capabilities, is appropriate for the protection of public health.

²⁵ Some of these features already appear in cannabis vaping devices sold by Pax Labs, the predecessor of JUUL, and may provide insight into how Bluetooth technology may be activated in ENDS devices. These devices feature Bluetooth technology to connect to an app for various functions, including customizing the exact vaping temperature, creating vaping sessions to track the amount inhaled during each session, and verifying the pods used with the device. The Pax 3 model also has two games that users can play within the device and has been referred to as “the iPod of vaporizers.” Dave Kriegel, *PAX 3 review: The Best Portable Vaporizer is Now Better*, Vaping360.com (Dec. 1, 2016), <https://vaping360.com/reviews/pax-3-review/>; Mark Wilson, *Pax’s clever new app stops you from getting too high*, Fast Company (June 19, 2018), <https://www.fastcompany.com/90176328/paxs-clever-new-app-stops-you-from-getting-too-high>; Matt Burns, *Pax unveils a vape that increases transparency around cannabis consumption*, Tech Crunch (Jan. 6, 2020), <https://techcrunch.com/2020/01/06/pax-unveils-a-vape-that-increases-transparency-around-cannabis-consumption/>; Dave Kriegel, *PAX 3 review: The Best Portable Vaporizer is Now Better*, Vaping360.com (Dec. 1, 2016), <https://vaping360.com/reviews/pax-3-review/>.

²⁶ Philip Morris USA Inc., *Electrically Heated Smoking System*, U.S. Patent No. US 8,851,081 B2, Patent granted Oct. 7, 2014, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetacgi%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=8,851,081.PN.&OS=PN/8,851,081&RS=PN/8,851,081>.

system” and the host for the software, which originates from the tobacco company. Additional actions that the communication link can facilitate include:

- personalized settings to be downloaded to the device that “may assist with managing smoking behaviour” or “optimize the smoking experience” for a particular brand cartridge;
- process for users to upload data on their smoking behavior for clinical trials;
- applications to access “an approved support group Internet site for assistance with smoking cessation”;
- applications to “offer a controlled amount of smoking time whilst monitoring the smoking behaviour”; and
- applications to monitor use to enable pre-ordering additional cartridges.²⁷

In the hands of the tobacco industry, with its history of manipulating products to worsen the public’s health, this functionality will more likely be exploited to harm users rather than help them quit.

The expansive capabilities of Bluetooth technology in the hands of a tobacco company demonstrate why it is urgent for FDA to carefully scrutinize any PMTA for a tobacco product that features Bluetooth technology. The capacity to add and upgrade features available through Bluetooth-enabled devices also raises concerns about how FDA will review subsequent features that may be added to a tobacco product through software upgrades using its Bluetooth capability after the initial PMTA is granted.

II. Bluetooth Technology in Tobacco Products Controlled by a Tobacco Company is Not Appropriate for the Protection of Public Health.

In evaluating a PMTA for a tobacco product with Bluetooth technology, the FDA must closely consider such a technology’s impact on public health. The Tobacco Control Act requires that FDA deny an application for a new tobacco product if the applicant fails to make a showing that the marketing of the product would be appropriate for the protection of public health.²⁸ Whether this statutory public health standard is met must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account: (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.²⁹ It is also important for FDA to

²⁷ *Id.*

²⁸ 21 USC § 387j(c)(2).

²⁹ 21 USC § 387j(c)(4).

consider the consequences on specific populations – whether it be youth or other populations that have been targeted by the tobacco industry, including African-Americans, Hispanics and the LGBTQ community.

The capacity of Bluetooth technology to give tobacco companies access to user data that they can use to increase use of their addictive products, thereby promoting greater addiction and deterring quitting, will harm the public health. This, along with the high potential of tobacco products with Bluetooth technology to make tobacco products more addictive to all users and attract youth, demonstrates that Bluetooth-enabled tobacco products cannot be found to be appropriate for the protection of public health.

Tobacco companies have a long history of claiming that they care about the health of their consumers and that they can be trusted to take steps to reduce the harm of their products to their consumers. Those claims have always proven to be false. While tobacco companies now claim their goal for including Bluetooth technology in their addictive products is to aid a smoker's transition to noncombustible tobacco products, in practice they have always used technological innovation to make their products more modern and trendy, and thus more appealing to youth. For instance, research shows that novel features, including technological designs, draw in youth and young adults to try e-cigarettes.³⁰ The Bluetooth technology will give companies the added capacity to collect and abuse private user data to the company's advantage by enhancing tobacco addiction. Ultimately, no tobacco company that markets addictive products can be trusted to use the information that it will gain through Bluetooth technology to benefit public health.

The discussion about PMI's plans for its Bluetooth connectivity at the January 2018 TPSAC meeting underscores these concerns. Moira Gilchrist, Vice President of Scientific and Public Communications at PMI, described the use of this technology in IQOS products in other countries that demonstrates PMI's intent to manipulate user behavior:

“So we're using it [Bluetooth functionality] to be able to help consumers remember, for example, when they have to clean or when they may need to reorder HeatSticks so that they don't run out and have to go back to combustible cigarettes. We're doing it to help encourage them to stop using combustible cigarettes. You know, for example, a message

³⁰ Emily McDonald & Pamela Ling, *One of several 'toys' for smoking: young adult experiences with electronic cigarettes in New York City*, 24 Tobacco Control, 588-593 (2015); Lee, H-Y et al., *Determinants Associated With E-cigarette Adoption and Use Intention Among College Students*, 65 Addictive Behaviors, 102-110 (2017); Craig Trumbo & Raquel Harper, *Use and Perception of Electronic Cigarettes Among College Students*, 61 J. of Am. Coll. Health, 149-155 (2013); Grace Kong, et al., *Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults*, 17 Nicotine & Tobacco Rsch., 847-854 (2015).

may come up, hey, you haven't used your IQOS device today. Have you stopped smoking, or is it because you've gone back to combustible cigarettes?"³¹

JUUL's patent application for connected vaporizers device systems demonstrates a similar intent to alter user behavior so as to increase the risk of addiction. The application abstract states:

"A vaporizer system may include a vaporizer device communicatively coupled with a user device configured to control the functions and/or features of the vaporizer device. The vaporizer device may serve as a replacement for traditional combustible cigarettes. Accordingly, the user device may be configured to collect usage data from the vaporizer device and generate recommendations to enhance and/or expedite the transition from traditional combustible cigarettes to the vaporizer device. For example, the user device may provide puff coaching to enable a more satisfying initial experience. Alternatively, and/or additionally, the user device may recommend pod types and/or puff patterns that are associated with a reduction in overall intake."³²

The patent application further describes a "cessation program" app that asks users for an extensive list of personal information³³ that can be used to develop a program that controls how the device works, including "an amount of nicotine per vaporizer dose and/or vaporizer session, ... a time of day for nicotine consumption, and/or the like."

This "dose control" provides a tremendous opportunity for a tobacco company seeking to maximize sales of highly addictive products instead of its professed interest in smoking cessation. Users can then provide feedback to the program, which "may include an adaptive pattern recognition system, such as a machine learning algorithm (e.g., a neural network), that may identify optimal tunings to the first cartridge and/or the first program for the user."³⁴ Here a tobacco company, not a trained health care professional, claims it is proposing an automated smoking cessation program, but one under the control of a tobacco company, not under the supervision of a tobacco cessation specialist and, among other things, "optimizes" nicotine levels and delivery times to users. History shows that, no matter what a tobacco company says – provide them information about an individual and they will use that information to maximize their profit by promoting addiction while claiming to care about health and tobacco cessation.

³¹ PMI Presentation to TPSAC, Transcript, January 25, 2018, <https://www.fda.gov/media/111450/download>.

³² JUUL Labs Inc., Connected Vaporizer Device Systems, U.S. Patent Application No. 16/455629, filed June 27, 2019, <https://patents.google.com/patent/US20200000143A1/en?q=20200000143>.

³³ The list included "height, weight, ethnicity, location, ... eating habits, exercise habits, ... personality type, flavor preferences, and/or the like." *Id.*

³⁴ JUUL Labs, Inc., *supra* note 20.

These are brazen approaches for a tobacco company whose then-chief product officer stated in a Congressional hearing, “I cannot state more emphatically: JUUL is not a cessation product.”³⁵ When the product first launched, a JUUL R&D engineer stated, “We don’t think a lot about addiction here because we’re not trying to design a cessation product at all.”³⁶

FDA must not allow tobacco companies to collect data about individuals via Bluetooth technology that will allow the manipulation of their products to make them more addictive for users and jeopardize their ability to quit tobacco use. Tobacco companies will be motivated to use data received through the Bluetooth technology to maximize user addiction and maximize profitability of their tobacco products. As described in one published paper, “[T]he fact that IQOS measures a user’s puff-by-puff heating profile, integrates IQOS’s Bluetooth capability with mobile phones and computers, and automatically reminds consumers to continuously use the device and to reorder tobacco sticks suggests that it calibrates the delivery of nicotine to ensure not only ‘satisfaction’, but also the potential for PMI to customise the dose, speed of delivery and continuous use of nicotine to maximise addictive potential for individual users.”³⁷ Thus, by capturing the pattern of nicotine delivery, tobacco companies will be able to influence factors that enhance nicotine abuse liability.³⁸ Given that FDA found IQOS to be as addictive as cigarettes,³⁹ the capacity for a tobacco company to use this technology to ensure frequent and continued use of the product represents a real risk of ensuring a lifetime of nicotine addiction for the user. In this way, the addition of Bluetooth technology in tobacco products may increase the risk of individual harm.

Indeed, there is a significant danger that in the hands of a tobacco company, apps similar to the one Dr. Gilchrist suggested will enable PMI to prompt a user to use IQOS even if the user has quit the use of tobacco products entirely. For instance, if IQOS users have not used their

³⁵ Sarah Oweremohle, *House panel questions Juul marketing tactics, youth programs*, Politico (July 25, 2019).

³⁶ Nitasha Tiku, *Startup behind the Lambo of vaporizers just launched an intelligent e-cigarette*, The Verge (Apr. 21, 2015), <https://www.theverge.com/2015/4/21/8458629/pax-labs-e-cigarette-juul>. JUUL’s use of the term “cessation program” is evidence that the intended use of the product may be smoking cessation, a therapeutic usage that would render the product a “drug” under the Food, Drug and Cosmetic Act subject to the jurisdiction of FDA’s Center for Drug Evaluation and Research and the applicable safety and effectiveness standards.

³⁷ Lauren Lempert & Stanton Glantz, *Heated tobacco product regulation under US law and the FCTC*, 27 Tobacco Control, s118-s125 (2018), <https://pubmed.ncbi.nlm.nih.gov/30291201/>.

³⁸ Gregory N. Connolly, *A Reduced Risk Nicotine Delivery Device or a Device to Enhance and Control Abuse (Addiction) Potential through Manipulation of the Pattern of Nicotine Delivery?*, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM594333.pdf> (last accessed Feb. 15, 2018).

³⁹ Technical Project Lead Review, *supra* note 2, at 11 (“PK studies show Marlboro, Smooth Menthol, and Fresh Menthol Heatsticks have nicotine delivery, addiction potential, and abuse liability similar to CC [combustible cigarettes].”).

device in a while because they quit all tobacco use, receiving this type of reminder could drive them back to tobacco products.

Similarly, although JUUL claims that plans for its app include features that would cause “users to limit their vaping, and geofencing against usage in public areas such as schools,”⁴⁰ this is the same company that claims it has not marketed to America’s youth despite overwhelming evidence to the contrary. Moreover, there is no evidence that JUUL has used these features in the C1 device already marketed in other countries to prevent youth usage.

Significantly, there is also no evidence that that features such as geofencing are an effective method for curbing youth usage. Even if geofencing could curb use of vaping products in or near schools, youth could still use vaping products at other locations. Additionally, such limited use of geofencing would come at the expense of giving tobacco companies vast amounts of location data on youth. A recently published paper recognized that the ability of tobacco companies to track users for marketing purposes through geofencing would be a risk of this feature.⁴¹ Similarly, geofencing also raises broader concerns about how location data can be used and/or shared with third parties. For example, potential concerns could include sharing such data with law enforcement as evidence to prosecute youth for violating purchase, use, and possession (PUP) laws.⁴² If FDA authorized a tobacco product with Bluetooth technology, it is unclear how FDA would monitor, limit, or enforce such abuses of privacy.

The youth appeal of Bluetooth technology adds to the privacy concerns outlined here. Tobacco companies have embraced the comparison of the sleek designs of tobacco products to popular Apple devices. Not surprisingly, the IQOS store that opened in Atlanta late last year has also been compared to an Apple store.⁴³ The pattern of marketing of tobacco products with

⁴⁰ Alice Hancock, *Juul launches ecigarettes that monitor users’ vaping*, Financial Times (Aug. 4, 2019), <https://www.ft.com/content/a66e527a-b505-11e9-bec9-fdcab53d6959>.

⁴¹ David Ashley et al., *E-cigarettes: How can they help smokers quit without addicting a new generation?* Preventive Med. (May 27, 2020), <https://doi.org/10.1016/j.ypmed.2020.106145>.

⁴² For example, similar privacy concerns about geofencing were expressed in recent legislation regarding use of geofence warrants to identify protest participants in New York City. See Emma Whitford, *Protests, Virus Boost NY Bill to Ban Geofence Warrants*, Law360 (June 12, 2020), <https://www.law360.com/articles/1281815/protests-virus-boost-ny-bill-to-ban-geofence-warrants>.

⁴³ James Hamblin, *The Next Vaping*, The Atlantic (Dec. 12, 2019), <https://www.theatlantic.com/health/archive/2019/12/heated-tobacco-iqos/603505/>; Victoria Churchill, et al., *IQOS debut in the USA: Philip Morris International’s heated tobacco device introduced in Atlanta, Georgia*, Tobacco Control, Epub ahead of print (Feb. 5, 2020), <https://tobaccocontrol.bmj.com/content/early/2020/02/05/tobaccocontrol-2019-055488>; Annalise Mathers et al., *Marketing IQOS in a dark market*, 28 Tobacco Control 237-238 (2019); Minji Kim, *Philip Morris International Introduces New Heat-not-burn Product, IQOS, in South Korea*, 27 Tobacco Control e76 (2018).

Bluetooth technology substantiates this point. The technology has been marketed to promote vaping products as a lifestyle choice and not as a functional product to help current smokers switch. blu noted that its Smart Pack’s “new tech-enhanced features” allowed it “to raise the bar for the cool factor as much as personal ease-of-use and enjoyment.”⁴⁴ A focus on features that make tobacco products seem fashionable is entirely inconsistent with the public health standard and the Tobacco Control Act.

Therefore, the substantial risk that Bluetooth technology will enable tobacco companies to abuse private user data, enhance the appeal of tobacco products to young people and increase the risk of long-term addiction for all users precludes any application from a tobacco company for a tobacco product equipped with this technology from meeting the public health standard.

III. A Supplemental PMTA is Not Appropriate Where the Modification Involves Addition of Bluetooth Technology.

As discussed in section II, Bluetooth technology in tobacco products has the potential to increase harm to individual users and increase youth initiation. Consequently, any tobacco product that is modified to add Bluetooth technology must be required to submit a complete PMTA for an extensive review of all the novel public health issues raised. An abbreviated supplemental PMTA is not appropriate.

FDA discussed the availability of a supplemental PMTA in § 1114.15 of its proposed rule, Premarket Tobacco Product Applications and Recordkeeping Requirements, published on September 25, 2019.⁴⁵ This rule has not yet become final. FDA stated in the preamble to the proposed rule that “[s]upplemental PMTAs are an alternative format of submitting a PMTA that meets the requirements of proposed § 1114.7 that would reduce the burden associated with the submission and review of an application.”⁴⁶ According to the proposed rule, “[A]pplicants that have received a marketing order would be able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing order. The applicant would be able to submit a supplemental PMTA only for modifications that require the submission of limited information or revisions to the PMTA to make it apply to the modified tobacco product.”⁴⁷ FDA provided examples of modifications to ENDS products that are likely not appropriate for supplemental PMTA format:

⁴⁴ blu Cigs, *supra* note 7.

⁴⁵ FDA, Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566 (proposed Sept. 25, 2019) (to be codified at 21 C.F.R. pt. 1100, 1107, and 1114).

⁴⁶ *Id.* at 50,611.

⁴⁷ *Id.* at 50,611-12.

- Any modification that might increase the risk of harm to an individual from the product.
- Modifications that may alter tobacco product use behavior and initiation, such as modifications that have strong youth appeal.
- Design modifications that change the category or subcategory of the product (e.g., modifying a closed e-cigarette to be an open e-cigarette).⁴⁸

Modifications that include the addition of Bluetooth technology would not be appropriate for a supplemental PMTA format because the addition of this technology is not the type of modification that would require only the submission of limited information or revisions to a previously submitted PMTA. As discussed in sections I and II, Bluetooth technology has capabilities that, if added to a tobacco product, are likely to alter use behavior and initiation, particularly among youth. Consequently, the addition of Bluetooth technology is likely to affect significant aspects of the previously submitted PMTA, particularly parts related to the health risks and appeal of the product and the research findings submitted by the manufacturer. A supplemental application with cross-references to the non-Bluetooth authorized tobacco product would be insufficient.

As noted above, PMI announced that it has submitted a supplemental PMTA for its IQOS 3 product.⁴⁹ Because the PMTA is not public, it is unclear whether the IQOS 3 product for which PMI submitted a supplemental application includes Bluetooth technology. However, if the IQOS 3 model being considered for introduction in the U.S. includes Bluetooth technology, a supplemental PMTA would not be appropriate for several reasons.

First, since the rule authorizing supplemental PMTAs has not been made final, there is currently no legal pathway for PMI to submit a supplemental PMTA.

Second, even if the final rule were to adopt the supplemental PMTA format for certain modifications to tobacco products, PMI's IQOS 3 application would not be appropriate for a supplemental application if it includes Bluetooth technology because it would fall under the exceptions outlined by FDA in the proposed rule. The addition of Bluetooth technology would increase the risk of harm to individuals from the product, is likely to have strong youth appeal, and is likely to alter tobacco product use and behavior. The version of IQOS that received a marketing order from FDA and is currently being sold in the U.S. does not have any Bluetooth capability.⁵⁰ The addition of Bluetooth technology is likely to affect significant aspects of the IQOS 3 PMTA, including parts related to the health risks of the tobacco products, its youth

⁴⁸ *Id.* at 50,612.

⁴⁹ Philip Morris International Inc., *supra* note 1.

⁵⁰ *PMI Presentation to TPSAC*, Transcript (Jan. 25, 2018), <https://www.fda.gov/media/111450/download>.

appeal, addictiveness and impact on quitting, and the research findings submitted by the manufacturer. For instance, if PMI-directed feedback to devices via Bluetooth technology increases puff topography by users (e.g., encouraging them to inhale more deeply), then users could be exposed to increased levels of harmful or potentially harmful constituents, which would not have been reported to FDA. A supplemental application which simply includes cross-references to an IQOS product without Bluetooth technology would be insufficient to determine whether IQOS 3 is appropriate for the protection of public health.

Third, the adoption of such technology in devices raises concerns regarding protection of health privacy of user data. By measuring a user's nicotine uptake and frequency of use, the device collects significant health data about a user that can then be shared with tobacco companies. Moreover, if a manufacturer claims that a Bluetooth-enabled tobacco product may help a user quit or reduce smoking, these claims raise questions about whether such a device would be subject to FDA's medical device regulations.

Because of the extensive public health concerns and novel issues raised by the addition of Bluetooth technology, it is essential that FDA require a complete PMTA for any tobacco product that seeks a modification adding Bluetooth technology. A supplemental application would not be sufficient.

Finally, given the major scientific and policy issues raised by Bluetooth technology, FDA should exercise its authority to submit any PMTAs related to Bluetooth technology to the Tobacco Products Scientific Advisory Committee (TPSAC) for review. In addition to obtaining important advice from TPSAC, submitting the applications to TPSAC would make them available for public comment, which would allow the scientific community and public to provide input to the FDA that moves beyond general discussion of these issues to ones focused on specific proposals.

Thank you for your consideration of our views.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative