

Report of Russell S. Winer

I. INTRODUCTION

A. Qualifications

1. I am the William Joyce Professor of Marketing and Deputy Chair of the Marketing Department at the Stern School of Business, New York University. I received my Ph.D. in Industrial Administration from Carnegie Mellon University in 1977.
2. At the Stern School, I teach marketing management courses to graduate students in our executive, part-time, and full-time MBA programs. I have also taught in MBA and executive programs around the world. Topics I teach in these courses include strategic frameworks such as the product life cycle and what are called the “4Ps” of marketing—price, new products and other issues related to products such as branding, distribution channels and retailing, and advertising and other communications issues, particularly new digital methods.
3. Prior to joining NYU, I have been on the faculties of the University of California at Berkeley, Vanderbilt University, and Columbia University. I have also been a visiting faculty member at the Massachusetts Institute of Technology, Stanford University, the Helsinki School of Economics, the University of Tokyo, École Nationale des Ponts et Chaussées (France), Cranfield School of Management (U.K.), Henley Management College (U.K.), and Singapore Management University.
4. I am the author of over 80 articles and four books in the area of marketing. Over the span of my career, I have made methodological and other substantive contributions to the field of marketing in the areas of pricing, advertising, consumer choice and decision-making, and a number of other areas. In my textbook, *Marketing Management*, a textbook that is used by leading business schools around the world, I cover all the major issues involved with marketing decision-making.
5. I have been given a number of awards for my research including a lifetime achievement award in pricing from Fordham Graduate School of Business Administration's Pricing Center which is dedicated to developing a better understanding of prices and pricing and the inaugural long-term research contribution award from the Institute for Operations Research and the Management Sciences (“INFORMS”) Society of Marketing Science (“ISMS”). I was named as an inaugural ISMS Fellow. ISMS is the leading organization for marketing academics whose work involves quantitative modelling. I was also named an inaugural Fellow of the American Marketing Association, the leading organization for marketing academics in the world. In 2016, I was named a Legend of Marketing by the American Marketing Association.
6. I have extensive academic editorial experience. I have been the editor of the *Journal of Marketing Research* (“JMR”) twice. JMR is widely considered to be among the most prestigious two or three journals in the field of marketing. I have been a Senior Editor for the journal *Marketing Science*, the leading quantitative journal in marketing. I am currently an Area Editor of the *International Journal of Research in Marketing* and an Associate Editor of the *Journal of Consumer Research*. In addition, I have served on

numerous editorial boards, acted as associate editor, and generally been involved with the peer review process both as a reviewer and editor for over 40 years

7. I have served as an expert witness in a number of cases involving brands and brand/trademark infringement, survey methodology, corrective advertising, and a number of other areas.

B. Assignment

8. I have been asked to provide my opinions regarding how imposing stringent marketing regulations for Potentially Reduced Risk Products (“PRRPs”), specifically (i) modern oral products including tobacco-free nicotine pouches and pouches containing tobacco; (ii) snus; (iii) vapor products (also referred to as e-cigarettes); and tobacco heating products (“THPs”) may affect the growth and awareness of these products and their potential to reduce rates of smoking and smoking-related diseases for existing adult tobacco and nicotine users who do not want to stop using tobacco and/or nicotine (also referred to as “consumers”).
9. In preparing this report, I reviewed and considered a wide range of marketing texts and articles, some authored by me. This report contains my findings and opinions as of May 18, 2021.

C. Background

10. Before providing my opinions, it is important to first define two key terms for this assignment: (1) **marketing**, and (2) **PRRPs**.
11. Marketing, broadly defined, is comprised of firm activities that present products' and brands' selling points to the marketplace. Typically, marketing is broken down into four key functions: activities concerning the **Product** (e.g., features and benefits), **Promotion** (e.g., traditional and digital advertising, sponsorship, etc.), **Place** (e.g., distribution channels such as direct-to-consumer and retailers), and **Price** (e.g., price points, discounts, price perceptions). These are typically referred to as the 4Ps of marketing.
12. For a marketing strategy to be effective, all 4 of the Ps have to satisfy the product's consumers. Notably, decisions cannot be made on one element of the 4Ps without considering its impact on other elements. Indeed, if any of the Ps is restricted in a way that results in a product and marketing that are not what consumers want, it will lower consumer interest and acceptability of the product.
13. PRRPs are alternative nicotine and tobacco products that do not burn tobacco to deliver nicotine to the user. While I am not an expert in these products or their health risks, it is my understanding that there is a growing consensus among public health authorities and governments that the exclusive use of these PRRPs is significantly less risky than continued smoking of combustible cigarettes. I will discuss the following PRRPs:
 - **Modern oral products.** Many modern oral products are tobacco-free nicotine pouches.. These products are offered in a range of flavors and

nicotine levels and are intended to be placed under the lip for nicotine absorption.¹ While there is scant data on the relative risk profile of tobacco-free modern oral products compared with combustible cigarettes, it stands to reason that such products likely would have lower risk profiles because there is no combustion and the products are tobacco-free.²

- **Snus.** Snus, a traditional oral tobacco product, is a moist powdered tobacco pouch that is placed under the lip so that nicotine can be absorbed. Public health authorities including the US FDA and the UK Royal College of Physicians have stated that the comparative risk of using snus exclusively is significantly lower than the risks posed by continued smoking of combustible cigarettes. In fact, in late 2019, the FDA announced "that exclusive use of the eight General Snus products [by Swedish Match] will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users. . . [and] exclusive use of these products poses lower risks than cigarette smoking for many of the major causes of tobacco-related disease."³ The FDA determined that these snus products can be marketed with the claim "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."⁴ Previously, the Royal College of Physicians 2007 Report also noted that, "in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favourable."⁵
- **Vapor products.** These tobacco-free products are battery-powered devices that aerosolize a liquid that typically contains flavors and nicotine that users then inhale or "vape."⁶ There appear to be two types of vapor products, open system vapor products and closed system vapor products but for purposes of this report, I will focus on closed vapor products ("vapor products") which employ pre-filled eliquid pods that generally contain nicotine and flavorings providing users with an array of flavor choices. It is my understanding that vapor products' risk profile stands in stark contrast to that of combustible cigarettes. For example, an independent expert review commissioned by Public Health England (2018) found, among other things, that: "[v]aping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping."⁷ This was

¹ <https://www.bat.com/snus>

² Robichaud, M.O., Seidenberg, A.B., Byron, M.J. Tobacco companies introduce 'tobacco-free' nicotine pouches. Tobacco Control Published Online First: 21 November 2019. doi: 10.1136/tobaccocontrol-2019-055321

³ Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

⁴ Id.

⁵ Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007 at 160-161.

⁶ https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DO9DCGT9

⁷ McNeill, A., Brose, L., Calder, R., Bauld, L. & Robson, D. (2018), Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England (2018).

reiterated in a further evidence update by Public Health England in 2021, which concluded that: “[a]lternative nicotine delivery devices, such as nicotine vaping products, could play a crucial role in reducing the enormous health burden caused by cigarette smoking.”⁸ Similarly, a large scale systematic review of the scientific literature undertaken by the National Academies of Sciences, Engineering, and Medicine (“NASEM”) for the FDA (the “NASEM Report”) found, among other things, that “[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes.”⁹ More recently, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment concluded that e-cigarettes, when produced and used appropriately and instead of continued smoking, are “likely to be associated with a reduction in overall risk of adverse health effects, although the magnitude of the decrease will depend on the effect in question”.¹⁰ Given the reduced risk posed by vapor products compared with combustible cigarettes, public health authorities have suggested that such products can contribute to harm reduction by offering adult smokers who do not want to stop smoking a potentially less harmful alternative to smoking.

- **Tobacco Heating Products.** THPs are devices that heat tobacco to generate a nicotine-containing aerosol with a tobacco taste which the user inhales. I understand that THPs have potential reduced risk properties compared with combustible cigarettes because the tobacco is heated and not burned and the resulting aerosol potentially can contain substantially lower levels of the toxicants found in the smoke produced when tobacco is burned. In April 2019, the US FDA announced in its Premarket Tobacco Product Order for a THP product, that the “marketing of [this product] is appropriate for the protection of public health” because, among other things, the products produce fewer or lower levels of some toxins than combustible cigarettes, and that “the current evidence indicated that CC [combustible cigarette] smokers who switch completely to [this THP] will have reduced toxic exposures and this is likely to lead to less risk of tobacco-related diseases.”¹¹ More recently, the US FDA authorised the marketing of the same THP product with reduced exposure information, including that the product significantly reduces the production of harmful and potentially harmful chemicals, and that scientific studies have shown that switching completely from conventional cigarettes to the product significantly reduces the user’s exposure to harmful or potentially harmful chemicals. In announcing the authorisation, the FDA stated: “*Data submitted by the company shows that*

⁸ McNeill, A., Brose, L., Calder, R., Simonavicius, E., Robson, D. (2021), Vaping in England: an evidence update including vaping for smoking cessation, February 2021, A report commissioned by Public Health England. London: Public Health England (2021).

⁹ NASEM (2018) Public Health Consequences of E-Cigarettes.

¹⁰ The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, [Statement on the potential toxicological risks from electronic nicotine \(and non-nicotine\) delivery systems \(E\(N\)NDS – e-cigarettes\)](#) July 2020 - A report commissioned by the Department of Health and Social Care and Public Health England.

¹¹ US Food & Drug Administration, PMTA Marketing Order PM0000479 dated April 29, 2019 at 10-11 <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>; <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

marketing these particular products with the authorized information could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch.”¹² In addition, peer-reviewed evidence on THPs indicates that they are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes.¹³

14. If the harm reduction promise of PRRPs is to be fulfilled, it is critically important, in my view, that manufacturers of PRRPs are given appropriate advertising and promotion freedoms to market products that meet consumers’ needs and to communicate with existing adult tobacco and nicotine users about these products, their attributes, how to use them and their availability among other things. Without such freedoms, there will be less awareness and use of PRRPs, as predicted in the marketing literature and theory and as can be seen in real world data from across the world where (not surprisingly) markets with less restrictive marketing regimes for PRRPs have higher rates of PRRP awareness and use and lower rates of combustible cigarette use.

D. Summary of Opinions

15. Based on the analyses and findings described in more detail later in this report, it is my opinion that:
- Marketing, including the ability to offer and package products that consumers want to buy at consumer acceptable price points, to promote these products via traditional advertising (TV, print, radio, outdoor media, and point-of-sale), new/digital marketing (internet, etc.), to establish distribution channels including bricks and mortar stores, retail chains, direct marketing and online channels is essential to , among other things, create awareness about a product or brand, impart knowledge about the product and/or brand attributes, build a relationship with consumers and respond to consumers’ pre-existing preferences such that they will consider using the product or brand.
 - In order to be commercially viable, all 4 of the Ps must be available to PRRPs, especially considering their lifecycles from a marketing perspective (see below). Each of the Ps works in tandem and supports the other Ps. As an example, we can consider the German brand Stihl which makes expensive handheld power equipment like trimmers and blowers. Their marketing strategy is to target high-income home owners with a brand positioning featuring high-quality products. Their 4Ps are consistent with each other and the brand strategy. The price is high, the product has professional features, their advertising is in outlets such as the Wall Street Journal and The Economist which target high net-worth individuals, and the product can only

¹² <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.

¹³ Simonavicius, E., McNeill A., Shahab, L., et al., Heat-not-burn tobacco products: a systematic literature review, Tobacco Control Published Online First: 04 September 2018. doi: 10.1136/tobaccocontrol-2018-054419

be purchased at their proprietary dealers, not in mass outlets such as the Home Depot.

- A second example of how the 4Ps work together is when Nestlé introduced Nespresso, a one-cup-at-a-time pod-style brewing system. When introduced to consumers in the late 1980s, it was an expensive, high-tech item targeting upscale serious coffee drinkers. As a result, the price of the machine and the pods was high. Interestingly, Nespresso management combined the promotion and place Ps by forming a coffee club that had outstanding customer service befitting the high-end brand. Replacement pods were sold only through the club and the company did not use mass advertising, only word-of-mouth by like-minded consumers.
- Marketing serves different functions at different points in time depending on the stage of the product life cycle -- that is, whether it is a new, growing, mature or declining product market. PRRPs would constitute new and growing product categories unlike combustible cigarettes. Other examples of new products include LED light bulbs and music streaming services. LED light bulbs were developed to replace traditional incandescent bulbs and have a longer life span and save on electricity. The new category did not really take off until Cree spent considerable sums marketing them to consumers in 2013. Similarly, although music streaming started with Napster in the late 1990s, the category did not significantly expand until Spotify started and marketed its service in 2006. As with these products, while the ingestion of nicotine is not new, the method of delivery of nicotine is different with modern oral products and THPs being newer products and vapor products and snus being growing product categories.
- In new and growing product markets, such as the PRRP market, the first objective of marketing is to make a product that consumers want and to make consumers aware of the product including its function, how to use it, where to buy it and its cost. Simply put, the success of new and growing product categories rests and falls on the ability of firms to develop a product that meets consumers' needs and to communicate with potential consumers (here, existing adult tobacco and nicotine users) about the existence of the product, its features and potential differences when compared to smoking. Without such communications, these consumers will remain "in the dark" about new products, and not avail themselves of these products due to their lack of awareness, information or confusion about them.
- Marketing freedoms for PRRPs are critical to a firm's ability to inform existing adult tobacco and nicotine users about PRRPs and their unique attributes and differences when compared to cigarettes. Through firm communications, advertising and other forms of promotion, firms can create awareness of PRRPs amongst existing tobacco and nicotine users, inform them of the products' and brands' features and generate interest and trial use among these consumers who would otherwise continue to smoke by tapping into their pre-existing preferences, which for many adult tobacco and nicotine users may include wanting to enjoy the sensorial and pharmacological effects

of nicotine but in ways that may pose lower health risks than from smoking combustible cigarettes.

- Because the marketing communication environment has changed dramatically over the past 10-20 years with the rise of the digital economy, firms need to avail themselves of more varied marketing communication platforms including, among other things, a wide mix of digital marketing as well as more traditional advertising channels such as television, radio, print and outdoor media, direct marketing and point-of-sale advertising, to effectively inform consumers about new and growing products. Digital marketing provides certain benefits to firms and consumers over traditional advertising because it allows firms to better target the intended consumers and to provide those consumers with marketing that serves their interests. In fact, as the US FDA has recognized, digital marketing technologies have evolved such that firms using a variety of data management tools can more accurately target digital advertising to their intended adult audience and restrict youth access to a minimum.
- In addition, marketing is important for the development of strong brands and brand identities which in turn provides other benefits to consumers by dramatically cutting down on consumer search costs, allowing for easy comparisons across brands and enabling consumers to efficiently locate products and brands that meet their preferences.
- Beyond conveying information about new products and brands, advertising, other promotional efforts and packaging can, particularly over the longer term, help firms build brand awareness and positive brand images and associations in the minds of consumers. In addition, building brands is important to differentiate a firm's brands from those of competitors and create goodwill. Allowing firms to advertise and thereby compete on the basis of their respective brands fosters a competitive market, which leads to better consumer welfare by forcing competitors to compete for market share through prices and/or higher quality or more innovative products.
- Along with the importance of communications in the new and growing product diffusion process, establishing retail channels is critical to the success of new products. Consumers need to be able to buy the products they hear about from communications or word-of-mouth whether in bricks and mortar stores, specialist product shops (e.g. specialty vapour stores) or online. Often, in bricks and mortar stores communications and retail channels are linked as stores will not carry a new product unless there is a promise of significant advertising support. Thus, limiting the freedom PRRP marketers have to communicate the features and benefits to consumers can have a secondary effect on their ability to gain shelf space in retail outlets.
- A firm's ability to price products that consumers will want to buy is critical to the product's success. In other words, imposing restrictions on a firm's ability to price PRRPs at a level that is acceptable to consumers likely would jeopardize the viability of PRRPs. For example, taxing vapor products and other PRRPs the same as combustible products may discourage switching to

these products; and convey the message that these products are equally risky - contributing to the increasing misperceptions about the comparative risks of PRRPs compared with combustible products.

- It stands to reason that restrictions on marketing for new and growing product categories for PRRPs will have an impact on consumer awareness and use of such products. For example, real world evidence indicates, not surprisingly, that there is higher awareness and use of e-cigarettes in jurisdictions with less restrictive marketing regimes and lower awareness and use of e-cigarettes in more restrictive marketing regimes. Real world data also suggest that jurisdictions with higher rates of e-cigarette use are seeing higher rates of decline in smoking initiation and overall smoking prevalence.
- Similarly, marketing communications are necessary to prevent and clear up consumer confusion and misperceptions about PRRPs. There is an increasing body of literature that consumers are confused and ill-informed about the relative risks of PRRPs in relation to combustible cigarettes, and that those misperceptions are growing. For example, a large number of consumers in many markets believe that PRRPs such as e-cigarettes and snus are as risky, if not more risky, than combustible cigarettes. Allowing firms that sell PRRPs to provide accurate information about the comparative risks of these products compared to combustible cigarettes could serve a very important educational function and better align consumer beliefs about these products with the available scientific evidence. Moreover, restricting firms' abilities to market such products and inform consumers of their attributes have real potential to undermine public health efforts to move smokers who do not want to stop using nicotine towards PRRP use.
- In addition, and while PRRPs are not marketed as authorized smoking cessation devices, the use of PRRPs has been associated with increased smoking cessation. These data confirm what the marketing literature and theory predict, which is that marketing freedoms are important for growing the e-cigarette market and the entire PRRP category, and thus, for achieving harm reduction goals of reducing rates of smoking and smoking-related diseases.
- One legitimate concern with allowing PRRPs robust marketing freedoms (including the ability to use digital marketing, the ability to sell PRRPs online, product display and communications at the points of sale, etc.) is the risk that such marketing could have "spillover" appeal to youth. This is an important risk that needs to be balanced against the harm reduction benefit to existing adult tobacco and nicotine users that may be obtained by allowing PRRPs marketing freedoms. There are sensible ways to regulate the marketing of PRRPs to reduce the risks of youth "spillover" while still allowing marketing freedoms that facilitate the ability of PRRPs to displace smoking and contribute to tobacco harm reduction. Indeed, digital marketing, in particular, can be quite narrowly tailored to adult audiences in ways that reduce the risk of spillover exposure or appeal to youth.

- As explained above, any restrictions on the marketing mix (the 4Ps) that affect the manufacturer's ability to market a product that meets consumers' needs will result in lower consumer awareness and uptake of the product. For example, banning or restricting the use of certain additives, flavors or other ingredients used in vapor products, prohibiting online sales of PRRPs, increasing taxes on PRRPs comparable to traditional products, banning advertising, etc. would make it difficult for manufacturers to develop marketing strategies to optimally present their products and grow the market to help move adult tobacco consumers away from the cigarette market.
- In sum, stringent restrictions on any of the 4Ps of marketing would threaten the commercial viability of the PRRP market and risk foreclosing the growth of the market in such products and undermining the potential for the products to play a role in tobacco harm reduction.

II. MARKETING

A. Fundamentals of Marketing

16. Marketing is a set of activities taken by firms and other organizations to facilitate transactions in the marketplace. A distinction can be made between marketing strategy and marketing tactics or programs. The former is a conceptualization of how the firm wants to approach the market and typically involves identifying, among other things, which customers the firm wants to target. A marketing strategy always begins with the set(s) of customers on which the marketer wants to focus, those that have the greatest proclivity to purchase the product. Here, for example, I understand that PRRPs are intended for existing adult tobacco and nicotine users who do not want to stop using nicotine. A marketing strategy also would involve identifying competitors and determining what information the marketer wants consumers to have about its products and brands.
17. Once the strategy is established, decisions are made about the specific marketing programs to implement the strategy. These are the classic "4Ps" of marketing: product (specific product specifications to meet consumers' needs, benefits), promotion (communications/advertising), place (distribution channels), and price. Broadly speaking, key features of the 4Ps would include offering a product that meets consumers' needs and wants at a price that is acceptable to the target market, promoting the product via traditional advertising media (e.g., television, print, radio, outdoor platforms, point-of-sale advertising, etc.) and new/digital media (e.g., internet, search, banners/display ads), and establishing distribution channels including bricks and mortar stores, specialized shops, retail chains, direct marketing (e.g., direct communications with targeted consumers via a variety of media including mail, email, brochures, etc.), and online channels which I discuss further below in Section C.

B. Importance of the Product Life Cycle to the Marketing Mix

18. It is generally understood among marketing scholars that marketing serves different functions at different points in time over the life of the product. This concept is referred to in the marketing science literature as the product life cycle ("PLC") and

explains the process a product goes through when it is first introduced into the market until it declines or is no longer sold. Understanding the PLC and identifying what stage the product is in is critical to determine the most effective marketing strategies needed to educate and inform existing adult tobacco and nicotine users about PRRPs to achieve the promise of tobacco harm reduction.

19. There are four stages of the PLC:

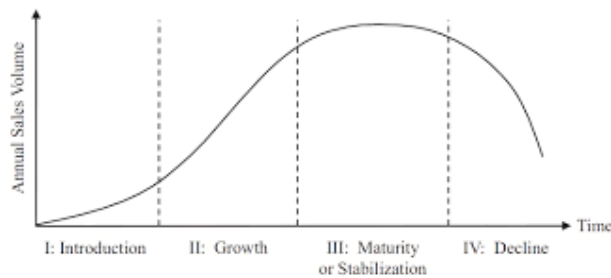
- Introduction (New): In this phase, the product is brand new. Consumers are unaware of the new product and its attributes and marketing efforts focus on creating awareness for the new product and gaining distribution in stores or other appropriate outlets.
- Growth: At this stage, sales volume is increasing rapidly and, if the market for the new product looks attractive, competitors are starting to enter. The marketing efforts of both the innovator and the later entrants help to propel the sales. Due to the increased competition, there is greater focus on brand building to differentiate.
- Maturity: During the mature phase, competitors are competing for market share and with that, price competition is increasing as are sales promotions (discounts).
- Decline: At some point, the sales of many product categories start to decline and even disappear (e.g., music cassettes).

20. New products are those that differ significantly in their characteristics than products currently on the market. New products are intended to meet a consumer demand or preference and can replace a current product or take over an existing product, such as the case with PRRPs and combustible cigarettes. Many new products have been launched in the last 20 years; examples are streaming music services (mentioned earlier), smartphones (e.g., Apple's iPhone), ip telephony (e.g., Skype), digital payments (e.g., Paypal, Venmo), and many others.

21. The sales of these new and growing product categories typically follow the PLC. The shape of the PLC follows the model shown in Figure 1. The two dimensions of the PLC are annual sales volume (vertical axis) and time (horizontal axis). The time dimension is purposely vague as different new products' sales follow the curve at different rates of speed.

Figure 1

The Product Life Cycle



22. From the consumer side, the process that is causing the PLC to take its shape is called diffusion.¹⁴ New product purchases come from two groups of consumers: innovators who want to be among the first to try a new product and hear about the new product through communications, and imitators who learn about the product from word-of-mouth, blogs, etc. from the innovators. I will elaborate below on the importance of marketing on this diffusion process.
23. To determine where the PRRPs are in the PLC I performed a PLC analysis for these products based on data I obtained from the 2020 report on Smokeless Tobacco and Vapor Products in the US produced by Euromonitor International, a leading global marketing research firm.¹⁵ I note however that modern oral products were not included in the Euromonitor report because it appears that these products were not introduced in the US market until 2019.¹⁶ I have used the US data as an illustrative example of the PRRP PLC in a jurisdiction where these products have been progressively regulated.

Closed Vapor Products

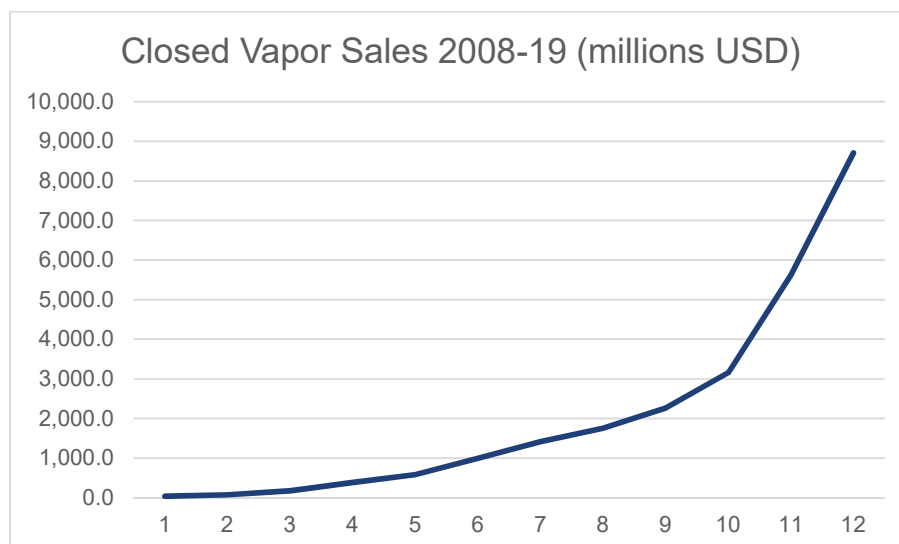
24. For this category, I used retail sales in constant 2011 dollars covering the period 2008-19.¹⁷ The graph of these data is below:

¹⁴ See, for example, Ofek, E., Muller, E., and Libai, B. (2016), *Innovation Equity*. Chicago: The University of Chicago Press.

¹⁵ *Passport: Tobacco 2020* (March 18, 2021), Euromonitor International.

¹⁶ Robichaud, M.O., Seidenberg, A.B., Byron, M.J. Tobacco companies introduce 'tobacco-free' nicotine pouches. Tobacco Control Published Online First: 21 November 2019. doi: 10.1136/tobaccocontrol-2019-055321

¹⁷ *Passport: Tobacco 2020* (March 18, 2021), Euromonitor International.



25. This category is still clearly in the growth phase of the PLC with the sales curve still sloping upwards. An examination of the forecasts for the next several years beyond 2019 supports the fact that the category will continue to grow (if the marketing freedoms are not curtailed).¹⁸

THPs

26. Due to the fact that the category (in its current form) is new, there is only one year of data through 2019. This is evidence that the category is at the beginning stage of the PLC. Forecasts indicate extraordinarily rapid growth for this new product (if the marketing freedoms are not curtailed).¹⁹

Modern Oral Products

27. Similarly, it is my understanding that tobacco free modern oral products are new products that were introduced in the US in 2019.²⁰ Accordingly, the data is not sufficient to conduct an analysis but it stands to reason that these products are new products.

Snus

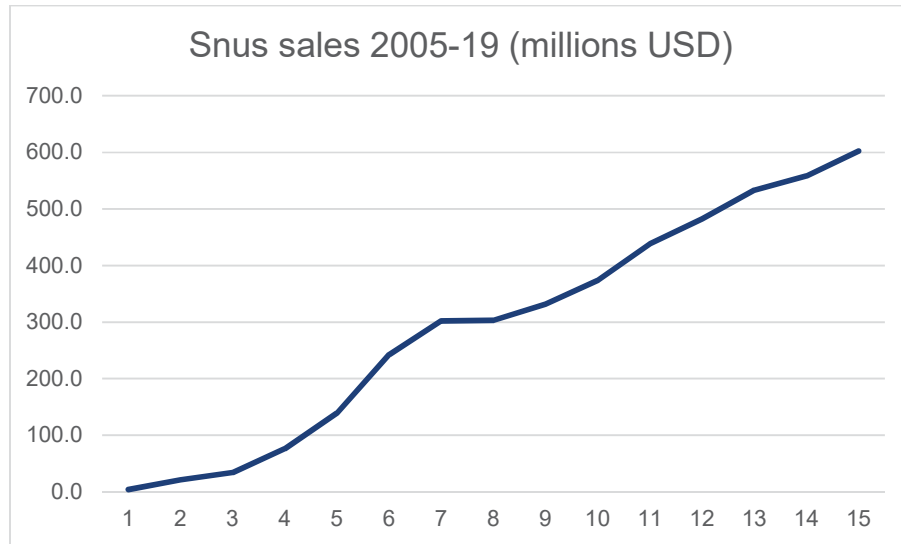
28. As can be seen from the graph below, we can capture the PLC for snus virtually from its introduction in the U.S. from 2005-2019.²¹

¹⁸ Based on interviews with Euromonitor staff and information documented in the report, the forecasts were developed using a combination of statistical methods and interviews with industry participants. I am satisfied that the forecasts can be used, at least in the short run, say, through 2020.

¹⁹ *Passport: Tobacco 2020* (March 18, 2021), Euromonitor International.

²⁰ Robichaud, M.O., Seidenberg, A.B., Byron, M.J. *Tob Control* Nov. 19, 2019(0):1-2. doi:10.1136/tobaccocontrol-2019-055321; see also <https://www.reuters.com/article/us-swedish-match-results/swedish-match-rolls-out-non-tobacco-nicotine-pouch-in-u-s-idUSKCN1Q20SM>

²¹ *Passport: Tobacco 2020* (March 18, 2021), Euromonitor International.



29. Snus has had a remarkable rate of growth in the U.S. Except for a period around 2011-12, the growth rate has been continually positive thus indicating that snus is still in the growth phase of the PLC. This is also supported by the forecasts.
30. In sum, based on their stages in their PLCs, I conclude that closed vapor products, THPs, modern oral products and snus are most vulnerable to restrictions on the marketing activities that can be undertaken to support brands in those categories.

III. MARKETING MIX FREEDOMS ARE CRITICAL TO THE GROWTH OF PRRPS

31. The successful marketing of PRRPs, new and growing products, depends on the deployment of the 4Ps. Below I will discuss the 4Ps and their importance to PRRPs.
32. As I indicated above, all of these elements of the marketing mix need to work together to satisfy customer needs in order to optimize the demand for a product. Companies first establish their target consumers and then perform marketing research (often called insights) to better understand how to make the right decisions about the 4Ps.
33. For example, luxury good manufacturers know that their consumers are relatively insensitive to price but want to shop in exclusive stores with premium customer service. In addition, they often want products that can be identified by other luxury buyers as being high-priced and exclusive. Communications will be personal and/or in limited distribution media rather than delivered through mass communications outlets. Thus, the 4Ps in this case (price, product, place and promotion) are all consistent with what the consumers value and work together to provide the luxury buyer with the total experience that they want. If any one of these is deficient, the whole strategy can collapse. Luxury buyers do not want to see the products they are buying to be accessible to just anyone so if the price is too low or the product is not readily identifiable, the brand's success will suffer. The same holds for the communications and distribution channels. Again, each P has to be consistent with what the target consumer wants and be consistent with each other.

34. Marketing communications are the voice of the company and the means through which firms can inform and remind consumers about their products, services or brands and establish a relationship and discourse with their customers. This latter point is particularly important today with the increased use of digital media where communication is more of a conversation with consumers as opposed to the old “one to many” model of communications. This also allows firms to communicate with their target market better, here existing adult tobacco and nicotine users.
35. For new and growing product categories in particular, marketing communications work by informing consumers that the product exists and showing consumers how and why a product is used, by whom, where, and when. With respect to PRRPs for example, these communications can provide the following essential factual information including (i) the names of the product, (ii) a description of the product components including, where applicable, how to open and how refill the device, if applicable, (iii) the price, (iv) instructions on how to use and store the product, (v) product ingredients, (vi) factual descriptions of the flavors, vapors, etc., (vii) nicotine content, and (viii) a warning that the product contains nicotine, an addictive substance and is not intended for use by young people and others.
36. In addition to providing information about the product's attributes, marketing communications can alert consumers about relevant product or brand options that may be oriented to remove a problem, avoid a problem, more fully satisfy a pre-existing preference or for other reasons. Here for example, with respect to PRRPs, making existing adult tobacco and nicotine users aware of PRRPs via, among other things, sales promotions, product display, and digital and point of sale communications could tap into a desire to switch from smoking combustible cigarettes to a potentially reduced risk product insofar as those consumers want to continue to use nicotine.
37. Marketing communications, in addition to creating product awareness, can instill brand awareness by reminding the consumer about the brand and strengthening consumers' loyalty. Brand awareness refers to how strongly consumers recall or recognize the brand under different circumstances. Brand image refers to consumers' perceptions of and preferences for a brand, as reflected by the various types of brand associations held in consumers' memory. In this way, brand awareness and brand image can create brand equity.²² Brand equity refers to the brands' value as a function of brand awareness and brand image.
38. Developing a strong brand offers a range of important benefits to the firm and consumers. For the consumer, strong brands help identify a preferred brand and provide assurance regarding the origin and quality of the preferred brand. Brands also provide consumers with a level of comfort in their choice of products.²³
39. For firms, a strong brand offers a variety of benefits, including improved perceptions of product performance, greater customer loyalty, less vulnerability to competitive marketing actions and marketing crises, larger margins, more elastic customer

²² Keller, K.L. and Lehmann, D.R. (2003), How Do Brands Create Value, *Marketing Management*, 12, 26-31.

²³ Winer, R. and Dhar, R. (2011), *Marketing Management*, Fourth Ed. Upper Saddle River, NJ: Pearson Education, at 179.

response to price decreases and inelastic customer response to price increases, greater trade or intermediary cooperation and support, increased marketing communication effectiveness, and additional licensing and brand extension opportunities.²⁴ Research indicates that branded products typically command price premiums because consumers will pay more for the same product if it has a stronger brand.²⁵

40. In addition, building strong brand equity can increase the effectiveness of marketing communications because consumers may be more inclined to attend to additional communications for a brand, process these communications more favorably and have a greater ability to later recall the communications.

Product

41. Integral to any successful marketing strategy is developing a product that consumers want to buy. Potential restrictions or changes in the product's features, such as restricting or banning the use of certain ingredients in vapor products or imposing restrictive nicotine content limits, could negatively impact the viability of the product if those features are critical to consumer acceptance. A change to any product feature or ingredient in a popular brand can have a negative effect on consumer acceptance. A good recent example is when the popular food spread Nutella announced that it was increasing the amount of powdered skim milk in its formula which would create a lighter toned product. Many consumers of the brand announced their displeasure on the Internet.²⁶ Another example of this is when Coca Cola introduced a sweeter version of "Classic" Coke in 1985. It was so unpopular that Classic Coke was re-introduced within 3 months.
42. In addition, packaging, particularly with respect to new and growing products, plays an important role in consumer decisions because it builds and maintains brand equity.²⁷ For new and growing products such as PRRPs, packaging can convey important information about the products that will help inform consumers of the products and aid in their purchase decisions.²⁸ For example, the brand Seventh Generation is a line of laundry, personal care, and other home products. Their point of difference is that their products are made of natural, plant-based, and sustainable ingredients and that the package is made from recycled materials and is itself recyclable. All of this information along with the specific ingredients in each product is listed on the package.

²⁴ Id. at 179-180; Keller, K.L. and Lehman, D.R. (2003), How Do Brands Create Value, *Marketing Management* 12, 26-31; Hoeffler, S. and Keller, K.L. (2003), The Marketing Advantages of Strong Brands, *Brand Management* 10, 421-445.

²⁵ Lindermann, J., *The Economy of Brands* (2011), Basingstoke: Palgrave MacMillan, at 15.

²⁶ <https://www.news.com.au/lifestyle/food/eat/national-outcry-after-ferrero-confirms-change-of-nutella-recipe/news-story/77c0852a07ce7a4bbe11b4ccddb34f2>.

²⁷ Algrave MacMillan, at 15.

²⁸ Keller, K. *Strategic Brand Management*, 3rd Ed, Upper Saddle River, NJ Prentice Hall 2008, at 172. Underwood, R.I., Klein, N.M. and Burke, R.R. (2001), Packaging communication: attentional effects of product imagery, *J Product Brand Management*

Promotion

Traditional Advertising

43. Advertising is a paid form of communication to inform consumers about a product or service. It is one of the most important platforms for marketing communications. The ability to advertise across a variety of traditional media channels (TV, print, radio and outdoor media) is vital to new and emerging PRRPs growth because consumers likely know little about the products and brands, have not formed preferences, and may be misinformed about the products and their attributes.
44. During the new and emerging growth stage, advertising is vital to help induce trial and promote word of mouth and diffusion, that is how a new product is accepted by the market. Here for example, real world data demonstrate that consumer awareness of e-cigarettes in countries that tightly regulate marketing communications about, and access to, e-cigarettes are significantly lower than in countries that allow for greater access and marketing freedoms.²⁹
45. .In addition, when consumers are unfamiliar with a new product and its attributes, they are often less efficient at incorporating important advertising information into memory. For example, consumers who are unfamiliar with PRRPs may take longer to digest critical messaging information than consumers in older markets. As such, advertising elasticity, that is the effect of an increase or decrease in advertising on the market, will be higher for products in the early stage of the life cycle than in the mature stage.³⁰ This has been supported by a number of other studies as well.³¹

Digital Marketing

46. To communicate effectively with consumers, "marketing communications must go where consumers are, and, over the past ten to twenty years, that is increasingly online."³² Indeed, the rise of digital marketing (e.g., display ads including banner and pop-ups, search ads (e.g. Google Ads), search engine optimization, ad retargeting, mobile, etc.) has changed fundamentally the means and method of communication between people and between a customer and a brand or organization.
47. Digital marketing, that is the marketing of products using digital technologies mainly on the internet in different channels (desktop, laptop, mobile devices), has become

²⁹ Gravely, S., Driezen, P., Ouimet, J., Quah, A. C. K., et al., (2019), Prevalence of awareness, ever - use and current use of nicotine vaping products (NVPs) among adult current smokers and ex - smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross - sectional findings from the ITC Project. *Addiction* 114: 1060 - 1073. <https://doi.org/10.1111/add.14558>

³⁰ Sethuraman, R., Tellis, G., & Briesch, R. (2011), How Well Does Advertising Work? Generalizations from Meta-Analysis of Brand Advertising Elasticities. *Journal of Marketing Research*, 48(3), 457-471. <https://doi.org/10.1509/jmkr.48.3.457>; Misra, S. (2015) Price and Advertising Effort Over the Product Life Cycle: The B.C.G. and Dorfman-Steiner Approaches. In: Hawes, J.M., Glisan, G.B. (eds) *Proceedings of the 1987 Academy of Marketing Science (AMS) Annual Conference. Developments in Marketing Science: Proceedings of the Academy of Marketing Science*. Springer.

³¹ See, for example, Parson, L. (1975), The Product Life Cycle and Time-Varying Elasticities. *Journal of Marketing Research*, 12, 476-80.

³² Keller, K. (2009), Building strong brands in a modern marketing communications environment. *Journal of Marketing Communications* Vol. 15, Nos. 2 - 3, April- July 2009, 139-155, at 147.

an increasingly important and central component of a company's marketing mix. Indeed, the IAB Internet Advertising Revenue Report found that "[d]igital revenues for full year 2018 surpassed \$100 billion for the first time. Internet advertising revenues in the United States totaled \$107.5 billion for the full year ("FY") of 2018, with Q4 2018 accounting for approximately \$31.4 billion and Q3 2018 accounting for approximately \$26.6 billion. Revenues for FY 2018 increased 21.8% over FY 2017."³³ Digital marketing is now an integral part of a firm's relationship with consumers and continues to show more rapid growth than traditional media.³⁴

48. In addition, digital marketing provides certain benefits over traditional advertising because it allows firms to better target their intended audience. Indeed, the FDA Public Health Rationale for Recommended Restrictions on New Tobacco Product Labelling, Advertising, Marketing, and Promotion ("FDA Public Health Rationale") notes that

"the data sources, methodologies, and technologies used to deliver and track digital media consumption have also evolved, enabling product marketers to create sophisticated, highly targeted digital marketing plans and paid media buys designed to reach their intended audiences based on specific demographics, psychographics, and media passion-points while also limiting reach or 'spill' to unintended audiences. Thus, it is possible, efficient, and necessary for firms to take advantage of these technologies to help ensure that tobacco product marketing is targeted to adults and that 'spill' to youth audiences is minimal."³⁵

49. Indeed, there are many ways in which digital technologies can be used to better target consumers and prevent spillover to unintended recipients. These include, among others, behavioral targeting where advertisements are targeted at users based on their past purchase activity, day parting which allows firms to specify what time of the day an ad is to be shown, and interest-based targeting which refers to the ability to advertise to customers with a specific interest or hobby. For instance, services such as Google's Advanced Audiences technology provides marketers with tools that allow them to identify people based on their interests ("pre-built affinity audiences"), to create their own groups of audiences based on specific interests tailored to their brands ("custom affinity audiences"), and to reach people who are actively researching certain products or services ("in-market audiences").³⁶

³³ IAB internet advertising revenue report 2018 full year results, prepared by PWC (May 2019). <https://www.iab.com/wp-content/uploads/2019/05/Full-Year-2018-IAB-Internet-Advertising-Revenue-Report.pdf> IAB internet advertising revenue report 2018 full year results, prepared by PWC (May 2019). Banner ads are small, rectangular ads that run along the top or side bar of a web page. Popup ads are another form of paid online advertising methods and are intended to capture email addresses or attract traffic to a website. Ad retargeting is a strategy that utilizes cookies on a website to anonymously track users' activities as they move across the Web. These data can then be used to show ads that are relevant to them based on their prior search activities. [rnet-Advertising-Revenue-Report.pdf](https://www.iab.com/wp-content/uploads/2019/05/Full-Year-2018-IAB-Internet-Advertising-Revenue-Report.pdf)

³⁴ Keller, K. (2009), Building strong brands in a modern marketing communications environment. *Journal of Marketing Communications* Vol. 15, Nos. 2–3, April–July 2009, 139–155.

³⁵ FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

³⁶ Diddarms, H. and Behmke, T. We Analyzed 75,000 YouTube Campaigns – Here's What We Learned About Using Demographic Data, *Ad Week* (November 4, 2019) <https://www.zinio.com/read/readsvg/442856/G1>

50. The FDA Public Health Rationale also recognizes that paid digital advertising targeting capabilities offer PRRP marketers with the ability to target adults who meet specific age criteria through the use of first- and/or second-part age-verified data on any digital property accepting paid advertising relating to PRRPs, while also restricting youth-access to such advertising.³⁷ As the FDA acknowledges, "this precision marketing ... represents an opportunity to limit youth exposure to digital marketing" of PRRPs."³⁸
51. Social media marketing has become an important component of digital marketing. Social media marketing primarily covers activities involving social sharing of content, videos, and images for marketing purposes. Unlike more traditional marketing platforms such as TV or print media, social media provides consumers a forum where they can learn more about companies and their products and allows consumers to interact with branded content.
52. The FDA Public Health Rationale further notes that, while there are no universal age restriction controls on social media platforms, many social media platforms have started to offer firms the option to place age restrictions on some or all of their account pages, followers, and content including specific posts.³⁹
53. Increasingly digital technologies have shifted companies' focus from mass communications to a more targeted, two-way communication with consumers.⁴⁰ This form of communication is often perceived by consumers as more interesting and relevant. With social media sites, companies can enhance the customer interaction that has already been established through traditional media (i.e., TV ads, print ads) to a more personal level.⁴¹
54. The importance of digital marketing, including social media platforms, is further underscored by the fact that more and more consumers use social media and rely on it for making shopping decisions. Firms can develop and grow closer relationships with new and existing customers through social media and can expand the market to the customers they could not reach before.

Point of Sale ("POS") Communication and Display

55. POS communication "is a form of retailer promotion that includes information related displays and other company-paid advertising inside the store."⁴² With POS communication, brands can be represented in a cohesive way at the point where the shopper can directly interact with the product. POS communications offer the opportunity to educate shoppers about new products and help shoppers to choose the right product for them. POS communications are sometimes referred to as "shopper marketing." POS communications are particularly important with respect to

³⁷ FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

³⁸ Id.

³⁹ Id.

⁴⁰ FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labelling, Advertising, Marketing, and Promotion (April 2019).

⁴¹ Rautela, S. and Singhal, T. (2017), Leveraging Social Media for New Product Development: A Review at 94.

⁴² Winer, R. and Dhar, R. Marketing Management (4th Ed. 2011) at 326.

new and growing products, in order to create awareness and educate consumers about new products which may otherwise get lost on shelves amongst existing products.

56. The retail display of products performs a number of functions for consumers that are particularly important in relation to new and growing products like PRRPs, in order for them to achieve awareness and for them to be seen as effective alternatives to combustible cigarettes for smokers who are looking to switch, specifically by alerting customers to the existence, availability and characteristics of these products.

Place

Retail and Online Channels and Direct Marketing

57. A critical aspect of marketing is giving consumers access to the products under consideration. In other words, the establishment of retail channels, both bricks and mortar stores, specialized shops, and online, is critical to the success of new and growing products because consumers need a readily available place to purchase the new product.
58. I understand that rules restricting the availability of PRRPs to age-restricted shops or shops that are licensed to sell these products, prohibiting online sales and prohibiting PRRPs from being sold in vending machines are under consideration by some governments.
59. Today, many of the PRRP purchases take place online. Even before the COVID-19 pandemic, the online channel had become very popular as many consumers shifted much of their purchasing from bricks-and-mortar stores to the Internet. This trend is expected to increase. In general, any restriction on channels of distribution inhibits consumers who use those channels from purchasing. In the U.S., for example, it is still the case that 90% of retail buying takes place in “bricks and mortar” locations. Thus, the ability to find retail space is critical to the success of a new product.
60. At the same time, there are a number of barriers to obtaining retail space. Even for established channels, the retailer’s scarce resource is shelf space and displaying a new product often means something else has to be replaced. As a result, competition for shelf space can often be fierce. To give retailers the incentive to do that, new products offer both marketing support (advertising) and, in some cases, what are called “slotting” fees, that is, direct payments for the space.
61. A channel that is often used is called direct marketing. Direct marketing is any form of direct communication that gives the consumer access to the firm's products without any intermediary. Traditional methods of direct marketing include telemarketing, infomercials on radio and TV, and teleconferencing. With the rise of digital marketing however, the nature of direct marketing has changed as well.⁴³
62. Given that consumers are buying more goods through the internet, direct marketing via the internet (such as email direct marketing) has become increasingly important

⁴³ Winer, R and Dhar, R. Marketing Management (4th Ed. 2011).

for firms to market new products. As with digital marketing, digital direct marketing has increased exponentially because technologies have increased firms' ability to target consumers more efficiently.⁴⁴

63. In sum, any restriction on channels of distribution inhibits consumers who use those channels from purchasing new and growing products, including PRRPs.

Price

64. Price is always a critical marketing variable and is often the variable that customers react more to than any other. However, as with the other Ps, the price must be consistent with the overall marketing strategy. Depending on the price sensitivity of a product's consumers, any factor that increases the price of a product has the potential to decrease demand, in some cases, significantly.
65. I understand that two potential regulatory decisions are under consideration by a number of governments: taxing PRRPs in the same way as cigarettes, and setting a minimum price for PRRPs. For example, adding an onerous tax to e-cigarettes would certainly cause a decline in demand much like what has happened with increased taxation of combustible cigarettes. In addition, taxing PRRPs in the same way as cigarettes may contribute to the increasing consumer confusion about the estimated risks of PRRPs compared with traditional cigarettes. Some commentators have suggested that in order to support tobacco harm reduction strategies, the taxation of tobacco and nicotine products should reflect their position on a risk continuum - with a significant tax differential between combustible cigarettes which are the most risky product, and PRRPs - to encourage smokers to switch to the less costly and potentially reduced risk alternatives. For example, the UK House of Commons Science and Technology Committee has stated: "*[t]he level of taxation on smoking-related products should directly correspond to the health risks that they present, to encourage less harmful consumption. Applying that logic, e-cigarettes should remain the least-taxed and conventional cigarettes the most, with heat-not-burn products falling between the two.*"⁴⁵
66. In addition, sales promotions such as short-term price discounts, coupons, free samples, are also useful marketing tools in many product categories. Prohibiting or severely restricting sales promotions would likely effect new and growing products success in the marketplace.

IV. ANALYSIS OF LIKELY IMPACT OF MARKETING RESTRICTIONS ON THE PRRP MARKET

67. I understand that some governments have implemented or are considering marketing restrictions that would significantly impact the marketing mix of the PRRP market. Other restrictions under consideration may affect the product by banning or restricting the use of certain additives, flavors, and/or ingredients used in e-liquids or other new products. Other potential restrictions would affect the packaging of PRRPs by standardizing requirements (e.g., plain or standardized packaging) and instituting requirements for packaging to include the same warning labels used in certain

⁴⁴ Id.

⁴⁵ House of Commons Science and Technology Committee, E-Cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018

markets as traditional combustibles (e.g., graphic health warnings). In addition, other contemplated restrictions include restricting the promotion of PRRPs and restricting the sale of PRRPs in bricks and mortar channels and online. Below, I will discuss how such restrictions of the 4Ps would likely negatively affect the success of PRRPs because they will impair the firms' ability to market products that meet consumers' needs, will impair the firm's ability to make consumers aware of these products and to provide access to them, and to dispel consumer confusion about PRRPs; and that doing so will likely undermine public health efforts to encourage smokers who would not otherwise quit, to switch from combustible cigarettes to PRRPs.

68. Consumer preferences drive the demand for products. The restrictions noted above can result in products that do not meet consumer preferences for PRRP products and thus have a negative effect on demand and the growth of the product category. Although all elements of the 4Ps are important (product, price, promotion, place), particularly important are restrictions on the product itself. If consumers want certain flavors, ingredients, or additives and the industry cannot supply them, they will purchase other products that better satisfy their preferences or even possibly revert to smoking cigarettes.

A. Marketing Mix Restrictions Will Likely Undermine Public Health Efforts to Get Smokers to Switch From Combustible Cigarettes to PRRPs

69. There is a growing body of research that e-cigarettes, THPs and snus are considered to be significantly less harmful than combustible cigarettes. For example, as the UK Royal College of Physicians Report states, "[a]lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoking tobacco products, and may well be substantially lower than this figure." And, as noted above, the US FDA has authorized the marketing of a THP product with reduced exposure information, on the basis that the agency determined that the applicant had demonstrated that because the THP heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke.⁴⁶ Similarly, the FDA has recently permitted Swedish Match USA, a manufacturer of snus, to advertise its products through the modified risk tobacco product pathway and is allowed to claim that its snus products are less harmful than combustible cigarettes.⁴⁷ Specifically, the FDA found that Swedish Match "has demonstrated that, as actually used by consumers, the eight General Snus products sold or distributed with the proposed modified risk information, will significantly reduce harm and the risk of tobacco - related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."⁴⁸ Given that many modern oral products do not contain or burn tobacco,

⁴⁶ US Food & Drug Administration, PMTA Marketing Order PM0000479 dated April 29, 2019 at 10-11 <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>; <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application> pathway

⁴⁷ Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

⁴⁸ Id.

it stands to reason that they likely have a reduced risk profile compared with combustible cigarettes and even snus.

70. In light of this evidence base, several public health authorities have encouraged smokers to switch completely to certain PRRPs, specifically e-cigarettes and snus, if they do not want to stop using nicotine. In order to facilitate this goal, some public health authorities have recognized the need to have balanced regulations including marketing regulations (regarding e-cigarettes, in particular) because of their potential to reduce smoking prevalence.
71. As one study noted, the most restrictive policies would effectively eliminate e-cigarettes as a viable alternative to smoking.⁴⁹ The authors noted that "[h]arm reduction recognizes that the proposed alternatives carry uncertainties. It involves making a strategic determination: when the risks are considerable – as they surely are with cigarette smoking – moving forward in the face of uncertainty is unavoidable.... Opting for a harm-reduction approach in name isn't enough if the specific policies employed are so restrictive that e-cigarettes contribute very little to reducing smoking-related risks in the long term. To be sure, a permissive approach demands continuous health and safety monitoring along with the will to change course if necessary. Yet if policymakers are serious about mounting a largescale attack on smoking, we believe they must be willing to consider strategies, by any name, that are true to the spirit of harm reduction and could have a population-level effect."⁵⁰
72. Similarly, in its 2016 report the Royal College of Physicians ("2016 RCP") urged smokers who did not want to quit to switch to e-cigarettes. The 2016 RCP found that whilst "[a] risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm... if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking."⁵¹
73. Moreover, in October 2017 the British Psychological Society published a briefing on e-cigarettes, which recommended that regulators should "[f]or e-cigarettes, avoid taxation and 'vape-free' legislation and promote unrestricted advertising of factual information"; and that they should "[r]egulate to promote product development" so as to "allow e-cigarettes to further evolve and improve so they are safer, more appealing and satisfying for more smokers. This means allowing higher nicotine strength e-liquid to remain on the market where there is no evidence to suggest

⁴⁹ Fairchild, A. L., Lee, J. S. Bayer, R., Curran, J. (2018), E-Cigarettes and the harm-reduction continuum. *New England Journal of Medicine*, 378:216–219.

⁵⁰ Id.

⁵¹ Royal College of Physicians of London. *Nicotine without smoke tobacco harm reduction*. Royal College of Physicians of London; 2016.

harm, and avoid unnecessary burdensome and costly procedures for manufacturers so they can focus on improving the safety and efficacy of their products."⁵²

74. In sum, imposing stringent marketing restrictions on any of the 4 Ps by for example prohibiting higher nicotine strength e-liquid would likely undermine public health efforts to get smokers to switch from traditional cigarettes to PRRPs if they do not want to stop using nicotine.

B. Marketing Mix Restrictions Would Reduce Consumers' Awareness and Use of PRRPs

75. Given the importance of marketing to the commercial viability of new and growing products, onerous restrictions on the 4Ps of marketing for PRRPs likely would threaten the success of the PRRP market. For example, if restrictions are placed on the product, such as ingredient or flavor restrictions or nicotine concentrations then this can make products unacceptable to many consumers and risks limiting the acceptability of PRRPs as an alternative to cigarettes for some smokers. If the promotion of PRRPs is restricted so that smokers do not have sufficient information about PRRPs and their attributes, they are unlikely to switch to these products. In addition, if significant marketing restrictions limit the placement (retail distribution) possibilities for PRRPs, this would also significantly reduce the market potential of the product. For example, restricting the sale of PRRPs (or products with certain features, e.g. flavours or nicotine levels) to only specialty shops, rather than allowing them to be sold in the same retail channels where cigarettes are sold (including convenience, grocery, and general retail stores and online), will reduce consumer awareness of these products (including at the point of purchase, where they might consider trying a PRRP) and the potential for these products to be perceived by consumers as an acceptable alternative to cigarettes. Price measures, such as excise taxes, can also reduce the financial incentive for smokers to switch to PRRPs.

76. For example, there is consistent real world data from large national surveys that provide evidence that e-cigarette awareness and use is correlated with a country's marketing regulations insofar as there is greater awareness and use of e-cigarettes in countries with more liberal marketing regimes compared with more restrictive marketing regimes.⁵³ For example, a 2019 cross-sectional analysis of adult current and former smokers from 14 countries participating in the International Tobacco Control Policy Evaluation Project "(ITC Project)" found that, on the whole, there was higher awareness and use of e-cigarettes among current and ex-smokers in countries with less restrictive marketing policies (e.g., UK and US) and lower awareness and rates of use in countries with more restrictive policies (Australia) or no policies (Bangladesh).⁵⁴ This study provides evidence that patterns of e-cigarette use are likely to be influenced by the e-cigarette regulatory policy environment including

⁵² British Psychological Society (2017), Changing Behaviour: Electronic Cigarettes. Available at: <https://beta.bps.org.uk/sites/beta.bps.org.uk/files/Policy%20-%20Files/Changing%20behaviour%20-%20electronic%20cigarettes.pdf>

⁵³ Gravely, S, et al., (2019), Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project, *Addiction*; Gravely, S, et al., (2014) Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project, *Int. J. Environ. Res. Public Health* 11:11691-11704; doi:10.3390/ijerph111111691

⁵⁴ Id.

regulations surrounding marketing. In short, this literature shows that real world data support the marketing theory and predictions – to wit, marketing has a significant impact on awareness and use of e-cigarettes among adult smokers and ex-smokers. Moreover, it stands to reason that awareness of and use of other PRRPs similarly would be influenced by the PRRP regulatory environment including regulations surrounding marketing.

77. In sum, imposing strict limits on marketing would be counterproductive to the harm reduction goal of reducing rates of smoking and smoking-related diseases because it would prevent smokers from becoming aware of and moving to PRRPs.

C. Marketing Mix Restrictions Would Contribute to Consumers' Confusion and Misperceptions About the Relative Risks of PRRPs

78. Overly restrictive marketing regulations, such as banning marketing communications including at point-of-sale or via digital media and on or in product packaging, and restricting retail placement and product display would restrict consumer information and awareness and would likely exacerbate existing misperceptions and undermine the ability of consumers to make informed choices; and are liable to deter smokers from considering PRRPs as an alternative to combustible products. This will make it harder for smokers to know of their availability and attributes and limit the potential for smokers to transition away from cigarettes. Accurate consumer education and widespread availability are key to enhancing smokers' awareness of PRRPs as an alternative to combustible cigarettes and facilitating the transition from cigarettes for those smokers that want to switch.
79. There is a real risk of consumer confusion and misinformation about PRRPs when there are restrictions on what firms can say in their advertising and other marketing communications about these products or where PRRPs are regulated in the same way as combustible tobacco products – such as requiring the same oversized or graphic warnings or requiring plain or standardized packaging with no branding.
80. Similarly, taxing PRRPs at the same level as combustible tobacco products may contribute to consumers' misperceptions about the relative risks of PRRPs and combustible tobacco products.
81. Studies of consumer perceptions about the relative risk of e-cigarette use compared with combustible cigarettes demonstrate that consumers are ill-informed about the estimated health risks of e-cigarettes compared with combustible cigarettes.⁵⁵ Along these lines, surveys have shown that a large percent of "the public and smokers fail to recognize that e-cigarettes are less harmful than smoking."⁵⁶
82. In fact, it is my understanding that public health authorities have expressed concern over consumers' misperceptions about the comparative risks of e-cigarettes and THPs compared to combustible cigarettes.⁵⁷ Public Health England's March 2020 evidence

⁵⁵ Majeed, B., et al., (2016), Changing Perceptions of Harm of E-Cigarettes among US Adults 2012-2015.

⁵⁶ <http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-report-e-cigarettes/>

⁵⁷ McNeill, A., Brose, L., Calder, R., Bauld, L., Robson, D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England, London: Public Health England, 2018.

update on e-cigarettes⁵⁸ found that: “[p]erceptions of harm from vaping among smokers are increasingly out of line with the evidence. The proportion who thought vaping was less harmful than cigarettes declined from 45% in 2014 to 34% in 2019. These misperceptions are particularly common among smokers who do not vape.” The report also concluded that: “increasingly incorrect perceptions among the public about the harms of vaping could prevent some smokers using vaping products to quit smoking.”⁵⁹ This concern was reiterated in Public Health England’s most recent 2021 report which found that perceptions of the harm caused by vaping compared with smoking are increasingly out of line with the evidence and that misperceptions were more pronounced among smokers from lower social grades. The report concluded that: “[m]isperceptions of the relative harms of smoking and vaping should be addressed.”⁶⁰

83. Restricting a firms' ability to communicate with consumers about the attributes of PRRPs may also perpetuate the fallacy that PRRPs have a similar risk profile to combustible cigarettes and will further discourage consumers who would otherwise continue to smoke to switch from combustible cigarettes to PRRPs. For example, the evidence shows that a substantial portion of the public believes that e-cigarettes are just as hazardous as combustible cigarettes. For example, a 2016 study by Majeed et al., found that a higher percentage of US adults misperceived e-cigarettes to be equally or more harmful to combustible cigarettes between 2012 and 2015 and that these “[h]igher risk perceptions ... could deter current smokers from using e-cigarettes as a cessation aid of smoking combustible cigarettes and preventing a potential public health benefit.”⁶¹ Moreover, a study carried out by Perski et al. (2020) found that the decline in the belief among current smokers that e-cigarettes are less harmful than combustible cigarettes was strongly associated with declines in the use of e-cigarettes among current tobacco smokers in England.⁶² Similarly, studies have found that smokers misperceive snus to be as or more harmful than smoking cigarettes and will likely need more accurate information about the relative risk of snus compared with combustible cigarettes before making the switch to products such as snus.⁶³
84. In sum, regulating marketing communications (4Ps) of PRRPs similar to regulations of combustible cigarettes, including restricting the product (e.g. by ingredient and flavor bans, nicotine content restrictions, packaging restrictions, and warning requirements), placement (e.g. restrictions on sale channels or retail display), promotion (e.g. advertising restrictions) or price (e.g. through taxes and excise

⁵⁸ McNeil, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.

⁵⁹ Id

⁶⁰ McNeill, A., Brose, L.S., Calder, R., Simonavicius, E. and Robson, D. (2021). Vaping in England: An evidence update including vaping for smoking cessation, February 2021: a report commissioned by Public Health England. London: Public Health England.

⁶¹ Majeed, B., et al., (2016), Changing Perceptions of Harm of E-Cigarettes among US Adults 2012-2015.

⁶² Perski O., Beard E., and Brown J., “Association between changes in harm perceptions and e-cigarette use among current tobacco smokers in England: a time series analysis” BMC Medicine (2020) 18:98

⁶³ Wackowski, O, et al., (2019), Smokers' perceptions of risks and harm from snus relative to cigarettes: A latent profile analysis study, Addict Behav 91:171-174.

increases) may perpetuate the misleading message that PRRPs and combustible cigarettes confer similar risks.

D. Restricting Marketing Freedoms May Undermine the Ability of PRRPs to Reduce Smoking Prevalence By Providing an Alternative to Cigarettes

85. It is my understanding that there is a growing body of scientific research suggesting that e-cigarette use has contributed to reduced smoking prevalence. In the UK for example where there is a flexible regulatory environment that allows public vaping, reasonable access to e-cigarettes, retail displays and some consumer communications, smoking prevalence among adults aged 18 and over in England declined by 5.9 percentage points from 2011 to 2019, following the introduction of e-cigarettes.⁶⁴ Similarly, smoking rates among adults in the US -dropped to record low levels in 2018, declining to 13.7% according to the Centres for Disease Control and Prevention's National Center for Health Statistics.⁶⁵ Moreover, the 2018 Public Health England Report concluded that "[w]hile caution is needed ... the evidence suggests that e-cigarettes have contributed to tens of thousands of additional quitters in England."⁶⁶ The most recent 2021 Public Health England evidence update of e-cigarettes⁶⁷ also found that nicotine vaping products were the most popular aid used by smokers trying to quit in England in 2020, and it is estimated that in 2017, more than 50,000 smokers stopped smoking with the aid of a vaping product who would otherwise have carried on smoking.

86. In addition, studies have shown that e-cigarette users are more likely to try to quit smoking and to successfully quit smoking.⁶⁸ For example, a study assessing the relationship between e-cigarette use and smoking cessation in a representative sample of the US population found that e-cigarette users were more likely than non-users to make a quit attempt and 70% more likely to successfully quit smoking.⁶⁹ The most recent Eurobarometer survey of the Attitudes of Europeans towards tobacco and electronic cigarettes⁷⁰ also found that 31% of respondents who smoke or used to smoke, and use or used e-cigarettes or THPs, said that they stopped smoking tobacco completely and 27% said they reduced their tobacco consumption.⁷¹

⁶⁴ ASH (2020), Use of e-cigarettes (vapes) among adults in Great Britain.

⁶⁵ <https://www.cdc.gov/media/releases/2019/p1114-smoking-low.html>

⁶⁶ McNeill, A., Brose, L., Calder, R., Bauld, L. & Robson, D. (2018), Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018.

⁶⁷ McNeill, A., Brose, L.S., Calder, R., Simonavicius, E. and Robson, D. (2021). Vaping in England: An evidence update including vaping for smoking cessation, February 2021: a report commissioned by Public Health England. London: Public Health England

⁶⁸ Zhu Shu-Hong, Zhuang Yue-Lin, Wong Shiushing, Cummins Sharon E, Tedeschi Gary J. (2017), E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys BMJ 358 :j3262

⁶⁹ Id.

⁷⁰ Kantar. (2021) Attitudes of Europeans towards tobacco and electronic cigarettes. Special Eurobarometer 506. Brussels: European Commission, p129.

⁷¹ Id.

E. Balancing Marketing Freedoms for PRRPs with the Need to Reduce Youth Exposure to Marketing to the Greatest Extent Possible

87. It is important that firms take all feasible steps to try to prevent marketing spillover to the under-aged. Many industries deal with this issue and the tools of marketing, especially with regard to digital marketing and social media, have improved tremendously allowing firms to better target their intended audience.
88. For example, in early 2018, Diageo pulled all ad spending from Snapchat due to concerns that underage drinkers were being exposed to their products' ads. Since then, a number of advertisers including Heineken have started advertising on Snapchat when the latter moved away from users' self-declared ages to utilizing other data such as how long someone has been a user, the age of their closest friends, and the content that they view. Facebook and YouTube have been similarly aggressive in changing the way they age-gate viewers of advertising targeting 21 and over consumers.⁷²
89. A second example is from Diageo's 2018 UK Twitter campaign for its Captain Morgan brand. Although there were issues raised about the copy of the promoted tweets, the relevant issue is whether the use of Twitter included consumers under 18 years of age in violation of the UK's Committee of Advertising Practice guidelines, the CAP Code. It was ruled that Diageo had taken reasonable steps to ensure that consumers under 18 years old would not be exposed to the promoted tweet because (1) Twitter can select users 18 and over due to registration information and match their interests to the product as well, and (2) that, in fact, Twitter is not a popular social medium among the younger age group. Therefore, Diageo had taken all reasonable steps to prevent its promoted tweets to be seen by young consumers.⁷³
90. While it is not possible to screen out underage users of products with minimum age restrictions with 100% effectiveness, these two examples with different social media demonstrate that marketers of products that have legal age restrictions can, in fact, use modern digital marketing techniques to target legal users far more effectively than traditional media such as TV, radio, print, and outdoor.
91. In the US, the FDA Public Health Rationale provides guidance on how marketing spillover can be limited through sensible marketing regulations that balance the harm reduction benefits of allowing marketing to reach smokers while limiting the potential for youth and other nicotine-naïve consumers to be exposed/influenced to use PRRPs by PRRP marketing. Indeed, the FDA notes that digital marketing offers some distinct advantages over traditional advertising that allow firms to more accurately target their intended audiences through data mining technologies and age restriction. Employing data management systems and algorithms can connect individuals to a "range of data points, including their demographic characteristics, purchase behaviors, preferences political opinions, internet search terms, browsing history, interactions with digital content ... digital accounts, connected devices, physical location, and information about other members of their household."⁷⁴ Moreover,

⁷² Ilyse Liffreing, "Snapchat Lures Back Alcohol Brands," Digiday, October 31, 2018.

⁷³ ASA ruling on Diageo Great Britain Ltd (June 6, 2018).

⁷⁴ FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

paid digital advertising targeting capabilities offer firms "the ability to target adults who meet specific age criteria through the use of first- and/or second-party age-verified data ... on any digital property accepting paid tobacco advertising, while also restricting youth-access to such advertising." The FDA also reports that "marketers can also layer on additional demographic and psychographic data (e.g., tobacco product purchase behaviors) to further enhance the efficiency of their paid digital media buys."⁷⁵

92. In addition, the FDA in its Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead for Swedish Match notes that "many social media platforms are beginning to offer branded – account owners the option to age – restrict some or all of their account pages, followers, and content, including even specific posts, photos, videos, events, etc."⁷⁶ Moreover, the FDA recognizes that, while these have some limitations, "users are increasingly prompted to “link” digital profiles and accounts (e.g., option to sign – up for a new account using an existing email account or social media account), increasing the likelihood of more accurate self – reporting."⁷⁷ These safeguards demonstrate the many ways in which companies and regulators can minimize the risk of digital marketing spillover to youth without banning the advertising at issue.

V. CONCLUSION

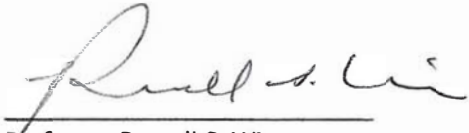
93. Marketing for new and growing products, here PRRPs, is critical to inform existing adult tobacco and nicotine users who otherwise may have been unaware of the products that the products exist, and in so doing, can provide these consumers with essential information about the product's function and attributes such as where to buy them, price, how to use them, etc. As I have noted several times above, it is crucial for the 4Ps to be consistent both with the consumer's preferences and with each other.
94. The success of PRRPs in potentially contributing to reductions in projected tobacco-related diseases depends on their acceptance by a critical mass of existing adult tobacco and nicotine users as a satisfactory alternative to combustible tobacco products. To achieve this, it is essential that the regulatory framework for PRRPs provides effective measures such as appropriate advertising and marketing freedoms to enable firms that sell PRRPs to inform consumers of about these products. Indeed, overly strict marketing restrictions will – as real-world data already show – lead to lower consumer awareness and use of PRRPs, along with consumer misperceptions about these products and their attributes, including their health risks compared to combustible cigarettes. While there are legitimate concerns about the importance of preventing "spill-over" of PRRP marketing communications to youth, there are sensible ways to reduce this risk so that PRRPs can fulfil their harm reduction promise for smokers that would otherwise continue to smoke.

⁷⁵ Id.

⁷⁶ Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

⁷⁷ Id.

95. In sum, imposing stringent marketing restrictions could severely limit the growth of the PRRP market, and the corresponding harm reduction promise of PRRPs to reduce rates of smoking initiation and consumption. Overly restrictive marketing regulations would undermine PRRPs as a possible reduced risk alternative to smoking combustible cigarettes since existing adult tobacco and nicotine users will not be aware of these products, learn about their offerings, and be motivated to switch. In this case, the potential for harm reduction will be lost.

A handwritten signature in black ink, appearing to read "Russell S. Winer", written over a horizontal line.

Professor Russell S. Winer

May 18, 2021