PMI | U.S. U.S. Businesses of Philip Morris International

July 28, 2025

Leana S. Wen, MD MSc FAAEM
[redacted]

By Email: [redacted]

Dear Dr. Leana S. Wen,

We, at the U.S. businesses of Philip Morris International ("PMI U.S."), appreciate that you share our goal of reducing smoking rates and ensuring that anyone under the age of 21 does not have access to any nicotine product. As you mention in your recent article, the current landscape is complex due to many factors, and we welcome a fact-based dialogue rooted in science to further underscore the role of smoke-free products in reducing tobacco-related harm and the tremendous public health benefits that could be achieved as a result.

However, regarding your recent column "Do Nicotine Pouches Have A Public Health Benefit? It's Complicated." published on July 24, 2025, we are writing to identify some significant factual errors and misleading statements contained throughout the column and request that you correct these immediately:

1. **You wrote "*Most readers I heard are concerned that the product is the latest cynical ploy by Big Tobacco to draw in a new generation of users.***

   This allegation is false and misleading. Swedish Match, which became a subsidiary of Philip Morris International ("PMI") following our acquisition in late 2022, first launched *ZYN* in 2014 as a better alternative for legal-age nicotine consumers who would otherwise continue smoking or using other traditional tobacco products. *ZYN* was introduced as an evolution of tobacco-leaf containing snus which has been around for many decades.

   There is no "ploy". PMI was the first major company to announce in 2016 a vision to move away from cigarettes and products like *ZYN* are part of that harm reduction strategy to offer legal age consumers better nicotine products which don't burn tobacco if they don't choose to quit. We are clear that those below the legal age should not use tobacco or nicotine products. PMI and our affiliates go above and beyond what's required by law to ensure our products are used only by their intended audience: current 21+ nicotine consumers. These responsible marketing practices include but are not limited to:

- We do not use paid social media influencers in the United States or people under the age of 35 years old in any of our marketing materials.
- We employ independent age-verification systems to direct digital advertising to only consumers 21 years of age and over.
- Our owned digital platforms are age-gated at the point of access and restricted to current legal-age nicotine consumers.
- Swedish Match is a member of the *We Card* Advisory Council, a national nonprofit serving retailers of age-restricted products as well as a founding board member and investor in *TruAge*, a free age-verification technology for retailers that includes the ability to detect fake IDs to ensure access only to those who are 21 years old and above.

2. **You wrote *"Which leads to me another important point: Pouches, e-cigarettes and the like are not authorized by the FDA as smoking cessation products. The FDA has approved a variety of over-the-counter nicotine replacement therapies, including skin patches, nicotine gum and lozenges. It also approved a nicotine spray and inhaler, as well as two medications (bupropion and varenicline), that require a prescription."***

   As you may be aware, cessation aids are a specific class of therapeutic products meant to help consumers completely stop nicotine use. *ZYN* is not intended as, nor marketed as, a cessation product— it is intended only for legal-age consumers who wish to continue using nicotine products. These consumers, even if not interested in smoking cessation, need and deserve better alternatives to cigarettes.

   Additionally, it is informative to highlight some of the relevant findings from the FDA about *ZYN* in its extensive (nearly five-year long) scientific review:

   - "*The toxicology review concludes that cigarette users who switch completely to the new products are expected to experience reduced risk of cancer, respiratory toxicity, and cardiovascular toxicity*." (pg 51)
   - "*…based on evidence suggesting the potential for reduction in lung cancer risk following significant reduction in CPD [cigarettes per day], the new products may also post a benefit to adults who switch and significantly reduce their cigarette use."* (pg 57)
   - *"…the social science review concluded that appeal and likelihood to buy for the new products were low among former tobacco users and never-users, regardless of age*." (pg 51)
   - *"Finally, the new products' potential health benefits to adult tobacco product users are not outweighed by risks to nonusers, including youth."* (pg 54)

The FDA also stated the following in its press release announcing authorization of *ZYN*:

> *"The applicant also provided evidence from a study showing that a substantial proportion of adults who use cigarette and/or smokeless tobacco products completely switched to the newly authorized nicotine pouch products."*

3. **You wrote *"PMI insists it does not market to teens. After my last article, a spokesperson for the company followed up multiple times with links to corporate materials emphasizing this point. Fair enough, but a cynical person might point out that tobacco companies adopted this stance after the peak of the e-cigarette boom, when 1 in 4 high-schoolers and 1 in 10 middle-schoolers reported using the product."***

This is false and there has been no change to the position we have *always* taken that people below legal age should not use or have access to tobacco and nicotine products. PMI businesses were not even selling any products in the U.S. during the "e-cigarette boom" you refer to. For those of legal age that choose to consume nicotine, what matters most is moving them away from combusted cigarettes, which is, by far, the most harmful form of nicotine consumption.

In addition to this and the points above on responsible marketing, it should also be noted that PMI U.S. does not, has not and never will, sell combusted cigarettes in the United States. PMI U.S. had no business in the U.S. before the acquisition of Swedish Match in late 2022.

We're proud that our efforts to guard against unintended use have real-world impact. For example, when FDA authorized *ZYN* in 2025, it concluded that:

> *"As part of its evaluation, the FDA reviewed data regarding youth risk and found that youth use of nicotine pouches remains low despite growing sales in recent years."*

Additionally, we know that our ability to help adults move away from smoking and traditional tobacco products hinges on our ability to help keep our smoke-free products out of the hands of anyone under 21 years old. We are invested in responsibility. Our comprehensive 10-Point Prevention Plan addresses key areas such as, marketing and social media, retail practices, and real-world monitoring, with a focus on continuous evaluation and improvement. These actions include but are not limited to the following:

- Directing marketing of our products to those aged 21 years and over

- Limit our own social media presence to platforms that enable age-restricted controls
- Mandate that our advertising features only individuals aged 35 years and over
- Never use paid social media influencers and refuse all requests for influencer partnerships
- Regularly monitor user-generated content on social media to the extent platforms allow and request social media companies take down inappropriate content
- Enforce rigorous online age verification (21 years old and over) for our branded websites
- Require distributors and retailers to comply with all applicable federal, state, and local laws, including age verification requirements at points-of-sale

As previously mentioned, to further enhance our retail efforts, Swedish Match serves as an Advisory Council member for the *We Card* Program, championing comprehensive training for retail employees, alongside in-store signage and pointof-sale materials underscoring the minimum age of 21 years old for purchasing tobacco and nicotine products.

Efforts by public health, regulators, *and* the industry are seeing real impacts. According to the CDC, in 2019, 23% of youth surveyed reported using one or more tobacco product in the past 30 days, and, by 2024, that rate had fallen to 8.1% — a decrease of 65%. That is incredible progress, and the goal is to see even more progress over coming years.

Additionally, smoking rates among youth and adults today are at all-time lows.

4. **You wrote *"Mitch Zeller, former director of the FDA's Center for Tobacco Products, explained that as much as 70 percent of people who vape continue to smoke. He showed me industry data from two years ago that showed 84 percent of adult pouch users kept up cigarette use"***

At PMI, we are centered around a science-driven policy. That means not only doing the best science but being transparent and publishing our findings in peer-reviewed scientific journals. The statistics cited by Mr. Zeller are interesting, and, as you mentioned, may just be people on their way to moving away from cigarettes. But, there is no way of knowing how representative they are for all alternatives such as *ZYN* or the rigor of the methods involved. FDA took a hard look at *all available data* (not just the data cited in your article) and determined the following in relation to *ZYN*:

- *"Nearly one quarter (83 of 346 participants) of those who used the new products completely switched from other tobacco products and reported exclusive use of the new product by end of the 10-week prospective study period."* (pg 27)
- *"…based on evidence suggesting the potential for reduction in lung cancer risk following significant reduction in CPD [cigarettes per day], the new products may also post a benefit to adults who switch and significantly reduce their cigarette use."* (pg 57)

It should also be noted that, according to FDA's searchable tobacco product database, under the helm of Mr. Zeller, CTP authorized more than 2,800 cigarette products to be marketed while only authorizing 30 novel smoke-free products (heated tobacco products, Swedish snus, and vapes). These actions resulting in 100 times more authorizations for combusted tobacco than novel smoke-free products are in direct opposition of CTP's stated mission *"To protect the public health of the U.S. population from tobacco-related death and disease...".* To that end, it is equally surprising that you would devote two columns largely critical of better, smoke-free alternatives like *ZYN*, when 30 million American adults still smoke cigarettes.

5. **You wrote "*But research suggests that this might not be better for their health. A 2023 study conducted by the tobacco industry concluded that dual-users who vaped and continued to smoke 10 cigarettes a day or more did not have a significant difference in harmful biomarkers as exclusive smokers. Other studies have found similar exposure to tobacco-related toxicants between dual-users and those who just use cigarettes.* "**

The debate whether dual use offers health benefits or not requires an understanding of the relative risks of tobacco and nicotine products. FDA summarizes it as follows:

> *"...the health risks for different tobacco products exist on a spectrum, which is sometimes referred to as a "continuum of risk." Combusted, or smoked, tobacco products—such as cigarettes—are the most harmful type of tobacco product. Non-combusted products—such as e-cigarettes and other smokeless tobacco products—generally have lower health risks than cigarettes and other combustible tobacco products."*

In the cited 2023 study, it is true that those who smoked more than 10 cigarettes a day had no significant change in biomarkers of exposure because they are still significant daily smokers. However, you omitted that *"Among [exclusive] ENDS users, 16 of 18 other BOEs were significantly lower than smokers'; 9 BOEs were not significantly different from nonusers."*

It is important to not treat dual-use as a monolith but rather as a spectrum with some consumers being predominantly cigarette users, some being roughly equal cigarette and e-cigarette users, and some predominantly e-cigarette users. Dual-use is a spectrum of behaviors and is often a transitory phase leading to completely switching away from cigarette smoking. To that point, a study by FDA found that:

> "*U.S. adult dual users of e-cigarettes and cigarettes who perceive e-cigarettes as less harmful than cigarettes appear to be more likely to switch to exclusive ecigarette use, more likely to remain dual users, and less likely to switch to exclusive cigarette use one year later than dual users with other perceptions of e-cigarette harm.*"

We and the FDA are clear that those who switch completely from combustible cigarettes are more likely to reduce the potential harm than people who continue to smoke. Efforts to discourage all smoking must continue which is why it is critical that adult smokers have access to accurate information so they can make informed choices for their health.

6. **You wrote "*And a meta-analysis of 107 studies, published in New England Journal of Medicine Evidence, concluded that dual users did not have a lower risk of cardiovascular disease, and may even have a higher risk of some diseases compared to smokers*."**

This meta-analysis was published by Stanton Glantz and, given that similar studies of his have been retracted, it is not surprising that several independent academics had concerns. In fact, there were so many concerns around this publication that the journal published a response from Michael Cummings, Nancy Rigotti, Neal Benowitz, and Dorothy Hatsukami. The response can be found here and includes the following line, "*We challenge the validity of the authors' conclusions, which we believe are premature and reflect a serious misinterpretation of the epidemiologic evidence*." Rigotti, Benowitz, and Hatsukami are all past presidents of the Society for Research on Nicotine and Tobacco (SRNT), and Michael Cummings is a professor who has testified against tobacco companies including during the Master Settlement Agreement.

In addition to the many errors in the cited meta-analysis, the comparison of dual use of vape and combusted cigarettes to dual use of nicotine pouches and combusted cigarettes is not a scientifically valid comparison. As the FDA noted in its authorization of *ZYN*:

> *"Also, these PMTAs demonstrate that at least some dual users are likely to become exclusive users. By the end of a 10-week patterns of use study conducted by the*

applicant, 24% of dual users had switched completely to the new products...As TPL, I conclude that while the number of adults who currently smoke that switch completely to the new products may potentially be small, the reduced HPHC exposure will produce substantial reduction in risk of adverse health effects for adults who currently smoke that do switch completely." (pg 56-57)

6. **You wrote "*The FDA is clear that "these approved medications, along with behavioral counseling, should be the first line of therapeutic treatment for adults seeking to quit smoking." Counseling and medications are "independently effective," but are even more effective when used together. People trying to quit smoking should start with these proven cessation methods rather than products that move them from one tobacco company profit center to another.*"**

   We have always been clear—the best thing anyone concerned about their health can do is quit, or never start, using tobacco or nicotine products. And, indeed, our goal is to eliminate smoking. Smoke-free products are not intended to replace cessation products and other tobacco control initiatives; their role is to offer potentially less harmful alternatives to smoking for those adults who choose to continue using nicotine products.

   Smoke-free products are actively accelerating the decline of cigarette smoking, beyond what cessation treatments and traditional tobacco control measures can achieve alone. But, to phase out cigarettes completely, this is not enough— policy and regulation can complete this change or perpetuate the status quo. Therefore, regulation should not leave America's 30 million legal-age smokers without accurate information about and access to better alternatives to cigarettes.

   A smoke-free future is attainable, and the benefits it can bring to the people who would otherwise continue to smoke, and hence to global public health, are enormous. That said, it should also be made clear that the webpage you cite also clearly states that:

   > "*Combusted, or smoked, tobacco products—such as cigarettes—are the most harmful type of tobacco product. Non-combusted products—such as e-cigarettes and other smokeless tobacco products—generally have lower health risks than cigarettes and other combustible tobacco products.*"

7. **You wrote *"Besides, if Big Tobacco really wanted smokers to switch completely to these alternatives, it has a straightforward way to make that happen: Stop selling cigarettes."***

As we said above, we don't sell combustible cigarettes in the U.S. and have no intention to do so. In any case, a unilateral decision by PMI to stop selling cigarettes in a market would not resolve the problem—competitors, potential new manufacturers, and the illicit market would all step in to fill the void. Only behavioral change will solve the problem.

Our aim is not only to make our company smoke-free, but also to make cigarettes obsolete. And our approach is working. As we just announced in our Q2 2025 earnings, our smoke-free business accounted for 41% of total net revenues globally—and we continue to advance this progress.

To achieve this goal, we have done the following:

- Invested more than $14 billion to develop, scientifically substantiate, and commercialize innovative smoke-free products over the past 17 years.
- Spent 99.5% of our research and development funds on smoke-free products last year.
- Expanded sale of our smoke-free products to 97 markets.

We will continue to responsibly sell cigarettes outside the United States, taking a consistent, disciplined, and steadfast approach to one day completely leaving them behind.

While perhaps contradictory in the eyes of some stakeholders, this is a necessary trade-off that is vital to driving a successful industry transition for the benefit of public health. It requires a holistic approach that considers the broader impact of decisions and recognizes that short-term sacrifices can lead to long-term benefits for society as a whole.

We are convinced that impactful and systemic change can best be achieved by transforming from the inside out, engaging constructively with different parts of society, and ultimately influencing our entire industry to follow our lead and adopt business models that also seek to completely replace cigarettes with smoke-free products for those of legal age who continue to use nicotine.

Notably, certain large cigarette markets [(such as Thailand, Vietnam, India, Turkey, Argentina and Brazil)] have so far made policy choices that enforce regulations contrary to tobacco harm reduction principles, including bans on smoke-free products, while still allowing the sale of cigarettes. This hinders our ability to commercialize smoke-free

products in these geographies and importantly deprives legal-age smokers of the possibility to access these better alternatives to continued smoking, while leaving combusted products as the only available option for those who do not quit—resulting in the perpetuation of combusted cigarette consumption.

In conclusion, we hope these changes will be clearly highlighted and consistently conveyed in your writing so that readers can assess complete and accurate information on this topic. Where you or the Washington Post have distributed content to third parties, we request that you notify them immediately and ensure that corrections are published with due prominence in both print and online versions. We will be following up with the Washington Post to ensure that the corrections are made.

Additionally, we wish to remind you that in keeping with PMI's commitment to fostering open and transparent dialogue, we will make all of our correspondence regarding the erroneous information you have published available to the public via our website and through our owned media channels. All rights are reserved. Please confirm receipt of this letter.

Sincerely,

[redacted]

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Chief Scientific & Regulatory Strategy Officer, U.S.
Philip Morris International