The boy who cried vape

Philip Morris International's call for a smoke-free world echoes past efforts by cigarette manufacturers to burnish their nicotine-stained image. But what if this time they're serious…and have science on their side?

By Alan Blum, MD

"We allow science to be politicized and polarized at our peril." This comment, in a full-page advertisement in 2017 in *The Wall Street Journal* signed by former Philip Morris International (PMI) chief executive officer Andre Calantzopoulos, may be the most honest observation in recent memory by the head of a cigarette company. It's unfortunate that it wasn't made by one of his predecessors 60 years ago on January 11, 1964, when Dr. Luther Terry issued *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the U.S. Public Health Service*, the landmark document that indicted cigarettes as the principal cause of the rising epidemic of lung cancer. "Cigarette smoking is causally related to lung cancer in men," the report concluded. "The magnitude of the effect of cigarette smoking far outweighs all other factors."

Instead, for the next half-century Philip Morris and the other cigarette manufacturers did everything possible to cast doubt on the report, to prevent the federal government from taking the "appropriate remedial action" against smoking called for by Dr. Terry, to continue making implicit health claims in cigarette advertising, and to wage war on science. The tobacco industry would disseminate a torrent of misinformation, sophistry, casuistry, and spin to debunk

the growing evidence of the deadly dangers of smoking. It would continue to hire academics and government health officials to chant the industry's mantra, "We just don't know enough about smoking and health. We still need more research." Although the 10-member multidisciplinary Advisory Committee to the Surgeon General, selected from a list of more than 150 public health and medical authorities generated by the Public Health Service and approved by the tobacco industry, would base its conclusions on a review of 7,000 published studies on smoking, the industry dismissed the findings as "statistical" and lacking clinical proof.

In addition, two months before the release of the report, the tobacco industry had quietly arranged with the American Medical Association (AMA) for it to retreat from its pledge to defer to the Committee's findings on smoking's role in disease. Instead, the AMA's Education and Research Foundation (AMA-ERF) would conduct its own "independent" research on smoking and health -- funded by $5 million from the cigarette manufacturers, a figure that would balloon to $18 million over more than a decade. Incredibly, three members of the Surgeon General's Advisory Committee agreed to serve on the AMA-ERF's committee, and researchers at 54 US medical schools (plus 13 in other countries) would wind up accepting the tobacco industry's largesse.

The AMA-ERF did not publish its own conclusions until 14 years later, and although they concurred with the Surgeon General's findings from 1964, the tobacco industry had achieved its objective of buying the silence of America's largest medical organization in the crucial years following publication of the landmark report. In a further setback, by 1967 the role of the Surgeon General

had been reduced from directing the entire US Public Health Service to that of a figurehead, doubtless in retribution for the black eye Dr. Terry had inflicted on the almighty tobacco industry.

Koop: Charisma, But No Cigar

Flash forward to 1982, by which time the American Cancer Society's most visible effort against smoking was its 6-year-old, one-day-a-year Great American Smokeout. Meanwhile the tobacco industry hadn't skipped a beat in disputing smoking's many harms. Through its Council for Tobacco Research (CTR) and its public relations and lobbying operation The Tobacco Institute, the industry publicized statements by hirelings from academia that cigarettes were getting a bum rap. "Lung cancer, like many other human cancers, remains a biological mystery," said pathologist Sheldon C. Sommers, MD, scientific director of the CTR, in testimony before a US House of Representatives subcommittee hearing on proposed new cigarette health warnings in 1982. "The biomedical experimentation does not support the smoking causation hypothesis." Sommers was one of more than 30 scientists and physicians enlisted by CTR to submit testimony opposing the warnings.

By 1985, in response to the tobacco industry's unending denial that smoking caused lung cancer (even as it introduced filters and other gimmicks to allay consumers' fears and implicitly make cigarettes seem safer), Surgeon General Dr. C. Everett Koop was using his bully pulpit to rally public support for anti-smoking measures, such as in these remarks at a press conference:

"If you look at the biomedical literature of the past 30 years, you have to be impressed with the extraordinary amount of evidence that has been generated to prove the causal relationship

between cigarette smoking and some two dozen disease conditions. The medical literature now holds an inventory of more than 50,000 studies regarding smoking and health. The overwhelming majority of them clearly implicate cigarette smoking either as a contributing cause or the primary cause of illness and death.

"Now these are facts. They are part of the case built by medical researchers here and the world over for the past three decades, a case that is scientifically conclusive. And the verdict is clear: Smoking is the leading preventable cause of disease and death in this country."

But as with Dr. Terry's entreaties for government action to deter and reduce cigarette smoking a generation earlier, even the plea from a charismatic surgeon general was not enough to dissuade Congress or state legislatures (mindful of huge cigarette tax revenues) and the mass media (covetous of cigarette advertising) from giving the tobacco industry the final say: "The science is inconclusive"; " Dr. Koop just wants a nanny state"; "We need more research."

Fear and Foot-Dragging in Academia

Directors of cancer centers and deans of public health and medical schools hardly disagreed, fearful of risking the loss of NIH research grants by standing up to the politically tobacco industry. (When I joined the faculty at Baylor College of Medicine in 1987, I was urged by a dean to consider dropping my anti-tobacco advocacy and "get into something more socially acceptable, like cocaine.")

The result? Since 1985, more than 360,000 additional papers on smoking have been published that have added relatively little to what we already knew and needed to do in 1964. In 1999, when the cigarette companies finally acknowledged that their product causes lung cancer, they continued to challenge the evidence on most other aspects of smoking, including the adverse effects of exposure to second-hand smoke. All they would concede was that the

preponderance of researchers agree that smoking can cause lung cancer and other duseases. Yet to this day they continue to deny in court that such evidence applies to the plaintiffs who died from diseases allegedly caused by cigarettes.

After publishing “A Frank Statement to Cigarette Smokers” in full-page ads in over 330 daily newspapers across the country in January 1954 [*see image*], in which the tobacco industry promised to conduct unimpeachable research to identify and remove any harmful substances from the smoke, the cigarette manufacturers used every trick in the book to deceive their own consumers. And they’ve been successful beyond their wildest dreams. Filters, which seem intuitively reassuring but lack any health protective value, are now consumed by 99% of those who smoke. One of the first was P. Lorillard Tobacco Company’s Kent cigarettes with the Micronite filter, which was advertised in medical journals as “made of a material so safe, so pure, it’s used to filter the air in many hospitals.” That material was asbestos. In fact, filters have resulted in *greater* harm to consumers not only because of their complacency in believing that the filter makes smoking safer and postponing any thoughts of stopping, but also because of compensatory smoking, ie, having to inhale more deeply to get the smoke through the filter, thus accelerating the damage to the larynx and lungs.

“Low-tar” implies that there are fewer carcinogenic chemicals and other toxins in the condensed smoke. We would never buy a can of tuna that’s “lowest in mercury” or a loaf of bread that has “only one ounce of poison.” Yet the so-called “tar derby” had manufacturers competing for the title of lowest in cancer-causers. The notion of not inhaling any cancer-causers at all eluded cigarette manufacturers in their ads…and consumers at the checkout counter. By the early

2000s Liggett would be so bold as to launch a national ad campaign for Omni cigarettes with the claim of "reduced carcinogens" [*see image*].

Who Do You Trust?

60 years after the Surgeon General's Report on smoking and health, then, what should we make of the crusade by leading cigarette maker PMI for a "smoke-free world" of noncombustible nicotine products as a safe, science-based alternative to smoking? Are the vocal supporters of the company's harm reduction pitch in the vanguard of efforts to combat medical disinformation? Or might they be misguided in encouraging nicotine dependence in any form?

To further an understanding of PMI's proposal, here is one of a series of full-page advertisements by PMI in *The New York Times*, *The Washington Post*, and *The Wall Street Journal* over the past three years:

A LETTER TO ALL WHO ASPIRE TO A BETTER FUTURE

We stand at a crossroads leading to two distinct futures: One is defined by division, doubt, and distrust. The other is a future in which reason, fact, and science prevail. A future in which ambitious and coordinated action has created a more sustainable and equitable world.

An optimist at heart, I choose to champion the latter. I believe a better future is possible. And – as a father, husband, citizen, and newly appointed CEO of Philip Morris International (PMI) – I will try to do my part to make it a reality.

When I consider how PMI can contribute to this better future, one action stands above all others: Replace cigarettes as soon as possible with better alternatives for women and men who would otherwise continue to smoke. And as our company continues to pursue its mission to deliver a smoke-free future, I will do everything in my power to build on my predecessors' progress and accelerate our pace of change.

Five years ago, essentially zero percent of our net revenues came from smoke-free products. In 2020, nearly a quarter did. By fundamentally transforming our business and investing billions of dollars in developing better alternatives, we are on the path to unsmoking the world.

By 2025, we aim to be a predominantly smoke-free product company, with more than 50 percent of our net revenues coming from these innovative products – an aspirational goal that exceeds our previously stated ambition. By that year, we also aim to make our smoke-free products available in 100 markets, up from more than 60 today.

While our goals are ambitious, they speak to our commitment to change and the success we have achieved. To get to 2025 and beyond, we will:

*Continue to invest in science and apply scientific rigor to all we do

*Ensure PMI is an attractive and engaging employer for all – creating an environment in which everyone is empowered to perform at their best

*Deliver innovation through our global footprint and scale

*Continue to improve our performance across key ESG areas – most notably, addressing our product impact by moving away from cigarettes and enabling switching to better alternatives as quickly as possible

*Expand our portfolio away from tobacco and nicotine, leaning into our expertise in life and medical sciences and our ability to help consumers make better choices

The magnitude of change needed is undeniable. But it's not daunting – at least not for those who believe in our collective power. The greatest impediment we must overcome is a rigidity of thought. It is all too easy to allow emotion and preconceived beliefs to overshadow evidence, to retreat into long-established camps rather than join forces in common cause.

This is why our greatest task is to always bring new thinking forward. To demonstrate through action, transparency, and verification proof points the integrity of our promises. And to work ceaselessly to forge partnerships with those who can accelerate the change we seek.

Together, we will unsmoke the future.

Jack

***UN*SMOKE THE FUTURE**

We're delivering a smoke-free future, faster.
See our progress at **PMI.com/unsmokethefuture.**

by Jack Olczak
Chief Executive Officer
Philip Morris International

The New York Times, May 11, 2021

I'd never read anything like it: a cigarette company ceo announcing the firm's intention to abandon the very product that has kept it among the most profitable corporations in the world. But I couldn't shake the feeling that I'd heard this going-out-of-business spiel before. I confess that I'm no friend of PMI or its domestic twin Altria, aka Philip Morris USA. I've spent more than 40 years tracking the formerly combined companies like parasitic organisms in what I call the Philip Morris Genome Project---documenting their links to all facets of society. As the most profitable company on the New York Stock Exchange between 1957 and 2007 (when it was dropped from the prestigious 30-stock Dow Jones Industrial Average), Philip Morris built an unparalleled network of alliances with agricultural, chemical, pharmaceutical, financial, entertainment, shipping, packaging, food, retail, marketing, sports, and technology companies, plus ties to hundreds of museums, arts organizations, universities, libraries, and charities that address problems such as AIDS, domestic violence, hunger, and illiteracy.

It's an enviable record for any corporation, much less one whose main product is responsible for hundreds of thousands of deaths each year. By the late-1980s, Philip Morris was named by *FORTUNE Magazine* as the second-most admired US company in a survey of 8,000 business executives. Beginning in 1985, I attended Philip Morris annual shareholders meetings for more than 20 years as part of a group of individuals and faith-based organizations trying to expose and reform the company's business practices through shareholder resolutions. This theatrical strategy attracted modest national publicity, notably at the 1992 shareholders meeting in Richmond, where we introduced Wayne McLaren, a former cowboy model in Marlboro ads who was dying of lung cancer. I also wrote a passionate commentary in 1990 in *The Chronicle of Higher Education* urging universities,

especially those with medical schools, to eliminate tobacco stocks from their investment portfolios.

But these symbolic efforts, which I hoped would be adopted and expanded by public health, medical, and nursing organizations, academia, and philanthropic foundations, accomplished little, and I begrudgingly came to admire the dynamism and resilience of Philip Morris. The nation's top cigarette maker had absorbed our best punches, which by the mid-1990s included lawsuits brought by numerous state attorneys general (for repayment of the costs of caring for those with illness caused by smoking) and a charge of racketeering by the US Justice Department.

The Emergence of Tobacco Harm Reduction

Meanwhile, as cigarette makers were finally taking the heat they'd long succeeded in dodging, a new hypothesis emerged in 1996 from the research of a dental pathologist Brad Rodu and colleagues at the University of Alabama at Birmingham. Finding that the vast majority of cases of oral cancer were caused not by the use of snuff or chewing tobacco of tobacco but by smoking cigarettes, Rodu (now professor and endowed chair in tobacco harm reduction research at the Brown Cancer Center of the University of Louisville) proposed a public health strategy to encourage cigarette smokers to switch to moist snuff, which had been cleverly re-named "smokeless tobacco" [as in "smoke less" and "no smoke"] in the late-1970s by the United States Tobacco Company (UST), maker of the best-selling brands SKOAL and Copenhagen. Although he was attacked by numerous dental, medical, and public health groups, he also drew support from many in both tobacco control and other health areas in which reducing harm is considered a

more realistic and achievable strategy than abstinence or prohibition. Rodu also began receiving funding from UST, whose ubiquitous TV advertising campaign through the late-1980s (only cigarette commercials on TV and radio had been banned by Congress in 1971), featuring athletes and country music singers had helped turn a once-rural southern custom into a nationwide addiction in high schools and colleges.

Perhaps the best summary of why a major health department ultimately chose to reject the smokeless/harm reduction strategy was articulated by Greg Oliva, Assistant Deputy Director, Center for Chronic Disease Prevention and Health Promotion in the California Department of Public Health at a conference convened by the California Department of Public Health in 2004, "The Seduction of Harm Reduction." Here is an excerpt of his presentation:

"The way the term harm reduction is being used today, it means nicotine maintenance, and that means switching from a more hazardous product to a less hazardous product. Harm reduction also can have a more global meaning. After all, a comprehensive tobacco control program can be viewed as harm reduction. Tax increases, clean indoor air policies, smoke free workplaces, cessation interventions, and anti-tobacco industry media campaigns all have certainly reduced harm in California, but the term 'harm reduction' does not usually refer to these kinds of efforts. In the absence of definitive scientific studies, using exposure to toxicants as a measure of potential harm is insufficient; exposure should not be used as a proxy for actual risk…

"As recently as 1981, the Surgeon General was recommending that smokers switch to low yield cigarettes as a way to reduce health risks. This switching created an illusion of risk reduction and slowed the decline in smoking rates. Over a 20-year period, smokers who switched were more likely to consider quitting but less likely to quit than those who smoked high yield brands. Those low yield brands were designed to show lower tar and nicotine yields on the federal trade Commission (FTC) smoking machine, but the machine did not mimic how humans actually used low yield cigarettes. Promotion of low yield (filtered) cigarettes turned out to be a serious case of public health fraud."

Analogous to the increased adoption of low-tar filter cigarettes following the first smoking and lung cancer scares of the 1950s, sales of moist smokeless tobacco have continued to increase. But this has had less to do with users switching away from cigarettes than from aggressive marketing, including on college campuses until the late 2000s, and a plethora of attractive new products and flavors.

I respect Dr. Rodu's persistence, and I appreciated the logic and the early promise of the smokeless harm-reduction hypothesis. Even though I have never been a proponent of the hypothesis, I saw no problem with recommending these products to inveterate smokers, usually men. But most of the time, I've observed a resulting dual use of cigarettes and smokeless tobacco products. Overall, I'm more convinced than ever by Greg Oliva's argument, which also had been long promulgated by noted public health researchers Prakash Gupta in India and Greg Connolly and Scott Tomar in the US, that the use of smokeless tobacco is not an effective smoking cessation strategy and undermines the messaging to adolescents to avoid initiating use of these products.

Déjà fooled?

But back to my initial admiration of a statement by the PMI ceo about the peril of our allowing science to be politicized and polarized. Since PMI and Altria have revealed their new identities as tobacco harm reduction companies, should their latest appeal to trust in science deserve to be taken seriously?

How different, really, is the new pledge to clear the air by closing its cigarette business by 2029 from the past claims of top Philip Morris executives like George Weissman in the 1954 ("Believe me, if any one of us believed that this product we

were making and selling was in any way harmful to our customers' health – and our own as well – we would voluntarily go out of business.") and James Bowling in 1972 ("If our product is harmful, we'll stop making it.")

It's still galling to look back at Philip Morris' blitzkrieg of ads in 1978 and 1978 for its Merit cigarettes with banner headlines blaring "Study Hails Low Tar Merit!" "Merit Science Wins!" and "Research Results Conclusive" [*see image*], which didn't make clear that they were referring to *market* research and surveys of *taste* preferences.

Is it any different from Philip Morris' massive TV advertising campaign in 1989 and 1990 that boasted of its patriotism and support for the Bill of Rights, freedom of speech, civil rights, without mentioning that the company made most of its money from a product that kills over 400,000 Americans a year? In June 1994, not content to refute the Environmental Protection Agency's (EPA) report declaring secondhand smoke a Class-A carcinogen through its own submissions to peer-reviewed scientific journals or in public debates at medical conferences, Philip Morris took out a series of full-page ads in *The Wall Street Journal*, *USA Today*, *The New York Times*, and other newspapers castigating the EPA for having "manipulated science to serve a political cause." It's hard to think of a more pristine example of the pot calling the kettle black.

Then there was the campaign launched in 2003 to showcase the new and improved Philip Morris after the company changed its name to the altruistically sounding Altria, with the motto "Align with Society." For that matter, is a "Smoke-Free World" (and a Cigarette-Free Philip Morris International) by 2029 any more

realistic, or any less grandiose, than Surgeon General Koop's call in the 1980s for a Smoke-Free Society by the Year 2000? Can a tiger ever change its pinstripes?

Several of PMI's recent "*UN*SMOKE YOUR MIND" ads [*see images*] that speak raptuously of the company's leadership in tobacco harm reduction are signed by women who serve as scientists or executives at the company, and many of the articles in the industry's venerable trade publication *Tobacco Reporter* are written by women who are researchers or consultants for Altria and other tobacco, vaping, and cannabis firms. It's hard to square their faith in Philip Morris with the knowledge that the flattening of the mortality curve for lung cancer among women has still not caught up to that of men and that more women than men will be diagnosed with lung cancer in 2024.

If You Can't Beat 'em…

The title of this editorial refers to the plea of the historically science-denying cigarette maker PMI to now follow the science. That's because in this instance, like the boy who cried wolf, PMI may finally have the science on its side. There's more than a kernel of truth to the PMI ceo's plea to opinion-leaders and the public to support policies that encourage adults who smoke cigarettes to switch to the company's non-combustible nicotine products. At long last, there is generally agreed upon evidence that heated nicotine vapor delivery products can play a role in getting individuals who smoke to reduce their risk of developing lung cancer, which could be especially beneficial to those with mental health problems, a population with a much greater smoking prevalence.

The cigarette makers would appear to genuinely believe they've found the Holy Grail of the safe cigarette in the form of a different kind of inhaled, heated-not-burned tobacco product. And in their push for a healthier society of contented users of noncombustible nicotine products, the cigarette companies have hired a slew of public health researchers from academia (most recently attorney Cliff Douglas, director of of the University of Michigan Tobacco Research Network, to become president and ceo of the PMI-funded Foundation for a Smoke-Free World [FSFW]); officials from the World Health Organization's tobacco control program (most notably its former director, Derek Yach, MD, who became the first head of FSFW in 2017); top guns from the FDA (eg, Matthew R. Holman, PhD, former chief of the office of science in the Center for Tobacco Products); and attorney David Dobbins, a former ceo of the anti-smoking American Legacy Foundation, re-named TRUTH, an entity funded by $2.5 billion from the cigarette makers in 1998 as part of a legal settlement with the state attorneys general (Dobbins has been an “independent consultant” to Altria for nearly a year).

The lure of helping to promote reduced-risk products that hold the promise to save millions of lives must seem like doing God’s work to these tobacco control stalwarts, even if it means having to endure the skepticism and derision of their former anti-smoking colleagues, to whom nothing is more insufferable than a reformed anti-smoker. They’re aghast that these individuals are now occupying corner offices at corporate headquarters of the villainous tobacco industry. I’m also guessing that the huge paychecks they’re receiving are more of a lure.

Come to Harm-Reduction Country

I know the feeling. In 2009 Congress passed a bill giving putative regulatory power over tobacco products to the FDA, a measure co-authored by the Campaign for Tobacco Free Kids--- and, incredibly, Philip Morris, which became the bill's biggest backer. In 2007 I'd testified *against* the bill in both the Senate and House hearings, and in 2005 I'd co-authored a commentary with Dr. Michael Siegel in *The Lancet* in which we renamed the bill the Marlboro Preservation Act because cigarettes were grandfathered in. You read that correctly: under the oddly named Family Smoking Prevention and Tobacco Control Act, Congress forbade the FDA from removing from the market the most lethal tobacco product by far, cigarettes, which are still responsible for nearly half a million deaths each year in the US -- even as that same government health agency can remove cancer treatment drugs that cause unacceptable side effects.

On October 27, 2010, I received this personal email from a partner in the firm Amrop Battalia Winston:

"I was given your name by my research department as one who is quite familiar with the tobacco issues facing the FDA regulators. I am in the executive search industry and am conducting a search for the Altria Corporation to find a physician who could head up their Scientific Affairs group and interface with the FDA on all scientific matter vis-à-vis tobacco products. The Company is trying to move smokers to lower risk products on a risk continuum of tobacco products. We are looking for an MD who has hands-on experience with the FDA and the passion and energy to provide research data to deal with the variety of issues pending before the FDA. This is a ground-breaking position since it will create a paradigm for an industry that has never been regulated by the FDA. It is located in Richmond, Va. and has a very attractive remuneration package."

A week later, I sent the following reply:

"Thank you for your thoughtful letter. As a speaker and author on tobacco-related issues for more than 30 years, as well as a longstanding Altria shareholder, I wish the Company well in its quest to create a paradigm related to FDA regulation that will enhance public health.

“The position you describe is intriguing. I would be interested in learning more about it.”

We arranged to speak by phone a few weeks later and had a candid and cordial conversation. Without my asking, the head-hunter described the position as the equivalent of a senior vice-president or chief medical officer at a pharmaceutical company with a base salary of more than $300,000 plus preferential stock options offered only to top executives. His firm had sent out feelers to 200 drug company executives, of whom 100 expressed interest. “We talked to 20,” he told me, “brought in 7 for interviews, and took 4 to Philip Morris for more interviews. They’re still looking.”

He gave a nuanced summary of the tobacco-related issues under consideration by the FDA. The company had supported FDA regulation of tobacco products to level the playing field and play by a set of rules. Also, the head of PM USA, Mike Symanczyk, championed the company's move away from being a single product (cigarette) company. But once the FDA bill passed, the company began perceiving that there was no support for its attempt to move smokers down the continuum from cigarettes and toward safer tobacco products because the FDA equated all tobacco products as nicotine delivery devices.

To make its case for harm reduction, Altria brought aboard James E. Dillard III, who’d worked at the FDA for 14 years, including as director of the Division of Cardiovascular and Respiratory Devices. He in turn urged Altria to hire an MD to promote the company's harm reduction strategy to the FDA to help gain

acceptance of smokeless tobacco, basing its argument on the so-called Swedish experience with that nation's own form of oral tobacco, snus.

I suggested that if the company truly wanted to reduce harm it would need to do a lot more to lessen its dependence on Marlboro cigarettes. But I decided to go whole-hog by adding:

"There is a clear, unprecedented, and unequivocal strategy that could well succeed by leaving no doubt about the company's sincerity and would, at the very least, engender serious debate: Altria could announce a timetable for phasing out the production of cigarettes, based on the shift in profit from cigarettes to smokeless.

"This would not be a publicity ploy (such as in the Norman Lear film "Cold Turkey," in which a cigarette manufacturer, aiming to emulate dynamite inventor Alfred Nobel's Peace Prize, offers $25 million to the first community in the nation that entirely stops smoking for 30 days), and it is not so far-fetched.

"Finland has just announced its intention to ban smoking entirely, including the sale of cigarettes, by 2040. Altria could trump this by ending cigarette manufacture by 2030 or even sooner. Apart from antitrust questions and the states' objections to the loss of their annual Master Settlement Agreement payments from the company, I would anticipate Altria would receive overwhelming public support for such a reorganization of its product line."

Referring to a recent Federal Court of Appeals ruling that the FDA could not ban electronic cigarettes, I suggested that Altria might even consider venturing into the lucrative market for this product.

Now that Altria and PMI have done just that, how much more hypocritical could I possibly be in questioning PMI's sincerity in 2024 after writing that in 2010? The answer hinges on my other suggestion for Altria, which I'm still waiting for the company to do:

"A crucial component of such a strategy would be educating consumers for real that filter cigarettes do not in fact confer any health protection from the diseases caused by the inhalation of cigarette smoke."

The Unspoken Word: Addiction

But another reason for my reluctance to give PMI the benefit of the doubt is that there hasn't been sufficient time (e-cigarettes were introduced less than 20 years ago) to study the actual, not theoretical, impact of the long-term inhalation of heated nicotine vapor on the heart, lungs and other organs. For that matter, two heated tobacco products, RJ Reynolds' Premier and Philip Morris's Accord, *were* brought to market in 1988 and 1998, respectively, with enormous hoopla and major advertising campaigns, only to flop quickly with consumers. Premier resurfaced as Eclipse in 1994, but it, too, never caught on.

Second, there's the problem of addiction, a word that is absent from either of the current PMI or Altria campaigns. And there are already nicotine products on the market that have had to undergo clinical trials before being approved by the FDA for smoking cessation, beginning with nicotine polacrilex, aka Nicorette gum, in the mid-1980s. Inhaled, transdermal, and lozenge nicotine products have since been approved for smoking cessation by the FDA, as has varenicline (Chantix) and a few other non-nicotine medications. But even though the effectiveness of FDA-approved, pharmaceutical nicotine-based medications for smoking cessation is much more modest than the manufacturers claim, they have an established, potentially harm-reducing role as an adjunct to the reinforcing, behavior-modifying messages of health care professionals, health organizations, and the mass media.

This does not apply to companies like PMI and Altria that make and promote alternative nicotine products for pleasure -- the so-called recreational nicotine. To put it another way, the pharmaceutical companies may have the good, FDA-approved nicotine, but Philip Morris has that good old nicotine, which one might infer from their harm-reduction ads is no more hazardous to health than a can of Red Bull, a Big Mac, or a pack of M & M's. (Recall every one of the major cigarette company ceo's famously testifying in April 1994 before a Senate committee hearing on tobacco products and health that "nicotine is not addictive": https://www.youtube.com/watch?v=A6B1q22R438). The companies now want to have their claim of reduced harm – as well their *implied* but unproven claim of smoking cessation -- while wanting consumers to remain pleasurably dependent on nicotine.

And let's not forget that nicotine isn't innocuous. In his masterful behind-the-scenes report on the quest for a safer smoke ("Reinventing the Cigarette," *Washington Post*, February 8, 1999), reporter John Schwartz wrote this vivid description:

"A jolt of nicotine speeds up the user's heart rate by about 15 percent and temporarily increases blood pressure by 10 to 20 points. Moments after this initial amphetamine effect, however, the drug causes an equally powerful sedative reaction, blocking the initial stimulation and slowing heart rate back to its previous level. Over time, this constant up-and-down metabolic tinkering can contribute to smoking's toll on the heart and circulatory system.

"Ultimately, though, nicotine is controversial not because of the limited health risk it poses but because of its addictiveness. It's what keeps smokers smoking and ingesting all the other toxins in cigarette smoke. There are only two solutions to this public health dilemma: Stop people from smoking altogether – in some cases with the help of nicotine replacement devices — or create a cigarette that will do less harm."

A lifetime of dependence on nicotine is the unspoken side of PMI's clever and sophisticated ads, as well as in *Tobacco Reporter*'s never-say-die coverage of the cigarette makers' "pharmaceutization" [*see image*]. And that's what the PMI and Altria ad campaign is all about. If enough pressure can be applied to the FDA, then the agency will approve their "reduced harm" products for market without having to wade into the dicey area of smoking cessation -- or have to fend off questions about whether these products truly reduce smoking or might instead hinder getting off nicotine entirely (or both). Advocates of smokeless products scoff at opponents of the nicotine harm reduction strategy as forcing smokers to either "quit smoking or die."

And It's Not Just Lung Cancer

In my opinion, then, the entire PMI and Altria case boils down to a single claim: heated nicotine and smokeless products won't cause lung cancer. Although we began to understand in the 1930s (when lung cancer cases dramatically increased among veterans who had started smoking in World War I) that it takes 15 to 20 years for lung cancer to develop, with non-combustible tobacco products there isn't going to be a similar spike in this disease as the 20-year mark approaches. However, the same can't be said of future heart disease, hypertension, asthma, pulmonary fibrosis, pneumonia, bronchitis, or conditions of the oral cavity.

In their review article, "Cardiovascular Toxicity of Nicotine: Implications for Electronic Cigarette Use," published in 2016 in the journal *Trends in Cardiovascular Medicine* (https://www.sciencedirect.com/science/article/abs/pii/S1050173816000530?via%3Dihub), Neal Benowitz and Andrea Burback write that "The cardiovascular

safety of nicotine is an important question in the current debate on the benefits vs risks of electronic cigarettes and related public health policy." Their findings affirm the argument that short-term use of e-cigarettes (as well as smokeless tobacco and nicotine medications) pose a low cardiovascular risk in healthy users. They note, however, that

"Nicotine exerts pharmacologic effects that could contribute to acute cardiovascular events and accelerated atherogenesis experienced by cigarette smokers. Studies of nicotine medications and smokeless tobacco indicate that the risks of nicotine without tobacco combustion products (cigarette smoke) are low compared to cigarette smoking but are still of concern in people with cardiovascular disease."

The elephant in the room, of course, is the *long-term* impact of nicotine addiction. The dual use (of both heated tobacco products and cigarettes) is seldom mentioned by harm-reduction advocates. As I've noted above, in my experience in a heavily smokeless tobacco-using state, most patients who turn to a smokeless product to stop smoking wind up doing both. I agree that fears about switching from cigarettes to e-cigarettes are overblown, and I roll my eyes in disbelief every time I hear a patient who has smoked for decades say that he or she is scared of the chemicals in e-cigarettes or that "they made me sick." And on this point, as with smokeless and snus, e-cigarettes and newer heated tobacco products are more widely taken up by young people than by older individuals trying to stop smoking.

After failed attempts in the 1990s and early 2000s, backed by an enormous advertising push to convince the smoking public that switching to "smokeless" tobacco or the newly introduced product, snus, would be a better alternative for enjoying tobacco (based on what was called "the Swedish experience," which has

never been replicated elsewhere), harm reduction proponents became intrigued with the newer electronically heated nicotine vapor products that emerged from China. Today, then, in a role reversal, it's the cigarette company executives who are yelling that the sky is falling because the public health and medical communities won't encourage patients to switch to their life-saving e-cigarettes and support the science that noncombustible tobacco products reduce harm.

Armed with promising data and the advocacy of its contingent of former academics, government scientists, and lawyers that heated products can reduce the harm caused by smoking, the executives of cigarette behemoth PMI aren't just sharing their hopeful findings, as their ads at first appear to do. Instead, they're *admonishing* us to stop scaring people into believing that breathing in heated nicotine vapor is as deadly as smoking cigarettes, to stop being prohibitionists, and to permit the company to continue its life-saving message to smokers about the relative safety of its heated products.

HTP Interventional Clinical Trials A Bust?

But here's the rub: the industry's dissemination of research data to prove the "fact" that heated tobacco products are safe and effective is premature. A recent critical appraisal published in the journal *Tobacco Control* by Sophie Braznell and colleagues in the UK (https://tobaccocontrol.bmj.com/content/early/2023/03/28/tc-2022-057522) of the known published interventional clinical trials of these products does not inspire confidence in recommending them:

"Of the 40 identified interventional clinical trials assessing heated tobacco products (HTP), 29 were industry affiliated and 11 were independent. Many characteristics of these trials, such as short durations, confined settings and choice of comparators and participants, are not

representative of real-world use and fail to adequately investigate whether HTPs reduce harm and are beneficial to public health."

The authors' overall conclusion is that

"The conduct and reporting of HTP interventional clinical trials were poor in many respects and limited to investigating effects of short-term exposure. These trials fall short of what is needed to determine whether HTPs are beneficial to public health, meaning they may not be a sound basis for tobacco control policy decisions."

The Best Way to Stop Smoking May Not Be with Nicotine

Thus PMI's hopeful new rhetoric comes after more than 70 years of denying the evidence that cigarette smoking causes lung cancer, or, for that matter, any other health problems –in other words, of willfully *not* trying to save lives. Only in 1999 did Philip Morris acknowledge, undoubtedly for legal purposes as it faced the possibility of financial ruin from an onslaught of tobacco product liability lawsuits and federal charges of racketeering, that "the preponderance of evidence believed by most health authorities" suggests that smoking causes cancer and heart disease.

I'm not entirely comfortable siding with opponents of heated tobacco products, but proponents of these products also fail to adequately address the problem of adolescents taking them up. The manufacturers are using the same playbook as cigarette-makers used to do, only more subtly, while claiming they don't want kids to use them because they're too young. What better way to lure them in than to tell them they're too young to do adult thing, just as Philip Morris did in the 1990s and early-2000s with its Youth Smoking Prevention program (written by hirelings from Harvard and other prestigious institutions). One of these individuals, Cheryl K. Olson, PhD, writes frequent pro-harm reduction articles for

Tobacco Reporter and works for a consulting company that brings new tobacco and cannabis products to market.

In my opinion, both sides in the how-to-stop-cigarette smoking debate—proponents of the pharmaceutical approach for complete cessation on the one hand and advocates of the harm-reduction approach by switching to noncombustible products on the other—are addicted to the profits from the sale of nicotine. This means that one thing Philip Morris and the drug companies also have in common is that they don't like to remind consumers that the most effective and least expensive smoking cessation method is to stop buying cigarettes--namely, going cold turkey. Instead, they reinforce the notion that those who smoke cigarettes can't stop on their own. And, unlike Philip Morris, the drug companies even mock trying to go cold turkey, as in this current TV commercial by Johnson & Johnson subsidiary McNeil Laboratories:

"Quit smoking cold turkey? Yeah, right! Warm up to quitting like millions of Americans and start stopping with Nicorette."

And here's the way Pfizer promotes its blockbuster drug:

"It's tough to quit smoking cold turkey, so Chantix can help you quit slow turkey. Along with support, Chantix is proven to help you quit. With Chantix you can keep smoking at first and ease into quitting. Chantix reduces the urge, so when the day arrives, you'll be more ready to kiss cigarettes good-bye. When you try to quit smoking, with or without Chantix, you may have nicotine withdrawal symptoms Stop Chantix and get help right away if you have changes in behavior or thinking—aggression, hostility, depressed mood, suicidal thoughts or actions, seizures, new or worse heart or blood vessel problems, sleep-walking, or life-threatening allergic and skin reactions. Decrease alcohol use. Use caution when driving or operating machinery. Tell your doctor if you've had mental health problems. The most common side effect is nausea. Quit smoking slow turkey. Talk to your doctor about Chantix."

The only side effect Pfizer fails to mention is the likelihood of resuming cigarette smoking.

Since the publication of the 1964 Surgeon General's Report (and even a decade earlier when it published its Frank Statement to cigarette smokers), the tobacco industry has been between a rock and a hard place: if a company has developed a new product that it considers to have a dramatically lower risk to health, then it must acknowledge that its other products are high risk, which the cigarette companies are still disputing in courtrooms in ongoing product liability lawsuits.

In other words, PMI and Altria are claiming that they want a smoke-free world while continuing to derive more than 80% of net revenues from conventional cigarettes. When challenged by skeptics to simply stop selling cigarettes *now*, the company and its paid consultants like Dobbins raise the specter of a huge black market that would quickly emerge, run by rogue elements who take over the industry and circumvent all regulations.

Point of Agreement

But there is at least one major point on which PMI, its Foundation for a Smoke-Free World, and I agree: the need to address the glaring void in medical school curricula and postgraduate training on preventing teenage-onset tobacco use, on teaching behavior-modifying techniques to facilitate smoking cessation, and on helping prevent patients from relapsing. The Smoke-Free World Foundation reports that in a recent survey it commissioned of physicians and medical students in 11 countries, 77% believe that nicotine causes lung cancer. Good grief!

PMI's seemingly incredible transformation calls to mind a scene in the movie "Swiss Miss," in which Laurel and Hardy are thrown out of a tavern, put on fake mustaches, go back in, and are immediately recognized by the owner, who

exclaims, "I thought I told you two not to come back here!" Stan Laurel turns to his sidekick Oliver Hardy and says, "He thinks we're us. Isn't that silly. We're not us. We're two other fellas."

As long as Marlboros continue to drive PMI's and Altria's profits, I won't go along with their insistence that they're two other fellas. But, as in 2010, I wish them well in trying to pull it off.