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Take a Deep Breath: Vaping in perspective

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In 2009, Congress passed a bill giving the Food and Drug Administration (FDA) the authority to regulate tobacco products.

When the treacly named Family Smoking Prevention and Tobacco Control Act was signed by President Obama, the bill's proponents, notably the Washington lobbying group Campaign for Tobacco Free Kids, touted it as a long-awaited victory over Big Tobacco. When it was revealed that the Campaign had secretly co-written the bill with Altria, maker of the top-selling cigarette Marlboro, we realized that the brand's iconic cowboy wouldn't be riding off into the sunset just yet.

But few could have predicted that the efforts to protect Americans from the harmfulness of tobacco would become more confusing and convoluted by adding it to the FDA's portfolio.

Because the FDA is the nation's watchdog over medications and medical devices, a provision in the FDA tobacco bill distinguishes drugs and devices from tobacco products, in order to prevent duplicative regulation by different centers within the FDA. And therein lies the origin of the unfettered explosion of vaping, or the use of device to inhale a heated, flavored nicotine solution.

That's because in their eagerness to get the FDA bill passed, Senate Democrats rejected a Republican amendment to regulate electronic

cigarettes (or e-cigarettes) as tobacco products and deliberately left e-cigarettes out of the bill. After all, proponents reasoned, e-cigarettes were new, expensive, and gimmicky, and they were manufactured by only a handful of companies. The proponents also counted on using a provision of the bill in which the FDA could “deem” as tobacco products both e-cigarettes and any future nicotine-containing products that regulators couldn’t yet envision.

But a not-so-funny thing happened. While the FDA hemmed and hawed about these newfangled electronic nicotine delivery systems (called ENDS for short), hundreds of manufacturers entered the market, costs dramatically dropped, and e-cigarettes could be purchased at any convenience store for the price of a pack of Marlboros.

Finally, in 2016, the FDA issued its deeming rule that named e-cigarettes as tobacco products subject to the agency’s regulatory authority.

In July 2019, a US District Court in Maryland upheld the FDA’s rule. Meanwhile, products such as JUUL, craftily designed to resemble a USB drive and promoted through social media to the wired generation, became an essential accoutrement of high school and college students. That JUUL was also engineered to deliver nicotine more rapidly than any previous e-cigarette and came in appealing flavors such as mango and mint contributed to its capturing 75% of the e-cigarette market in just three years after it was introduced in 2014.

In December 2018, Altria paid \$12.8 billion for a 35% stake in JUUL Labs, Inc. At the same time, the vape shop industry burgeoned, as did online sellers of e-liquids and paraphernalia aimed at a counter-culture that rejected commercial tobacco products. The legalization and commercialization of marijuana by several states also led to the proliferation of “e-cannabis” the vaping of liquids containing the active ingredient of marijuana, THC. In turn, the bootleg market in such e-cannabis liquids and cartridges has resulted in an outbreak of vaping-

related pulmonary illness in 2019, causing more than 30 deaths and sickening upwards of 1600 users of electronic vaping devices.

Thus the FDA lost a full decade in which it could have required e-cigarette manufacturer registration and ingredient-reporting, inspected e-liquid-making facilities, and acted against adulterated or misbranded products. Lost, too, was the opportunity to slow the introduction of e-cigarettes, to temper so-called harm reduction health claims about these products compared to cigarettes, to verify their value in smoking cessation, and to thwart their marketing to young people.

The FDA's efforts have been too little and too late. But what should the new FDA commissioner, Congress, and the health community do now? Here are a few suggestions:

1. Revamp, reduce, or eliminate the FDA's Center for Tobacco Products. The Center's very existence has taken our eyes off the prize, namely cigarettes, which still take the lives of nearly half a million Americans each year.

Because Congress essentially grandfathered cigarettes from strict regulation by the FDA, I testified at both the Senate and House hearings on the bill in 2007 that it might as well have been called The Marlboro Preservation Act. As incredible as it sounds, the FDA has actually approved new cigarette products because the bill permits them to be sold as long as they are no more harmful than existing products! Yes, it's true: if a cancer drug causes too many side effects, the FDA can pull it from the market; yet the FDA can't lay a finger on Marlboro. If the FDA now intends to play catch-up by clamping down on e-cigarettes, then it should just get on with it and stop pretending that it has done anything to protect Americans from the harm of tobacco products.

2. Consolidate mass media campaigns against cigarettes and other tobacco products under the Centers for Disease Control and Prevention (CDC). Chevy Trucks, Coca Cola, and Burger King may all offer local special prices on occasion, but they don't churn out a jillion

different advertising campaigns running independently from one another. Rather, they have one nationwide advertising campaign at a time. In stark contrast, seemingly every state and county health department, voluntary health organization like the American Cancer Society, and state and national medical society has produced some sort of anti-tobacco public service announcement.

The CDC's Media Campaign Resource Center lists more than 1900 different anti-tobacco and anti-vaping campaigns, posters, and billboard, radio, TV, and internet ads. Such duplication is both wasteful and misguided. In 2012, nearly 50 years after the Surgeon General's Report on smoking was issued by Alabamian Dr. Luther Terry, the CDC finally launched the first *paid* TV campaign aimed at getting Americans to stop smoking.

The "TIPS from Former Smokers" campaign won widespread public approval, yet the CDC lacks sufficient funds to air these ads for more than a few months a year. There is no reason for the FDA or other federal health agencies other than the CDC to continue using funds for separate campaigns such as the FDA's little-seen effort to discourage the use of smokeless tobacco. Meanwhile, most states, including Alabama, have squandered the bulk of yearly funds from the 1998 Master Settlement Agreement with the tobacco industry that was supposedly going to be used for anti-tobacco education. Less than 2% of such funding is currently used by the states to fight smoking.

3. Shift the focus to the filter. This is the elephant in the room when it comes to cigarette smoking. 99% of cigarettes consumed in the US are now filtered brands because those who smoke naively assume that the filter reduces the risk of getting lung cancer, heart disease, or emphysema. In fact, the adoption by smokers of filtered cigarettes since their introduction in the 1950s has not reduced these consumers' risks for cancer and other diseases. Indeed, the filter may even increase the chances of disease because the user must inhale more deeply to draw the needed amount of nicotine and in so doing become exposed to

greater quantities of carcinogens and toxic gases such as carbon monoxide, ammonia, and formaldehyde. Although efforts have been made to eliminate the use of misleading descriptors such as “low tar,” “lights,” and “mild” from cigarette marketing, the elimination of the cigarette filter has been largely overlooked as a strategy to reduce cigarette consumption.

4. Restore the bully pulpit of the Surgeon General. In 1964 US Surgeon General Terry called for appropriate remedial action to reduce smoking in America. Overnight Dr. Terry became the nation’s anti-smoking symbol. Several of his successors, notably Dr. C. Everett Koop, proclaimed loud and clear that cigarette smoking remains the nation’s leading preventable cause of death and disease. But the candid and outspoken efforts of Dr. Jocelyn Elders to raise public awareness of ways to prevent teen pregnancy and sexually transmitted diseases led to her firing by President Clinton and the muting of the office. Virtually all public comments by the Surgeon General have since been scripted by the White House.

5. Rev up the curriculum in schools of medicine, dentistry, public health, and nursing. The training of health professionals is long on the diagnosis and treatment of diseases in individual patients but short on preventing or reducing the burden of disease in the population as a whole. Medical schools and allied health institutions must include greater emphasis on strategies in the clinic, in schools, and in the community as a whole for preventing and reducing the use of tobacco products.

6. Restrict both e-cigarette and cigarette sales to tobacco shops. The misinformation and hysteria surrounding the recent surge of vaping-related illnesses and deaths has led the Massachusetts legislature and other state and local government agencies across the country to consider imposing a ban on all flavored e-cigarette products as well as a ban on the sale of e-cigarettes to anyone under 21. The rationale is

that we don't want to see vaping become the next addiction pandemic, and we don't want to miss the boat as we did with smoking. So why not put the same restrictions on the sale of cigarettes (which take half a million lives a year) as well as e-cigarettes, as Dr. Michael Siegel of Boston University School of Public Health has proposed, and confine their sale to tobacco shops? Why have health organizations, medical societies, and legislative bodies been silent on this logical idea? Perhaps it's because the supermarket chains, gas stations, convenience stores, and chain drugstores still make a killing from cigarette sales—and still are big donors to health organizations and politicians.

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