FDA GUIDANCE RESTRICTS E-CIGARETTE FLAVORS, LEAVING TOBACCO AND MENTHOL ON THE MARKET

FDA Jan. 2 issued a final guidance that will restrict the sale of e-cigarette flavors most popular with minors.

FDA E-CIGARETTE FLAVORING BAN LEAVES A BAD TASTE

PAZDUR ON THE CHALLENGE OF APPROVING DRUGS FOR SMALL INDICATIONS

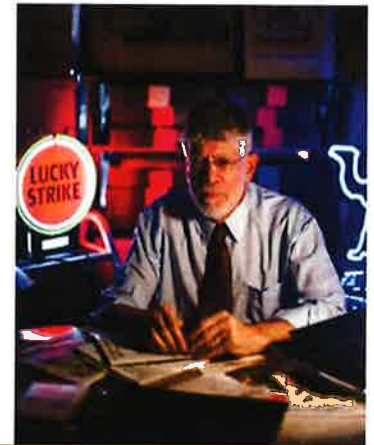## MOFFITT CEO ALAN LIST, DIRECTOR THOMAS SELLERS RESIGN OVER CONFLICTS OF INTERESTS INVOLVING CHINA

TRUMP APPROVES $212.5M INCREASE TO IMPROVE NCI SUCCESS RATES; FY20 SPENDING BILLS PROVIDE NEW FUNDING FOR CHILDHOOD CANCER, RAISE TOBACCO-PURCHASE AGE TO 21

FDA e-cigarette flavoring ban leaves a bad taste

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"TRUMP ERODING ROLE OF SCIENCE IN GOVERNMENT"

The ink hadn't dried on the headline of the lead story in the Dec. 29 issue of The New York Times when on Jan. 2 HHS Secretary Alex Azar and newly arrived FDA Commissioner Stephen M. Hahn made the following announcement:

"Amid the epidemic levels of youth use of e-cigarettes and the popularity of certain products among children, the U.S. Food and Drug Administration today issued a policy prioritizing enforcement against certain unauthorized flavored e-cigarette products that appeal to kids, including fruit and mint flavors.

Under this policy, companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) within 30 days risk FDA enforcement actions."

That's it then? A ban on fruit and mint flavored nicotine e-liquid cartridges? A free pass for menthol, the heavy fa-

vorite among African Americans for both cigarettes and e-cigarettes? No mention of JUUL, the sleek flashdrive look-alike that dominates the youth e-cigarette market, or of the fact that JUUL had voluntarily pulled these very flavors on Nov. 7?

Back on Sept. 11, President Trump had announced at a White House press conference that his administration was considering a ban on all flavored vaping products. "It's causing a lot of problems," he said.

The next day, when asked by reporters if he and the First Lady had discussed vaping with their 13-year-old son, he added, "We haven't told him anything,

except don't vape. Don't vape. We don't like vaping. I don't like vaping."

The Trump family's concern about teen addiction to e-cigarettes is justifiable. The CDC reports that more than 5 million teenagers have taken up e-cigarettes.

However, the main reason the issue came up last summer at the White House was the rapidly growing public fear raised by the CDC's alarming report of over 1000 hospitalizations for lung injuries, including 6 deaths, in individuals who had used e-cigarettes or other vaping devices.

Immediately after the September White House meeting, Azar announced that "the Trump administration is making it clear that we intend to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities. We will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."

Yet just two days later, Trump backed off his pledge to ban flavored vaping products, tweeting "While I like the Vaping alternative to Cigarettes, we need to make sure this alternative is SAFE for ALL! Let's get counterfeits off the market, and keep young children from Vaping!"

His mention of counterfeit products suggested he had had strong pushback from the vaping industry. CNN reported that three former administration officials work for JUUL and that a third former official is a JUUL consultant.

I say, add the FDA's minimalistic action on e-cigarettes, then, to the catalogue of industry-influenced erosion of science under the Trump administration, such as weakening of water and air pollution regulations, increasing presidential input into hurricane forecasts, head-

in-the-sand denial of climate change and global warming research results, and loosening of wetlands protections.

The FDA's action is reminiscent of the crusade by the D.C.-based anti-smoking group Campaign for Tobacco-Free Kids against cherry, vanilla, and banana-flavored cigarettes in 2009, even though not a single one of these products was being marketed by the major cigarette manufacturers.

But while the fruit and mint-flavored cartridge ban will likely reduce some teen e-cigarette consumption (while other teens switch to menthol), it is unlikely to curtail the lung injuries and deaths from vaping.

That's because although the relationship between vaping and lung injuries was still a mystery in September, we now have a much better idea of what's causing the problems.

As Andrea Speedy summarized in the Fall 2019 issue of College Health and Wellness in Action, published by the American College Health Association, "among 867 patients with information on substances used in e-cigarette or vaping products in the three months prior to symptom onset, about 86% reported using tetrahydrocannabinol (THC, the active ingredient in marijuana)-containing products; 34% reported exclusive use of THC-containing products. About 64% reported using nicotine-containing products; 11% reported exclusive use of nicotine-containing products."

CDC has also identified vitamin E acetate, a thickening agent in THC-containing e-cigarette product, as a chemical of concern among those with e-cigarette or vaping product use associated lung injury (EVALI). [As of Dec. 4, the Centers for Disease Control and Prevention reported 48 vaping-related deaths and 2,291 hospitalized cases of e-cigarette or vaping product use associated lung injury (EVALI).]

It's the THC, stupid. But that's doesn't diminish the importance of the FDA's announced flavoring ban in reducing youth e-cigarette use, according to The CDC's point-person on vaping, Dr. Brian King, deputy director for Research Translation in the Office on Smoking and Health (OSH) at the CDC.

As he told Andrea Speedy, "The landscape for tobacco products is changing dramatically. The devices are small and easily concealed, there's strong advertising behind these products—especially on social media—they come in appealing flavors, and they're highly addictive because of their nicotine content. It's a perfect storm from a public health perspective."

Dr. Michael Siegel, of Boston University School of Public Health, a leading proponent of e-cigarettes as a method of smoking cessation, insists that the flavoring ban is misguided. His testimony at a Congressional hearing in October on legislation to curb teen vaping:

"The real danger of youth e-cigarette use is not the flavors. It's not the flavors that are causing the harm. It's the high levels of nicotine and the special nicotine formulations being used in some of these products that are resulting in youth addiction to vaping.

"For example, prior to the introduction of JUUL, 74% of nonsmoking youth e-cigarette users reported using e-cigarettes about once a week and only 4% used them every day. [Daily use is considered a likely addiction.] But by 2018, 12% of nonsmoking youths used e-cigarettes every day, and 42% of non-smoking young e-cigarette users only used them less than once a week.

"A complete ban on e-liquid flavors would have devastating health consequences. More than 2.5 million adult smokers in the U.S. have quit smoking completely by switching to electronic cigarettes, and most of these ex-smokers rely on flavored e-liquids to keep them off of real cigarettes. If flavored

e-cigarettes are banned, there is no question in my mind that many of these ex-smokers will return to cigarette smoking. Most of those who don't will turn to a new, potentially dangerous black market that would be created by such a policy."

The FDA's not getting things right when it comes to tobacco product regulation didn't begin with the current administration. That dubious distinction lies squarely with the Obama administration and the Democrat-backed, treacly named Family Smoking Prevention and Tobacco Control Act.

In 2009, when Congress passed the bill giving the FDA the authority to regulate tobacco products, proponents hailed it as a long-awaited victory over Big Tobacco.

But when it was revealed during the hearings in Congress in 2007 that the co-author of the bill with the Campaign for Tobacco-Free Kids was none other than Altria, maker of the top-selling cigarette, Marlboro, at least a few of us realized that the brand's iconic cowboy wouldn't be riding off into the sunset just yet.

I'm a Democrat, but I readily accepted invitations by Republican members of Congress to testify against the bill at both the Senate and House hearings.

Among my main points, I noted that "in spite of the fact that the cigarette filter does not confer any reduced health risk whatsoever, more than 95% of persons who smoke buy filtered brands in the false belief that they are safer. Yet, this bill will not ban the filter, the biggest and longest-running scam of Big Tobacco. However well-intended, the bill is misguided. It could well be renamed the Marlboro Protection Act."

As Dr. Siegel and I had written in The Lancet in 2006, "Philip Morris' support for the bill should prompt scep-

ticism about the legislation's public-health benefits.

Reading the fine print bears this out. Consider the following: First, the measure would stringently regulate new and potentially less hazardous tobacco products, but would not apply these same regulatory standards to the most irredeemably harmful form of tobacco, existing cigarettes, which cause the deaths of nearly half a million Americans each year.

"Second, although the bill would require the FDA to prevent the introduction of new cigarette brands for which 'there is

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– Michael Siegel

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a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health,' the bill permits Marlboro and the other most popular existing cigarette brands to remain on the market, even though these products are one of the leading threats to the public's health.

"Third, the bill bans the use of strawberry, grape, chocolate, or similar flavoring additives in cigarettes but does not require the FDA to eliminate (or even reduce the levels of) toxic gases, including hydrogen cyanide or the more

than 40 known cancer-causing constituents of cigarette smoke such as benz(a) pyrene, benzene, and radioactive polonium. The Agency would be given the authority to take such action but, unlike for the flavorings, there is no mandate that the FDA do anything to regulate these toxins."

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 de-

vices, 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.

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 gim-

micky, 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 U.S. 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 accessory 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. JUUL uses a special nicotine formulation that is absorbed much more rapidly into the bloodstream. The formulation uses nicotine salts instead of just nicotine alone, which greatly enhances the speed at which it enters the bloodstream.

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 THC. In turn, the bootleg market in such e-cannabis liquids and cartridges appears largely responsible for the outbreak of vaping-related pulmonary illness in 2019.

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 too late. But what can the new FDA commissioner, Congress, and the health community do to turn things around?

> **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. As unbelievable as this sounds, the FDA has actually approved new cigarettes.

That's because the bill permits them to be marketed 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; but the FDA is

barred by Congress from laying 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.**

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 1,900 different anti-tobacco and anti-vaping campaigns, posters, and billboard, radio, TV, and internet ads. Such duplication is wasteful and misses the mark.

We also need a lot less finger-wagging and fear-mongering and a lot more humor, satire, and parody. There's absolutely nothing wrong with telling a high school student that she's too old to smoke or vape ("that's for sixth-graders"), remarking about her cool yellow teeth, or recommending that she switch to that new cigarette brand Urine Breath 100s, that old brand Fartboro, or

that best-smelling e-cigarette, STUUL. Besides, sucking on a flashdrive is sheer stupidity and conformity, with a side order of addiction. Let's be direct for a change.

In 2012, nearly 50 years after the Surgeon General's Report on Smoking and Health was published, 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. Meanwhile, with few exceptions, the states have squandered the bulk of the yearly funds they each receive 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 U.S. 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, U.S. Surgeon General Luther 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 rise of youth e-cigarette use and the recent epidemic of vaping-related illnesses and deaths has led to the FDA's ban on some flavored e-liquid products, which follows on the heels of similar bans in several states and cities, as well as bans 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. Siegel has proposed, and confine their sale to adults-only 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 are big donors to health organizations...and elected officials.

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