

# **Big Tobacco Won't Let the FDA**

## **Cut Nicotine Without a Fight**

**Lobbyists will likely lead the campaign against making cigarettes less addictive.**

By  
Anna Edney and Jennifer Kaplan

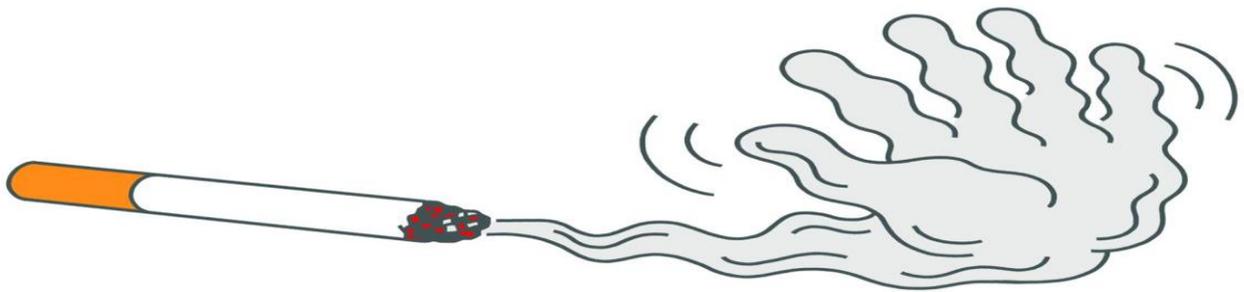


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In 2009 a Democratic Congress and president gave the U.S. Food and Drug Administration the power to regulate tobacco. Eight years later, under a White House and Congress controlled by Republicans, the FDA made its strongest use of that authority. On July 28 it said it would move to cut the level of nicotine in cigarettes to nonaddictive levels. The news shocked Washington and Wall Street, sending tobacco stocks plunging and lobbyists scrambling to respond.

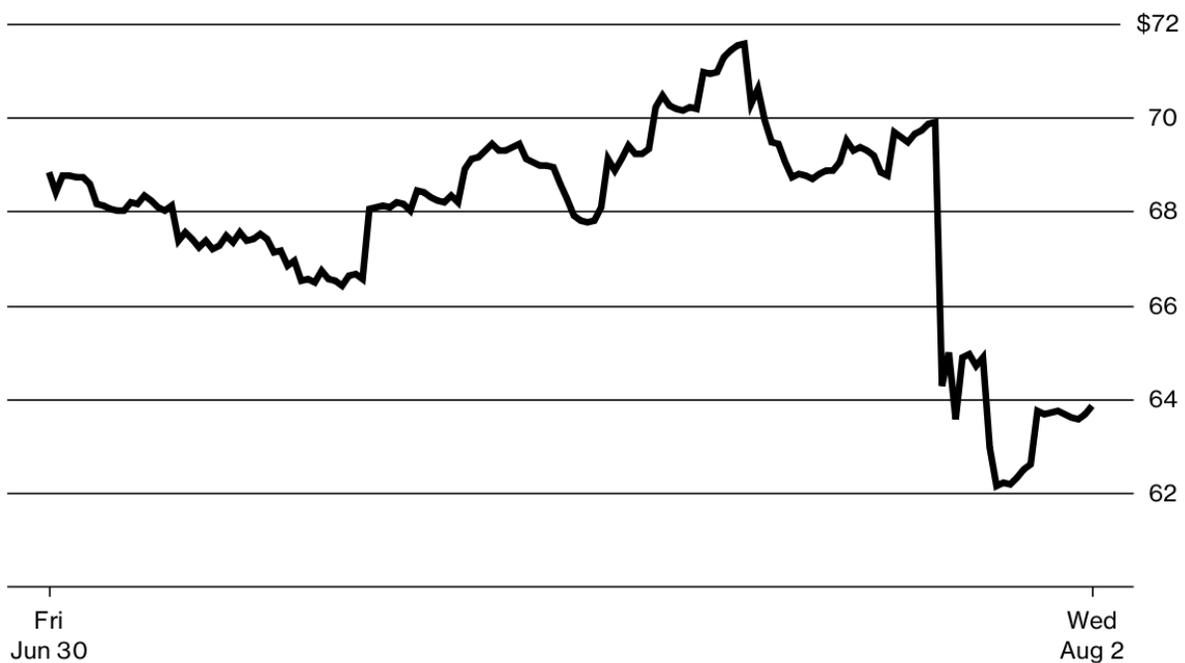
The policy is the latest sign that FDA Commissioner Scott Gottlieb, who was confirmed in early May, is turning out to be among the most aggressive (and unpredictable) cabinet officials during the early days of the Trump administration. In less than three months, Gottlieb, a 45-year-old physician and cancer survivor, has moved quickly on a number of issues not typically within the FDA's purview, including the high cost of prescription drugs and the opioid crisis. In June, Gottlieb took the rare step of asking a drug company to pull a powerful opioid pain medication off the market. Although the company wasn't legally required to do so, it complied.

“I’ve pledged a deep commitment to taking aggressive steps to address the epidemic of addiction to opioids,” Gottlieb said in announcing the nicotine policy. “I’ll pursue efforts to reduce addiction to –nicotine with the same vigor.”

His proposal to make cigarettes less addictive could lead to the most sweeping effort to reduce smoking in the U.S. since 1965, when President Lyndon Johnson signed a law requiring packs of cigarettes to carry a health warning. It also strikes an adversarial tone with the \$130 billion tobacco industry, a surprising move for an administration that’s rolling back regulations. It’s not clear whether Gottlieb personally sought President Trump’s counsel before making the announcement. An administration

### British American Tobacco

Brands include Dunhill, Lucky Strike, and Camel



Data: Bloomberg; Graphic by Bloomberg Businessweek

official says the White House –supports the policy and disagreed that it was a break from Trump’s antiregulation agenda.

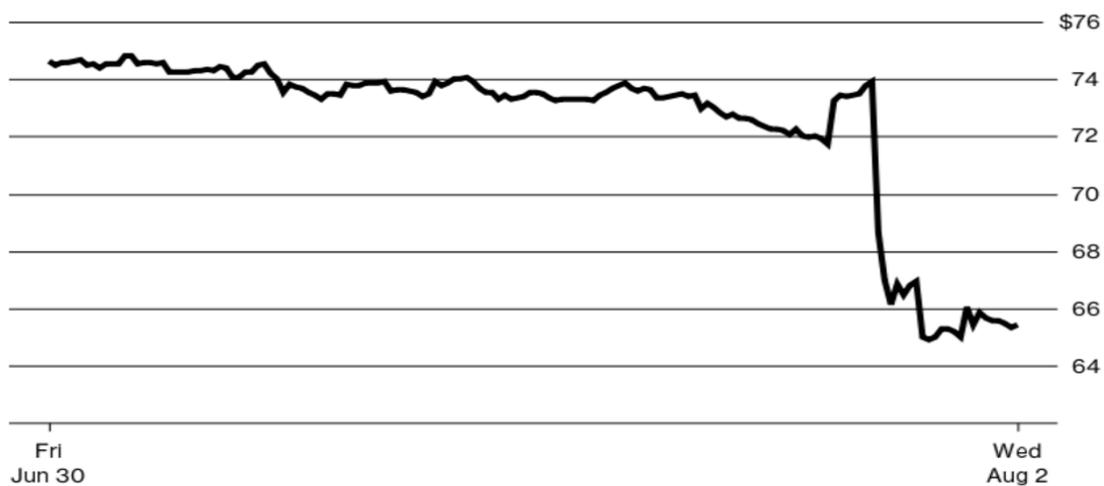
The move won Gottlieb praise from a former Obama official. “I was worried, given the rhetoric about regulation from the current administration, that he would be held back, but he’s done

really well,” says Robert Califf, the last FDA commissioner under President Obama. Califf said the agency had been considering ways to lower nicotine content in –cigarettes for some time. In announcing the policy, the FDA also said it will delay by five years a deadline for –e-cigarette companies to get their products cleared for sale by the FDA, meaning that market will remain unregulated until 2022. That could be good news for tobacco companies developing alternative products. It also has some antismoking advocates worried. “I am concerned by delay in implementing the commonsense rules finalized last year,” Senator Richard Blumenthal, a Democrat from Connecticut, said in an emailed statement. “By dragging their feet, the FDA risks rolling back the incredible gains we have made to protect a new generation from a lifetime of disease.”

In his July 28 briefing, Gottlieb called nicotine both the “problem” and “ultimately, the solution.” The FDA “must also recognize potential for innovation to lead to less harmful products,” he said. In an interview following the announcement, Gottlieb said the agency needs more time to craft –regulations for e-cigarettes, which would allow the industry to develop technologies such as vaping. “We were thinking about, or thought we could, potentially reduce levels of nicotine to create that inflection point in public health,” he said. “Taking a new, balanced approach to new

### Altria Group

Parent company of Philip Morris USA, maker of Marlboro, Merits, Virginia Slims



Data: Bloomberg; Graphic by Bloomberg Businessweek

Product innovations could make a lot of sense and help people transfer off cigarettes in a world where cigarettes were no longer addictive.”

The FDA wants to collect input from the public before proposing a rule, which still could be years away. In the meantime, the policy is sure to set off a lobbying fight. Tobacco companies could sue to stop it. They could also lobby members of Congress to defund it or block the FDA from imposing or enforcing it. According to tobacco lobbyists, the industry could argue that the policy amounts to a de facto ban on cigarettes. While the 2009 law gives the FDA the power to regulate cigarettes, it explicitly states the agency may not ban them.

Even some antismoking advocates think the FDA is on shaky ground. “The legal mandate that they have to do this is extremely weak,” says Clive Bates, a public-health activist. “They say they’re not banning cigarettes, but they are banning cigarettes with any meaningful level of nicotine in them.” Bates says the rule will probably be stopped by Congress or in the courts.

**BOTTOM LINE** - FDA Commissioner Gottlieb’s plan to cut the nicotine in cigarettes to nonaddictive levels will likely spark a lobbying fight from the tobacco industry.



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