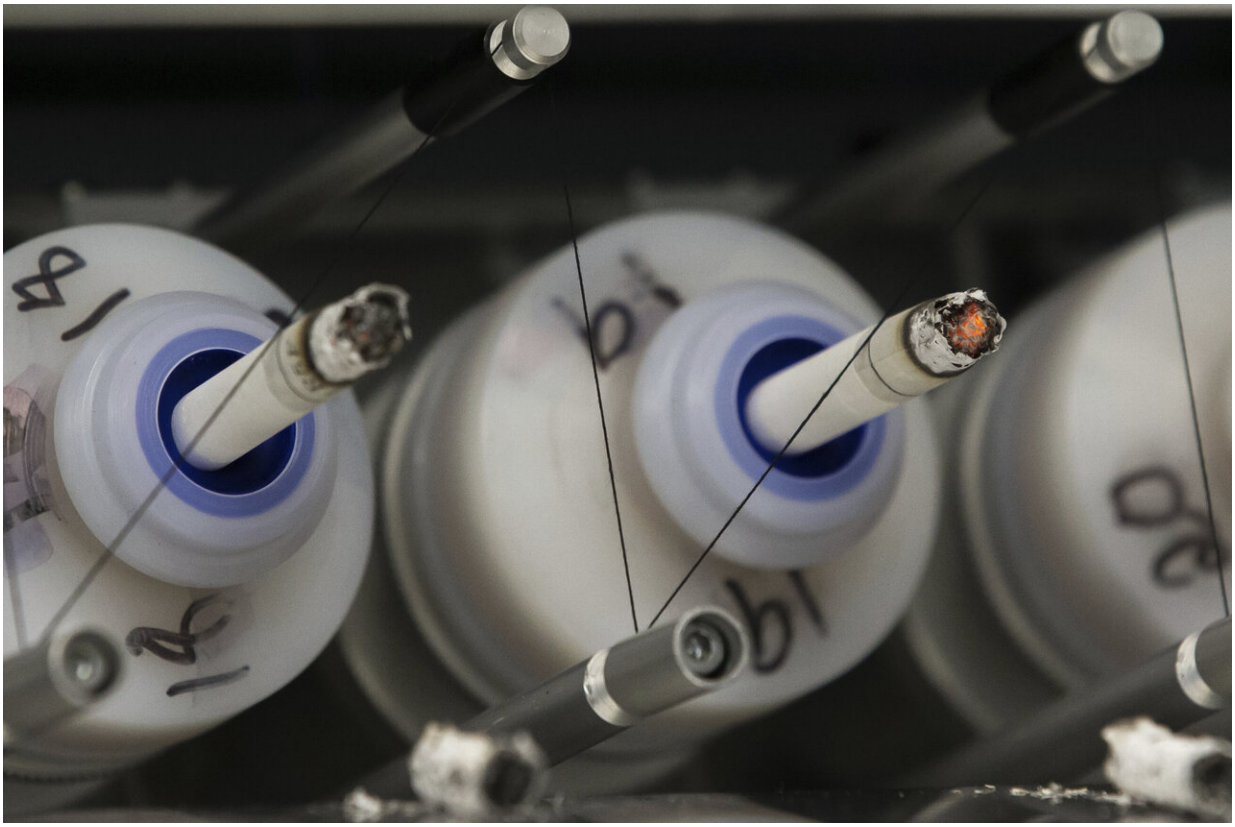
Anti-smoking advocates bemoan 'faltering' pace of FDA action

August 29 2019, by Matthew Perrone



In this Thursday, Nov. 10, 2016 file photo, test cigarettes burn in a smoking machine at the Centers for Disease Control and Prevention in Atlanta. A decade after President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act into law in 2009, health advocates say the Food and Drug Administration has yet to put in place the most sweeping changes envisioned by Congress. (AP Photo/Branden Camp)

It seemed like a new era in the half-century battle against the deadly toll of tobacco: U.S. health officials for the first time would begin regulating cigarettes, chew and other products responsible for a half-million American deaths annually.

"The decades-long effort to protect our children from the harmful effects of smoking has finally emerged victorious," then President Barack Obama said in a speech before signing the 2009 measure into law.

But a decade later, health advocates say the Food and Drug Administration has yet to put in place the most sweeping changes envisioned by Congress. Efforts to bolster cigarette warnings and ban harmful ingredients have been stymied by tobacco companies. And the pace of progress is so slow that the FDA now faces lawsuits from its traditional allies: anti-smoking groups who are suing the agency to take action.

"If you're not moving forward on your own with a clear goal in mind then, at some point, this is what happens," said Eric Lindblom, a lawyer at Georgetown University's O'Neill Institute who previously worked at the FDA's Center for Tobacco Products.

Ten years after the center's launch, Lindblom and others say they underestimated the obstacles that would crowd FDA's path, including industry lawsuits, lobbying and the grinding pace of government bureaucracy.

Earlier this month the agency proposed new graphic warning labels for cigarette packets, a court-ordered move triggered by a lawsuit from the American Lung Association and other health groups who alleged the agency was dragging its feet on the effort. A 2011 attempt at requiring the labels was defeated in court by tobacco companies.

In this Feb. 20, 2014, file photo, a patron exhales vapor from an e-cigarette at a store in New York. Under the Trump administration, former FDA commissioner Scott Gottlieb kicked off his tenure in 2017 with the goal of making cigarettes less addictive by drastically cutting nicotine levels. He also rebooted the agency's effort to ban menthol flavoring in cigarettes. But those efforts have been largely eclipsed by the need to respond to an unexpected explosion in e-cigarette use by teens. (AP Photo/Frank Franklin II, File)

FDA tobacco director Mitch Zeller said the agency's critics have overlooked the enormous accomplishment of setting up the new center in the first place.

"There was and there still is no other regulatory agency in the world with

these authorities and responsibilities," Zeller said in an interview.

He noted that the FDA has invested more than $1.6 billion in tobacco research to guide its future decisions, such as how to regulate electronic cigarettes. He also pointed to the agency's $870 million in spending on anti-smoking advertising campaigns. Last week, researchers estimated that one of those campaigns, dubbed "the real cost," prevented between 380,000 and 587,000 young people from starting on cigarettes.

In a statement, agency acting Commissioner Ned Sharpless also highlighted the "extraordinary investments the FDA has made in science, education and enforcement," asserting that they "are already paying public health dividends and are sure to yield even more in the years to come."

The Family Smoking Prevention and Tobacco Control Act did immediately ban misleading terms like "light" and "mild" from cigarettes and prohibited all flavors, except for menthol. But the more transformative powers to remake the tobacco industry were to be written by the agency itself as federal regulations. They include the ability to:

— reduce nicotine to make cigarettes less addictive

— remove cancer-causing ingredients to make tobacco products less harmful

— restrict packaging and advertising to make products less appealing

Micah Berman, a public health lawyer at Ohio State University, argues that FDA regulation has not yet had a measurable impact on the U.S. smoking rate.

This Aug. 28, 2017 file photo shows cigarettes displayed on a store shelf in New York. Since 2009, the U.S. smoking rate has fallen by about a third—from 21% to 14% of adults. But Micah Berman, a public health lawyer at Ohio State University, says this decline continues a decades-long trend attributable to longstanding measures, such as smoking bans, cigarette taxes and anti-smoking campaigns. (AP Photo/Mark Lennihan, File)

Since 2009, the U.S. smoking rate has fallen by about a third—from 21% to 14% of adults. But Berman says this decline continues a decades-long trend attributable to longstanding measures, such as smoking bans, cigarette taxes and anti-smoking campaigns.

"FDA was given the authority to make tobacco products less toxic, less addictive and less attractive and it has not finalized one product standard

to do any of those things," said Berman, who previously served as a senior FDA adviser.

In a recent paper, "The Faltering Promise of FDA Tobacco Regulation," Berman says FDA officials are not to blame for the lack of progress, but rather the "immense" structural challenges of getting new regulations through the Washington political machine.

This combination of images released by the FDA shows proposed warning labels

for cigarette packaging from 2010, top, and 2019. In August 2019, the Food and Drug Administration proposed new graphic warning labels for cigarettes packets, a court-ordered move triggered by a lawsuit from the American Cancer Society and other groups who alleged the agency was dragging its feet on the effort. A 2011 attempt at requiring labels was defeated in court by tobacco companies. (FDA via AP)

He argues that the 2009 tobacco law merely shifted the longstanding battle between anti-smoking groups and Big Tobacco to federal institutions like the White House and Congress, which hold sway over the FDA.

"All of these are areas where the tobacco industry can spend a lot of time and money lobbying and has a lot of expertise and incentives to spend as much as it can," Berman said.

Lindblom, who worked at FDA from 2014 to 2016, noted that all proposed FDA regulations must be reviewed by the White House's Office of Management and Budget, which assesses their economic impact. Lindblom says that during his years at the agency, White House staff repeatedly called the FDA with concerns that echoed those of industry.

"It was clear that these were questions right out of industry's playbook," Lindblom said.

Perhaps the biggest regulations finalized under Obama were rules that expanded FDA's oversight to newer tobacco products, including electronic cigarettes, which the agency is still trying to implement. Other agency initiatives, including scrutinizing the harms of menthol cigarettes—used disproportionately by young people and

minorities—were derailed by industry challenges.

Meanwhile, tobacco companies have their own grievances. The 2009 law offered industry the unprecedented opportunity to win FDA clearance for "reduced risk" tobacco products, which would be federally endorsed as posing lower risks to tobacco users. The FDA has yet to grant any such request.

In this Monday, June 22, 2009 file photo, President Barack Obama, joined by members of Congress and others, signs the Family Smoking Prevention and Tobacco Control Act, during a ceremony in the Rose Garden of the White House in Washington. "The decades-long effort to protect our children from the harmful effects of smoking has finally emerged victorious," Obama declared in a speech before signing the measure into law. (AP Photo/Pablo Martinez Monsivais)

"They are still establishing the rules of the road, but there has been some progress," said Joe Murillo, a vice president with Marlboro-maker Altria. The company is awaiting an FDA decision on whether it can market a heated tobacco product called iQOS—made by Philip Morris International—as less harmful than combustible cigarettes.

Under the Trump administration, former FDA commissioner Scott Gottlieb kicked off his tenure with the goal of making cigarettes less addictive by drastically cutting their nicotine content. He also rebooted the agency's effort to ban menthol flavoring in cigarettes.

But he spent most of his time at the agency responding to an unexpected explosion in e-cigarette use by teens.

Gottlieb left the FDA in April shortly after proposing new restrictions on retail sales of e-cigarettes. That regulation has not been finalized and is expected to face legal challenges. And the FDA has yet to introduce a concrete plan for cutting nicotine in cigarettes, but says it is on track to publish one later this year.

Matthew Myers of the Campaign for Tobacco-Free Kids says the FDA is at a "crossroads" that will largely determine whether tobacco regulation is ultimately successful. Among other decisions, he points to an upcoming deadline to begin reviewing the health effects of e-cigarettes.

"FDA has sitting before it now decisions of such importance that they will impact tobacco control and public health for decades to come," Myers said.

This March 28, 2019 photo shows cigarette butts in an ashtray in New York. A decade after President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act into law in 2009, health advocates say the Food and Drug Administration has yet to put in place the most sweeping changes envisioned by Congress. (AP Photo/Jenny Kane, File)

But he isn't waiting to see what FDA does. Earlier this summer Myers' group and six others successfully sued the agency to move up its deadline for reviewing e-cigarettes to May 2020.