

# Q&A: How the FDA can help more people stop smoking

May 3 2023, by Joshua Sharfstein

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Although smoking rates have decreased in the U.S., more than 30 million people continue to smoke, resulting in nearly half a million deaths each year.

Many people who smoke want to quit, but the available FDA-approved products for smoking cessation—like [nicotine patches](#) or gum—don't work for everyone. In a recent commentary in the *New England Journal of Medicine*, tobacco policy expert Joanna Cohen, Ph.D., MHSc, and colleagues call for the FDA to take steps to bring more smoking cessation therapies to the market.

In this Q&A, adapted from the May 1 episode of Public Health On Call, Cohen, director of the Institute for Global Tobacco Control, talks with Josh Sharfstein, MD, about why new therapies are needed and where to find evidence to support their use.

## **Let's start with where things stand today with tobacco use.**

Most of us have been affected by the death of a family member or friend as a result of smoking tobacco products. In fact, one in eight U.S. adults smoke. That's over 30 million people in this country, and the highest prevalence is among some groups that are affected by the greatest health inequities.

Over two-thirds of people who smoke cigarettes want to quit, and over half try to quit each year. The problem is that less than one in 10 people who try to stop smoking quit successfully.

## **Is it true that the rates of smoking have come down over the last few years?**

We've made a lot of progress. And it's particularly exciting to look at the [smoking rates](#) among [young people](#), and they continue to decrease. They are at record-low rates right now. We're pleased that our interventions and policy work have really made a difference.

**But at the same time, there are a lot of people still smoking and addicted to nicotine, who want to quit but can't.**

That's right. We know that any behavior change is difficult, but it's especially so when addiction is involved. We currently have three different kinds of approved smoking cessation therapies—nicotine gum, patches, and some medicines—but no new treatment has been approved in the past 17 years. While these therapies do improve the likelihood that you'll quit smoking, the effectiveness could be much higher.

They do help, and people who are trying to quit should try those first, because they are FDA-approved therapies. They will make a difference, but not for everyone, so we're hoping that the FDA can encourage the development and approval of more therapies to help people quit smoking.

**What about electronic cigarettes? Some people are using them to try to quit.**

Electronic cigarettes can certainly go through the process of approval through the FDA to be a smoking cessation therapy, and my colleagues and I encourage that in our new article.

[The most recent Cochrane Review](#) says that electronic cigarettes are more effective than nicotine replacement therapy at helping people quit based on a handful of studies. But there's still more work to do on these products. There's a whole range of products out there, and what we want to learn is, which ones are best at helping people quit smoking? How do you use them appropriately? And then they should be going through the FDA review process to get approved to help people quit.

## **Why go through the FDA review process if people can just get them today in any gas station?**

First of all, too many people are getting them today in the current regulatory environment, and particularly people who don't use tobacco products are using them at high rates, including youth. And we see that even, you know, a significantly high proportion of adults who are using e-cigarettes never used any [tobacco products](#). We definitely don't want that situation to continue. The only people who should be using e-cigarettes are cigarette smokers who are trying to quit smoking.

There's such a variety of products out there, and they all have different nicotine concentration and deliver nicotine in different ways and at different rates. We want to learn which products are most effective to help people actually quit smoking. And we want to make these products available just to those people who are trying to quit smoking, and in a way that informs them how to use the product in the most efficient way to help them quit. Then, eventually we want to help people get off the [electronic cigarettes](#) because it still involves a nicotine addiction. But at least getting off cigarettes is the most important step.

If these products can get FDA approval, I think clinicians will be much more willing to recommend them to their patients. There's also the possibility that these products will be covered by insurance, which will probably help get them used more widely. And people want to know that the products that they're using are going to be effective. For all those reasons, getting FDA approval as a smoking cessation therapy is absolutely beneficial.

**Your article talks about the two parts of the FDA. There's the Center for Drug Evaluation and Research, which looks for evidence on smoking cessation. And**

**the Center for Tobacco Products oversees the market, which includes these products that you can get today.**

We are in an Alice-in-Wonderland topsy-turvy regulatory space right now: Cigarettes, which are the deadliest form of nicotine delivery, have been subject to limited oversight, whereas products that are marketed to help people quit smoking face far more substantial regulatory barriers. We're calling for the Drug Center to consider how harmful cigarettes are and that we need more therapies that will be acceptable to consumers, so they have a broader reach and have greater impact.

**I have worked with the FDA, and I can imagine them saying that you just have to do a study showing that the smoking cessation device works.**

One challenge is that a lot of these e-cigarette companies can just sell their products to anyone now with almost no regulation. That's obviously a lot cheaper than doing a clinical trial and going through all the hoops of getting approval through the Drug Center.

Also, the Drug Center has been for many years really holding its requirements for safety and efficacy at the forefront, which it should. But in this case, we have over 480,000 people dying from smoking cigarettes each and every year in this country. We have to consider that in the standards we set and the requirements we have for these therapies to help prevent those deaths.

**It sounds like you and your co-authors are calling on FDA to loosen its standards and approve products for smoking cessation that aren't quite as safe as the products that are on the market.**

I wouldn't say they should completely loosen the standards—the products still have to be efficacious. We want them to be even more effective than the therapies currently on the market.

But there are lots of other things the FDA can do. For example, e-cigarettes are on the market, a lot of people are using them, and some of those data we already have could be part of an application for approval, for example.

**Your position and the position of your fellow experts is not likely to make people who are on either side of this long-running debate perfectly happy.**

Well, I do want to say that the agreement reached by the authors of this piece and the accompanying recommendations are coming from public health experts and [opinion leaders](#) whose viewpoints are known to diverge on other important topics. So this piece, I think, is particularly important because it focuses on the need for the Drug Center to step up and do more to help people quit [smoking](#). That represents an area of strong agreement and consensus on actual steps that can be taken from across the field.

**More information:** Neal L. Benowitz et al, How the FDA Can Improve Public Health—Helping People Stop Smoking, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMp2301700](https://doi.org/10.1056/NEJMp2301700)

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