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U.S. Department of Health and Human Services
Food and Drug Administration
21 CFR Parts 201, 801 and 1100
[Docket No. FDA–2015–N–2002]
RIN 0910–AH19

Comment by Dr. Joel Nitzkin, R Street Institute

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments

Acting Commissioner Ostroff:

Cigarettes are the most hazardous and addictive tobacco product. All of the 480,000 U.S. deaths each year attributed by federal authorities to tobacco products are due to a single product – the cigarette. Deaths from all other tobacco products are so few and so hard to discern from background noise that they are not even included in this statistic.

We long have known that those smokeless products that are widely available on the American and Scandinavian markets are, while not risk-free, far less hazardous than combustible cigarettes and likely less addictive. Unfortunately, the Tobacco Control Act, as currently written, deals with smoking as if it were a disease, not a behavior. It therefore dismisses this entire body of research in favor of a process that imposes huge costs to duplicate such research for each proposed new and low-risk product.

The Food and Drug Administration recently issued a request for comments on its proposed clarification of when products made or derived from tobacco are regulated as drugs. This proposed rule, Docket No. FDA-2015-N-2002, provides the clearest picture to date as to why seven years of FDA regulation of tobacco products has been a study in frustration for all involved.

Such clarification is needed for manufacturers of e-cigarettes and related vapor products to understand what the FDA would accept as evidence of public health benefit. Demonstration of such benefit is required by the Tobacco Control Act for a premarket application to be accepted by FDA.

According to this "clarification," a tobacco-related product can be either recreational or medicinal. It can provide enjoyment for the user or help the user quit smoking. It cannot do both.

Herein lies the rub. Since the law requires that any new tobacco-related product be beneficial to public health, and the only likely benefit is to help a smoker reduce or quit smoking, it's not possible for any tobacco-related product not licensed as a drug to be approved. This flows necessarily from the FDA's

characterization of smoking as a disease, not a behavior. A product intended to treat a disease must be licensed as a drug.

There is nothing in the law or the clarification statement (filling 24 pages of the Federal Register) that points out any other possible public health benefit that might be accepted by the FDA as fulfilling the requirement for public health benefit. Thus, despite a lengthy description of the application process for a new tobacco-related product, one is left with the impression that there is no way, under the Tobacco Control Act, for the FDA ever to approve an application for a truly new and innovative product.

Even a product approved by the FDA as lower in risk than cigarettes cannot claim that it would help a smoker reduce or quit smoking without being licensed as a drug. Such products can claim less harm, but cannot claim any public health benefit unless licensed as a drug.

While many smokers are addicted, many others are not. None of the kids experimenting with tobacco-related products are addicted. For them, and even for those addicted, smoking is a behavior, not a disease. Most want to cut down or quit to reduce their risk of potentially fatal tobacco-related illness, not because they see themselves as sick. They seek a consumer product to assist them, not a drug to treat what they do not perceive to be a disease.

From the perspective of manufacturers and users of e-cigarettes, related vapor products and other low-risk tobacco products, any product that is capable of satisfying a smoker's urge to smoke will result in smoking fewer cigarettes and move the user in the direction of eventual cessation. How could it be any other way?

Public health authorities castigate e-cig manufacturers and vendors for using the same marketing techniques previously used by cigarettes. But so long as they are prohibited by law from telling the truth to consumers about the far lower risk posed by e-cigs, how else could they market their products?

When dealing with a disease, a randomized controlled trial is the gold standard. This research design presumes the only important factor is the chemical profile of the product. It assumes that behavioral, social and economic factors have nothing to do with the efficacy of the product.

However, when dealing with a behavior, open population studies are far more pertinent. The FDA does not accept these as evidence of efficacy because the FDA considers smoking to be a disease, not a behavior.

In implementing the Tobacco Control Act, the FDA also has demonstrated hypervigilant attention to preventing teen recruitment to tobacco use. For example, each premarket applicant must show their product will not attract teens, which requires proving a negative, with the already skeptical FDA judging whether the proof is sufficient. Ironically, a strong case can be made—primarily from federally sponsored survey data—that the most substantial public health benefit of e-cigarettes and related vapor products is in diverting teens who otherwise would have become lifelong smokers to a nicotine-free life. Since there is no way that such benefits can be demonstrated by means of a randomized case-control study, it seems unlikely the FDA will ever approve a product for this reason.

We need effective FDA regulation of all tobacco-related products to protect consumers against poorly made products, contraband and predatory marketing. We need such regulation to assure accurate information to consumers as to the risk and potential benefits posed by each type of product.

What we have instead is a system designed (if not intended) to keep new products off the market and to prevent anyone from claiming reduced risk or efficacy in smoking cessation, no matter how strong the evidence from behavioral and population studies. The current system protects big-tobacco cigarette companies and big pharma. It does not protect the public health.

From my perspective as a public-health-physician, what we need is a bill that recognizes level of risk by class of product and encourages innovation and reductions in risk. Helping a smoker quit should not be defined as treating a disease, just because some drug companies opted to market their nicotine products as drugs 40 years ago.

Making these things happen, and opening American tobacco-control programming to the public health benefits that e-cigs and smokeless tobacco products can offer, will require amendment of the Family Smoking Prevention and Tobacco Control Act and FDA willingness to reframe smoking as a behavior, not a disease.

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