How to Use FDA's nicotine reduction proposal to save the most lives?

What Is and/or What Should be the Role of ENDS?

FDLI

October 20, 2017

1.The Need for a Comprehensive Approach with Clear Goals

FDA's Goal should be to reduce the death and disease caused by tobacco use. This requires a comprehensive approach

- Policies related to potentially less harmful tobacco-nicotine products need to be evaluated within the broader context of:
  - What is FDA doing to reduce the use of the most harmful products
  - What is FDA doing to accelerate the use of products that help smokers Quit
  - How Should FDA Use its Authority to Best Accelerate Progress

Two Key Components to a Comprehensive Approach

1) Accelerate the reduction in the use of tobacco products that cause death, including, but not limited to cutting the level of nicotine in cigarettes to minimally addictive or non-addictive levels and

2) Develop a more robust strategy to assist current smokers to quit the use of tobacco products entirely and for the subset of smokers unable or unwilling to do so in the near term, to determine whether there are less harmful nicotine products that help smokers to switch completely to those products.

How Do the Answers to the Question Posed Today Fit Within That Framework?

The Continuum

For the first time FDA now has authority over ALL nicotine containing products, across the agency. It should exercise that authority to:

1. Place the greatest barriers to those that cause harm, expand the market and serve no public health benefit
2. Create the smoothest pathway for those that help people quit all tobacco products.

This Requires an Approach that involves FDA's Authority Agency Wide

2. Prioritize FDA's Authority to Reduce Use of Combusted Tobacco

- Nicotine Reduction is potentially transformative BUT it must be a complement to, not a substitute for bold action to reduce cigarette use
- Tobacco Companies have not changed despite their rhetoric – Menthol; graphic warnings, flavored cigars, high TSNA smokeless, new variations of current brands – all are issues FDA Must Address

FDA must not put all of its Eggs in One Basket

3. Also Prioritize Cessation

- A comprehensive approach needs to place a priority on Quitting – the goal should be to help people quit or provide a path to quit
- CDER's approach must be transformed
- Top Priority should be given to fostering innovation in products and use of products that are effective in helping smokers quit – a greater priority than MRTP
- Fast track; post market surveillance; review of how best to use a product

4. Where Does Harm Reduction Fit in the Overall Picture?

If the evidence demonstrates that some ENDS reduce the death toll on an individual and population basis, FDA should adopt policies to move smokers

- who can't or won't otherwise quit, or,
- as Dr. Warner states, otherwise will quit in the future but not for a long time

to *ENDS products that have been shown to Be Less Harmful and help smokers switch* –

ENDS that don't lead to quitting or switching violate the public health standard

- For any ENDS product to have a positive public health impact, there must be sound science that it leads to quitting or switching
- Some e-cigarette makers use the same marketing practices the tobacco cos. used for decades to attract kids to smoking
- Some use sweet, kid-friendly flavors with names like Cherry Crush, Chocolate Treat, Cotton Candy and Gummy Bear

Not only should these not have the benefit of Fast Track, they should not be allowed

5. Regulation Is Needed to Foster Innovation

While some express the view that innovation is fostered by a lack of regulation, the experience to date leads to the opposite conclusion. The absence of regulation has:

- decreased the incentive to do sound science,
- made it harder to get the information to guide good policy and smart consumer decisions,
- Enabled products that produce no measurable benefit to prosper and dominate

The Unregulated Free Market Has Slowed Progress

6. Be Wary of Simple Solutions

- It is easy to say – provide consumers with truthful information. But the tobacco industry has mastered the art of providing technically factually accurate information that leads consumers to misperceive risk and take actions that are harmful.
- There is a science to risk communications and FDA's statute instructs FDA to understand how the information it provides will be understood and used.

FDA/CDC Education Role

- FDA should not fall into the false trap of allowing companies to make relative risk claims outside of Section 911
- However, FDA and the CDC both have the ability to run public education campaigns that are truthful, informative and based on sound communications science that tracks how consumers perceive and understand the information communicated

7. ENDS are not a Product, but a Product Category

Not all ENDS are created equal.

- It is necessary to stop making broad categorizations and scientific conclusions about a product category whose benefits, uses and risks vary widely.
  - Treating all ENDS alike is bad science
  - Treating all ENDS alike undermines useful communication
  - Treating all ENDS alike creates a disincentive for innovation that promotes public health

8. There is No Magic Wand

ENDS may or may not help, but they are not a panacea

- Best British data shows ENDS to be about as effective as Chantix
- Publication by American Cancer Society shows ENDS more effective than placebo e-cigarette and slightly more effective but not statistically different than the patch

In the absence of Government oversight, many who try ENDS quit in frustration because there is no way for consumers to know which are most effective

Conclusion

This is not a debate about whether harm reduction is good or bad – it is about how to maximize the benefits and minimize the risks

- It is not a debate about kids v. adults –FDA regulation protects both
- The FDA statute has provisions to deal directly with these issues and the flexibility to do so in a way FDA determines will best protect the public health
- The track record of this industry in the US makes the need for regulation clear