The Current FDA Authority Is Necessary to Both Protect the Public and Fulfill the Potential of New Products to Reduce Harm

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Proposals to Curtail FDA’s Authority will Undermine Both Goals
Why Is FDA Regulation Necessary

• The Tobacco Industry has demonstrated what happens in the absence of regulation

• In the United States the ENDS industry has engaged in behavior that demonstrates it is equally in need of regulation –
  – Its Marketing
  – Its response to government efforts to regulate
  – Its Products

• It is not just kids who are risk – smokers who want to quit are also hurt
Role of Regulation

The potential value of ENDS is to ameliorate or treat addiction to combusted tobacco products – using a substance that – even less harmful – is not harmless

• Here Government has five roles
  – Regulate for safety
  – Insure accurate information
  – Minimize harm to the non-smoking population
  – Regulate for efficacy

• The goal is objective, independent evidence based scientific oversight
Sec. 904/905 Basic Disclosures Needed to Understand the Products

• Registration and listing - Companies must register and provide a list of their products
• Ingredient reporting – Companies must provide a list of ingredients for products.
• HPHCs – Companies must provide a list of harmful and potentially harmful constituents in each product
• Health Documents – Companies must provide documents relating to research on health, etcetera that they possess or are aware of
905/910 - Product Entry and Changes That Effect Public Health

• Basically the law requires manufacturers to tell FDA what is in the product, what they know about the product and its impact on consumers and how they make it.

• FDA cannot protect consumers without this basic information, nor can FDA evaluate the science related to the public health impact of the product with any less

■ Unless those who will profit from the sale of these products has the burden to provide FDA enough science to make that determination FDA cannot do its job
A Pathway for Responsible Manufacturers

• Reports of ingredients, additives and properties and how the product operates
• Samples so FDA can test and verify
• Scientific burden - Does not require well controlled studies when “there exists valid scientific evidence which is sufficient to evaluate the tobacco product”
Flexible Approach

• To reduce the burden and increase efficiency – FDA created Master Files. Once information about an ingredient or constituent is sufficient others can rely on it

• Protection for small manufacturers in terms of added time and advice

• FDA Regulation does not prevent innovation – but creates a process to channel it for harm reduction
911 - Regulating Health Claims

- Prevent Unproven claims
- Incentive Manufacturers to do the science
- Provide those who are looking for help in quitting or reducing their harm scientifically verified information
Providing a Pathway for Health Related Claims Section 911

• Prohibit claims until science is adequate to reach meaningful conclusions
• Does not prohibit introduction of potentially less hazardous products
• A scientific standard to avoid mistakes but that doesn’t discourage scientific innovation
• Permits comparisons between product categories, such as between cigarettes and other products
• Post-market surveillance
Sec 911 – Modified Risk Tobacco Products

Health Claims

• When a Manufacturer represents that a tobacco product is less harmful than other tobacco products;

What Must Be Shown

• The product, 1) as it is used by consumers, 2) will significantly reduce the risk of tobacco-related disease 3) to individual tobacco users; and 4) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.
The committee’s goal was to develop enduring guidelines and considerations for the production of credible and comprehensive evidence of the effects of MRTPs”.

The committee’s recommendations are designed to articulate the minimum standards for producing credible and reliable evidence to demonstrate that the marketing of an MRTP is consistent with the protection of public health.
Sec 911 Modified Risk Products

Reduced Exposure Claims

- Claims limited to a representation that a tobacco product or its smoke contains a reduced level of a substance, or presents a reduced exposure to a substance --
- the approval of the application would be appropriate to promote the public health
REDUCED EXPOSURE CLAIMS

Basic Test

• scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

• `the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is anticipated in subsequent studies.
Reduced Exposure Claims

Additional Considerations

• the magnitude of the overall reductions in exposure ...is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

• The product as actually used by consumers will not expose them to higher levels of other harmful substances ...;

• `Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful`
Conclusions

• 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