How to Regulate E-Cigarettes? Are we asking the right questions?

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Background Information and Assumptions:

• No conflicts of interest. I was previously the Director of the Office of Policy in FDA’s Center for Tobacco Products and, before that, was General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids.

• The following presentation and its underlying analysis:
  – Assumes only that e-cigarettes are considerably less harmful to exclusive users and exposed non-users than cigarettes and that e-cigarette use causes some significant health harms and risks to users.
  – Takes as its goal maximizing public health gains and minimizing public health harms (especially to innocents).

• By “e-cigarettes” is meant any relatively clean nicotine product that delivers nicotine into the lungs of users without any combustion.

• By “cigarettes” is meant cigarettes and any other similarly smoked tobacco product.
Historically, three major claims or arguments have been made against banning cigarettes or restricting or regulating them severely (e.g., by allowing their sale only in adult-only tobacco shops or minimizing nicotine levels):

- Would prompt large new illicit trade in illegal or non-complying cigarettes
- Would be unfair to smokers. They would have nowhere to go to get legal nicotine they could suck into their lungs to feed their addiction – and desperate smokers would overwhelm available cessation resources and medical care system.
- Would be unfair to cigarette companies by putting them out of business.

Where e-cigarettes are readily available, none of these arguments against strong new cigarette restrictions or regulations work any more (if they ever did).
E-cigarettes are a game changer for more strongly regulating and restricting cigarettes because if cigarettes were banned – or if the nicotine levels in cigarettes were taken down to minimal, non-actionable levels – smokers could still legally obtain e-cigarettes to continue feeding their nicotine addiction by inhaling nicotine into their lungs. That means:

• No risk of smokers being left in the lurch with no place to go. No risk of desperate smokers overwhelming available cessation resources.

• Much less demand for illegal or non-complying cigarettes, which sharply reduces the risk of any new illicit trade emerging (which, in any case, faces substantial practical obstacles in the USA).

• Cigarette companies can stay in business by selling e-cigarettes, instead (and some of the big tobacco companies are already saying they want to shift from selling cigarettes to selling e-cigarettes).
• Because the ready available or e-cigarettes to smokers eliminates major arguments made against much stronger restrictions and regulations of cigarettes, e-cigarettes make much stronger cigarette restrictions or regulations much more politically viable.

• So one would expect that the tobacco control and public health communities would be proposing strong new restrictions or regulations of cigarettes – such as minimizing nicotine levels in all cigarettes – and would be pointing out how the availability of e-cigarettes supports implementing them now.

• But that isn’t happening. And it should.
• Instead, the public health and tobacco control communities are wasting a lot of time arguing about exactly how much less harmful existing e-cigarettes are than cigarettes and arguing about exactly what is going on in the existing regulatory framework with e-cigarette and smoking use perceptions and trends and related cessation, initiation, and dual use.

• But all we need to know to develop effective new policies is that e-cigarettes are considerably less harmful than cigarettes (both to users and exposed non-users) and that e-cigarette use has some non-trivial harms and risks.

• And arguing about e-cigarette and cigarette use, perceptions, trends, and the like might be largely irrelevant because all that could change drastically if new cigarette or e-cigarettes regulations are implemented.
• Moreover, when the public health and tobacco control communities talk about e-cigarette regulation, it often focuses on conflicts over such marginal smoking-to-e-cigarette switching strategies as allowing e-cigarettes to be marketed and sold with many different kid-attracting flavors or allowing e-cigarettes to be used where smoking is prohibited.

• If we really want large, new shifts by smokers to exclusive e-cigarette use or total quitting of all tobacco-nicotine use, we need to implement strong new restrictions and requirements on cigarettes – such as minimizing nicotine levels, sharply increasing cigarette taxes, banning menthol in cigarettes, or banning the sale of cigarettes in all or most locations.

• Just under-regulating e-cigarettes to try to make them more attractive to smokers will not get the job done.
But some say that there is little or no chance, right now, that we can get the kind of strong new cigarette regulations that are needed -- so we need to figure out how to let the market work to get smokers to switch to e-cigs.

- Even if that were true, we still need to be making strong, united e-cigarette-based push for stronger cigarette laws and rules to make them more viable and get them implemented as soon as possible. There is no downside to doing that.

- Hoping that market competition, by itself, will sharply reduce the public health catastrophe caused by smoking (even with weak regulations of e-cigs) could be wishful thinking.
  - The tobacco industry will do all it can to maximize its profits, and that means maximizing tobacco use and keeping tobacco use focused on cigarettes (where it gets its biggest profits and most addicted customers) for as long as possible).

- Even when relying largely on market competition, effective regulation of e-cigs and their marketing is needed to maximize health gains and minimize harms and risks.
What might such a regulatory approach for e-cigarettes look like – that all of us who care about the public health could support? Four suggested guiding principles:

1. Securing a substantial net gain for public health from e-cigarettes is not enough. Goal is to maximize total public health gains while minimizing health harms and risks, especially among youth and those who would not otherwise have been harmed by tobacco-nicotine use except for the marketing and sale of e-cigarettes.
2. **E-cigarettes should be made as minimally harmful and risky as is reasonably possible.**

For example, relatively simple, evidence-based regulations could be quickly implemented to:

- Reduce risks of explosions.
- Require child-proof packaging of nicotine liquids and other components that can cause serious harms.
- Ensure that clear instructions for use and helpful warnings are provided.
- Minimize contamination.
- Prohibit any additives that are toxic or potentially toxic when heated and consumed as an aerosol, unless they are necessary to enable the e-cigarette to serve as a cigarette alternative and deliver nicotine into the lungs of users.
3. The only reason to allow any e-cigarettes to be sold or marketed are either as cessation aids or as harm-reduction cigarette alternatives.

That means that:

• E-cigarette sales should be allowed only to those who can actually benefit from using e-cigarettes (i.e., pre-verified adults who say that they are either smokers or former-smoker e-cigarette users).

• E-cigarette advertising and other marketing should be permitted only through direct communications to those who can actually benefit from using e-cigarettes (i.e., pre-verified adults who say that they are either smokers or former-smoker e-cig users).

[No public health benefits from allowing marketing of e-cigarettes in ways that reaches kids, non-smokers, or former smokers who have quit all tobacco-nicotine use.]
4. Without strong new restrictions or regulation of cigarettes or sharply increased cigarette taxes, no large-scale constructive switching by smokers to e-cigarettes through market competition is likely without communicating to smokers that switching completely to e-cig use will significantly reduce their harms/risks.

For example: For quite some time in the USA, e-cigarettes have been largely unregulated – with little or no taxation, no flavor restrictions, and with e-cigarette use allowed in the vast majority of no-smoking locations. But there has been no major shift by adult smokers to exclusive e-cig use or to quitting all use via e-cigs. Only possible missing ingredient (other than stronger cigarette regulation or taxation) is that there has been no sustained, major reduced-risk messaging to U.S. smokers that encourages complete switching.
How might following these four guiding principles work in USA?

• So long as the current Tobacco Control Act and FDA deeming rule are in place, all e-cigarettes on the market now or that come onto the U.S. market will need to get permissive PMTA orders from the FDA to enter the market and will have to get permissive MRTP orders from FDA if they want to make reduced-risk claims. But deeming gives e-cigs now on the market two years to get such orders before any risk of being pulled from market.

• Any such permissive PMTA and MRTP orders may be granted by FDA only if allowing the marketing of the product or allowing the reduced-risk claim is “appropriate for the protection of the public health” – and FDA can put requirements or restrictions on the orders to make them “appropriate for the protection of the public health.”
That means FDA could readily do the following – without even having to issue a new rule (which can be very difficult and time consuming):

1) FDA announces that (starting in two years) it will allow e-cigarettes on the US market via PMTA only as harm-reduction alternative products for smokers that include the measures listed above to minimize harms and risks. [Or as cessation aids with FDA approval via its drug-approval pathway.]

• This announcement would give e-cigarette manufacturers and importers lots of advanced notice.

• It would make a strong, important statement about how e-cigarettes should be used and by whom (contradicting any views that they are new, fun products for anyone and everyone).

• Allowing e-cigarettes on the market for any other purpose would not be “appropriate for the protection of the public health.”
2) FDA creates a fast track to enable manufacturers to get PMTA orders more quickly and cheaply for clean e-cigarettes that can serve as less-harmful cigarette alternatives if they agree:

- To allow the e-cigs to be sold only to verified adults who formally state to the sellers that they are either smokers or former-smoker e-cig users.
- To advertise the e-cigarettes only through direct communications to adults who say they are smokers or former-smoker e-cig users (e.g., via email, direct mail, social media, or materials provided at retail).
- To offer the e-cigs only in neutral, tobacco or menthol flavors (unless they show that offering additional flavors will produce much bigger switches by smokers to e-cig use without increasing initiation into e-cig use by youth who would not otherwise smoke).

[FDA could establish a similar fast track to speed up approvals of e-cigarettes as cessation assistance products.]
These proposed restrictions on sales and marketing might sound odd – and they would be relatively easy for never smokers to evade (by simply saying they are smokers or former-smoker e-cig users). But:

• The sales restrictions would eliminate any 1st Amendment rights by e-cigarette manufacturers or sellers might have to advertise to anyone other than adult smokers or former-smoker e-cigarette users (thereby making the advertising restrictions much more clearly viable legally).

• The advertising restrictions would prevent publicly visibly advertising (that reaches everybody) and would make it much more difficult to do direct advertising that reaches kids, non-users, or former smokers who have already quit.

• The only people who would receive e-cigarette advertising or make e-cigarette purchases would be those who could benefit from using e-cigarette and those willing to lie explicitly to do so.

• [Similar sales and marketing restrictions could be applied to cigarettes, too.]
3) FDA requires e-cigarette manufacturers wanting to make reduced-risk claims to meet the preceding requirements and either use pre-approved generic reduced-risk messaging provided by FDA or their own reduced-risk messaging if it:

- Is completely accurate and not misleading
- Has no images but just text (except possible for simple informative graphics)
- Includes information on smoking harms
- Says that quitting all tobacco-nicotine use is best way to reduce harms and risks
- Says that harm reductions from switching requires complete switching to e-cigarette with no smoking
- Says that dual use increases harm unless smoking levels are taken down to very low levels.
- Says that e-cig use is not harmless or risk free
- Says that e-cig use delivers nicotine and is addictive
- Provides guidance on how to switch effectively.
In these ways, FDA would be:

- Targeting e-cigarette sales, marketing, and reduced-risk claims directly to those who could benefit from it.

- Reducing exposure to e-cigarette sales, marketing or reduced-risk claims by those who could not benefit.

- Structuring the reduced-risk messaging to work as effectively as possible to promote constructive switching by smokers without increasing reducing or delaying complete cessation.

- Minimizing the risk that the reduced-risk messaging would increase initiation or relapse into either e-cigarette use or subsequent smoking if seen by youth, never smokers, or former smokers who had already quit all tobacco-nicotine use.
This approach by FDA would not only follow the four guidelines outlined above, but would also:

- Allow and encourage constructive reduced-risk-based competition between e-cigs and cigarettes
- Facilitate new innovations to make e-cigarette less harmful and more effective cigarette alternatives
- Make the PMTA and MRTP processes more readily accessible and fairer to small companies.

FDA could readily implement this approach under existing law, under the existing deeming rule. But the amendments to the Tobacco Control Act or the deeming rule that Congress is considering would make it much more difficult, it not impossible, for FDA to do so (and would seriously impede any other efforts to implement reasonable and constructive e-cigarette regulations).

On the other hand, a public health community unified behind the new approaches outlined here could make good things happen much sooner than later.
For more information on the preceding approach to regulating e-cigarettes, please see:


For more on the benefits from minimizing nicotine levels in cigarettes, and the nuts-and-bolts of establishing such a cigarette regulation (in any country), see:


For more related fun: