



Should FDA try to move smokers to e-cigarettes or other less-harmful tobacco-nicotine products and, if so, how?



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Food and Drug Law Journal Symposium: FDA and Health Behavior Regulation

Washington, DC. October 20, 2017



First part of question

Should FDA try to move smokers to e-cigarettes or other less-harmful tobacco-nicotine products?

- *Answer to question as posed: No.*

Important rephrasing of question:

Should FDA try to move some smokers to e-cigarettes or other less-harmful tobacco-nicotine products?

- *Answer: Yes.*



Why?

- E-cigarettes not harm-free. FDA should try to move to e-cigarettes only smokers who
 - *otherwise cannot/will not quit*
 - *otherwise will quit in future but not for a long time*



Challenges

1. Determining which smokers should be encouraged to move to e-cigarettes
 - a. *Precise targeting impossible*
 - b. *Imprecise targeting possible*

2. How (Second part of our question)
 - a. *How to target inveterate smokers*
 - b. *How to move them away from smoking*
 - i. Effectiveness of measures
 - ii. Limit potential adverse consequences





Steps to encourage inveterate smokers to move to e-cigs

- Serious regulation of cigarettes (and other combusted products) to make them less hazardous and/or less appealing; e.g. -
 - *Basics, like prohibiting menthol*
 - *Nicotine reduction (to non-addicting level)*
 - Most radical policy under consideration
 - Potentially most game-changing
 - *Set minimum pH*
 - *Maximum allowable levels of various toxins*



Steps to encourage inveterate smokers to move to e-cigs (cont'd.)

- Revise product review procedures to encourage substantially reduced-risk product (RRP) innovation
 - *Ensure that regulatory burden is not an impediment to novel RRP* (Make individual applications affordable and easy)
 - *Fast track new product/MRTP applications*
 - *Evaluate entire classes of RRP* (like e-cigs) to determine their collective acceptability; then develop specific product standards



Steps to encourage inveterate smokers to move to e-cigs (cont'd.)

- Work with govts. to encourage differential taxation of nicotine/tobacco products based on relative risk
- Marketing restrictions/requirements
 - *Restrict advertising themes/imagery*
 - *Marketing vehicles/targets (e.g., to identified adult smokers only)*
 - *Require RRP's to carry specific messages*
 - E.g., through package labeling, product inserts



Steps to encourage inveterate smokers to move to e-cigs (cont'd.)

- FDA media campaigns
- FDA collaboration with other govt. units and NGOs on their messaging
- Keep all messaging brief, clear



Messages (with challenge of how to convey them effectively)

1. Smoking cigarettes (and other combustible tobacco products) is by far the most dangerous form of tobacco use.
 - *Smoke – not nicotine – is responsible for disease and death.*
2. Most important thing smokers can do is to quit smoking.
3. FDA-approved reduced risk products (if/once approved) are substantially less dangerous to health than is smoking.
4. If smokers can't quit nicotine altogether, they should
 - Try relying on FDA-approved nicotine replacement products.
 - Use FDA-approved reduced risk products, like e-cigs (if/once approved).
5. If they use alternatives, they should try to do so temporarily.



Need for honest, accurate messaging

- Americans deserve clear, accurate information about products they may consume
 - *Informed choice; their health is at stake*
 - *Govt.-disseminated info on smokeless tobacco and e-cigarettes has been misleading, sometimes inaccurate*
- Public's interpretation of "Smokeless tobacco is not a safe alternative to smoking."





Knowledge of risks of smokeless tobacco

Do you believe that some smokeless tobacco products, such as chewing tobacco and snuff, are less harmful than cigarettes?

HINTS Dataset	Display	Mode
HINTS FDA (2015)	Tabulated	Mail

Response	ESTIMATED US ADULT POPULATION		SURVEY RESPONDENTS	
	Number	Percentage	Responses	Percentage
1 Yes	26,613,125	10.9%	445	11.9%
2 No	162,356,089	66.2%	2,444	65.5%
3 Don't know	54,040,392	22.0%	796	21.3%
-9 Missing data (Not Ascertained)	2,156,260	0.9%	48	1.3%
Total	-	100%	3,733	100%

Source: Health Information National Trends Survey , NCI, HINTS FDA, 2015



Perceived risk of e-cigarettes compared to cigarette smoking

Perceived risk	2012	2015
Less harmful	39.4	30.7
About the same	11.5	35.7
More harmful	1.3	4.1
Don't know	47.8	29.5

Majeed et al., AJPM, 2017



What has motivated misleading information about e-cigarettes?

1. Fear that kids' vaping is leading otherwise never-smoking kids to try cigarettes
 - *Meta-analysis of prospective studies of students' use of e-cigarettes and subsequent smoking: Pooled odds ratio for subsequent smoking = 3.62 (Soneji et al., JAMA Pediatr, 2017)*
2. Uncertainty about effect of e-cigs on adult cessation

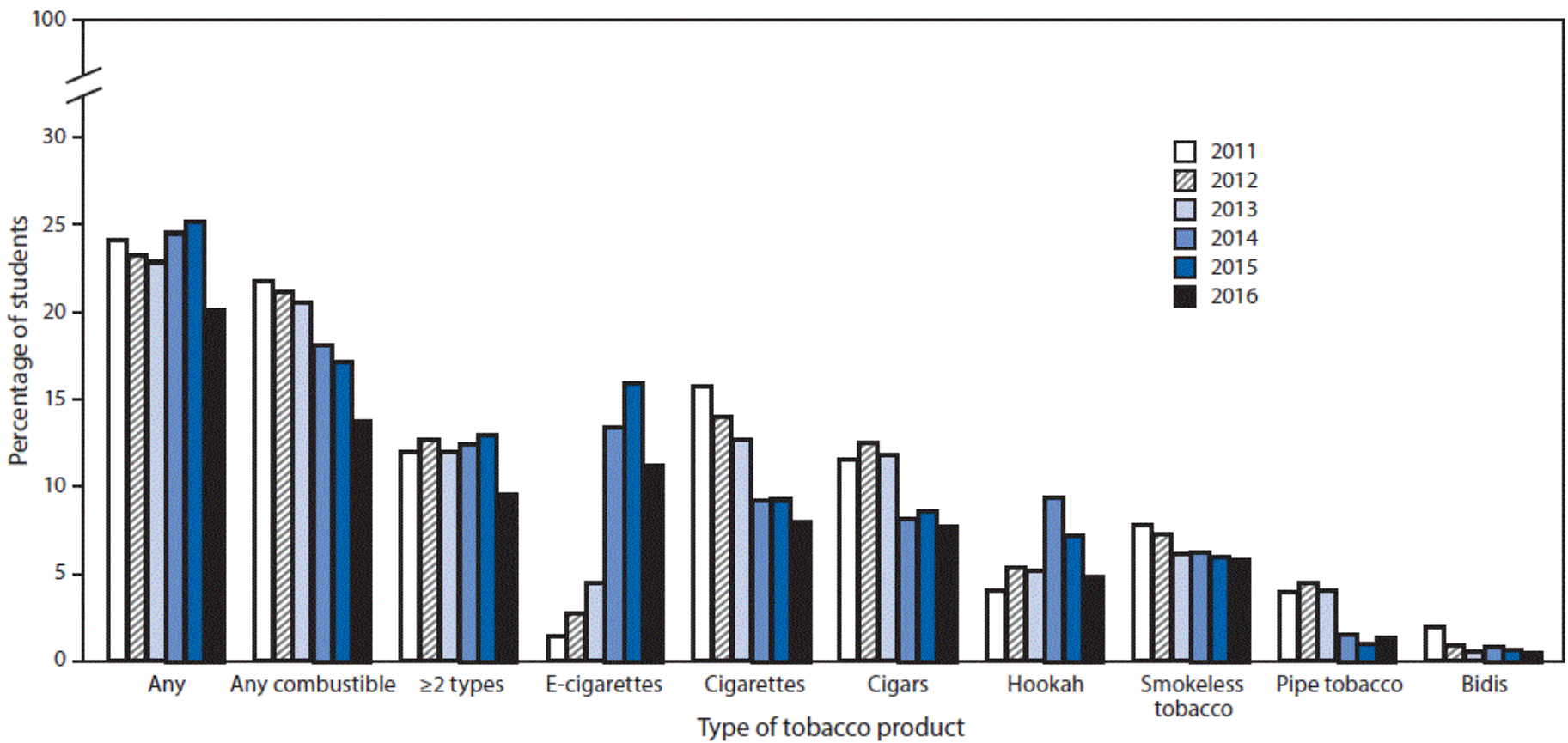


Limitations of prospective studies on never-smoking students' vaping increasing their odds of subsequent smoking

1. How control adequately for fact that vapers are different from non-vapers?
2. Control for use of other psychoactive substances
3. What happens when controls do capture major differences between vapers and non-vapers?
4. Extent of cigarette use at follow-up
5. Small size of some studies



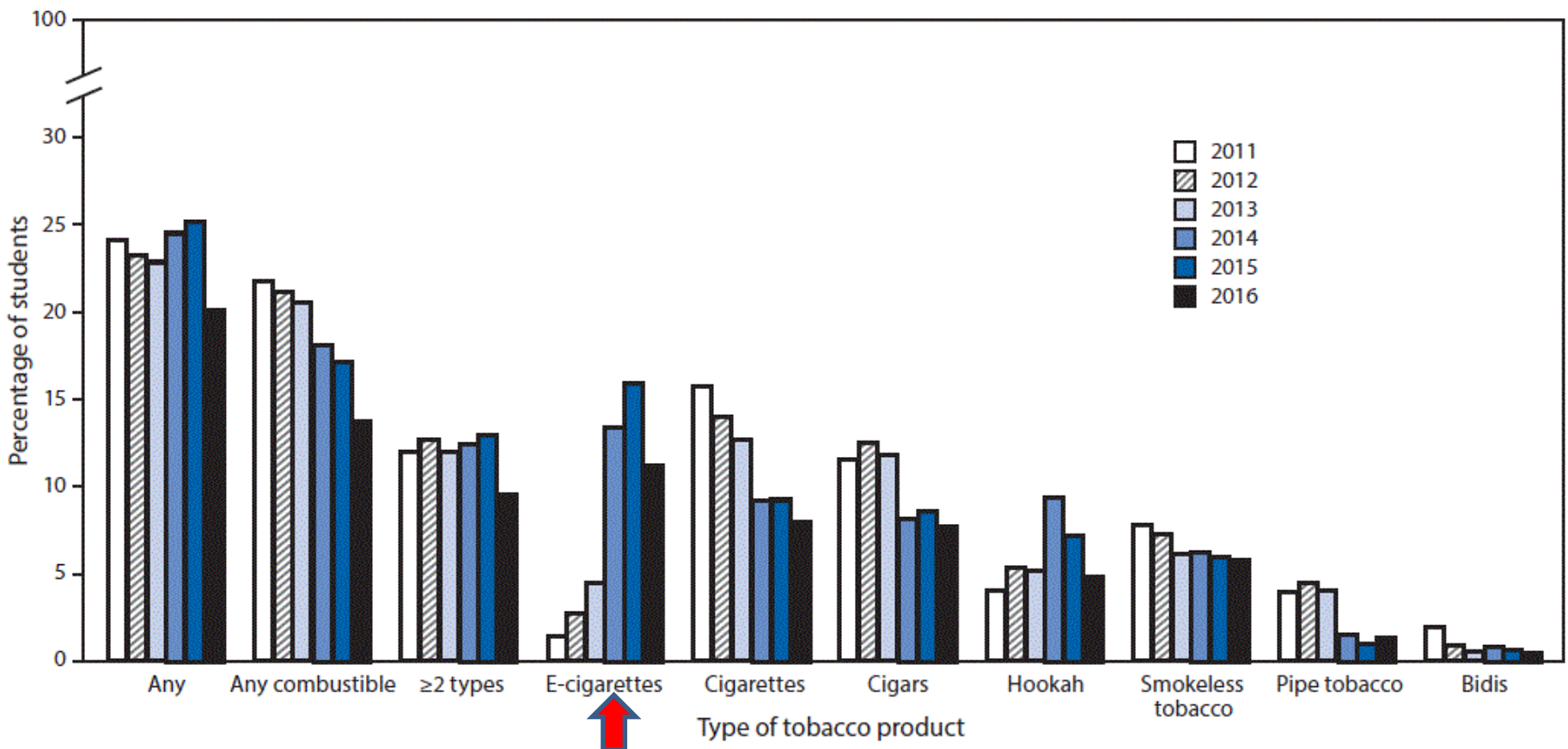
30-day product use by US high school students, NYTS, 2011-2016



Jamal et al., *MMWR*, 2017



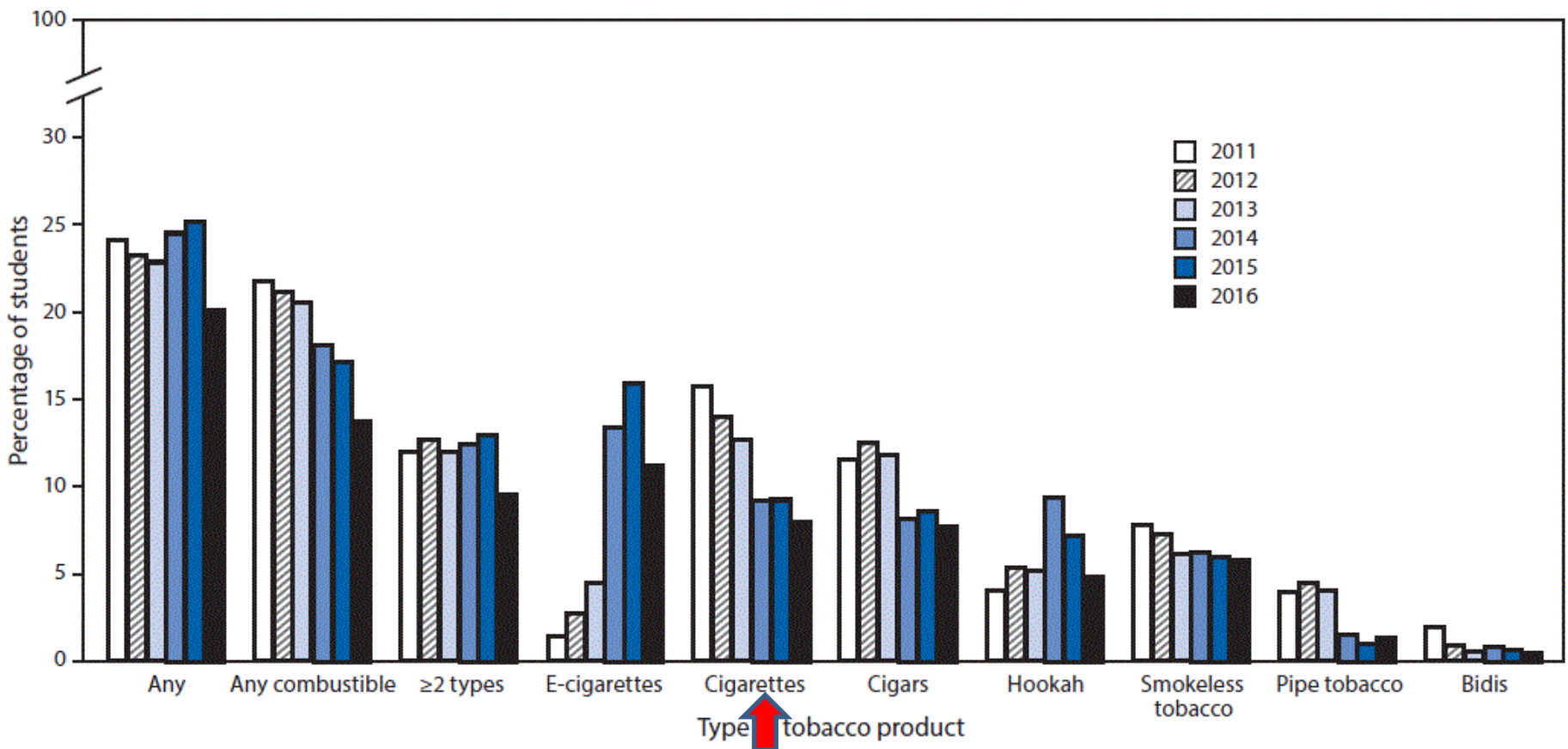
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Jamal et al., *MMWR*, 2017



30-day product use by US high school students, NYTS, 2011-2016



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Never-smoking kids vaping, last 30 days, 2016

- Low prevalence (7.1%)
- Infrequent use (half vaped 1-2 times)
- Few use e-cigs with nicotine (78% flavors only)
- Overall, 30-day vaping dropped >20% in 2016

Monitoring the Future, 2016



Recent studies find e-cigarettes increase smoking cessation

- West et al., *Addiction*, 2016
- Beard et al., *BMJ*, 2016
- Zhu et al., *BMJ*, 2017
- Giovenco and Delnevo, *Addictive Behaviors*, 2018
- Levy et al., *Nicotine & Tobacco Research*, in press



Simulation: Basic assumptions

1. E-cigarettes increase smoking initiation among otherwise never-smoking youth.
2. E-cigarettes increase cessation among adult smokers.





Cumulative life-years saved or *lost* by 2070

Model	Change in life-years		
I = initiation rate increase C = cessation rate increase	<i>Scenario #1:</i> Initiation rate ↑ only	<i>Scenario #2:</i> Quit rate ↑ only	<i>Scenario #3:</i> Both initiation & quit rates ↑
Base case I = 2%, C = 10%	258,359	3,526,607	3,273,771
<i>Sensitivity analyses:</i>			
a. Base case with 25% mortality risk from continued e-cig use	258,359	2,889,012	2,632,006
b. Pessimistic case I = 6%, C = 5%	775,078	1,820,108	1,053,680
c. Pessimistic case with 25% mortality risk	775,078	1,495,986	723,101



E-cigarettes: Bottom line

Potential benefits *much* > potential costs





Thanks