E-Cigarettes, JUUL and the FDA - Seeing Through Smoke and Mirrors

By Chuck Dinerstein, MD, MBA — April 23, 2018

Through education and taxation, the struggle to end tobacco smoking has made tremendous gains over the last fifty years; some believe that we are entering the final phase of stopping the plague. Public health thinking has evolved too, cigarettes are now considered “nicotine delivery” systems and so they have taken on new forms – from the “low to no” nicotine cigarettes, to gum, patches, and vaporizers.

If we cannot end smoking short of prohibition, and we know how well abstinence only works, then we are compromising by containment, reducing harm while promoting cessation.

As a physician, advising patients to stop smoking remains the standard best practice, but for those who find it more difficult to quit addictive behavior, we are more practical and consider harm reduction. Here are my considerations, as a clinician who has spent thirty years talking with smokers about quitting – they make up a large percentage of a vascular surgeons practice, repairing their damaged arteries, saving their legs and trying to prevent strokes.

Cigarettes

Cigarettes produce a mix of toxic combustible products, nicotine is the least harmful thing in them, but for smoking cessation and harm reduction we have to accept that smoking is also a social experience. By social experience I mean that smoking is embedded in the lives of smokers, associated with specific activities, from a cigarette with that first cup of coffee to a cigarette break at work with co-workers. Yes, it is nicotine’s chemical addiction at play but it is also the social experience that make cigarettes hard to quit.
“The scientific evidence is incontrovertible: inhaling the combustion compounds from tobacco smoke, particularly from cigarettes, is deadly.”

That is from the most recent report on smoking by the Surgeon General [2], and it has been stated as such since the time of former American Council on Science and Health advisor Dr. C. Everett Koop. Smoking results in respiratory disease and cancer. That is why I believe that the FDA’s “low or no” nicotine cigarettes are a poor choice. They have not worked well in the past and they carry all the risks of smoking while assuming nicotine is the health problem. Vaporizers that cause the tobacco to smolder rather than burn create far fewer carcinogens, at least 95 percent less. Lower nicotine smoking is not harm reduction. By analogy, this approach is the same as to continue using heroin with the same hepatitis infected needles and syringes, just at a lower dose.

Nicotine

Nicotine, tobacco’s addictive component, acts as a stimulant to our nervous system. In the Surgeon General’s words, “nicotine activates multiple pathways,” and the simplest way to think about its effect is that it activates our fight-or-flight systems. Nicotine makes our heart work harder as it increases our heart rate and the force with which our heart contracts – ready to spring into action. Nicotine heightens our attention and focus – increasing our vigilance. It increases our metabolic rate – providing the energy to fight or run.

Nicotine produces traces of carcinogenic metabolites, but the presence of a pathogen is not pathology and the dose makes the poison so a trace level is not worrisome. That is why we separate nicotine from smoking when it comes to risk, just like we separate spoonfuls of powdered caffeine from a cup of coffee.

“The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to nicotine and risk for cancer.”

The only area in which the Surgeon General found sufficient evidence of deleterious effects were the adverse effect on maternal and fetal health, specifically increased preterm delivery, stillbirths, and impairment of fetal brain development. There was suggestive evidence for a similar impairment of the adolescent brain. As a physician, I do not think that continually stimulating our fight-or-flight systems, being in a constant state of physiologic readiness, is good for our bodies. While the combustion of tobacco injures our lungs, the nicotine delivered impacts our heart and metabolism.

Nicotine gum and patches have much slower uptake of nicotine while the nicotine “rush” from vaporizers is closer to smoking; reducing their addictive potential. That is why vaping is twice as effective for quitting as gums and patches. Vaporizers and vaping also facilitate some of the social framing. Vaping with co-workers on a break looks an awful lot like smoking; it is a lot more social than, do you want to go out and chew gum or put on our patches?
As a clinician my message is loud and clear, stimulants should not be used by pregnant women, and probably shouldn’t be used by adolescents. As a father I am more adamant, nicotine is a chemical whose long-term risks exceed its short-term benefits, it is not something for my children.

But as a practical physician, providing nicotine through gums, patches and vaporizers will reduce the harm from tobacco combustion. If a pregnant woman is a smoker, vaping devices are going to be somewhere in the harm realm of multiple cups of coffee, which I also want pregnant women to avoid, but that's easier to recommend than to implement.

**JUUL, addiction and delivery systems**

After the U.S. FDA delayed what we termed a rather Draconian halt to vaping devices (despite our testimony at the White House) and shortly after the FDA met to consider a non-combustion tobacco alternative called iQOS, quit-or-die smoking groups began to attack a little-known product called Juul, which looks like a USB key and is described as "sleeker" in appearance than the large vaping devices of the past.

Last month, Campaign for Tobacco Free Kids and the American Academy of Pediatrics filed a lawsuit to have FDA impose the old limit, which would effectively ban vaping until groups could go through a new FDA approval. Though most M.D.s recognize that the pharmacologic profile of vaping devices has appeal for smokers who may not be able to quit right now, AAP’s involvement holds a special weight. The American Council on Science and Health has long said that "smoking is a pediatric disease" and if we end it in youth, we will end it overall.

Our approach has worked. Smoking, including by young people, is at an all-time low. Yet we recognize youth is a time for experimentation and rebellion. Authoritarian groups seeking bans on devices like Juul, which as Sally Satel, M.D., notes are just pods containing propylene glycol, glycerol, flavoring, and nicotine salts, isn't going to prevent smoking. It will encourage it. And it is causing young people to ridicule AAP, odd bans based on 'youth are patsies duped by a tiny company' patronization makes them think pediatricians are out of touch. They are making videos strapping Juul devices to balloons floating into the sky with sad music in the background. They are not really getting rid of Juul, they are getting rid of trust that the AAP is about protecting kids.

While it is true we know very little about the long-term health effects of nicotine use by itself and whether delivery through gum, patches or vaporizers makes a harmful difference, we do know smoking kills. Anything that reduces that harm is better than telling people to quit or die.

**Balancing 'Do No Harm' and 'Perfection Is The Enemy Of The Good’**

Here is where I stand as a clinician talking to patients, based on science and experience. It is my judgment and in some ways varies from the official peer-reviewed positions of the American Council on Science and Health.

- Nicotine in any form should not be used by pregnant women or women attempting to become pregnant.
- Nicotine in any form should not be used by adolescents. They do not have the life experience necessary to make an informed consent decision to use nicotine.
- If you want to reduce harm, e-cigarettes are better than cigarettes, they mimic smoking’s
social behavior making quitting smoking easier, but quitting nicotine altogether more difficult.

- Patches and gum have controllable dosages and do not mimic the social aspects of smoking. For some individuals, they may be better at ending the use of nicotine entirely. Statistics show that they have limited success.
- Low nicotine cigarettes are less addictive than cigarettes but are still far more harmful than vaporizers.
- We do not know the long-term effects of nicotine and if creating a frequent state of physiologic arousal violates the concept of everything in moderation.

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