Again, I think these arguments for, yes, they help certain people, well fine, then give them to those people. You can prescribe a vaping product and you can let adults make their own choices, but when we have a tripling, a tripling in just a few years of youth use, this is a national crisis and it must be addressed.

[I] and many people want adult smokers to switch to e-cigarettes but don’t kids on e-cigarettes, and when, when you do something that affects both groups equally, which in the flavors area is, is the case, then you get some benefit but you create some harm.

So, part of the balancing act was saying, okay, here are the flavors and here’s the product form that the data tells us are most popular with kids. We need to do something about that while also preserving adult access to other forms and certain flavors that the data says remain popular with adults.

[ musical interlude ]

Hello, welcome! This is the June 2020 podcast of the American Journal of Public Health. The June issue features the guidance of the US Food and Drug Administration, the FDA, about vaping products. This includes e-cigarettes and other electronic nicotine delivery systems, also known as ENDS. With Associate Editor, Nab Dasgupta, and Student Editor, Steve Fiala, AJPH has organized an experimental forum. We invited Mitch Zeller, the Director of the FDA Center for Tobacco Products, to summarize the guidance and explain their aims and also invited ten comments on the guidance. The experimental dimension of the forum is that we will ask all these contributors a year from now to reflect on their pre-implementation predictions. In this podcast, I review with Mitch
Zeller what is the rationale underlying the guidance emitted by the FDA. I then discuss
with Dr. Rebekah Gee, who until recently was Secretary of the Louisiana Health
Department, her concerns about the severity of the youth epidemic of vaping and finally
with Tom Miller, Attorney General of Iowa. I review how we can reconcile having been
a prominent anti-tobacco actor in the litigations that led to the tobacco industry settlement
of 1999 and now, 21 years later, defend the right of the industry which produces
electronic cigarettes such as JUUL to sell their products.

Everyone recognizes that at least until the Covid-19 pandemic began, we were witnessing
a fast-growing epidemic of vaping among teenagers which in a couple of years went from
12% to 32% of US high school students. I am Alfredo Morabia, the Editor-in-Chief of
AJPH, and we are May 6, 2020. My first guest is Mitch Zeller. He’s the Director of the
FDA Center for Tobacco Products. He’s also responsible for the FDA guidance for
industry. I started asking him why the guidance only came in 2020.

MZ Up until the summer of 2016, FDA didn’t even have regulatory authority over these
products. We now have the full panoply of regulatory tools in place to reduce access to
deal with the marketing to use all of our compliance and enforcement resources and, very
importantly, our public education resources to combat what remains epidemic levels of
kids use of e-cigarettes.

AM Got it, and what would, what are the objectives of the new guidance that FDA has
released?

MZ The guidance that we announced earlier this year eliminated the ability of certain types
of e-cigarettes that were the most popular with kids, based upon the 2019 data, to remain
on the market. Those products had to come off the market, and the only way that they
could come back to the market is if the companies submitted an application to us; and on a pre-market basis, on a case-by-case basis, we made a determination that the return to the market of any one of those products was, in the words of our statute, appropriate for the protection of the public health. We had to remove from the market flavored cartridge and pod-based e-cigarettes, with the exception of tobacco [and menthol], right? Because the data showed that those were the form and the flavors most popular with kids, and again, the only way those products could come back to market is with the burden being on the company to demonstrate to our scientists that a return to market was appropriate for the protection of the public health.

AM And tell me, Mitch, a year from now or two years from now, how could we actually quantify the impact of this guidance on the market and on the youth, the epidemic that’s occurring in the youth?

MZ I don’t know if we will have data that could enable us to conclude the independent effect of a policy. What we will have is nationally and generalizable data that will tell all of us how we’re all doing on combatting the epidemic of kids’ use of e-cigarettes. There are two important annual surveys. One is the National Youth Tobacco Survey; the other is Monitoring the Future. They are normally in the field each year between roughly February and May, and both are school-based surveys—cross-sectional, not longitudinal. The good news is those surveys were both well under way before schools closed and survey collection had to be halted, so we will have an early read in the coming weeks or months on how the whole approach—the guidance, the enforcement, our massive public education efforts, combined with everything else that’s going at the federal, state, and
local level—how we’re doing on the trend, because the trend was all going in the wrong direction for the last two years.

AM And Mitch, what about the impact of the guidance of smokers of tobacco, of cigarettes and the people who use vaping as a way of smoking cessation? What do you expect the impact of the guidance will be?

MZ That’s a really important question, and sort of fundamental to our thinking about what we put into the guidance in January was, what I would call, a public health balancing act. So, let me take a step back and describe the standard that we, the public health standard, that we operate under, under the Family Smoking Prevention and Tobacco Control Act. It is a population-level public health standard. The technical words are appropriate for the protection of public health, but really what it comes down to is a balancing act, sort of the net impacts of policy or marketing authorization. So, part of the balancing act was saying, okay, here are the flavors and here’s the product form that the data tells us are the most popular with kids; we need to do something about that while also preserving adult access to other forms and certain flavors that the data says remain popular with adults. So, it’s, it’s part of this balancing act, preserving at least some access to these products in a properly regulated marketplace where there isn’t targeting of kids in advertising which unfortunately there continues to be, so I would hope that through the policy that was announced in January we will see it is harder for kids to get their hands on flavors and the product forms that are the most popular with kids while preserving at least some access for adults.

AM I then asked Mitch if there was an increased risk of Covid-19 complications in teenagers and young adults.
For kids and teenagers, isn’t the situation different?

MZ It could be. We will follow the science. We will follow the patient histories, we will follow the literature. I understand what you’re saying, but I can’t point to a single piece of data, a single study that establishes that through an analysis of hospital admission records or case reports, but I understand the question and it’s a fair question. Let’s see what the science tells us.

[musical interlude]

AM My second guest is Dr. Rebekah Gee who is with Louisiana State University Health Care Services in New Orleans and served as the Secretary of the Louisiana Department of Health from 2016 to 2020. Her comment is entitled Shortcoming of the Food and Drug Administration Guidance Addressed by the Legislation Passed by the US House of Representatives, H.R.-2339. I first asked for her opinion on the FDA guidance.

RG Yeah, I mean the FDA guidance does not go far enough. Look, we’ve got to limit the flavors in tobacco products and [cigarillos]. We know that persons of color are disproportionately using menthol products. Congress has tried to address that and hopefully will be able to pass, you know, H.R.-2339 which is a bill that would ban nationwide sales of all flavored tobacco and vaping products with few exceptions and address the [cigarillo] issue. But certainly, look, any progress is good if any lives can be saved. We know that the use of vaping products leads to tobacco use. There is no doubt about that. We have a very good study out of Rand Corporation that was released in 2018 that followed more than 2,000 youth in California and completed three surveys over a three-year period. It clearly shows that vaping leads to cigarette use, and this is a gateway product. Nicotine is one of the most addictive substances on earth, and you, when you put
nicotine in vaping products, people use other products with nicotine. So, this is certainly a problem, and when we surveyed our youth, they’re using products like JUUL, they’re widely available. And unfortunately, these products have been marketed to youth, and we also know one thing which is that we cannot rely on the industry that makes these products and makes money off of selling these products to regulate itself. That is certainly—if we haven’t learned that by now, I don’t know what we should learn.

AM Yeah, but Rebekah, there is also all the other sector of the population, all the adult people who are tobacco smokers and for whom it seems that there is a harm reduction in switching tobacco to vaping products. I mean, these are a lot of people, a lot of deaths from cancer and other, and heart diseases, these are people that are often from low/middle class level and so shouldn’t we care about these people too?

RG Of course, yes, and as a practicing physician, I have had these discussions with patients about harm reduction, but what we’re talking about is youth. We know that the vast majority of people who smoke start before the age of 21. We know that nicotine has negative [it] impacts on the prefrontal cortex and the neuronal networks that are still forming in adolescents. We know that this is just simply not good. There is no reason why youth should be vaping or be allowed to buy these things. We know that adolescence is a time when people are still developing their brains, they’re developing their decision-making capacity; some people never get out of adolescence, but you know but we hope they do and as adults if they want to make that decision to smoke that’s their choice. They want to get on a motorcycle, they want to do other things that are dangerous, that’s their choice, but we’re trying to protect youth who are particularly vulnerable to peer pressure, and again I think these arguments for yes they help certain people, well fine.
Then give them to those people. You can prescribe a vaping product and you can let adults make their own choices but when we have a tripling, a tripling in just a few years of youth use, this a national crisis and it must be addressed.

AM And do I understand you well that, are you saying that if vaping products are used as evidence-based tobacco cessation products, then if they were such, they should be sold in pharmacy and should be free for people that are, have insurances and need them. Is this your opinion?

RG Well, I don’t know that we’re saying, that I was saying that you should get a prescription and get them for free. I don’t that the evidence base is there. If it is and evidence shows that they are effective cessation products, then I think that should be looked at. I think what needs to be covered is all evidence-based tobacco cessation products without co-pay. You know, we’ve got to be able to look at, you know, the financial implications of this and make sure that we’re addressing, you know, evidence-based approaches to cessation which, by the way, just really, I think, is in need of more research. We certainly, we have Chantix, we have nicotine replacement products, all of these things are okay, but, you know, there’s got, there needs to be more choices, and as those develop they ought to be covered with no co-payment. In Louisiana, we have the Medicaid expansion that we’re very proud of. People need to have supportive [and] counselling and they need to have tobacco cessation products that are covered by their insurance, and all of these things need to be supported because the cost of vaping and cigarettes on society is just tremendously high. And as a mother of five children and somebody who has three teenagers, I can tell you I, I think that we’ve got to be more aggressive about smoking in our youth. We know that vaping is a gateway to tobacco smoking; there is no question
about that, and that’s, I think, where most of us can agree, let’s protect our youth. You
know, we have a country of freedoms, and if the older adults want to smoke or whatever
they want to do, if it’s legal, let them do it, but we ought to support them in whatever
ways we can to quit and, and if this Covid epidemic doesn’t convince you that your
health is important, I don’t know what would. And so my hope is that people will stop. I
mean, the threat of being in an ICU on a ventilator ought to make you think twice about
putting a cigarette or vaping device in your mouth, I would think.

[musical interlude]

AM  My third guest is Tom Miller who is in his 10th four-year term as Attorney General of
Iowa. He’s the longest currently-serving attorney general in the nation. He was a leader in
the multi-state settlement agreement that resulted in the tobacco industry paying billions
of dollars to states. I first asked him how come 20 years after the settlement, he became
convinced that vaping products and their producers like JUUL were worth defending.

TM  It became fairly clear to me that we could save millions of lives if large groups of
Americans switched from combustibles to e-cigarettes, and you know in a career like
mine and in most careers, your ability to be part of an effort to save millions of lives
doesn’t come along very often. The numbers were dramatic, and currently there are 34
million American adults that smoke. If they don’t quit, 17 million of them will die from
tobacco-related disease. So, that’s, that’s what drives me, the opportunity to be part of an
effort to save millions of lives, and indeed a million lives may have been saved already.
There’s, there’s credible estimates that three million people have switched from
combustibles to the e-cigarettes already, and a number, and a number have switched, and
the best is of course, is a number have switched from e-cigarettes to combustibles to nothing to no tobacco. That’s, that’s, that’s the, that’s the best scenario.

AM But you know the counter argument, General Miller, that the same time period there’s been, what they call an epidemic of vaping in the youth that move, you know, from maybe 10% to about one-third of young people actually being potentially addicted to nicotine, and this was not a form of harm reduction, the opposite. So, how do you react with respect to this situation?

TM Well, none of us foresaw the, the incredible increase of kids, young people using e-cigarettes, and you know, that’s the unintended consequence of harm reduction and this concept. So, you know, like everybody else, I, I’m very concerned about kids using e-cigarettes. I’ve been out talking to them in Iowa, and you know it is, it is very prominent. So, you know, I think we should do everything we can to keep kids from e-cigarettes and have joined in the effort to, to do that. One of the reforms that I’ve advocated and many have is moving the age from 18 to 21 and then any enforcement in regard to marketing to kids is real important, dealing with the retailers that sell to underage kids is real important. You know, in a way, we’ve been here before with combustibles and kids. In fact, it was considerably worse, and one of the great success stories is the dramatic reduction of kids’ use of combustibles. One way to look at that is that, according to the Monitoring the Future Survey done by the University of Michigan, I think it’s a year or two old now, that for kids in the 8th, 10th, and 12th grades, those who were frequent users which is the most concern, it was 2%. So, you’d have to find, you’d have to round up 50 kids to find one that was a frequent user. The drops have been dramatic, so you know we can learn from there.
AM  So what about the guidance that was released by the FDA earlier this year, you know, banning all flavors but menthol and tobacco? Do you think this goes in the right direction?

TM  Well, you know, it’s, it’s pretty complicated and pretty nuanced, and you know I think, I think, you know, you folks in public health should do a good analysis to see, you know, how this works. The problem is that, you know, you want or at least I and many people want adult smokers to switch to e-cigarettes but don’t want kids on e-cigarettes. And when you do something that affects both groups equally, which in the flavors area is the case, then you get some benefit but you create some harm. And so, we’re going to have less adults switching; we’re going to have less kids using e-cigarettes. So, it’s, you know, it’s part good, part bad, and you know I think a good analysis as to what happens in both groups makes sense. And again, it, and also it may be a good strategic retreat in the sense of those of us in harm reduction that kids have used e-cigarettes way too much, and if this, if this reduces it, it may well be worth it. We may reach short of an equilibrium where we have e-cigarettes with only the menthol flavor and maybe even ultimately it’ll be only the tobacco flavor. Maybe that’ll work, maybe it won’t in terms of, in terms of public health. You do have to keep in mind that there’s the remarkable study in mathematics done by Ken Warner and his colleague, David Mendez that basically shows that whenever you do something that affects adults and kids on e-cigarettes in an adverse way to reduce the usage, you commit public health harm because you do more harm to adults than you do benefit to kids. And the reason for that is that there’s so many more adults at risk than kids, and with adults you’re talking about death; with kids, addiction. We hate to have kids be addicted, but that’s not as bad as death. You know, keep in mind
that the combustible cigarette is the worst consumer product in the history of the world. It’s a product that is, has all these health risks and death and it’s enormously addictive. There is nothing before or since that has the danger, the evil of the combustible, and it’s not likely that the e-cigarette, which has been around for a while, we know quite a bit about it, is going to rival that in any way.

[musical interlude]

AM Alright, the overall picture that emerges from these interviews is that there is a fundamental dilemma underlying the establishment of a public health policy with respect to vaping products. On the one hand, current cigarette smokers who switch to e-cigarettes may reduce their risk of dying from tobacco-related diseases, and the numbers of potentially prevented deaths from cancer, pulmonary, and cardiac disease would be in the millions. On the other hand, we are witnessing a fast-growing epidemic of high school students vaping regularly. It is estimated that five million US middle and high school students are current vapers and nearly one million students are daily vapers. Each one of my three guests has a different solution to the dilemma. For Mitch Zeller, the ban of all flavors but menthol and tobacco flavor should still offer an alternative to cigarettes to current cigarette smokers, and at the same time it should make e-cigarettes less attractive and less fun to use. Dr. Rebekah Gee considers that if e-cigarettes are smoking cessation tools, they should be evaluated as such and eventually prescribed to allow cigarette smokers to quit, but otherwise they should not be sold over the counter in order to make them less accessible to young people who are non-smokers. Attorney General Tom Miller considers that reducing the harm caused by cigarettes is a unique and massive public health opportunity that is achievable with e-cigarettes and that harm reduction
supersedes all the risks associated with nicotine addiction among teenagers. It should therefore not be jeopardized by bans on e-cigarettes, but it should be complemented by specific laws protecting younger persons such as a minimum age of 21 and an evolution towards a single flavor, the so-called tobacco flavor. Hopefully, evidence will help us decide between these opinions. The two stats that we will be monitoring are the prevalence of smokers and the prevalence of vaping in youth. Everybody agrees that the goal is to see both prevalences decline in the coming months. A continuing big unknown is whether the long irritation provoked by the inhaled content of e-cigarettes increases the risk of severe complications from Covid-19. We will surely have evidence about these two in the coming months. The jury’s still out, stay tuned.

I’m grateful to all my interviewees for their time and willingness to share their ideas. I also thank Emily D’Agostino and Michael Constanza for comments and edits on an earlier version of the podcast. Francis Jacob paraphrased a rock song about smoke which conveys a message of hope that, if I may say, vaping won’t burn our youth to the ground.

This is Alfredo Morabia at AJPH. For more podcasts including podcasts in Chinese, visit us at www.ajph.org or subscribe to it on your usual podcast app. A full transcript of the podcast is available on the AJPH website for persons with hearing disabilities. That’s it, thank you for listening!

[musical postlude]