



# DESIGNING THE FUTURE OF TOBACCO CONTROL

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# A NEW APPROACH TO END SMOKING

I appreciate the opportunity to discuss emerging issues in tobacco control. The Foundation for a Smoke Free World (FSFW) is prepared to address these, now armed with a [legal structure and preliminary funding of \\$80 million a year for the next 12 years](#).

In the previous presentation at this conference, Mitch Zeller, director of the Center for Tobacco Products at the U.S. Food & Drug Administration (FDA), whom for decades has been a true intellectual leader within the tobacco control world, highlighted an important new vision for tobacco control. It represents a major shift in tackling smoking for the first time in 50 years by fundamentally reassessing the current approach and giving greater focus to regulating nicotine.

**“WE SHARE A COMMON GOAL IN ACCELERATING THE END OF SMOKING AMONG THE ONE BILLION SMOKERS IN THE WORLD”**

We share a common goal in accelerating the end of smoking among the one billion smokers in the world. Without new actions, most of these people are predicted to die from tobacco use this century. That is a number that is simply unacceptable.

Mitch focused very strongly on the twin challenges of reducing the risks associated with smoking and helping smokers quit, while ensuring that kids do not start smoking.

He reminded us that there are [480,000 deaths from tobacco each year in the U.S.](#) Even as the prevalence of youth smoking declines, this number will continue to remain high for decades due to the long latency between smoking and its full health impacts.

The reality of latency is fundamental in how we communicate success in terms of risk, and important in considering long-term strategies for tobacco control. The benefits of quitting smoking or switching to reduced risk products will yield outcomes soonest. Slowing youth prevalence will pay off only 30-40 years from now.

Better communication of this dynamic is needed and could be informed by a visually clear roadmap showing which interventions impact early and which take more time to be effective. The FSFW hopes to work with others to develop such a roadmap.

In his talk, Mitch stated: “you all have an equal shot to take part in rule making.” I assume by “all,” he refers to those with the material interest, knowledge, and insights to contribute to tobacco control. This includes academics, scientists from the industries working on ways to reduce risk and improve cessation, government regulators, NGOs and users of tobacco and related products. However, this sharply contrasts with recently stated policies of the World Health Organization (WHO). WHO has increased its exclusionary policies, while the FDA is extending its outreach for broader and wider participation.



## PRIORITIZE SMOKERS

I'm also thrilled to be standing here a year after Attorney General Tom Miller of Iowa spoke at this event. Attorney General Miller has deep wisdom and the ability to empathize with smokers and farmers in ways that so many of us in public health have failed to embrace.

**“WHAT MATTERS IS THE  
REAL PEOPLE, STRUGGLING  
EVERY DAY”**

We can easily forget what tobacco control is about when we only focus on data and laws. What matters is the real people, struggling every day. From a smoker trying to quit a habit they know is going to harm them, or a farmer wondering where their next paycheck will come from.

Miller highlights the importance of communicating the issues at stake. Words matter, not only in rule-making, but also with regard to decisions individuals make: to continue to smoke, or try a reduced-risk product or nicotine replacement therapy.

The lack of understanding about relative versus absolute risk represents a major challenge. Sadly, many in public health leadership positions are signaling inappropriately where risk may be worse, when in reality it isn't, or where there is huge doubt when there may only be modest doubt, or where there may be a lot of benefit when there is none. Promoting doubt promotes continued smoking and its dire consequences.

## DISRUPTION DEMANDS NEW APPROACHES

Let me step back for a bit. I was in Davos last year for the World Economic Forum (WEF) meeting when Klaus

Schwab, chief executive officer of the WEF, tabled his new book, *The Fourth Industrial Revolution*. The book outlines major innovation cycles over time. We're now in this “fourth industrial revolution,” which is characterized by an intense speed of change and progress in information technology and biotechnology across all of the sectors, combining in ways that will change everything: prospects for improving health and the environment, and enhancing social interaction. It will have profound impacts on society and on our ethical, social and legal structures.

We know very well that when breakthrough technologies come, we have to make sure that our ethics and law making are as good as our science. The people who set up the Human Genome Project at the NIH were wise to put in place an [ethical, social and legal framework](#) to continuously assess these issues during the transformation and knowledge of the Human Genome Project.



The FDA's regulation of nicotine demands an equivalent response to address the transformation underway in how we address smoking. Disruptive technology disrupts the status quo and stirs deep emotions that can undermine progress if poorly managed.

This year's Nobel Prize went to [Richard Thaler](#) for his work on behavioral economics. He is the second major behavioral economist to receive a Nobel after

[Daniel Kahneman](#) in 2002. Both recipients remind us how we frequently we act irrationally, often in our worst long-term interest, both as individuals and as societies. They recommend that we consider emotional irrationality when approaching rulemaking and making daily decisions. Perhaps what is needed is a team of behavioral economists led by [Cass Sunstein](#), who worked in the White House to simplify rule-making, to review how behavioral economics could simplify the FDA to ensure that it acts faster to implement more effective ways of cutting smoking.

Every time a technology disruption occurs, people get upset: the Luddites of the 18th century, reactions to GMOs, concerns about driverless cars. What happens first is fear. “Ban it” is the natural response. But for most of these new technologies, the early adopters are finding benefits and helping enable others to share in the benefits. And eventually, if they succeed, scale occurs.

Professor Dorothy Hatsukami, associate director of Cancer Prevention and Control for the Masonic Cancer Center at the University of Minnesota, recently made this point when she said: “the onerous regulatory environment makes it difficult to scale up innovations that may even be working, and act in the best interests of consumers.” Disruptive technologies challenge the legacy and regulatory systems. They were not designed for the speed of change happening today, and they are responding to each innovation cautiously due to no fault of their own.

I wonder what an “FDA 2.0” would look like for accelerated tobacco control? A faster approval process, one that integrates trends in research to better reduce smoking in various industries: tobacco, e-cigarette, pharmaceutical, medical devices, personalized devices, and even the insurance sector. Industries that share a goal of trying to reduce smoking as fast as possible need to be engaged in an integrated way, rather than being subject to a complex and unconnected regulatory process.

The Foundation is ready to foster a discussion on this and draw upon and help bring leaders from oil, gas, transportation and agriculture to give their views about how some future regulatory systems could more rapidly support innovation and detect potential threats.

The PMI pledge of almost \$1 billion U.S. dollars to fund an independent foundation over twelve years has led to many forms of disruption.

Most of the disruption I’m seeing in the early phase is coming from the traditional tobacco control core. Deep emotional issues related to even considering engagement with the tobacco industry, combined with knowledge of past tobacco industry efforts to subvert science have led to early reactions.

These reactions are compounded by WHO’s views on excluding harm reduction from tobacco control. The [2014 WHO report on e-cigarettes](#) stated that while they “may be possibly less toxic, they are unlikely to be helpful aids to quitting.”

The Framework Convention on Tobacco Control (FCTC) Conference of Parties (COP7) in India held a discussion on e-cigarettes in November 2016. A number of governments recommended that the terms, “science” or “science-based” be placed before words related to policy, as a way of determining whether to include e-cigarettes. However, the COP disagreed and ruled against including science and science-based within their [final statement](#).

Instead, they used a statement that said governments may include the following interventions in addressing e-cigarettes: ban import, ban production, ban possession, and tax them. Words matter. In countries with very weak regulatory and scientific capacities, but with access to the media and the most strident tobacco external control voices, it is not unreasonable to read “may” as “should” and proceed to implement bans.

And indeed, bans on e-cigarettes are now in effect in Brazil, Thailand, the United Arab Emirates and other countries. The impact is obvious. Smokers continue smoking, despite most seeking to quit or lower their risk. We should remember many of those countries led the way in promoting needle exchanges to reduce the risks of HIV/AIDS.

## GUARANTEEING COMPLETE INDEPENDENCE

After the announcement of the FSFW, those who oppose harm-reduction, which had nothing to do with the Philip Morris statement, questioned whether the FSFW would be independent of PMI.

[Article 5.3 of the FCTC](#) says governments need to be wary of engaging with tobacco companies. It alerts governments of possible tobacco industry interference in their policy-making process. [The FCTC](#)



[recommends that governments be transparent](#) in dealing with the tobacco industry and its affiliates. The technical wording, though, does not get translated into how Article 5.3 it gets played out. Many key people in tobacco control believe it means: do not engage or talk to any tobacco company or anybody funded by a tobacco company.

A few years ago Dr. Joanna Cohen, professor of disease prevention at the Johns Hopkins Bloomberg School of Public Health, Scott Leischow, professor of health sciences research at the Mayo Clinic, and Mitch Zeller, wrote a [major article](#) spelling out eight criteria to consider in deciding whether an independent entity funded by the tobacco industry could fund academic research.

We have used this criteria as the basis for the FSFW (see chart below). You will find them embedded in several core documents used during the registration of the FSFW as a non-profit entity under Delaware law.

Despite what we believe are reasonable measures to assure our independence, WHO's FCTC secretariat issued a premature view that we are not independent and that there is little evidence to support harm reduction. On that basis, they recommend parties to the FCTC not interact or engage with us. Their statement has been used to justify additional measures, including refusing WHO health and medical journals to publish work by FSFW-supported scientists, and banning those who are associated with the FSFW from attending the World Conference on Tobacco or Health being held in my home city of Cape Town.

WHO is based in Geneva. Twenty minutes away across the French border is the little town of Ferney-Voltaire, named for Voltaire himself. In a quote attributed to him through Evelyn Beatrice Hall's 1906 [The Friends of Voltaire](#), she notes his sentiment: "I disapprove of what you say, but I will defend to the death your right to say it." Pity that those at WHO have forgotten the



power behind these words that underpin progress in science and serve as the cornerstone of democracies.

Professor Riccardo Polosa, director of the Institute for Internal and Emergency Medicine of the University of Catania, recently published [an article on journals rejecting industry-funded science](#), concluding that this practice is unethical because it disfavors the public interest, where the goal is to save lives. I certainly agree, and the FSFW will work extremely hard to promote and expand public speech, debate, dialogue, discourse, and scientific exchange in our work, in exactly this spirit. And we would hope to emulate the leadership that the FDA and FDLI have taken in encouraging open dialogue.

## WHEN THEY GO LOW, WE GO HIGH

When I was in London recently, I saw in a bookshop a new book by a colleague, Phillip Collins. He was the speechwriter to Tony Blair, but I met him while I was working at PepsiCo under Indra Nooyi. His book is about great speeches, and how good quality debate and discourse matters. The title of the book is [When They Go Low, We Go High](#). These were the same words Michelle Obama used when she and former U.S. President Barack Obama faced harsh attacks during the 2016 US Presidential campaign. I hope to emulate that spirit as the FSFW continues its work. In the words of Pericles: “the currency of persuasion in a democracy is not force or authority. It is speech.”

It will take work before people accept that the FSFW is truly independent. We hope to demonstrate this in ways that have been tested in tougher situations. When United States President Ronald Reagan met with Soviet leader Mikhail Gorbachev the stakes were obviously higher. Nuclear war. Reagan was questioned by people in America, “How can you trust Gorbachev?” And [his response](#) was, “We trust, but verify.” And he put in place systems not relying just on trust, but on data, access and reporting.

We will go even further. When U.S. Secretary of State John Kerry eliminated chemical weapons from Syria, and more recently the Iran nuclear weapon program, [he took this concept one step further](#), not only “trust, but verify,” but “verify and verify” through independent oversight, transparency and public reporting.

And so, this is not an issue of trust. This is an issue of defining a way of achieving a goal and verifying results. What I ask you to do is study our plans and let us know what else we might do to provide the needed verification of independence.

**“OUR SUCCESS DEPENDS  
UPON THE TYPE OF NEW  
INSIGHTS WE PROVIDE AND  
NEW ACTIONS WE TAKE”**

Our success depends upon the type of new insights we provide and new actions we take that lead tangibly to the end of smoking. Some early thoughts on these include:

**We need to help people better understand the benefits of quitting or switching to reduced products by age.** If you ask smokers at what age they think they should stop trying to quit, many in their 30s think it is too late. They believe they have been smoking for too long to make a difference. Yet the evidence tells us that if smokers quit at age 50, 55, 60, or 65, there are measurable material gains to longevity and quality of life. We need to better quantify the gains and communicate them widely. This will help smokers quit at any age.

**Policy makers need different types of information.** We need to draw upon work done in other complex areas to develop a visual map of the key drivers and impacts of smoking in ways that helps us lever systemwide change. It has been done for obesity and for the future of food and farming, bringing people from diverse disciplines together to focus on achieving a common goal together and in new ways.

**We need large-scale evaluations of grand experiments to reduce risks associated with smoking.** We understand what the goal is: to achieve the lowest attainable level of smoking by 2050. Millions of people across several countries around the world already use snus, e-cigarettes and heat-not burn products. We must determine the best biomarkers and clinical measures to assess real health outcomes of users at six months, twelve months, one year, two years. And how do we do this by leveraging the very best predictive capabilities that we have against a standardized protocol supported by the FDA? By implementing large-scale studies involving thousands of real users, we can monitor them for hard biological outcomes. We can do that if we put our mind to it, and the stakes are high enough already.

## BORROWING TRENDS IN INNOVATION

New knowledge is critical as technologies emerge rapidly. But without more young scientists from outside of the U.S. and U.K., and from a much wider set of disciplines, progress will falter. I am struck by how few young people are seeking careers in tobacco control. They are seeking careers in new areas of biotech, IT, and media, all which can have implications for the future of innovation in smoking if we frame the opportunity correctly and invest in novel centers of innovation.

We would do well to learn from how innovation accelerated in tackling HIV/AIDS.



At the start of the HIV/AIDS epidemic, we all thought prevention was going to be the solution to stopping the epidemic. But well-educated activists, many living with AIDS, organized and said, “that’s unacceptable” and put pressure on the pharmaceutical industry to say, “Accelerate the pipeline for HIV/AIDS drugs.” And they did. Millions now live with AIDS as a chronic disease because of their efforts.

The most recent [NIH review of the smoking cessation market](#) showed just how tiny the pipeline of innovation is for a condition set to kill one billion smokers this century. That truly is unacceptable. There must be a way of stimulating innovation with public, private and foundation money to accelerate innovation for cessation and for reduced-risk products. We seek your best ideas about how we might foster this, and importantly, where we might invest.

Many years ago, former U.S. President Bill Clinton wrote an article in *Science*. Throughout my career, I have kept a line from his article in the back of my mind: “Brains are globally distributed, their use is not.” Clinton meant we are not taking full advantage of the capacity of people to find solutions if we are only using brains centered in the U.K. and the U.S.

**“THE TRADITIONAL  
APPROACH TO TOBACCO  
CONTROL NOW NEEDS  
NEW MINDS”**

A core function of the FSFW is to strengthen research capacity, tap into those brains, and connect them to find new and innovative ways to make progress. The traditional approach to tobacco control now needs new minds -- people with backgrounds in product science, molecular biology and toxicology, and the full range in between. Also required are behavioral economics – the deeper understanding of individual behavior change – and similar disciplines that go well beyond what is usually put under the category of traditional health education and public health law.

Imagine if we created those centers of excellence? What I seek from you are ideas and themes both for the topics of centers that would have a large global impact, as well as where you think they might be geographically based.

## CONCLUDING THOUGHTS

I have a 14-year old son and wonder how he would perceive the discussion about youth smoking or e-cigarette use.

A child of 14 is not choosing to smoke a cigarette or an e-cigarette only. They have other options to confront: marijuana, opioids, alcohol... or tennis. I'm thrilled my son has chosen tennis. The problem lies in the way many tobacco control NGOs frame their work, assuming that the only thing decision in a child's life is whether to smoke or not smoke. It's a terrible thing if they smoke. But we need to be careful that stopping one habit does not put in place a policy that may push him or her into marijuana or opioids. Some will take up a substance with some addictive propensity.



Aldous Huxley's *A Brave New World* spoke of the so-called "soma," the elusive elixir of life that gives us a neuropsychological lift. Probably 10-15 percent of any population is going to seek that. Some may

obtain it from tennis, others may take it in opioids, some may use nicotine.

The regulator's task is to have a cross-risk perspective to ensure that we are maximizing the welfare of children across all possible risks. I see this as a major flaw in our current regulatory approach to addictive substances.

Finally, the FSFW will focus its work primarily outside of the U.S. and U.K., but will heavily depend upon the science and regulatory excellence of the U.S. and U.K. I hope that the FDA rapidly globalizes its vision and work since that will protect Americans from a continued smoking epidemic in the long run. The more the FDA engages and stimulates other countries to accelerate use of reduced risk products and mediate solutions, the faster we can put a dent in the predicted death toll, and the more U.S. scientists and innovators can engage and prosper globally as they contribute to progress.

The Foundation for a Smoke Free World stands to be a partner in expanding the global reach and vision of the FDA.

It's so easy to roll off the tongue: "a billion smokers," "a billion deaths this century." What I want to know is how would you deploy a billion dollars to remove this from reality?