

# ACSH Invited to White House to Advise on Tobacco Harm Reduction



By Hank Campbell — November 20, 2015



[1][The 40th Great American Smokeout](#) [2] took place on

November 19th, and it was an anniversary worth celebrating; as a nation we've made a lot of progress in curtailing cigarette smoking since the inaugural event was held in 1976.

Smoking uptake has shown a steady decline and many approaches deserve credit for successes that have been made. They include: better health awareness; effective legislative efforts; and smoking cessation and harm-reduction techniques that are far more successful than the "cold turkey" approaches of the past.

But our work is not done yet, so given the American Council's decades-long quest to end cigarette smoking, it is fitting that we spent the day at the White House with the Obama administration, discussing how best to help support the downward trend of cigarette deaths. Specifically, that involves making sure that responsible harm reduction and smoking cessation tools are available to everyone who wants to quit.

The purpose of the visit was to discuss the U.S. Food and Drug Administration's Tobacco Products Deemed To Be Subject to the Food, Drug & Cosmetic Act ("deeming regulations") law, which covers products that contain nicotine. Under a 2009 law, in addition to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, newly deemed products would include electronic cigarettes, cigars, pipe tobacco, waterpipe tobacco and similar products.

That means tobacco products, like pipes, are lumped in with nicotine products like e-cigarettes, which are instead marketed as cigarette harm-reduction. It is the first time they have been

regulated and proponents claim it will eradicate over 90 percent of the market.

But the current situation in effect, no regulation at all, except for some states and localities where childproof liquids or age restrictions, or bans on "vaping" in certain areas have been passed does nothing to address real-world concerns. So the White House asked us to share our insight.

Dr. Gil Ross, our Senior Director of Medicine and Public Health, visited the White House to talk with officials from the FDA, the Office of Management and Budget (OMB), and its Office of Information and Regulatory Affairs (OIRA) group, which was seeking guidance on how the new regulations might impact harm reduction efforts.

The market is growing, so it is true that regulations may impact existing businesses. But companies which have sold products that have manufacturing flaws, that have caused fires, and those with chemical contamination with substances known or suspected to be toxins or carcinogens (mostly in certain flavoring additives), will be the ones that are eliminated. Consolidation will occur, but that is not a bad thing. For example, there were once hundreds of .mp3 player companies but music didn't die when Apple came out with the iPod.

Obviously, that's a simplification and we recognize there is no magic bullet. But we wouldn't want the FDA to only take on the supplements industry after there are dead bodies, and we don't want officials to only take on e-cigarettes after they become even more popular, and people might be harmed by "bad actors" who exploit the lack of standards for financial gain.

In a perfect world, everyone would be ethical, but as we have seen with supplements, bad actors can damage an industry and public health when people assume products must be safe.

The regulatory assessment on small businesses, and the cost-benefit analysis, are separate issues that OMB is considering. We instead care about keeping a harm reduction and smoking cessation tool available to smokers who want to quit. So our specific recommendation was that the "substantial equivalence" date the date at which products could be allowed to continue to exist without going through new regulatory review be changed from early 2007 to the date that OIRA puts its stamp on the new regulations.

It makes sense from a regulatory point of view, though the law was passed six years ago no regulations have gone into effect, and in 2009, a 2007 date made sense. But Uber, Airbnb, Apple and other thriving modern companies could not be competitive if they were hobbled by a 2007 date, and e-cigarettes and other vaping devices are safer now than they were then. The costs to undergo regulatory review because they were manufactured after 2007 would be crippling, and that means people who want to quit smoking would be harmed.

There are a lot of knobs to turn in order to strike the proper balance between limiting one harm and aggravating another. It isn't a benefit to limit use of a product that results in addicted smokers continuing to smoke, because one product that may work in helping them is eliminated. The fact is no cessation tool works very well, so we want them all to be safe and available for people who need to kick the habit. That means reasonable regulation.

We appreciate that the White House asked us for guidance, and administration officials were appreciative of the expertise we brought.

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[1] <http://acsh.org/wp-content/uploads/2015/11/White-House2.jpg>

[2] <http://acsh.org/2015/11/stop-smoking-today-for-the-great-american-smokeout/>