The past is not the future – what lies ahead for tobacco and nicotine?

"Prediction is very difficult, especially about the future" – Niels Bohr, Physicist

Let's have some debate on the future of tobacco, nicotine, tobacco control and the tobacco and vaping industry. Here are three provocative pieces to get things moving.

First, directly below, *The past is not the future in tobacco control*, by pro-harm-reduction veterans of the tobacco wars with a historical perspective ending with four recommendations for a changed approach. I reproduce below the abstract and four main recommendations below and include my comments on the recommendations.

Second, a piece by me, *The endgame revisited*, highlighting the epic confusion of objectives at the heart of tobacco control and looking at where it is all heading – if

everything goes well.

Third, in an email exchange, I was asked and answered the question: *What is going wrong?*. That was also the subject of my 11-minute talk at GFN, so I add the video from that too.

Please give me your views in the comments... if we get a good debate I might make a new blog from it or add them to this blog.

1. The past is not the future in tobacco control

Cummings KM, Ballin S, Sweanor D. The past is not the future in tobacco control. Prev Med (Baltim). 2020 Jun 27;106183. [link][temporary access to PDF via Google Drive]

Abstract

In this paper we have attempted to identify missed opportunities to change the trajectory of smoking and smoking caused diseases in America over the past 100 years. Many of the missed opportunities identified are due to the actions of cigarette manufacturers who misled the public about the dangers of cigarette smoking, the addictiveness of nicotine, and the feasibility of providing lower risk alternative nicotine delivery products to addicted smokers. An important lesson learned from the past is that treating all tobacco/nicotine products as equivalently harmful is counterproductive to public health as it only serves to protect the most lethal nicotine product – cigarettes. Since 2000, the evolving marketplace of lower risk nicotine products combined with regulatory authority over tobacco products represents a new opportunity to dramatically transform the cigarette business in ways that were never imagined when the war on tobacco was raging decades ago. However, this requires embracing risk-proportionate regulation, taxation policies, and providing consumers with accurate public messaging on product relative risks. A regulatory framework based on sound science that encourages and rewards new or existing manufacturers to invest in consumer acceptable lower risk products to replace cigarettes needs to be encouraged. The past is indeed not the future in smoking control, but it may be difficult to escape the past unless a realignment of market forces and policies can be achieved.

The payload of the paper is 4 major recommendations and a summary, which I reproduce below… my brief take on the four follows that:

1. Embrace the Concept of Regulating Tobacco Products Based on the Continuum of Risk

> *Regulating based on the continuum of risk was a major component of the FDA/CTP July 2017 announcement and has conceptually been supported by many in the public health and scientific community, consumers, and even many in the manufacturing sector [44, 78]. As a start, public health organizations should be unified in supporting FDA's logical 2018 plan to establish a very low nicotine standard for combustible tobacco rendering cigarettes non -addictive [44,78, 82]. If this plan were implemented, one analysis suggests that approximately 5 million additional adult smokers could quit smoking within one year of implementation and, over time, more than 33 million people – mostly youth and young adults – would avoid becoming regular smokers, thus avoiding many millions of tobacco -related deaths [82]. Simultaneously public health groups should recognize and support a more flexible and adaptable regulatory framework that that will allow science -based lower risk products into the marketplace more expeditiously, while working to ensure that such products are not available, targeted or used by any children or adolescents.*

Comment on 1. Yes, of course – risk-proportionate regulation is essential and in any other field it would be wholly uncontroversial and the normal practice of regulators (though not always successful). But its supporters including me need to do more to specify what this would look like and how it would address real or perceived problems. We need to understand, in detail, what is behind prohibitions of THR approaches – for example, the EU snus ban. It clearly isn't public health and for supporters of the ban, risk-proportionate regulation is an irrelevance. The alternative approaches [prohibition][medicine][cigarette equivalence] and the justifications for them demand a deeper analysis – because therein lies the barrier to risk-proportionate regulation.

2. Update the Tobacco Control Act

> *It has been over 10 years since the passage of the Tobacco Control Act. The statute needs to be critically reviewed and updated to reflect the changing marketplace of nicotine delivery products. Such review and updating of FDA statutes is routine in other areas of regulation such as foods, drugs, and medical devices. As a follow -up to the Institute of Medicine's 2000 report Clearing the Smoke, public health groups and others could ask the FDA/CTP to*

request that the Health and Medicine Division of the National Academies of Science to do a thorough assessment on how the Tobacco Control Act might be updated to adapt to a rapidly evolving tobacco and nicotine market place [98]. Areas of review might focus on and include:

a) defining common terminologies and definitions that can allow for greater public understanding, and provide consistency in statutory, regulatory, and legal relevance;

b) creating product standards for the various categories of products that includes combustible products, non -combustible tobacco, nicotine products, and other possible alternatives;

c) developing comprehensive labeling, marketing and educational campaigns that would reflect the risks and relative risks of the products both in terms of product categories as well as individual products so that the public, users of products, the medical profession, and others would better understand the risks and relative risks of using one type of product over another; and

d) restructuring oversight of products so that all tobacco and nicotine products are under the same regulatory authorization within the CTP.

Comment on 2. Re-opening the US Tobacco Control Act should only be attempted once (1) has been successful – which probably requires (3) and (4) to work first. The four recommendations would have been better cast as sequential and contingent. As things stand in the US Congress, a new TCA would be even worse than the one there is. Much better in my view would be to persuade FDA to use its considerable latitude in interpreting the TCA to implement risk-proportionate regulation using the existing law. For example, making category-wide decisions about non-combustibles, using more standards to bring transparency and efficiency to the authorisation process, relying more on individual risk for pre-market approval and addressing population risk with post-market surveillance.

3. Support Civil Dialogue on Issues of Smoking Harm Reduction

The current climate in smoking harm reduction has become toxic and emotional, non – scientific, and counterproductive to achieving the public health goal of reducing premature deaths caused by using smoked tobacco (i.e., mainly cigarettes). We are not suggesting that we dismiss the past bad actions of the cigarette manufacturers, nor accept the claims of manufacturers of alternative nicotine products. Rather, we need to heed the lessons of the past so

as not to make the same mistakes going forward. The Tobacco Control Act created a framework that should incentivize manufacturers to move away from profiting from the sale of cigarettes that causes so much harm to consumers. Promoting dialogue summits would allow for participants to engage in a civil manner, educate one another about challenges and opportunities and agree to specific measurable goals and objectives. Bringing stakeholders together will not resolve all differences but it will allow serious and responsible stakeholders the opportunity to bring ideas forward and find areas of common ground that can more rapidly advance population health. As an example, issues and concerns related to adolescent use of tobacco and nicotine products should be a major topic of concern, not only by the public health and tobacco control communities but by federal, state, and local policy makers and regulators, parents and teachers, responsible retailers and distributers, and many of those associated with the manufacturing businesses. While many stakeholders share common ground in this area, the polarizing and media driven approach that has been taken over the last several years has, in our view, caused what has become a war of rhetoric, with a lot of finger pointing and a failure to bring interested parties together to discuss how to collectively deal with the issue and find workable solutions to protect youth while allowing smokers to have access to cleaner alternative nicotine products.

Comment on 3. I do not think the reluctance to engage in civilised discourse is symmetric or the fault of THR advocates. The authors need a better analysis of why this has not happened successfully and inclusively despite many well-intentioned and ongoing attempts. Even attending GFN now is deemed a sign of being a tobacco industry front. In my view, the abstinence-only advocates have worked tirelessly to marginalise and delegitimize pro-THR voices, especially the user community and its representatives. I think the reason is that they know the debate would be unsettling and the introduction of *empathy* into the discourse (essentially the proposal made here) would be destabilising to ideological positions they hold for reasons other than public health. I don't like, but can't help, this negative tone because it's how I see it and feel it.

4. Encourage Collaborative Scientific Research and Product Innovation

It is often said that it should be good science that drives the implementation of sound policies. The FDA/CTP could be doing much more to encourage academic scientists to partner with new or existing manufacturers to advance science in ways that would accelerate the introduction of lower risk products into the market place. All parties and stakeholders should be held accountable to

meeting and following the strictest standards for peer review. There should be greater collaboration and data sharing, and a shared commitment to open science. Science should not be cherry picked for public relations purposes. The FDA/CTP can play an important role in further facilitating such discussions, helping set research priorities which would have a positive impact on the regulatory decision -making. For example, the FDA/CTP could in theory invite manufacturers to voluntarily utilize their peer review system to vet proposals designed to assist manufacturers prepare their PMTA and MRTP applications thereby opening this process , making it more competitive, transparent, and less secretive. Product manufacturers also ought to be incentivized to share their internal research and market data more widely with public health scientists so that there is greater confidence in product claims. The FDA/CTP and other groups can and should do more to hold scientific workshops that allow scientists and researchers to meet in a safe -haven environment and where opportunities would be allowed for seemingly opposing interests to find common ground in areas of science, research and innovation. Innovators of products should not be shut out because some regard them as industry.

Comment on 4. FDA/CTP and NIH could do a great deal to change the culture that its research funding nourishes. But they have not done that. In fact, they have celebrated and lavishly funded institutions and PIs with hard advocacy and unscientific perspectives. It's almost as if as regulator, they are spending money to make the case for regulation and therefore their own pivotal role. Those signals may change with a change of leadership, though I doubt it because the problem-finding incentive structure will not change. Until it does, the scientific community in this field needs to own the problem, to clean house and stop tolerating the tsunami of really poor science that pours out of universities with made-for-media conclusions and press releases.

Summary

In summary, embracing risk -proportionate tobacco product regulation and taxation policies along with providing consumers with accurate public messaging on product relative risks offers the prospect of aligning market forces with public health goals to reduce deaths caused by cigarettes in ways that were never imagined decades ago. A regulatory framework based on sound science that encourages and rewards new or existing manufacturers to invest in consumer acceptable lower risk products to replace cigarettes needs to be encouraged. The past is indeed not the future in smoking control, but it may be difficult to escape the past unless a realignment of market forces and policies can be achieved.

Comments on summary: I agree with much of the analysis and prescriptions, but I fear the authors are trying too hard to frame the problem as a misunderstanding between people with common aims but a different way to go about it. This is commendable, but in my view a departure from a quite nasty and cynical reality – I think a closer look at the incentives and priors of those involved will explain why these perfectly reasonable recommendations have so far and will continue to struggle to find traction. One subject of study that is conspicuously absent in tobacco control is sociological or anthropological research into tobacco control itself – what are its aims and methods? What characteristics predict leadership? What are the attitudes to smokers and vapers? What moral intuitions underpin the work of researchers and activists?

2. The endgame revisited

The endgame revisited, Tobacco Reporter, 1 July 2020 [link]
By Clive Bates

> *It is time to confront the fundamental confusion about the public health aims for tobacco and nicotine policy*
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> *In 2013, the journal Tobacco Control published a supplement, "The Tobacco Endgame," setting out various ways in which various experts thought a tobacco-free society could be attained. Ideas included annually increasing age limits, a cap and trade system, outright prohibition, taking control of the industry and making it put itself out of business, and removing most of the nicotine from cigarettes. In the intervening seven years, most of these ideas have not progressed at all. And rightly so, as I argued in a detailed critique, these policies are mostly impractical or excessively coercive and would fail if tried. The only one that attracted any real interest was the idea of lowering nicotine concentrations in cigarettes to make the product subaddictive (i.e., to eliminate the main reason people smoke). But even this de facto prohibition has not fared well. After backing the idea in 2017, the U.S. Food and Drug Administration (FDA) dropped the reduced nicotine rule from its regulatory plan in 2019. The most senior researchers engaged in the idea recently acknowledged that its viability would depend on the availability of credible safer alternatives to smoking.*
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> *So, all this begs the question, where is the endgame now? Or maybe the more interesting prior question is: endgame for what? What will end and what, if*

anything, will continue? Does the endgame mean the end of tobacco and nicotine use? Or is the endgame, as I believe, the final stages of a transition—a shift from an unsustainable to a sustainable nicotine market?

At the heart of this question is a fundamental confusion about the public health aims for tobacco and nicotine policy. This dispute is rarely surfaced and never resolved but confronting it has now become unavoidable. At least five objectives can be identified in tobacco control: (1) reducing disease and premature death; (2) eliminating smoking and smoke exposure; (3) eliminating tobacco; (4) destroying the tobacco industry; and (5) achieving the nicotine-free society or "ending nicotine addiction." When the consumer nicotine market was supplied almost exclusively by cigarettes, it was possible for activists to say, "all of the above." Activists could get away without having to declare or even recognize their underlying aims or to face the trade-offs and tensions between them.

No longer.

Even in the 1990s, splits in tobacco control were already emerging over snus, an obscure Scandinavian oral tobacco product. The faction interested in reducing disease was intrigued by Sweden's abnormally low smoking rate. Toxicology and epidemiology suggested that substantially lower rates of disease in Swedish men were due to use of snus as an alternative to smoking. For that group, the harm reduction potential of snus had great potential. However, the faction interested in the end of tobacco saw the European Union's ban on snus (other than in Sweden) as a win and incremental progress toward their goal of the tobacco-free society. Thirty years later, snus remains banned in the European Union despite undeniable evidence that snus reduces smoking and by doing so, reduces individual and population harm. This willingness to forego major public health benefits should tell us something fundamental: The dominant tobacco control faction is engaged in a war-on-drugs mission and not, as often assumed, a public health crusade. It is trying to forge a path toward a nicotine-free society with little concern for the collateral damage inflicted to health on the way to meeting its goal.

However, the rise of vapor and heated-tobacco products in the last 10 years means this is no longer a localized conflict. The harm reduction "proof of concept" of snus can now be generalized to an experience much closer to smoking in every respect other than harm to health. Add in the recent

developments in oral nicotine pouches, which will make snus-like products more acceptable to a much larger population, and the diverse portfolio of smoke-free alternatives to smoking is starting to look quite formidable. The products available to nicotine users have changed beyond recognition in the last 10 years. If we project forward through another 10 years or 20 years of innovation in these new categories, imagine how the market could look in 2030 or 2040.

This is the opening phase of the technology disruption now roiling the industry. But it is also disrupting the tobacco control community by surfacing the tensions between its objectives. In particular, we are seeing the goal of the "nicotine-free society" coming to the fore, with an increasing stress on nicotine and the inclusion of goals to end nicotine use or "nicotine addiction" where there was previously an aim to pursue the end of smoking or to prevent disease.

Even many public health supporters of "tobacco harm reduction" see the smoke-free products as an expedient and effective way of helping to stop smoking—a sort of pimped-up nicotine-replacement therapy. And that is a good argument, as far as it goes. But it doesn't really settle the question of our collective attitude to nicotine over the longer term.

To look ahead, let's consider the situation in Norway where daily smoking among 16-year-old to 24-year-old women has fallen from 15 percent to only 1 percent in just 10 years, according to 2019 data from Statistics Norway. Have they stopped using nicotine? No, they have been using snus from the outset. By 2019, daily snus use was at 14 percent in this group. That group is now using nicotine without ever starting to smoke, and they probably never will. Harm reduction supporters argue that this is "a win" for public health because without the use of snus, many of these young women would otherwise be smoking. But how will that argument look in 10 years or 20 years when cigarette smoking may be well on the way to obsolescence?

Here we need to confront the deeper question about nicotine that goes beyond harm reduction in which the cigarette is the reference point for harm. The concept of harm reduction feels unsatisfactory in this context—what if no one uses a harmful product to start with? If there is going to be a long-term market for nicotine, the question becomes how to regulate a recreational nicotine market based on consumer-appealing products with risks that are within our

normal appetites for risk? I believe the product portfolio is now evolving toward how it could look over the longer term—smokeless and electrically heated tobacco and nicotine products. I don't expect the combustible products to disappear but to become a niche interest—like vinyl records in a world dominated by digital music streaming.

For some in tobacco control, this is a nightmare vision. This is not the nicotine-free society that has been their ultimate endgame. But if the harms are not particularly large and the drug is popular, why should governments stop people using it? Drug use is pervasive in human society and throughout history, perhaps started by our hominid ancestors millions of years ago. Nicotine, a relative newcomer, was domesticated between 6,000 years and 8,000 years ago. To say that a drug should be legal and available in relatively safe form is not to endorse its use or somehow to recommend it but to acknowledge that some people may wish to use it, and there isn't a good reason to stop them by force of law. That idea has both philosophical and practical underpinnings. The philosophical foundation recognizes adult autonomy and the right to indulge in risky behaviors that do not harm others. The practical experience of prohibitions is that they do not work (a new supply chain is established by criminals) and cause serious harms to the individual and to wider society.

Prohibition does not even protect adolescents. Despite federal prohibition, past-30-day use of cannabis among U.S. 12th graders has been over 20 percent for at least a decade. The recent U.S. lung injury outbreak that hospitalized 2,800 and killed 689 was largely a consequence of reckless criminal behavior in the illicit supply of cannabis (THC) vapor products.

As a drug, nicotine is relatively innocuous—it doesn't cause serious disease, intoxication, overdose, violence, road accidents, sexual vulnerability, incapacitation or family breakdown. Perversely, this relative safety becomes a serious tactical problem for the war-on-drugs tendency in tobacco control. If the prospects of cancer, lung disease and heart disease are greatly diminished, why should people fear nicotine? It is even possible that more people will take up nicotine if the consequences of using it are much less dreadful—that would be the economist's assumption. Harm (from smoking) is the most persuasive reason not to use nicotine, and that reason is going up in a puff of vapor. In a weirdly inverted way, the greatest threat to the nicotine-free society is the availability of relatively safe nicotine products. I think that explains why so

much strenuous, even desperate, effort is going into finding serious harms in smoke-free products though, beyond reasonable doubt, there are none.

3. What is going wrong?

I'm quite sure that most of the tobacco control community is currently acting in a way that supports the market for cigarettes and is prolonging the epidemic of smoking-related disease. As David Sweanor puts it: they never miss an opportunity to miss an opportunity. Where is the problem?

Candidates for responsibility for the faltering progress of tobacco harm reduction, especially in the United States, are as follows:

- the multi-million dollar campaign against vaping/THR driven by arrogant billionaire prejudices and the ideological preferences of a few high profile activists
- the flagrant bias and deceits of public health agencies like CDC (e.g. over EVALI, popcorn lung, brain disease, youth vaping and SG reports),
- the modern media bias to producing clickbait driven by online engagement metrics and scientifically-illiterate (or scientifically-indifferent) journalists
- the leadership in tobacco control and its approach – it was brought up fighting tobacco wars and that's what it does
- the work of ideologically motivated bad actors in science and their extensive networks of influence
- the generation of a moral panic about vaping with anti-vaping campaigns like the Real Cost that are likely to generate curiosity and interest in vaping
- the biases induced by FDA funding – it establishes a problem-finding rather than opportunity-seeking dynamic
- the poor policy-making and implementation by FDA and states and worldwide (try to find impact assessments that consider unintended consequences),
- the incredibly burdensome and uselessness of the PMTA route to market and MRTP route to claims combine to deny informed choice and this will get worse
- the failure (or determination) of FDA not to make PMTA/MRTP more

efficient, transparent and predictable
- the prohibitionist outlook of WHO and its dogmatic stance against innovation in tobacco and nicotine products
- the political grandstanding of European Union politicians and officials who do not understand the consequences of regulation and apparently do not care
- the insularity of tobacco control – why so little interest in snus in Scandinavia, HTP in Japan, vaping in the UK – why so little interest in debate/discussion?
- the misplaced unconditional opposition to anything the tobacco or vaping industry does, even if it is good, and the false premises of FCTC Article 5.3 and its guidance

Until public perceptions of relative risk are roughly aligned with reality and there is a supportive pro-innovation, policy, regulatory and communications environment, we do not know the potential of vaping, smokeless, oral nicotine and heated tobacco as consumer technologies. The weakness is not in the products or their likely evolution over the next two decades, but in the hostile environment into which they have been introduced.

GFN 2020: what has gone wrong?

4. Comments

Please comment on this and give you view. Rule: please keep it polite and don't get personal and start accusing individuals.