Comments on The Tobacco Endgame by Clive Bates

Joe Gitchell, PinneyAssociates, Inc., 8 March 2015

1 Introduction

In his concise and thoughtful analysis and critique of the range of potential strategies to produce the "Tobacco Endgame", Clive Bates uses logic and available evidence to eviscerate strategies proposed in the supplement to *Tobacco Control.* Importantly, he closes by proposing an alternative endgame strategy. Clive framed his response with a masterful answer to the question: "is tobacco control controlling tobacco?"

In my response, I will touch on a few broad points before reviving the viability of one strategy, the Nicotine in Cigarettes Reduction Strategy (NCRS), which was a strategy that was not fully considered in Clive's piece. I will then close with some observations on Clive's vision of a preferred approach to maximize human welfare as it relates to nicotine consumption and how his proposed strategy might be supported and made even more efficient if coupled with NCRS.

2 Clarity of Objective

I agree completely with Clive's call for clarity of objective for any strategy as far reaching as a tobacco endgame. I also agree that tobacco control has frequently struggled with how to best set and follow concrete goals. In addition, I accept that the goals of destroying the industry or stopping the use of nicotine completely are more fictional than plausible. And I find Clive's mention of "the end of cognitive dissonance" as an objective alluring and frankly, inspired. It is very human/user focused and respectful. It will generate howls of discontent given the theoretical concerns of nicotine by itself (and the likely irresolvable debate about addiction as a disorder/disease), but those plausible reactions suggest that this goal is sufficiently innovative to be worth pursuing.

Clive's proposed objective in Section 4 where he outlines his vision of a future very different from the status quo strikes me as balanced and aspirational.

3 Health vs. Welfare Tension

I will not (cannot) quibble with Clive's thoughtful explanations and examination of the overarching moral, ethical, legal, and feasibility considerations of the range of endgame proposals. The resolution of those issues turns, in my view, fundamentally on judgments on the role of government and hard and soft paternalism (see any number of writings by Thaler and Sunstein for much more detail). Again, there will not be consensus on these matters, but it will be critical for policymakers to consider all of them, thoughtfully, before setting policy.

4 Nicotine in Cigarettes Reduction Strategy (NCRS)

I will focus the majority of my comments on the NCRS as it is the one strategy with which I am most familiar and also believe holds the most promise for minimizing (and eventually eliminating) the harm caused by smoke (and thus removing the fundamental cause of cognitive dissonance invoked by Clive's proposed objective). Clive thoughtfully

and carefully dissects the potential risks and unintended consequences with this approach, asserting, unambiguously:

> While I can find no reasons to support this idea at all, I think its proponents would make a more convincing case if they linked it explicitly to the availability of alternative cleaner nicotine delivery (future e-cigarettes, heat not burn products, snus etc) with pharmacokinetics similar to smoking

Clive then piths the NCRS with the following conclusion:

> It is not clear to me whether the authors see switching to snus, e-cigarettes, heat-not-burn tobacco as part of this strategy. It doesn't sound like it from the statement above, and this is not discussed in their paper. Lowering the nicotine in cigarettes would tend to relatively strengthen the alternatives by weakening the cigarette value proposition to smokers. That is a viable strategy, but I would prefer to rely on improvement in the alternatives rather than degrade the nicotine delivery performance of cigarettes in a way that is likely to increase toxic exposures and amounts to prohibition.

To begin my attempt to broaden this discussion, one of Clive's most pointed criticisms is that this is a strategy seeking an objective (e.g., he asks "is it to eliminate nicotine addiction or to eliminate cigarettes as a delivery system for addictive nicotine?"). I fear that Clive may have overlooked details within the 2013 paper as well as the broader literature on this concept as the proponents have answered this very directly: the goal is to end the use of combustion cigarettes as a way to deliver nicotine (so 'yes' to the second half of Clive's rhetorical question). And the primary mechanism to achieve this goal was most clearly expressed in the original 1994 conceptualization of the NCRS: to minimize and even eliminate the ability of cigarettes to create and sustain dependence among young people.

In addition to this unfortunate misunderstanding, I fear that Clive may have overlooked some other critical elements in the detailed descriptions of the NCRS, both in the 2013 summary paper and in earlier versions, and this oversight has hampered his ability to judge it fairly. The reality is that the 2013 paper lays out a clear and important role for alternative nicotine sources to address many if not all of the issues and concerns raised in the paper and above by Clive. You can judge for yourself based on the excerpts I include below from the 2013 paper, and reviewing the full 2013 paper and the 1998 position piece adopted by the American Medical Association, in particular the entire section under the heading "Components of a nicotine reduction strategy."

> **From the 2013 paper:**
>
> **"Social, practical and other factors that are relevant to the potential viability and outcome of a cigarette nicotine reduction policy**
>
> Evaluations of the nicotine reduction approach since the original proposal have concurred that it should only be implemented in the context of a

national comprehensive tobacco control programme (eg, refs.8, 14,and 23) Such a programme would include public education to prepare smokers for the nicotine reduction strategy, provision of treatment and alternate nicotine delivery systems for those who may need such support, and implementing a surveillance system that could quickly detect potential unintended consequences so as to enable appropriate interventions and modifications of the strategy.8,14 The Workshop on Endgame Strategies in Tobacco Control provided additional support for these conclusions and for the conclusion that the approach appears more compelling today in light of the projections that on its current course, the global tobacco death toll will continue to rise for decades to come.

Access to alternative forms of nicotine, including medicinal nicotine

The harm from tobacco smoking derives primarily from inhalation of combustion products, not from nicotine per se.24 Ensuring alternate forms of nicotine for those who would continue to seek it as levels of nicotine in cigarette tobacco decline is important.14 In 1998, in a report on the reduced nicotine content cigarette strategy which was endorsed by the American Medical Association, we assumed that this need could only be safely provided by approved nicotine replacement pharmaceuticals, which are manufactured to stringent safety standards, and are labelled, packaged and marketed so as to promote appropriate use. At that time, a major challenge was variously described as the ‘unlevel playing field’, meaning that the most deadly tobacco products were far more readily available, permissively regulated and attractively designed for users, compared to nicotine replacement therapy (NRT) products.25–28

Since the initial proposal, new products that could arguably be regulated either as tobacco or nicotine and which appear to contain substantially fewer toxicants than traditional tobacco products have been marketed. These include ‘tobacco’ lozenges, dissolving strips, sticks or pouches, and cigarette-like devices that deliver nicotine without products of combustion. Such products and NRT products may provide the support that is at least temporarily needed for some smokers to give up cigarettes entirely and to manage a world in which nicotine use by burning tobacco is less available. An additional regulatory approach that could be incorporated into a nicotine reduction policy is differential taxation, such that taxes on combusted tobacco products are much higher than those on cleaner nicotine delivery products.

Education, addiction treatment and cessation support to support nicotine reduction

Public health policy is premised on a clear understanding by the public as to what is intended and why it is important (eg, washing hands to reduce the spread of influenza). A nicotine reduction policy would require extensive education of tobacco users, their friends and relatives, and

> health professionals to prepare them for the process and guide them along the way so as to minimise unintended consequences and improve the outcome.
>
> A nicotine reduction policy will be very likely to increase tobacco cessation efforts in anticipation of the policy and as it is implemented. As discussed in the 1998 report, it would be important to increase access to treatment for tobacco dependence and withdrawal, including behavioural counselling, smoking cessation medications and broad coverage by insurance programmes.14 This should include individualised services for special populations such as people with co-morbid psychiatric disorders who may warrant extra assistance."

5 Conclusions and Next Steps

So I've shown that Clive did not fully represent the objective of the NCRS nor critical elements of its intended execution, and thus likely came to a biased conclusion. But a fair rebuttal is whether even revising that judgment would change Clive's closing prescription of 'creative destruction?' In my view, the answer is "**No. But…**".

'**No**,' because, as Lynn Kozlowski has elegantly argued in this recent piece, why wait for notice and comment rulemaking (and all of the uncertainties and perils that go along with that torturous process) when we have the tools now to entice current smokers away from products that burn? Obviously many in public health have answered this question with "because we're worried that these tools may make the situation worse, not better" (see this excellent piece by Fairchild and Bayer for more details), yet I find myself persuaded much more by Kozlowski's logic and arguments, and clearly Clive does, too.

'**But**,' because I believe that the two approaches of offering an increasingly appealing and acceptable range of substitutes for combustion cigarettes while also reducing the appeal and addictive capabilities of those burning sticks could allow us to realize Clive's vision even faster. I completely accept that the essential and foundational elements for progress in this arena are the pillars of creative destruction Clive describes—they have to come first. But I do believe that pushing creative destruction could allow and foster the adoption of a nicotine reduction strategy targeting cigarettes. And those two vectors working in tandem could produce massive synergistic benefits.

I am also sufficiently optimistic to imagine that coupling these approaches may nurture some much needed bridge- and consensus-building across the range of factions agitating to improve public health. That dream may be a step too far, but I cannot think of any other approach that has as much promise to realize that hope.

6 Disclosures and Acknowledgment

My employer, PinneyAssociates, provides consulting services on tobacco harm minimization (including nicotine replacement therapy and digital vapor products) to Niconovum USA, RJ Reynolds Vapor Company, and RAI Services Company, all subsidiaries of Reynolds American Inc. In the past three years, PinneyAssociates has

consulted to GlaxoSmithKline Consumer Healthcare on smoking cessation and NJOY on electronic cigarettes. I also own an interest in intellectual property for a novel nicotine medication an option for which has been sold to Niconovum USA.

The clarity of ideas and expression in this piece were greatly improved by input from Mr. David Sweanor and Dr. Bethea “Annie” Kleykamp. The views expressed in this paper (and any remaining errors) are my own.