RESEARCH PAPER

The future of tobacco regulation: a response to a proposal for fundamental institutional change

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There is much debate about the future of tobacco regulation. Some have argued that to achieve maximum possible reduction in the harm tobacco causes, new regulatory models that involve fundamental institutional change must be adopted. The tobacco industry will continue to undermine tobacco control, and, so it is argued, we must change the way in which it operates if we are to be able to make the necessary progress. Such proposals may have an immediate appeal, especially for those frustrated that progress in tobacco control is not as rapid as they would hope—with all the avoidable loss of life and livelihoods that that entails—but they need to be carefully analysed and assessed, and much thought must be applied before spending time and resources advocating for them. One such proposal, advanced by Borland, involves the establishment of a monopsonistic statutory purchasing agency and wholesale distributor of tobacco products. Borland argues the relative benefits of such a model as compared to a more “conventional” model. On close examination, the benefits of the Borland proposal, as compared to the conventional model, appear overstated, and the Borland proposal introduces significant regulatory problems. There is still much that can be achieved in tobacco regulation through more conventional approaches, and within the “existing system”. We should be wary of allowing the understandable allure of new or radical approaches to distract us from this reality.

It is widely recognised that the behaviour of the tobacco industry must be regulated if the tobacco epidemic is to be arrested. The Framework Convention on Tobacco Control¹ contains provisions dealing with the regulation of tobacco advertising, promotion and sponsorship, packaging and labelling, product contents and product disclosures.

Tobacco industry conduct over the last 50 years has been widely condemned.^{2–4} Much of this behaviour continues today,⁵ its extent and harmfulness varying by jurisdiction, mediated by local laws, enforcement practices and broader social norms.

It has been argued that if we are to regulate the tobacco industry better, it may be more useful to understand its conduct primarily as rational, calculated, and profit-motivated than as simply wrong, immoral or unethical.^{6–7} Shareholder-based corporations exist for commercial, and not moral or ethical, purposes and directors of corporations are under a legal obligation to act in the best interests of shareholders—usually to maximise shareholder value. They may be expected to do whatever they can to fulfil this obligation.⁸ Under these analyses, tobacco industry behaviour is rarely surprising. The companies act in the way they are programmed to act. What is unusual about the tobacco industry's behaviour is not the nature of that behaviour, but the extraordinary product to which it relates.

Callard *et al.*^{7–9} Borland,¹⁰ and Liberman⁶ have argued that the tobacco industry's incentive—to sell more and more of a product that is harmful and addictive when used as intended and that has no safe level of use—is a core structural problem that inevitably weakens tobacco regulation. This needs to be challenged if we are to make better progress in tobacco control.

Borland¹⁰ has proposed a way in which we might respond to this core structural problem. He has argued for a non-profit-motivated monopsonistic government purchasing agency and wholesale distributor that would purchase tobacco products from manufacturers and be responsible for their distribution to consumers.

Borland's model seems to have gained some traction.^{11–12} His paper was also voted equal sixth in the “Policy analysis,

advocacy, legislation and litigation” section of the recent poll of the “most important and influential papers” on tobacco control.¹³ Having gained that traction, it is important that it be subjected to critical examination.

In engaging in such an examination, I aim to demonstrate that much may still be done through more “conventional” regulatory approaches, and to suggest that we should be careful of moving too quickly from an understandable frustration about lack of political will to implement further tobacco control measures to calls for fundamental structural and institutional regulatory change.

INCENTIVES AND DISINCENTIVES—THE HEART OF REGULATION

Borland's, Callard *et al.*'s and my papers represent attempts to acknowledge and deal with harmful tobacco industry incentives. Borland favours a monopsonistic government purchasing agency and wholesale distributor because “[i]f a system could be devised where the incentives on tobacco companies were consistent with the goal of harm reduction, the challenge of regulation would be greatly simplified”.¹⁰ Similarly, Callard *et al.* argue that “[i]f we want to have better success controlling the disease, we need to consider changing the disease vector” and they hope to “move to an era of a cooperative tobacco industry that helps us to reduce tobacco consumption”.⁹ My paper also attempts to address “the nexus between profit and the causing of harm; [to structure] a regulatory system under which the incentive is to contribute to the reduction of harm, rather than to do that which causes it”.⁶ My concern is both for the way that the profit incentive leads to population harm, and the way that acting in its pursuit offends against law and legal principle.

Each of the three papers cited (and Callard *et al.*'s fuller exposition of their proposals¹⁰) contemplates fundamental structural change largely because of the difficulty of adequately addressing incentives within “the existing system”. Each tries to grapple with the problem of the tobacco industry—structured in its present form—wanting to do

what is clearly, in public health terms, the wrong thing—that is, everything it can to sell as much of its product as possible, knowing that the resulting levels of death and disease will track its commercial success.

However, before moving from concerns about dealing with incentives within the current system to calls for fundamental structural change, it is worth considering how incentives (and disincentives) are used in regulation generally, and how they might be used within the “existing system” to make the industry do the “right thing”. Industry may be persuaded (or coerced) to do the “right thing” either because we have changed the system so that its overriding incentive is better aligned with public health objectives—that is, to act to reduce harm—or because we have regulated it so comprehensively, with genuinely deterring sanctions that we are prepared to apply, that it is not in its interests to act in ways in which we do not want it to act. Does it necessarily matter—for a product like tobacco—*why* industry does the “right thing” if it does the right thing? Incentives can operate at different levels, and much that is tremendously important can be missed if we think about them too much at a general level and pay insufficient attention to how they might operate to affect very specific forms of behaviour—such as marketing, or certain manufacturing techniques—that we may want to discourage or prevent.

Regulating behaviour—whether by corporations or natural persons—by enacting laws or regulations that are backed by penalties for contravention inevitably involves the creation of incentives and disincentives. “Penalties seek to punish undesirable behaviour and thereby to promote desired behaviour.”¹⁴ While “[s]everal purposes...can often be discerned in any one penalty...the deterrence of wrongdoing is ultimately an aim of all penalty regimes”.¹⁴

Financial penalties (whether by way of payment of fines or of compensation), imprisonment, and licence suspension or revocation are all common examples of penalties. If penalties are to work, they need to be set high enough to deter and they need to be accompanied by both a willingness and a capacity to enforce them. According to the economic approach, “[f]or each potential offender deterrence flows from expected punishment, which is the probability of punishment times the magnitude of the punishment (e.g. the quantum of the fine)”.¹⁵ The value of the deterrent varies with “the private benefit likely to be derived from the offending”.¹⁵ The task is to introduce well-drafted laws and set—and enforce—penalties that actually work in deterring the behaviour we want to prohibit.

This is not to downplay the difficulty of strong and effective enforcement against an industry as wealthy, powerful and litigious as the tobacco industry, or to ignore the many factors—whether political, legal or financial—that combine to create that difficulty.^{16 17} On the contrary, it is to suggest that these lessons of enforcement difficulty be learned, and that we give adequate thought to how we might address them within the “existing system”^{17 18}—at least as much thought as we give to imagining alternative regulatory universes in which such difficulties are argued not to exist.

Regulation can also create positive incentives for certain behaviour, such as through offering significant regulatory or even financial advantages to those who act in particular ways, or in relation to particular products or services that are better at achieving specified health or social objectives than others.

RESPONDING TO THE BORLAND MODEL

A preliminary disclosure

Before critiquing Borland’s proposed model, I disclose that I was very involved in the early work that led to the development of the model, and lead authored a paper with

Borland, Scollo and Barnsley, in which we proposed such a monopsonistic government purchasing agency and wholesale distributor. We distributed the paper to a small group of tobacco control researchers and thinkers in early 2002, and ran workshops to discuss the ideas. In August 2002, a paper I co-authored with Clough¹⁹ ended with a brief sketch of a purchasing agency, though what we said there would also be consistent with other kinds of independent statutory agencies. I also presented the ideas in a few forums in 2002 and 2003. By the time I wrote my 2003 paper,⁶ I had become more circumspect. I provide this brief history here so that readers who have read that earlier material or heard me present it will not think that I am whitewashing that period.

Borland’s proposed agency in outline

Borland’s paper sets out the kinds of regulatory measures required for comprehensive tobacco control. These essentially fall within three categories: powers over manufacture, over communication, and over availability. His argument is that regulation will work better if it is done by a monopsonistic government purchasing agency and wholesale distributor rather than by “conventional regulation”. The term “conventional regulation” is, of course, shorthand because any regulatory scheme can involve a range of measures, both “conventional” and “unconventional”. Here, I use it to mean a model in which an agency regulates without purchasing and distributing products.

Borland contrasts his monopsonistic agency and wholesale distributor with a “conventional regulator” to show how it would perform better. He believes his model is fundamentally different from and superior to a “conventional” regulator. In his model, his agency “can act as the ideal informed customer”—it will be better able to make judgments than individual consumers. He argues that his model breaks the “direct relationship” between manufacturer and consumer that presumably obtains under “conventional regulation”.

These points initially work well rhetorically, but care should be exercised before taking them too far. A “conventional regulator” with strong powers to regulate all aspects of manufacture, communication and availability would, as with Borland’s monopsonistic agency, also stand between manufacturer and consumer, making judgments that would be beyond the capacity of most individual consumers, and protecting them against manufacturers’ behaviour that was against their interests. The regulator would not need to be a “customer”—in the sense of an actual purchaser—to perform this role. It could perform this role by use and enforcement of regulatory powers. The “direct relationship” between a manufacturer and a consumer, in a context where an independent regulator regulated all aspects of manufacture, communication and availability, would not, in fact, be “direct” at all. “Direct” means “proceeding in a straight line or by the shortest course; without intervening agency; immediate; personal”.²⁰

Addressing Borland’s major claims

Reductions in product harmfulness

Borland writes that “[i]f tobacco products are to be legally available, there need to be controls to ensure that they...are as harm reduced as possible”. He concedes that a “conventional regulator is as able to mandate less harmful products as [a monopsonistic agency]”, but writes that “it is less clear how it could actively encourage new innovation”. His proposed agency would, as I understand it, be able to do this better by the offer of purchasing and distributing more products from manufacturers which had innovated products which satisfied criteria of reduced harm.

However, in drawing his comparison, he seems to give little, if any, consideration to the incentives for innovation

that a “conventional regulator” could offer through a combination of conferring regulatory advantages on less harmful products (relating to communication and availability—price and location), and prohibiting the sale of “more harmful” products, such as by requiring all products to meet certain prescribed standards—for example, those achieved by the market leader in reducing the delivery of particular substances such as tobacco specific nitrosamines. In their recent paper on long term nicotine policy, Gray *et al* make a similar point to the one being made here though in respect of “clean” nicotine, writing that “[t]here are many ways of making [it] more widely available including reduced prices, variable size packages, and more outlets”.²¹

A similar response can be made to Borland’s argument that while “conventional regulation” “requires capacity to make claims if it is to encourage production of products that better the minimum standards”, his model “[d]oes not require capacity to make harm reduction claims”. Presumably, in both cases the idea is for consumers to use the less harmful products, and for this to be achieved by communication, easier availability (price and/or location) or a combination of the two. However, there is no reason why industry need be allowed to make “claims” under conventional regulation—the regulator could still control communication, deciding what should and should not be said and how—and no reason why the industry would nevertheless do so, assuming that the regulations carried large enough sanctions and were adequately enforced.

Control of communication

Borland also argues that his model allows for better control of communication than can be achieved by “conventional regulation”. It could “effectively remove incentives for tobacco companies to promote to consumers, by selling products under [agency] livery”. He argues that his model “appears to enable effective controls over promotion by removing incentives to promote, something that does not seem possible while manufacturers compete to sell to end consumers”. This claim seems somewhat overstated. Presumably, under Borland’s model, in most cases, manufacturers will still know which products are theirs, even if they are sold with agency brands, and would therefore have an incentive to ensure that these products did well in the marketplace. Where identically packaged products were manufactured by more than one company, as Borland suggests, presumably the manufacturer would still know that some of its products were within that packaging. The point here is that the manufacturer would still know which products it wanted to be sold, and would have an incentive to ensure this. If it is argued that it would be more difficult for a manufacturer to promote products that did not carry its own chosen branding, we then need to consider the regulation of branding, on which much progress could be made under “conventional regulation”. But the claim of having removed the manufacturer’s incentive to promote products it manufactures cannot be supported.

Borland writes that the capacity to mandate “truly generic packaging” is limited under “conventional regulation” “as companies must be able to retain some identifiable link with their products, links that can be used for marketing”. While this is not spelt out fully in the paper, I understand from conversations with Borland that here he means that, for example, a “conventional” regulator could not require products made by different manufacturers to be identically branded and packaged (for example as type A, type B, and type C), with no information at all about the identity of the manufacturer, because it would be no more than a matter of luck which of the identically branded and packaged products

a consumer happened to end up with. This would be an untenable position for a manufacturer and a condition that cannot work in a system in which “companies are expected to compete for the consumer market”. This is a valid point, but not one that we should take too far. We may well want to ensure that products are branded, packaged, and marketed as generically as possible,²² with a regulator prescribing what communication should be allowed and/or mandated for all products, or for each category of products. However, we could do this under “conventional” regulation, as long as we allowed (or required) *some* mark that distinguished one manufacturer’s product from another. This need not be a mark—such as an attractive or interesting one—that the manufacturer could choose without regulatory approval. Nor, in fact, need it be a mark of the manufacturer’s choosing at all. And lest we be too concerned about the consequences of allowing *any* distinguishing mark, we should think about what strong, well-drafted legislation dealing with promotion, backed by appropriately strong sanctions, could achieve. It should be able to prevent industry promotion that makes use of the mark.

But a further point needs to be made here. Borland’s argument would, in any case, hold in only a very limited set of circumstances—where products produced by different manufacturers are, for all intents and purposes, identical from the perspective of the consumer: these products would taste the same, feel the same, and be equally harmful and addictive. One of the primary justifications of trademark law is to assist consumers by enabling them to differentiate between products that are different to them and identify those they wish to purchase and use. Trademarks “lower consumer search costs”.²³ The *WIPO intellectual property handbook: policy, law and use* explains that: “[C]onsumers need to be given the guidance that will allow them to consider the alternatives and make their choice between competing goods. Consequently, the goods must be named.”²⁴ If the advertised benefit of Borland’s model is that his agency could ensure that products produced by different manufacturers could be sold within identical packaging, he ought to acknowledge that, unless the products themselves were, for all intents and purposes, identical from the consumer’s perspective, his approach would actually create an impossible position for consumers. They would be unable to identify the products from among the identically packaged category that they wished to purchase. It may be that some would regard this as a good thing, but the issue needs to be acknowledged not just in terms of its impact on manufacturers, but also its impact on consumers.

Less attractive products

Borland argues that “moves to less intrinsically attractive products” would be “[v]ery difficult to achieve” under “conventional regulation”, because “[c]ompanies use taste and other differences to compete and will strongly contest any such changes”. In contrast, this “[c]an be achieved” under his model, though it would be “limited by consumer tolerance”. Again, the claim seems somewhat overstated. A “conventional” regulator could clearly regulate the manufacture of products in order to make them less attractive to consumers, by prohibiting or restricting the use of certain additives, ingredients, design features and manufacturing techniques—though it, too, would be “limited by consumer tolerance”. The companies may, indeed, want to compete on taste and other differences and “strongly contest any such changes”, but the response to that is a question of political will. If there is political will to reject industry wishes, it can be done under “conventional regulation”.

Disclosure of information by manufacturers

Borland argues that under his model, “[c]ontrol of product composition and other issues is easier than in the open market because companies have less incentive to hide information from [the agency] and often have incentives to provide unsolicited information as the [agency] is their customer”. He writes that “[s]uch a system actually creates incentives for manufacturers to disclose product information to the [agency]”.

Again, the claim seems overstated. Within “conventional” regulation, one could create enormous disincentives to hide information by applying severe sanctions for doing so, and implementing appropriate monitoring and enforcement procedures. In Borland’s model, the primary disincentive to hiding information seems to be that the agency can decide not to purchase the company’s product again. But in a “conventional” model, a regulator could equally withdraw or suspend a licence to operate. If it had adequate powers to require the provision of information, to enter premises, to search through company documents, and to require questions to be answered, the disincentive against withholding information could be extremely powerful. The agency might even have employees who regularly spent time within manufacturers’ premises with full access to company materials (of course, with penalties against inappropriately using information) or engage external auditors to perform a similar function. The positive incentive to provide unsolicited information that Borland finds in his model would, in a “conventional” model, lie in regulatory advantages that might be afforded to products that better met the regulator’s objectives.

Regulatory capture

Borland argues that his model would also do better at preventing regulatory capture because, under “conventional regulation”, “there is likely to be only a small number of companies in the market”. Under his model, “[c]ompetition in producing products for the [agency] will minimise the risk of regulatory capture by cartels”. “[S]maller tobacco companies are likely to proliferate as they can be competitive when they do not require the large size necessary for mass marketing.... The existence of a larger number of players makes it more difficult for the [agency] to do inappropriate deals with some companies without others getting upset and blowing the whistle.” Again, the comparison with “conventional regulation” is somewhat unfair. If attractive regulatory advantages—in communication and availability—were offered to “better products”, presumably there would be significant competition to produce them and to demonstrate this to the satisfaction of the regulator. If a conventional regulator assumed responsibility for what may be communicated to consumers about products, or even allowed manufacturers to communicate information through very limited channels, such as by leaflets available at the point of sale, presumably companies would not “require the large size necessary for mass marketing”.

Some fundamental problems with Borland’s model

So far, this paper has suggested that the claims that Borland makes about his model are somewhat overstated. It will now point to some fundamental problems with what he proposes.

Coordinated regulation of all nicotine delivering products

The creation of a monopsonistic government agency and wholesale distributor would actually make the introduction and operation of rational, comprehensive nicotine regulation—a goal of many in tobacco control, including Borland—much harder, rather than easier, to achieve. Gray *et al* argue that there is a “need to capture all nicotine into a regulatory

system” as the first step in moving towards a “comprehensive regulatory policy covering all nicotine delivering products”.²¹ They suggest doing this by “giving pharmaceutical regulators a new mandate to regulate tobacco or by setting up a special unit for the purpose”. The idea behind a comprehensive regulatory policy for all nicotine delivering products has often been stated. At present, smoked tobacco products, the most dangerous delivery device for nicotine, are the least regulated and most widely available.²⁵ More sensible policy would dictate the opposite. If the one agency had regulatory control over all nicotine containing products, it should be able to regulate them differentially in a sensible way, giving regulatory advantages—in each of manufacture, communication and availability—to the least harmful and imposing regulatory disadvantages, including, in appropriate cases, bans, on the most harmful.

Borland’s proposed agency would be the sole purchaser and distributor of *tobacco products*. There is no suggestion that there would be a similar system in place for other nicotine delivering products, and this is not surprising, given that the arguments that are said to justify the Borland model for tobacco products would not apply to other nicotine delivering products, particularly those sold in a pharmaceutical context. Even if it were possible to win a political argument about the need for a monopsonistic government agency and wholesale distributor for tobacco products—a pretty daunting task—it is even harder to imagine it being won, at least in countries that operate under essentially free market systems, in relation to the pharmaceutical industry. The effect of this is that either there would be two separate agencies, one purchasing and distributing tobacco products and the other regulating—but not purchasing and distributing—other nicotine delivering products, or the one agency would both purchase and distribute tobacco products, in which the government and perhaps the agency itself would have a direct financial interest, and regulate other nicotine delivering products. Under the former, the very significant potential benefits of regulation by a single agency—including timely, integrated, mutually-reinforcing decision-making, and the development and location of necessary expertise—would be lost. Under the latter, careful consideration would need to be given to how these different roles would play out within the one organisation.

The influence of revenue considerations

There is an inevitable regulatory tension that operates where the public purse benefits from the sale of unhealthy products, and one way to discourage their sale and consumption is through taxing to ensure high prices. The danger is that revenue considerations will be brought into the regulatory equation to the cost of other considerations, such as public health ones. But the problem seems to be made even worse in the Borland model in light of the purchasing role of Borland’s agency, because presumably the agency would continually want the stock it has ordered and paid for to be sold—else it would make losses on the product. It would be difficult for the agency to discourage the use of a product which it wanted to see purchased. In considering the potential problems here, one should not forget that presumably there would be a significant period between ordering of stock, delivery and then distribution and purchase, and that Borland proposes a tender process, which would also take considerable time, to precede all of this.

Agency involvement in all manufacturing and wholesaling activity versus targeted monitoring and enforcement

One of the very significant effects of introducing Borland’s purchasing and distribution model would be that the agency

would assume responsibility for deciding how much of what should be manufactured and when and by whom, and how much of what should be distributed and where and when. This is no small undertaking given the size of the tobacco market in most countries. Even in Australia, the country in which Borland writes, with a relatively modest population of 20 million, the value of the market is approximately A\$8.55 billion, with sales of around 23 billion cigarettes a year.²⁶ This should be contrasted with the capacity of a non-purchasing, non-distributing regulator to use strategic, targeted monitoring and enforcement action, rather than be involved in every single manufacturing and wholesaling activity. Given the importance of strategic, targeted monitoring and enforcement action—in a world in which no government or government agency has unlimited resources²⁷—Borland's statements that he is unaware "of any alternative proposal that is likely to be as *efficient* or *effective*" and that conventional regulation is "likely to be more expensive" seem frankly bold.

Antagonism versus cooperation

Borland prefers a system in which an agency "has a more cooperative relationship with manufacturers" to one in which the regulator and the industry have an intrinsically antagonistic relationship. This sounds good in theory, but it seems to be both wishful thinking, and probably also undesirable. First, we should not imagine that a commercial relationship will necessarily be smooth and cooperative. Presumably the manufacturer will want the agency to purchase as many of its products, and as little as those of other manufacturers, as possible. Presumably, it will try to achieve this by vigorously promoting its products to the agency and attacking those of its competitors. When analysed critically, this is, in fact, not the kind of relationship Borland imagines it would be, in which the two share the same goal. The manufacturer's goal is to sell as much of its product to the agency as it can—not to reduce population harm. Presumably it will act in the ordinary way of the profit-maximising company, carefully weighing up the pros and cons of different ways of relating to the agency, using, as and when it deems appropriate, the full range of tactics—charm, cooperation, pressure, bullying, legal threats and challenges. Presumably it will also lobby politicians where it considers this to be useful, encouraging them to make changes to the legislative framework under which the agency operates, and to appoint board members likely to be sympathetic to the company's interests and replace those who have proved to be less sympathetic.

Second, when we are dealing with products of the nature of tobacco and our aim is to discourage their use, it is not clear why an antagonistic relationship between the regulator—at least a strong, committed, well-resourced regulator with appropriate powers—and the manufacturer is not the appropriate one. While a "cooperative" relationship might offer some benefits for a product with social utility, it is not clear why it would be appropriate or even practical for a product the use of which regulation is seeking to discourage. Is there not a danger that an agency involved in the business of purchasing and distributing products will often have a harder time reducing their overall use than an agency that regulates without being involved in the business? Even if the introduction or mandating of less harmful and less attractive products is a social good, the better social outcome would be that the products not be used at all. It seems that the purchasing and distributing agency would find itself in a very difficult position, and one that ought not to be advanced without very careful thought given to how it would handle its different roles.

What this paper adds

Recent articles have argued that fundamental structural and institutional change is required if we are to reduce tobacco-related harm in the most effective way.

This paper contributes to this ongoing discussion about future approaches to tobacco regulation, examining a particular proposal advanced in this journal by Borland, and cautioning against its adoption. It makes broader points about the need to think carefully about how to address tobacco industry incentives and to assess critically new proposals for fundamental regulatory change.

Incentives of the purchasing agency in dealing with manufacturers

Under the Borland model, one can imagine an unhealthy incentive coming into play within the purchasing agency—to purchase the cheapest products it can obtain from manufacturers. It would have this incentive because the overall benefit either to it, or to the public purse, will be maximised if it can spend less on the products it purchases. There is a danger that these kinds of considerations—introduced once the agency is established as a purchaser—might begin to influence its decisions on which products it purchases and distributes.

Creating an enormous new agency—is it worth it?

We should always be wary of building new institutions and infrastructures that may either develop incentives to sustain themselves beyond their usefulness or in ways that might prove harmful, or that might quickly become redundant. For reasons earlier outlined, Borland's agency would need to be a very large one—larger than a more conventional agency—and one that it would take a long time and considerable expense to create. There is a heavy onus on Borland to demonstrate that creating such an agency would be more productive than counterproductive in a world in which continued developments in tobacco policy and regulation—such as further restrictions on promotion, on places where products may be sold, and on places where people are allowed to smoke, stronger consumer information regulation, stronger enforcement of tobacco regulation against industry, and better consumer funded consumer education programmes—and in the availability of treatments for tobacco dependence could continue to drive rates of tobacco use lower and lower.

POLITICAL AND LEGAL ACCEPTABILITY

This paper has not dealt with any issues of either political or legal acceptability or feasibility of various possible regulatory approaches. This is primarily because what is acceptable or feasible will vary by country, and over time, in accordance with domestic political ideologies, ideas about regulation, social norms, and legal and constitutional constraints. This paper does not seek to make any claims about any of these matters, though such matters ultimately determine whether particular proposals are implemented in particular jurisdictions and over what timeframes. Its focus has been on the mechanics of good policy, rather than implementability.

In respect of legal considerations, it is important to acknowledge that there may be legal impediments to some of the measures discussed, both under international trade law, and under the constitutions of particular jurisdictions (such as through restrictions on the regulation of commercial speech and the acquisition or expropriation of property). This paper has deliberately avoided these issues because it has

been endeavouring to discuss different regulatory proposals for the benefits they may offer, independently, for the time being, of whether they are legally feasible within particular jurisdictions. Whether particular regulatory proposals do or do not breach provisions of multilateral or bilateral trade agreements or national constitutions is invariably a difficult question, requiring very careful forensic analysis of the proposals, the provisions, and relevant case law. Answers to questions about legality will often be significantly speculative, with it being impossible to be certain how courts or adjudication panels will decide particular cases. Courts and adjudication panels are forever creating new law when new cases present themselves. There is also a "luck of the draw" element about the composition of the judicial bench that hears a case. The legal position is likely to vary by jurisdiction, and even, over time, within the one jurisdiction. There will never be a single answer that applies internationally or for all time.

Notwithstanding all of this, if particular regulatory proposals are more likely to conform to legal and constitutional constraints than others, that will, of course, be a highly relevant consideration in weighing up relative benefits. If certain models offer advantages in that they allow things to be done that could not be done, within the law, under other models, these would be important considerations. But one would want to see very careful legal argument made by experts in the relevant legal fields—international trade law and constitutional law—before taking such considerations into account.

CONCLUSION

In no country in the world do we yet see genuinely comprehensive regulation of tobacco products and the tobacco industry—covering all aspects of manufacture, communication and availability. Much has been written making the case for such regulation. More recently, more "radical" approaches for regulating tobacco have been proposed. The investigation of new approaches is to be encouraged, but such proposals must be forensically examined. There is always a danger that proposals for new approaches, or "calls for masterstrokes",²⁸ will fall into the "nirvana fallacy", in which their advocates "erroneously compare real-world institutions with some abstract or ideal institution, even if the ideal institution has never existed".²⁹ The danger is that all of the faults of the existing system can be laid out for all to see, while the imagined alternative, utopially described, will sparkle in comparison.

At the same time as new approaches and regulatory models are proposed and considered, we should ensure that we continue to give careful thought to what can be achieved within the "existing system" or through more familiar models of regulation: what laws can be enacted; how should they be drafted; what regulatory advantages can be offered and what regulatory disadvantages imposed; what agency or agencies would be needed to administer the laws and regulations; what sanctions can be imposed; how monitoring and enforcement can be carried out. These endeavours may often seem less exciting than proposing radical change, but they may well yet bear more fruit.

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