From FDA to PMI – a sell-out or a bold move for public health?

written by Clive Bates | 27 July 2022

Dear Dr Holman

You are making an interesting move at an important time, and I want to write an open letter to you to remark on its significance.

I am sure many will criticise your move as treachery or a sell-out, but this is a predictable knee-jerk reflex and overlooks the public health fundamentals. I hope you ignore the inevitable criticism and remain focused on the enormous public health prize that you can pursue in your new role. I think it is an ethical and high-integrity move, and I hope you make the most of it.

The case for moving from FDA to a tobacco company

How can anyone pursue a public health goal effectively from a tobacco company?

In reality, we are in the formative phase of a fundamental and highly beneficial technology transformation in the consumer market for nicotine. This is the move from high-risk combustible products (cigarettes) to low-risk non-combustibles (vaping, heated and smokeless tobacco, and oral nicotine products such as pouches). This is a game-changer for public health.

I know many employees at PMI and the other major tobacco companies whose *only mission* is to expedite that transition, and you will be joining them in a big

leadership role. In terms of its potential to reduce the burden of death and disease in the United States and worldwide, this transformation is probably the most significant technology change of the coming decades. Literally, millions of lives – maybe hundreds of millions globally – are on the line.

We have met several times at conferences, and I believe that you are sincerely focused on the public health goal of eliminating the burden of misery, disease and death caused by smoking. You have been immersed in the science in this field and have concluded that major public health gains can be made by large numbers of smokers switching from cigarettes to non-combustible products. You are one of the highest profile regulatory professionals to understand that potential, and your career move amounts to a very significant endorsement of this approach. I doubt you would be making this move if you did not see the public health opportunity in pursuing that strategy. I share your optimism about this.

Your move to a tobacco company will surprise or even shock many. But they should not be shocked or surprised. They misunderstand how a major technology transformation will come to pass. The tobacco companies will be prime movers in making this work globally. They will innovate (or acquire innovation) to respond competitively to growing consumer demand for safer products. They will be guided by the incentives created by the regulatory, fiscal and information environments in which they operate. These companies can slow or expedite progress, but so can regulators, tax authorities, politicians, academics and tobacco control advocates. *There is everything to play for in getting this transition right*. I hope all the companies will be proactive in shaping the incentive structure in which they operate to expedite a pro-health transformation of the nicotine market, and I believe this is the reason you have been hired.

In its 2021 investor presentation, PMI said the following:

> *The company … believes that with the right regulatory frameworks, dialogue and support from civil society, cigarette sales can end within 10 to 15 years in many countries.*
>
> *PMI press release, February 10, 2021*

I agree with this. And what a great goal to pursue as a career professional.

The objections to moving from FDA to a tobacco company

What about the objections to your move? I will list four and give my view on them.

A. Harm reduction is the nicotine maintenance strategy of Big Tobacco

The alternative to trying to end cigarette sales is to pursue a nicotine-free society. This goal is increasingly embraced implicitly and sometimes explicitly in the tobacco control community. In my view, this is a misguided Utopian idea underpinned by a war-on-drugs mindset. It has made too many in tobacco control indifferent to the huge variations in risk between nicotine products – what the FDA sometimes describes as the *continuum of risk*. This leads to *ad hoc* and unstrategic advocacy – taking the approach of eliminating every nicotine product possible whenever the opportunity arises. This is a bad strategy, as it will protect the incumbent cigarette trade and prolong the burdens of smoking and related harms. There might be something positive to say about this if the 'endgame' for *nicotine* was within reach, but I don't believe it is.

I think the endgame for *smoking* is within reach, but the demand for nicotine is far more robust. This is because, for some people, nicotine has functional and pleasurable effects, and there will be a permanent demand for this drug. Neal Benowitz, a global authority on nicotine, writing in 2009, summarised the effects:

> *In humans, nicotine from tobacco induces stimulation and pleasure, and reduces stress and anxiety. Smokers come to use nicotine to modulate their level of arousal and for mood control in daily life. Smoking may improve concentration, reaction time, and performance of certain tasks.*
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> *Benowitz, N. L. (2009). Pharmacology of Nicotine: Addiction, Smoking-Induced Disease, and Therapeutics. Annual Review of Pharmacology and Toxicology, 49, 57. [link]*

The public health challenge is to dramatically reduce the harm to people who wish to use this stimulant or find it useful. That harm is caused by the method of delivery, overwhelmingly smoking, not by the relatively innocuous but highly-

valued effects of the drug itself.

B. PMI is still a huge cigarette maker

A company like PMI cannot stop selling cigarettes while there is still a market for them and while it is a legal supplier in that lawful, regulated and taxed market established by governments. *That's what a tobacco company does, by definition*. If it tried to stop, its shareholders would revolt, its management would be fired, the company would be taken over, and the productive assets and intellectual property sold. It would achieve nothing, and it is pointless to call for it.

Instead of flaunting tobacco warrior credentials, we need to concentrate on what will cause actual change. We should adopt the perspective of clear-eyed strategists with an aim to eliminate as much harm as possible as quickly as possible. That would tell us that a pro-health transformation of the nicotine market is possible and desirable.

What a company can do is change the nature of the market through product R&D and innovation, marketing efforts, and regulatory and scientific engagement. It can do its utmost to move the market and to win market share for its low-risk products from smokers of its own brands and those of competitors – thus combining a public health gain with a competitive strategy.

This means we should judge these companies not on where they have come from and the behaviours of the past, though these should never be forgotten. We should judge them by their meaningful efforts to change and the direction they are trying to follow. The past is settled. What they are doing now and where they are heading is what matters. I think the international tobacco companies understand this and where their market is heading and are changing accordingly.

The problem is the "Bootlegger and Baptist" alliance between the dinosaurs of the global tobacco industry (especially the state-owned monopolies) and the dinosaurs of the tobacco control community, as they work tirelessly to obstruct a pro-health transformation. They are proving themselves incapable of looking beyond their longstanding animus towards "Big Tobacco", which is not, and never, was monolithic and singular in its approach. The facts have changed, and they will have to change too or find themselves marooned by reality.

C. Ruin the vape industry and join a tobacco company

One argument is that in your position at FDA, you have signed the death warrants of thousands of small businesses and vape shops (their Marketing Denial Orders), and now you want to work for the big companies that profit from the brutal barriers to entry imposed by FDA. As you know, I have been very critical of FDA's approach to the smaller vaping companies and harm reduction in general. But the fact is you have resigned from FDA and moved out of the Federal government machinery to pursue harm reduction by different means. That is not something I expected, but it is certainly something I welcome.

I know from my own experience as a civil servant that bureaucracies are extremely difficult to shape in your own image, especially if you are not in overall control. They are fashioned from a thicket of competing pressures, rival ideas and visions, personal ambitions, moral intuitions and ideologies, risk-aversion, alliances and enmities, principal-agent relationships and mandates, legal interpretations, personal political orientations, scrutiny and accountability pressures, and human judgement. If you are cause-driven, the art of working in a bureaucracy is to shape it to the extent you can in the hope that you will make it better. But that is never easy and not always possible… and that can take some time to discover.

My view is that FDA/CTP has made a set of bad policy choices about low-risk products. It failed to create a viable and proportionate regulatory regime for the thousands of low-risk products. It was too susceptible to the national moral panic over youth vaping and lost sight of the bigger picture: that being the means to drive down adult smoking. At the same time, FDA faced intense political pressure from a well-financed complex of anti-tobacco and anti-vaping interests that wilfully distorts science, promotes major scares and is indifferent to the harmful consequences of quasi-prohibitions or excessive regulation. This is where I lay the blame.

But the result was that FDA did not explore the options to simplify and lessen the regulatory burdens imposed on vaping companies to anything like the extent necessary or possible under the Tobacco Control Act. We probably disagree about how much latitude FDA could have used if it wanted to, but I hope you will have

more to say about this in your new role.

I don't know what role you played in all this or what you could have done differently, and what effect, if any, that might have had. I am not going to be an apologist for FDA's approach as it has very negative consequences. But neither do I think others should judge someone who has worked in a bureaucratic environment like this and tried to pursue public health objectives without as much success as they may have hoped. The point is that you are going to pursue the same agenda by different means, and that is the reason for your career move. I hope you will be an effective advocate for better policy and a better FDA, and we should all welcome that.

D. Conflicts of interest

Have you improperly moved from the regulator to the regulated? That is, from gamekeeper to poacher? I don't think we should dwell on this for long. As I understand it, there are strict government guidelines about standing down when you begin a job search and staying apart for two years when you move from a government job to a business with significant interactions with the department you worked in. This sort of move is normal, given the skills overlap. I assume the rules were followed to the letter and in spirit. If anyone wishes to criticise, they should show the rules were not followed.

Some advice

Finally, some advice on the challenges ahead (whether you want it or not…). In your new role and with your new team and the new company, I would try to do some or all of the following (and I realise this is not all down to you):

1. Do as much as you can to explain your personal rationale for this move and your view of THR and tobacco companies. There is a coherent, ethical and high-integrity logic to it that needs a wider understanding. Obviously, this is important for you personally, but it is also important for your colleagues, the companies more generally, and those of us in public health who want to see this market transformation work. This is about building trust.
2. Develop an optimum regulatory, fiscal and communications package that

would advance the transformation away from combustibles and build support for it among other nicotine companies, consumers, academics and public health professionals. This should shape the long-term direction and address issues like the place of nicotine in society, the embrace of innovation, the principle of proportionality, an appropriate balance between state intervention and user autonomy and, above all, clarity on goals.

3. Take the high ground and think at the *whole category level*, taking account of the diversity of companies, products, consumers, and consumer preferences. I hope you will avoid the counterproductive strategy of trying to rig the market to favour PMI products at the expense of others. I have seen this approach from tobacco companies, and it will not work for anyone in the long run. There is plenty of scope for competition without trying to tilt the playing field.
4. I would really like to see your ideas on how FDA could innovate to create a viable approach to pre-market authorisation, modified risk claims, and rule-making that puts the consumer interest first, including their interests in their own health. Also, if necessary, any legislative changes that are needed. There is no point or value in criticising FDA or anyone connected with it. What's needed now are constructive ideas to lift the agency out of its chaotic state and into being a trusted, efficient, transparent and predictable regulator.
5. Do more to address the tsunami of poor quality and sometimes malicious science that degrades and detracts from addressing the public health challenge. We all have interests in good quality science. I feel the companies have the deep expertise to do more to challenge junk science.

I appreciate this will take more than just your own efforts, but I hope that as a leader in the field taking on a new role, you can make some progress on this agenda.

Very best wishes for success in your new role.

Yours sincerely

Clive Bates