FDA shoots itself in the foot, cigarette trade celebrates, public health loses – a summary in two quotes

written by Clive Bates | 9 August 2016

A typical day at the FDA Center For Tobacco Products

The FDA's deeming rule went live yesterday, 8th August 2016. You will see a blizzard of expert comment about what it all means (feel the pain of Phil Bursado – see 8/8). In essence, FDA requires an enormously burdensome Pre-Market Tobacco Application (PMTA) to be filed and accepted by FDA for any new product from now on. So that's the end of innovation, including pro-health and pro-safety innovation. For all products currently on the market, a PMTA has to be filed within two years, with a further year for FDA to review – that will wipe out most products and most smaller firms and open the way to the black market. (For the official view, see FDA overview and Q&A)

When thinking about this regulation from a public health point of view, there are two quotes I think everyone should have in mind:

Quote 1: The Royal College of Physicians

The first is a proper public health perspective on e-cigarette regulation. In my opinion, this is the best quote in the April 2016 Royal College of Physicians report *Nicotine Without Smoke: Tobacco Harm Reduction* and it is what matters, above all, with the FDA's regulation.

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187)*

Quote 2: Wells Fargo Securities

The second is a take on how well FDA is dealing with the difficult challenge of "getting the balance right". This is the Wall Street view yesterday from Bonnie Herzog, the senior tobacco analyst at Wells Fargo Securities (my emphasis added):

> *Further Implications of Deeming Regs: (1) We expect to see a continued shift in consumption of e-cigs/vapor back to combustible cigs as e-cig choices become more limited — a net 'win' for big tobacco. This has continued to baffle us given the FDA's public health priorities. (2) We expect further e-cig/vapor consolidation and, as a result, manufacturers' pricing power and retail leverage to increase with MO and RAI best positioned given their scale and capabilities. (3) We expect increased, but manageable, timing risk for MO to be able to commercialize iQOS by late FY17/early FY18 assuming its premarket tobacco application (PMTA) is approved given PM & MO's active dialogue with the FDA.*

> *As Is, Deeming Regs Are A Clear 'Win' For Big Tobacco, Not Necessarily Public Health – Our main concern remains that the final deeming e-cig regs will realistically stifle innovation, which could dramatically slow industry growth by dis-incentivizing consumer conversion from combustible cigs to e-cigs. This ultimately has a net negative impact on public health, which is clearly in direct opposition to the FDA's goal. However, we have reason to be more optimistic given actions being taken by both MO & RAI to soften the current limitations of the deeming regs on innovation.*

Oh dear…

The problem with the FDA's regulation is that the claimed benefits are nugatory and don't actually address any real-world problems. However, the risks of unintended consequences leading to more smoking are clear and foreseen (by the Royal College of Physicians among many others) but are unacknowledged by FDA. When monetized, these risks and health detriments would completely dominate and destroy the cost-benefit analysis justification for the rule.

This is the theme of the *amici curiae* brief sixteen of us have just filed in the Nicopure Labs et al versus FDA legal case (see especially part C)

I'm prepared to believe they aren't doing it deliberately, but I just have this feeling that the big players behind the FDA's intervention, such as Mitch Zeller and Matt Myers, do not have *the faintest idea what they are actually doing*.