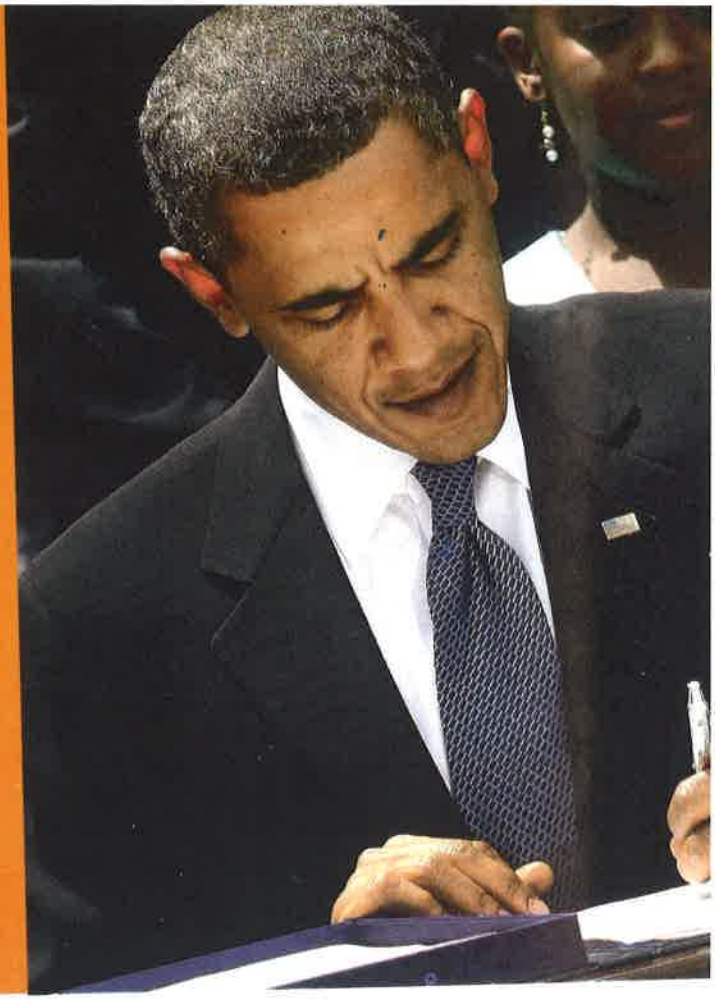
Signed, sealed, delivered

Following debate that lasted more than a decade, the Family Smoking Prevention and Tobacco Control Act, which entitles the US Federal Drug Administration (FDA) to regulate tobacco products, was finally signed into law on 22 June 2009, opening a new chapter for the US tobacco industry.



President Obama had not even signed the FDA bill when the first critical voices were raised. Public health advocates were disappointed and claimed the bill in its present form would perpetuate the myth that there are "safer" cigarettes while, at the same time, it bans new smoke-free alternatives, such as Swedish-style snus, and will mislead consumers into believing that they are as hazardous as cigarettes, despite proof that they are not. A further criticism was that, under the new law, tobacco-free products, such as electronic cigarettes, will be prohibited, too.

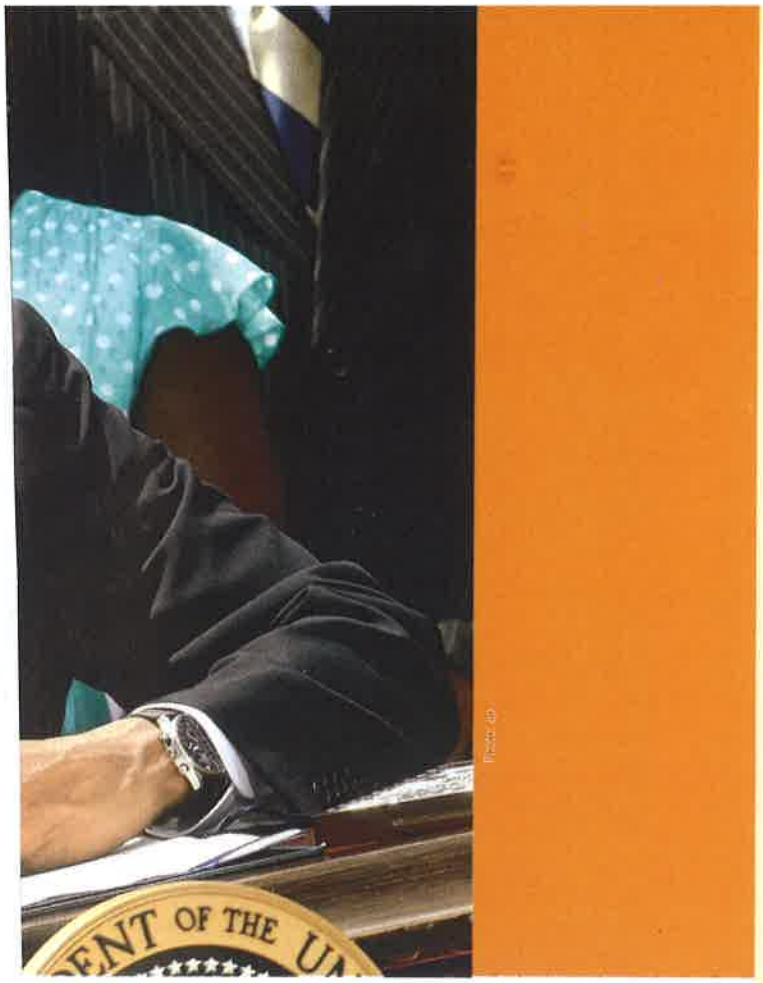
Other groups went further. The Association of National Advertisers, together with, amongst others, the American Civil Liberties Union, called the FDA bill "unconstitutional". FDA oversight of tobacco will also include restrictions on marketing and sales to youth; a ban on all outdoor tobacco advertising within 1,000 feet of schools and playgrounds; a ban on all remaining tobacco-brand sponsorships of sport and entertainment events, as well as on giveaways of non-tobacco products with the purchase of a tobacco product. It will limit advertising in publications with significant teen readership, as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-and-white text only. Advertisers and other entities claim that these restrictions violate the First Amendment to the US constitution, the right of free speech, and threaten to file a lawsuit.

Supporters of the legislation, however, say they drafted the law carefully to comply with the First Amendment; and according to legal experts, commercial free speech is not an absolute right. There are clear limits, for instance, on false advertising and on promotion of illegal activity. However, the issue grows more complicated if the advertising is both truthful and concerns a legal activity, like smoking by adults.

Outside the United States, it was the Indonesian kretek industry that was not exactly happy with the new US tobacco legislation. With the exemption of menthol and tobacco, the FDA bill will ban the use of flavours in tobacco products, which means that Indonesian kreteks or clove cigarettes are almost certain to be banned. In recent years, clove cigarettes have become increasingly popular in the United States; about 20 per cent of Indonesia's USD 500 million kretek exports go to the US each year. Gudang Garam, Indonesia's second-largest cigarette maker and the country's biggest kretek exporter, could be particularly affected – it has a factory in South America for the continental market. Indonesian trade officials have pointed out that a ban on cloves but not menthol was discriminatory; they now threaten to complain to the World

In essence

- Waxman/Kennedy bill was signed into law on 22 June 2009
- Critics argue that the bill violates cigarette manufacturers' right to freedom of speech
- Indonesian kretek manufacturers see their export business endangered



Trade Organisation.

Larger warning labels

The bill, HR 1256/S 982, also known as the Waxman/Kennedy bill, experienced strong opposition even before it went to the House and Senate. It was supported strongly by Philip Morris USA, raising concerns among competitors and critics that it might cement PM USA's market leader position. Others thought the FDA was not the right body to oversee tobacco product regulation, favouring the Department of Health and Human Services (DHHS) for the task.

On 11 June 2009, the US Senate approved a slightly amended version of the Waxman/Kennedy bill in a clear 79–17 vote. The following day, the House of Representatives voted 307 to 97 to approve the bill, and on 22 June, President Obama signed it into law.

The most significant change to the original draft was the size and nature of the cigarette health warnings. Being currently relatively small by global standards, under the FDA bill they will be required to cover the top fifty per cent of the front and rear panels of the pack. In addition, within three years a component of the warning label must include "colour graphics depicting the negative health consequences of smoking".

Tobacco analysts said they did not believe that the FDA tobacco regulation would have an adverse impact on the US tobacco industry's overall operating results.

Stefanie Rossel

The FDA tobacco bill at a glance

The Family Smoking Prevention and Tobacco Control Act (HR 1256/S 982), also known as the FDA bill, will:

- **Require tobacco companies and importers to reveal all product ingredients**
- **Subject new tobacco products to pre-market review, similar to a new pharmaceutical product**
- **Allow the FDA to severely restrict advertising, including a ban on magazine and point-of-sale advertisements**
- **Allow the FDA to create product standards for cigarettes, such as tar and nicotine levels, but it cannot reduce the nicotine level to zero**
- **Allow the FDA to change tobacco product content to protect public health**
- **Allow the FDA to issue public warnings, or even recalls of cigarettes**
- **Sets standards for so-called modified risk tobacco products**
- **Create larger, more "informative" health warnings**
- **Ban all flavouring other than tobacco and menthol**
- **Ban labelling cigarettes "light", "mild", and "low-tar"**
- **Establish a tobacco products scientific advisory committee**
- **Charge tobacco companies annual per-pack user fees, based on sales, to pay for the oversight.**

Threat to American-blend cigarettes

When it comes to organisational infrastructure, with its FDA regulation of tobacco, the US is now approaching a scale not far short of that already in place in Canada. But Canada is still a step ahead of the US; and its latest move in tobacco regulation recently annoyed its southern neighbours. On 17 June 2009, Bill C-32, an amendment to the Tobacco Act, passed the House of Commons in Ottawa, Canada, on its way to becoming law. The bill is a burning fuse as far as trade relations between the US and Canada go. It bans the addition of certain flavours and additives marketed largely to "vulnerable" children and juveniles. As such, the basic idea is in line with the thinking behind the US FDA tobacco bill and both bills also exempt menthol from the ban. However, a look at the new list of banned flavours and additives in the Canadian amendment came as a massive shock to US tobacco growers in Virginia, Kentucky and Tennessee.

Nearly all the additives used in American-blend cigarettes to cover the harsh taste of Burley are on the list, virtually banning the great majority of US cigarette exports into Canada. Although Canada is a Virginia-dominated market, with American blends holding less than one per cent market share, US farmers are worried about the effect the ban would have on other countries, especially at a time when US growers are trying hard to increase exports, because of lower domestic demand. It is worth bearing in mind here that 85 per cent of the 91 million kilograms of US Burley are already being exported. Feelings in the US are that the Canadian amendment has gone too far and contravenes both WTO and NAFTA trade agreements. (wmc)

"Beneficial effects will be fewer than anticipated"

TJI interview with Dr Adrian Payne

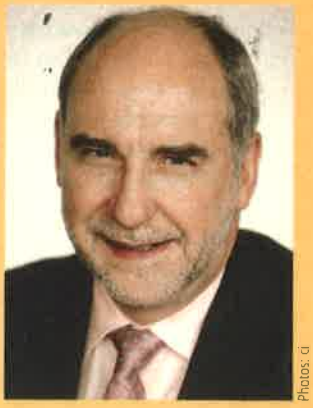
TJI: Dr Payne, can you please comment on the FDA bill regulating tobacco products, or Family Smoking Prevention and Tobacco Control Act, as signed into law by President Obama on 22 June?

Dr Adrian Payne: This event represents the culmination of ten years of legislative efforts by individuals and public health groups to get such a bill on the statute book, so you have to give them credit for their perseverance, even if you might not agree with the final outcome. What the bill does, is give the FDA regulatory authority over the manufacturing and marketing of tobacco products in the US. So, in essence, it rolls back the clock to the assertion of jurisdiction over tobacco products that the FDA initially claimed in 1996. When challenged by the tobacco industry, this assertion was invalidated by the courts in 2000, on the basis that the FDA had overstepped its regulatory authority.

Given the FDA bill's long gestation period, it's not really surprising that many of its provisions, in particular those relating to bans and restrictions on advertising and youth access, closely replicate the original FDA rule that was issued back in 1996. However, there are many important new provisions in the bill. These include the prohibition of the use of descriptors such as "light", "mild" and "low tar", and the use of fruit or sweet flavourings, including cloves, but controversially, not menthol. There is also provision for bigger warning labels, including pictorials. The FDA will have the power to require changes to products that reduce the levels of nicotine and other constituents that are potentially harmful. Having said that, the FDA cannot require that nicotine levels be reduced to zero, nor can it ban the sale of tobacco products entirely. Furthermore, there is a key requirement that companies that develop potentially less harmful tobacco products prove any claims that they might make about these products before obtaining authority to market them. Taken at face value, this requirement might seem to be common sense. But there has been, and still is, a lot of controversy about exactly how any such claims might be proved to the satisfaction of the examiners concerned. Certainly, the bar seems to have been set very high for companies to be able to approach this requirement with any real confidence of ultimate success, and I don't think this serves the best interests of either current or future tobacco consumers.

How will it shape the future of the tobacco industry in the US?

Even more controversial is that the passage of this latest FDA bill through the US Congress had the endorsement and support of the largest tobacco company in the US; Philip Morris. Whilst Philip Morris reportedly says it supports the bill because it would remove uncertainty regarding tobacco regulation, others question this motive, with some commentators going so far as to call the bill the "Marlboro Monopoly Act". It's informative that some rival US tobacco companies have openly acknowledged that the reduced ability to communicate with potential customers may give Philip Morris a competitive edge by locking the market in favour of the dominant player. Based on what has happened in other markets where advertising restrictions have been introduced, I think this is a justifiable concern. But much will



Photos: ci

Dr Adrian Payne is managing director of Tobacco Horizons, an independent company that offers consultancy services on tobacco and nicotine regulation. Previously, he was head of international public health and scientific affairs at British American Tobacco, and prior to that, head of corporate, social and regulatory affairs. Before joining BAT, Dr Payne held various senior management positions in the pharmaceutical industry, namely at GlaxoWellcome in the UK, Italfarmaco in Italy and Jouveinal/ Parke – Davis in France, where he was director of pharmacology.

While at BAT, Dr Payne played a key role in the development and initial test marketing in 2005 of Swedish-style snus in Sweden and South Africa as a response to suggestions from some involved in public health that snus might be a useful tool in tobacco harm reduction.

depend on the specifics of detailed regulations on retail sale that the FDA now has the job to establish, and it will be some time before these regulations are finally published. Also, it can't be guaranteed that some of the bans and restrictions on marketing and advertising in the bill will survive likely court challenges on First Amendment grounds.

industry, I think the mindset required to sign off on whether new medicines are safe and effective is very different from that required to evaluate the public heath impact of products that, whilst being potentially less harmful than those currently on the market, would nevertheless likely still pose a significant hazard. Also, there are some who

nority believe that it will result in a public health disaster because of an implicit stamp of approval that tobacco companies might gain by operating under the oversight of FDA regulation. My belief is that the claimed beneficial effects will be fewer than anticipated, but could have been very much greater if a more rational approach had been taken

But irrespective of the eventual outcome on this score, I wouldn't be surprised if there is further consolidation in the US tobacco industry, particularly when it comes the to smaller players, simply owing to the increased cost and complexity of doing business under the provisions of the FDA bill.

What do you think are the bill's shortcomings?

Well, I have already mentioned the contentious issue of how companies might prove any claims they might want to make about less harmful products. I think the provisions in the bill that relate to this will undoubtedly make it more difficult, if not impossible, to bring less harmful tobacco products to market. This to me is *a*, if not *the*, major shortcoming, and I'd like to come back to this point later. Also, whilst I respect the view of those who believe that the FDA is the appropriate agency to have the authority over tobacco regulation, I'm not so sure they're right. Based on my experience in the pharmaceutical

believe the FDA is already overstretched with its existing commitments and so would not be able to handle being given responsibility for another area. So, on balance, I think that maybe a better solution might have been, as was proposed by an alternative bill, to set up a separate agency within the US Department of Health and Human Services (DHHS). But that's a bit of a moot point now and I hope that the not insignificant user fees the industry will have to pay to support the new function within the FDA are put to good use.

How efficient can the bill be?

As for whether the bill will be effective in its stated objectives of reducing youth uptake and death and disease caused by tobacco products – well it's been clear for some time that there are basically two schools of thought on this. One, to which the overwhelming majority of public health groups that backed the bill not surprisingly subscribe, is that it will have a major beneficial impact. In contrast, a small, but vocal, mi-

when crafting the harm reduction elements of the bill.

If you rank the US in a world tobacco regulatory overview, where will FDA regulation of tobacco products put it?

It depends on whether you assess the situation in terms of the scope and impact of regulation or in terms of the size of the organisational infrastructure that underpins the development of regulatory policy. In some areas, notably advertising, the regulatory measures that the FDA bill mandates undershoot those measures recommended by the WHO Framework Convention on Tobacco Control (FCTC). In this context, the provisions of the FDA bill also fall short of more extreme initiatives, like the ban on retail displays that have been imposed in some countries. I'm not convinced by the evidence that such bans have any impact, far from it, but it's an illustration of where the leading edge of tobacco regulation is currently perceived to be by the tobacco control community.

When it comes to organisational infrastructure, by giving authority to the FDA, the US has joined the same league as countries like Canada and Brazil, which through Health Canada and ANVISA, respectively, have similar executive structures for informing tobacco regulation. Despite my misgivings as to the FDA being the appropriate agency within the US DHHS for regulatory oversight of tobacco, I think this is a good step, in that it would imply a more transparent and rigorous approach than might otherwise have been the case if the bill hadn't been passed. But there is no guarantee of this and until the new FDA function is up and running, it will be hard to judge if this is true or not.

Quite often developments in the US set the pace for many other countries – in how far do you expect FDA regulation of tobacco products to affect other tobacco legislation?

I think the passing of the FDA bill might well spur other countries into accelerating their own programmes of tobacco regulation. But I'm not sure it will influence the actual content of these programmes. It's the FCTC that is currently driving national tobacco regulatory agendas, rather than anything that is happening in the US, other than perhaps tobacco litigation. So I think any external impact will be somewhat limited and I'd include any influence on the EU Tobacco Product Directive in this assessment. However, the situation could change if the FDA bill results in the development of clear guidelines and realistic benchmarks for the development of less harmful products. If this were to be the case, I would hope that other countries might consider adopting them. There is a precedent in the international harmonisation of testing requirements for novel pharmaceuticals and there is a lot to be learnt from that particular process.

What does FDA regulation mean for tobacco harm reduction and product innovation?

Specifically, an application for the approval of any claims that a newly developed product might be less harmful would have to take into account the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. This includes (a) the increased or decreased likelihood that existing users of tobacco products will stop using such products, together with (b) the increased or decreased likelihood that those who do not use tobacco products will start using such products. Fair enough, you might say, given the undeniable negative impact of tobacco use on public health. Conversely, it's very hard to see how this kind of information can be derived before putting a new product on the market, because a lot will depend on consumer reaction. However, I do agree with the requirement for post-marketing surveillance following the launch of new products. This might assuage the understandable fears of those in public health who are concerned that the launch of a new less-harmful product might open some kind of Pandora's box that would be almost impossible to close thereafter.

But another, and more immediate, problem here is that it's not just less harmful products that might be developed in the future that are affected by the harm reduction provisions of the FDA bill. It's quite clear that, for reasons best known by the bill's sponsors, the drafting of the legislation failed to take into account recent advances in product innovation and scientific knowledge. From a product standpoint, examples are the recent US launch of low-nitrosamine smokeless tobacco products, such as Swedish-style snus, other novel forms of more user-friendly smokeless tobacco products and the increasing popularity of non-tobacco nicotine-containing products like e-cigarettes. I think most public health professionals would agree that by not exposing consumers to the harmful effects of inhaled tobacco smoke, these types of products, whilst not being completely safe, are nonetheless likely to be vastly less harmful than cigarettes. In the case of snus, the epidemiological evidence from Sweden that this is indeed the case is incontrovertible. Yet, by the bill's enactment, these very same products now run the risk of being banned from the US market, whilst cigarettes are guaranteed a grand-fathered future alongside more traditional smokeless products.

It's hard to understand the logic behind this eventuality, especially given that, during the passage of the bill, potentially life-saving amendments that would have established a much more pro-active stance on product innovation and consumer information were put forward. These included arguably more realistic criteria for new products to meet, the ranking of existing tobacco products in terms of risk, and warning labels that reflected this ranking. Yet ▸

these amendments were dismissed almost out of hand, for reasons of which I can only presume was political expediency. I very much hope that this particular aspect can be re-examined when the dust has settled. And I don't think I'm alone here. Surely, if ever there was an area in which the public interest should trump political interest, tobacco harm reduction should be it. But if the signing-off of the bill puts an end to political hyperbole and ushers in a new era of scientific discourse on harm reduction, that's no bad thing.

The US has not ratified the FCTC yet. Do you think it is more likely that this will happen now? If so, what will happen to harm reduction elements?

The US doesn't seem to have a particularly good record on ratifying international conventions that it has signed up to. When it does, it's often the result of a very slow and deliberate evaluation. Indeed, the US is one of only two countries in the world that have not yet ratified the International Convention on the Rights of the Child, even though this convention entered into force almost two decades ago. As for the FCTC, I tend to think that now the FDA bill has been passed, it is more likely that the US will ratify the FCTC. I say this because it's noticeable that some of the most prominent public health organisations that supported the bill are also members of the Framework Convention Alliance (FCA). Apart from performing a watchdog function for the FCTC, one of the objectives of the FCA is to support the development, ratification, accession, implementation and monitoring of the FCTC. So it would seem strange if those US FCA member organisations did not now lobby more strongly for FCTC ratification. But it doesn't mean that ratification will necessarily happen in the immediate future; digestion of the ramifications of what the FDA bill will mean in practice is bound to take time and resources away from considering such a measure.

If the US does eventually ratify the FCTC, I would hope that some of the harm reduction elements of the FDA bill, problematic though they might be,

would have a positive influence on WHO thinking, which currently is more focused on harm elimination rather than harm reduction. But at least the WHO Study Group on Tobacco Product Regulation (TobReg) does acknowledge that there is a continuum of risk when it comes to tobacco products, and with certain caveats, that smokeless tobacco products may have a role to play in harm reduction. This could be a platform to build on via cross-talk between the FDA and TobReg, many of whose members are based in the US and hence may also be involved in FDA rule-making.

The establishment of a tobacco products scientific advisory committee is one aspect of the FDA bill. What will it look like, how much say will the tobacco industry have in it?

Speaking from personal experience of the difficulty of finding a forum in which representatives of the tobacco industry can sit down with public health professionals, I think this is potentially a very positive aspect of the bill. What the bill actually calls for is the establishment of a twelve-member advisory committee composed of seven individuals who are physicians, dentists, scientists, or health care professionals practising in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant speciality; one individual who is an officer or employee of a state or local government or of the federal government; one individual as a representative of the general public; one individual as a representative of the tobacco manufacturing industry; one individual as a representative of the interests of the small business tobacco industry (on a rotating basis) and one individual as a representative of the interests of the tobacco growers. However, not all members will have equal status; those representing the tobacco industry and tobacco growers are expected to serve as consultants to the other committee members and will be non-voting representatives. But at least the industry will have the chance to share its expertise and put forward a point of view in such a multi-disciplinary committee. This will not be the case in countries that follow the guidelines on FCTC Article 5.3 to the effect that "parties to the convention should not allow any person employed by the tobacco industry or any entity working to further its interests to be a member of any government body, committee or advisory group that sets or implements tobacco control or public health policy". Whilst some might argue that this stance is entirely appropriate, I think it represents a very blinkered approach to formulating regulatory policy on such an important issue as tobacco.

Some of the topics the FDA tobacco products scientific advisory committee will consider includes the effects of the alteration of the nicotine yields from tobacco products, whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and the review of other safety, dependence or health issues relating to tobacco products. This latter responsibility includes reviewing the impact of the use of menthol in cigarettes and data on potentially less harmful tobacco products. I think that this forum could provide an invaluable opportunity to make regulatory decisions based on science rather than prejudice and politics. As a scientist myself, I certainly hope so.

Interview: Stefanie Rossel