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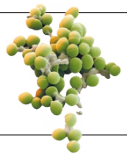

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Huffing and puffing

As vaping becomes ever more popular, a long-running battle between US regulators, lawmakers and industry drags on. The nation must act quickly to control the use of e-cigarettes.

In the time it takes you to read this article, at least one cigarette smoker in the United Kingdom will have switched to vaping. As economic uncertainty grips many industries, the use of e-cigarettes is booming. The £6.1-billion (US$7.9-billion) global market for them is now about 20 times what it was in 2010. It is expected to double again in the next three years.

Does vaping encourage adolescents to move on to the real thing? Precisely how much safer is it than smoking? Are there hidden dangers? Much remains for researchers and clinicians to debate. But studies suggest that e-cigarettes are considerably less harmful than cigarettes, and that they may help smokers to substitute a safer habit for a deadly one. In the United Kingdom, for example, public-health advisers have declared e-cigarettes safer than conventional cigarettes, and 850,000 UK vapers now consider themselves 'ex-smokers' — a likely win for public health.

Dozens of countries regulate vaping, using new or existing rules. But in the biggest market for e-cigarettes — the United States — the industry has grown up with few government controls. The country accounted for 43% of the world's consumption of vaping products in 2015. Yet the US Food and Drug Administration (FDA) has been slow to respond. E-cigarettes first hit the US market in force in 2006. It was 2014 before the agency released its first proposals to regulate them, and those rules were not finalized until last August.

Now the FDA's policy seems to be in jeopardy. Some lawmakers, with nudging from the e-cigarette industry, want to replace it. Last month they pushed — unsuccessfully — to exempt thousands of e-cigarette products from the regulations, by trying to add the provision to a crucial funding bill. President Donald Trump's young administration shows signs that it might push back against the new rules, too.

On 2 May, *The Washington Post* reported that the FDA had postponed a series of deadlines after which e-cigarette manufacturers will be legally required to list the ingredients in their products, and to label those products with addictiveness warnings.

The reason given was to allow the agency's new leadership to evaluate the rules. On 9 May, the US Senate confirmed that leadership by announcing the venture capitalist and physician Scott Gottlieb as FDA commissioner. Gottlieb has numerous ties to industry, and has served on the board of an e-cigarette company.

The FDA's e-cigarette regulations are unlikely to have been popular at that company. And, on the other side of the debate, many public-health researchers dislike them, too. Both sides are concerned that the regulations are so onerous that they will squash the industry.

Certainly, the rules place a curious onus on e-cigarette companies to prove that their products benefit the public health; one interpretation suggests that a company would have to do so for each new flavour. The FDA estimated that gaining approval would cost companies more than $450,000 for each product. This would squeeze out smaller firms and place the industry firmly in the hands of the major tobacco companies. And there are widespread fears that the plan could discourage innovation in the sector: why develop a new product, or fix a flaw in an old one, if it will cost your company hundreds of thousands of dollars to have it approved?

So if Congress or the new FDA administration does away with those regulations, there may be few tears shed. But the late-gained momentum must not be squandered. The FDA is under-resourced and struggles to keep up with its growing regulatory mandate. But it should still be able to move rapidly to produce more-feasible regulation on vaping that still protects consumers. One option would be to establish basic safety standards and require manufacturers to list their ingredients, but not to demand proof that each product benefits public health.

"The rules place a curious onus on e-cigarette companies to prove that their products benefit the public health."

E-cigarettes have prompted legitimate concerns. The rapid rise of vaping among adolescents — as well as the marketing of e-cigarette flavours such as 'gummy bears' and 'bubble gum', seemingly aimed at younger users — has caused particular alarm. Ideally, regulations would maintain safety standards and restrict marketing aimed at children and adolescents, while ensuring that e-cigarettes remain available to wean smokers off cigarettes.

Observers will also be monitoring how the FDA handles Gottlieb's potential conflicts of interest, the spectre of which threatens to haunt whatever alternatives the agency might develop. How the FDA manages the controversy over e-cigarette regulation could become an early test of how it intends to navigate Gottlieb's many other potential conflicts in the pharmaceutical industry. At the very least, the agency must be open and transparent about future changes to e-cigarette regulations — and about its reasons for making such changes. ■

Open doors

A meeting between the Pope, patients and researchers paves the way for fresh dialogue.

Dilia is the oldest of an unusual crowd of people due to meet Pope Francis next week at the Vatican. The 79-year-old widow from rural Colombia married into a family whose members carry the gene for Huntington's disease, a hereditary neurodegenerative disorder. Fate was cruel. Of her 11 children, 9 inherited the disease. Five have died and the remaining four are sick. The next generation is affected, too. One grandchild has died and five more show symptoms.

Those symptoms — involuntary, jerky movements accompanied by mood swings and cognitive decline — are aggressive and carry stigma.

Patients and their families often live out of sight and in dreadful conditions, especially in developing nations. Dilia's village has limited access to running water.

Despite their own hardship, many have helped research into the condition — with little tangible reward. Most of them are Catholics, so their meeting with Pope Francis is a thank you from the scientists who arranged the event. These researchers are acutely aware of how much they have relied on the patients — the gene that causes Huntington's was discovered thanks to tissue donations from poor Venezuelan families — and that they have not been able to do anything to change their dire situation.

The fact that Pope Francis quickly agreed to meet the families speaks to his hallmark philosophy of reaching out to poor and disadvantaged people. But it is also further evidence of a new openness towards science, which has followed a 2015 encyclical — a letter of guidance on particular themes written by a pope to his bishops — called *Laudato si'*. The encyclical argued for better stewardship of the planet and excited scientists with its forthright pronouncements on the need to control greenhouse gases and with its implicit acceptance of the principles of evolution in well-informed discussion of the need to protect biodiversity. It also acknowledges the value of scientific and academic freedom in society, and the need for open scientific debate on advances in biology.

The Huntington's event is a gesture that shows in a small but significant way in which religious leaders and science can work towards a common goal.

While the Vatican has supported its elite Pontifical Academy of Sciences for more than 80 years, other grass-roots initiatives are emerging. For example, last month Italian researchers collaborated with *The Lancet* to organize a conference in Rome called (with undeniable hubris) The Future of Humanity Through the Lens of Medical Science. Attended by Nobel laureates and Vatican officials, its discussions ranged beyond biomedicine to encompass themes such as climate change and migration, mirroring the spectrum of *Laudato si'*.

There is a chasm between religion and science that cannot be bridged. For all its apparent science-friendliness, *Laudato si'* sticks to the traditional Vatican philosophy that the scientific method cannot deliver the full truth about the world. However, there is still much to be discussed on how each side can help the other to converge on shared goals.

"There is a chasm between religion and science that cannot be bridged."

The Catholic Church has more than 1.2 billion members and can thus have broad influence on the acceptance of facts that some politicians choose to distort — such as the existence of anthropogenic climate change. Scientists can provide technical solutions for poor and sick people, thereby assisting the work of missionaries.

In Rome, Huntington's researchers still desperately seeking a treatment for the disease will have an opportunity to discuss with Pope Francis sensitive issues relating to avoidance of the disease, namely contraception and embryo selection. Francis rarely misses an opportunity to reiterate his view of the sanctity of the human embryo (a theologically debatable Vatican position that has hindered important stem-cell research in some countries) but he seems to keep his views on contraception — outlawed by the Church — deliberately ambiguous. The special audience may help to encourage a much-needed move from the Vatican towards the mercy (and reality — Catholics in rich countries routinely ignore the ban) of finally allowing followers, including those with devastating hereditary disease, to take control of their fertility. ■

In a hole

The nuclear-waste legacy of the cold war must be addressed.

The United States is still fighting the cold war. Thousands of its citizens had to take shelter last week because of the threat of radiation from nuclear weapons. But the opponent is no longer the Soviet Union. The enemy now is the legacy of an arms race and decades of government indifference to the mess that has been left behind.

On 9 May, the roof collapsed in a tunnel that houses highly radioactive waste at the US Department of Energy's sprawling Hanford site in Washington state. The tunnel is one of a pair that together shield 36 radioactive railway carriages, once used to carry nuclear fuel for reprocessing to plutonium. Radiation monitors showed no signs of airborne contamination after the collapse, so workers at the site were released and the hole was filled with fresh soil.

The incident is yet another alarming reminder of the risks posed by pollution at nuclear-weapons facilities in the United States and around the world. It could have been much worse. And without serious and sustained efforts to clean up these ageing facilities, one day it will be.

In August 2015, an independent panel of academics placed the Hanford tunnels on a list of high-priority dangers at the site, which spreads for more than 1,500 square kilometres along the Columbia River. The interim report, by the Consortium for Risk Evaluation with Stakeholder Participation (CRESP), said that the oldest tunnel — built in 1956 and covered with soil nearly 2.5 metres deep — could collapse and release radiation during an earthquake. The energy department is still investigating last week's breach, but the 6-metre section that gave way may have succumbed to little more than old age.

The energy department has spent more than US$164 billion cleaning up its nuclear-waste sites since 1989. But it will be many decades before the work is complete. Each year, the agency spends more money just to maintain old infrastructure and ensure workers are safe.

Science might yet offer more efficient and economic solutions. Whereas Congress and previous administrations have been willing to spend money to maintain — or upgrade — the nuclear weapons themselves, there is less interest in paying to clean up after them. US President Donald Trump is no different. His administration's initial 2018 budget outline would boost funding for the environmental clean-up of nuclear waste by around $300 million, to $6.5 billion. But the National Nuclear Security Administration, which runs the energy department's weapons programme, would fare better with an increase of $1.4 billion, or 11%.

Money is not the only problem. For more than a decade, organizations such as the US National Academies of Sciences, Engineering, and Medicine have been raising questions about the regulatory challenges that impede clean-up. For instance, the energy department's nuclear waste is still classified by where it comes from, rather than by its actual radiological risk. This often increases clean-up costs, and so heightens danger in a budget-constrained world. Nor is the department able to focus its resources on the highest priorities, given myriad legal agreements with state and federal regulators at individual sites — Hanford included.

In a second report in August 2015, CRESP said that the extent to which the clean-up programme is based on actual risk remains "unclear". The report recommended that Congress establish an interagency task force, with the participation of independent experts, to advise the department on clean-up activities and to help navigate legal and regulatory issues. Controversially, CRESP also recommended the creation of an alternative dispute-resolution process to replace the court-approved agreements that govern individual sites.

Objections to that report were raised by the governor and attorney general of Washington state, which has one such agreement at Hanford. This is testimony to the complexity of the problem. Still, the energy department would benefit from a broader reassessment of its clean-up mission — and a regular injection of unbiased risk analysis. The carriages in the Hanford tunnels are not going anywhere soon. But it should be science that dictates their timetable. ■