



The Pharmacist Activist

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Editorial

☆☆☆ EXTRA! EXTRA! ☆☆☆

FDA BANS SALE OF NICOTINE!

With an action that even caught many legislators and government officials by surprise, the Food and Drug Administration (FDA) announced today that it will ban the sale of nicotine. Those who were attending the press conference anticipating an announcement of the next hearing about the effects of tobacco on health were stunned by the boldness of the action. You could almost hear a cigarette drop as the FDA spokesperson described the events that have resulted in this momentous action. Reading from a prepared text, the spokesperson provided the following background.

“It was on January 11, 1964 that Dr. Luther Terry released the first report of the Surgeon General’s Advisory Committee on Smoking and Health. This report concluded that smoking causes cancer and pulmonary and other problems. Over the last 55 years since the release of that report, the FDA has been very closely monitoring this risk. We have held a lot of hearings, issued hundreds of warnings, including warnings right on packages of cigarettes, and have approved products that help people stop smoking. Several generations of FDA employees have deliberated how we can control this hazard, but we have recently had to conclude that warnings and other actions have not worked.

Early on, the number of people dying from tobacco-related causes was not that large – less than 200,000 per year, a number in the range of what would be classified as

a rare disease. However, that number grew quickly and, in recent years, an estimated 480,000 Americans die each year from tobacco-related causes. But it wasn’t really until one FDA official described the estimate as ‘half a million deaths’ that we were struck by the extent to which this problem had grown. The word ‘million’ has impact – these are real numbers, real people. Something needed to be done! A meeting of FDA staff was convened and one individual suggested that we hold a hearing. However, the Commissioner responded that we just held a hearing and that no action other than more warnings had resulted from the hearings on this subject over the last 55 years.

A new intern attending her first meeting at the FDA raised a question: ‘I know that nicotine is addicting but what is it actually approved for? Does it really provide any benefit for anything?’ A veteran FDA staffer quickly responded, ‘The only approved use for nicotine is to help people stop using nicotine.’ The intern appeared puzzled. Suddenly, an FDA official jumped to his feet and shouted, ‘I have the solution! If we ban the sale of nicotine, we can eliminate numerous problems!’ It was a Eureka moment that was immediately followed by many spontaneous observations:

‘If we require tobacco companies to extract the nicotine from tobacco, cigarettes and cigars will no longer be addicting and, if people still want to smoke, they can stop whenever they want to.’ ‘We will still

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warn people about the toxins in tobacco products but, if they die, it will occur from their choice because we will have required removal of the addictive substance.’

‘Tobacco farmers will not be threatened because instead of tobacco they can grow healthy products or even marijuana.’

‘Millions of teenagers will be spared the addiction to products like Juul. Our young people will be rescued from that fate!’

‘Following the phase-out of the nicotine-containing tobacco products, there will no longer be a need for nicotine replacement therapies. The ban on nicotine will be complete.’

‘This action may save more lives than the discovery of penicillin.’

‘How did this solution escape our awareness until now?’

The group was jubilant and snapped into action. The Commissioner contacted the President who tweeted his approval of the decision and its consistency with his Make America Great Again agenda. We were planning to announce the action on January 11, the 55th anniversary of the release of Surgeon General Terry’s report. However, the government shut down and we were delayed. But the delay turned out to be fortuitous because our Commissioner has recently informed us of his resignation from his position to return to semi-private life. Because concerns about smoking, vaping, and addiction have been his signature issues, today seemed like the perfect day to announce the ban on the sale of nicotine. To allow all parties sufficient time to implement changes in response to the ban, and to allow time for those currently addicted to nicotine to recover, the ban on the sale of nicotine will become effective one year from today, April 1, 2020. The effective date in the year 2020 is also symbolic of the clarity of the 20/20 vision of the FDA on this matter.”

At this point, the FDA spokesperson adjourned the press conference. She noted that questions would not be taken because the frequent and sustained applause had resulted in the press conference running much longer than anticipated, and FDA staff were running late for the gala din-

ner that would follow in honor of the Commissioner and there were already long lines at the security checkpoints.

The responses

Within minutes following the announcement of the FDA action, many organizations and individuals responded with statements, examples of which follow:

The *American Civil Liberties Union (ACLU)* stated that the action discriminates against people with random mutant nicotine receptor disorder (RMNRD) and those who choose to commit suicide, but slowly rather than suddenly. Its lawyers have started preparing a lawsuit against the FDA.

The *major tobacco companies* voiced strong opposition to the ban and noted that their research demonstrates that as the number of smokers increase, government expenditures actually decrease, and Medicare expenditures are reduced by approximately 50%. When asked whether this was because more smokers die before they reach the age of eligibility for Medicare benefits, the tobacco company spokesperson responded that the study could not include every variable. He also noted that although this action would kill their revenue stream in the United States, it was expected that these losses would be quickly offset by their marketing successes in other countries that permit more personal freedoms.

The *vaping industry* was both opposed and defiant. The CEO of one of the largest companies stated: “You don’t make billions of dollars in just several years by being dumb. Our devices are already used for vaping marijuana, mostly in states where that is legal. We have also identified a dietary supplement called nicotine that has properties that are essentially the same as those of nicotine, but it is spelled differently and is not included in the FDA ban. Our studies show that teenagers love it, continue to use it, and appreciate the assorted flavors of which there will be 31. We will be employing strict safeguards in preventing underage use and will not permit sales of the product within 15 feet of the entrances to elementary schools. We do have a cola-flavored product in the development stage for younger children that can be used in our current vaping devices (without the nicotine, of course). We are able to aerosolize caffeine – think of it as Coca-Cola with smoke. Our test marketing in kindergarten classes

predicts it will be hugely successful. If the FDA would ever try to ban this product, they would also have to prohibit young children from drinking cola beverages and that isn't going to happen. Given the success of stimulants like amphetamines and methylphenidate in treating children with attention-deficit hyperactivity disorder (ADHD), our pediatrician consultants feel our caffeine-containing vaping devices have great potential for kids with this condition."

Several *pharmaceutical companies* issued press releases in response to the announcement. *Pfizer* was particularly critical, noting: "Now that we have earned billions of dollars from selling Chantix in the prescription marketplace, the patent for the drug will soon expire and we are taking steps to switch it to OTC status and obtain additional years of market exclusivity. But when the sale of nicotine is banned, nobody will need to use Chantix. This action is extremely unfair to our company and marketing department, and we will be pursuing legislation to provide greater government protections for big business."

Chain pharmacy and big box store executives were particularly upset. *Walgreens* stated that in its 118-year history there had been at least two occasions on which its executives held meetings for the specific purpose of discussing the discontinuation of cigarette sales. However, both times they declined to take such action to spare their customers the disappointment of coming into a Walgreens and not being able to buy cigarettes. Walgreens was also upset because the FDA is prohibiting some of its stores from selling tobacco products because there were repeated violations of restrictions on the sale to minors. They were especially offended because the FDA Commissioner had singled it out for criticism by stating, "Walgreens is currently the top violator among pharmacies that sell tobacco products, with 22 percent of the stores inspected having illegally sold tobacco products to minors." The Walgreens statement notes, "Everyone does it – the FDA shouldn't single us out. Besides, it was a misunderstanding; our legal department thought the restriction was against sales to minors." Walgreens was also very critical of anti-tobacco activists for vandalizing its signs. "We had this great slogan – 'Walgreens – at the Corner of Happy and Healthy'. But vandals painted over the last three words and replaced them with Smoky and Sickly. We thought we outsmarted them by completely changing the slogan to - 'Walgreens – Trusted Since 1901.' However, then they used white paint to cover over the letters S, c,

and e in the word Since."

Rite Aid executives were somewhat philosophical because of their previous success in responding to charges of selling cigarettes to minors. As one of the executives recalled; "Some years ago our pharmacies were caught selling cigarettes to minors. We were very concerned that there would be severe penalties and our revenue from selling so many cigarettes would be cut off. But then, in a stroke of genius, one of our executives proposed a settlement that, if we were allowed to continue selling cigarettes to adults, we would discontinue selling *candy* cigarettes to children so that no child would be left behind in understanding the risks of any type of cigarettes. We struck a deal and we continue to sell tons of cigarettes, mostly to adults. In addition, our executives wisely anticipated that the time would eventually come when the sale of nicotine would be banned. We can't say that we thought that would occur as soon as 55 years after the Surgeon General's first report, but we do have a contingency plan. When the ban on nicotine becomes effective, we will roll out the Rite Aid brand of candy cigarettes, 20 in a pack, for only \$8.99 a pack. Place your order early because we expect a high demand!"

As the largest retailer in the world, *Walmart* presumably sells more cigarettes than anyone else, and upon learning of the FDA action, it immediately called a press conference at its headquarters. Because of the impact of any decision made by Walmart, reporters came from around the world and there was gridlock in Bentonville, Arkansas. A Walmart executive spoke for the first 20 minutes about the company's new commitments to reduce plastic packaging waste. A second executive then spent the next 30 minutes outlining what the company had done to force its suppliers of certain household products to remove trace amounts of materials that Walmart viewed as toxic. "We take our responsibilities as a corporate citizen very seriously, and will do everything we can to force our suppliers to conform to the standards we consider important," he declared. By this time those attending the press conference had become impatient. One reporter asked, "How many people have died from exposure to plastic packaging or obscure chemicals in certain household products?" The Walmart executive responded, "We actually don't know of any yet, but how can you challenge the importance of these actions?" Another reporter stated, "We thought we were coming here to learn how Walmart plans to respond

to the FDA action to ban the sale of nicotine. We know that almost half a million Americans die each year from tobacco-related causes. How many of those deaths can be attributed to cigarettes purchased at Walmart?" The Walmart executive responded; "We are a full-service retailer and recognize our responsibility to sell the products that our customers and communities want to buy. It is unfortunate if they die as a result of smoking cigarettes that we sold them, but it was their choice and not ours." Another reporter questioned; "With that policy about what you will sell, will you soon be selling marijuana because of the large number of people who wish to buy it?" "Who told you?" the executive immediately responded and then caught himself, "What I meant to say is that discussions are in a preliminary phase. Also, we have a question whether the ban of the sale of nicotine will actually occur. The FDA Commissioner who initiated it has now resigned, and we are supporting the current Vice President of a major tobacco company to be his successor."

Although CVS discontinued the sale of tobacco products about 5 years ago, executives were envious that Walgreens, Rite Aid, and Walmart were getting a lot of free publicity, and the public seemed to be forgetting that CVS officers had already taken visionary action in this direction long before the FDA did. The CVS spokesperson called a press conference to declare that CVS had been a leader among chain pharmacies in discontinuing the sale of tobacco products. To be as complete and clear as possible he noted that not only had CVS stopped selling tobacco products, they were prohibiting the use and recognition of words or terms such as smoky, flame, fire, and firewall, so that no one will have the mistaken impression that they are tolerating anything related to cigarettes and smoking. "What's a firewall?" asked a reporter. The spokesperson responded; "It's not a common term and I actually don't know because there is a high level of confidentiality surrounding it. However, I am sure one of our executives knows. Unfortunately, he could not join us today." Another reporter inquired how CVS had been able to offset

the loss of revenue when it stopped selling cigarettes. The spokesperson responded that, prior to making that decision, CVS had conducted a very careful evaluation of all of its operations and concluded that they had more pharmacists and pharmacy technicians than were really needed. Accordingly the company reduced the number of these positions. "But that financial challenge was small compared to the one we are facing now in trying to acquire Aetna," the spokesperson continued. "We have had to reduce hours and positions even more." The same reporter noted that he had been in a CVS store yesterday and there was a line of about 20 people waiting for prescriptions. He asked if that could be due to the staffing cuts. The spokesperson responded that that was not an unusual situation but had probably been worsened by the company's challenges in acquiring Aetna. He encouraged the reporters in attendance to help get the word out that, if people feel they have to stand too long in a local CVS store, that they can send their prescriptions to Caremark mail-order pharmacy as long as they don't have to start their medication in the next 14 days.

Of the national pharmacy associations, only Suzy Rosa Rassuh, the executive of the Hungarian-American Pharmacists Association (HAPA) was willing to speak on the record. She noted that none of the HAPA members sell nicotine-containing products or use these products themselves, so the ban doesn't directly affect them. She was very encouraged by the impressive doubling of the growth in membership of HAPA during the last year that had occupied much of her time. "However," she continued, "we must never be too busy to declare our emphatic support for banning an agent that has had such devastating health consequences for so many of our families and friends."

Daniel A. Hussar

Happy April Fools' Day!

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