

**To minimize illicit tobacco trade, FDA should reject any partnership with the tobacco industry, reject industry estimates and exaggeration of illicit trade, and use the FCTC Protocol on Illicit Trade as a model to counter the supply side of illicit trade**

**Docket No. FDA-2018-N-0529**

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The Family Smoking Prevention and Tobacco Control Act (FSPTCA) section 907(a)(3) gives FDA the authority to establish tobacco product standards that are “appropriate for the protection of the public health.” In addition to considering scientific evidence concerning the risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products, FSPTCA section 907(b)(2) requires FDA to consider the “countervailing effects” of the tobacco product standard on population health, such as “the creation of a significant demand for contraband or other tobacco products” that do not meet FDA’s tobacco product requirements and “the significance of such demand.”<sup>1</sup>

The actual risk of increasing demand for non-conforming products in the illicit market following adoption of a product standard will be highly dependent on the final standard adopted and the timeline for implementation. As these tobacco product standards are developed and implemented, it will be necessary for the FDA to prepare to respond to tobacco industry claims that the standard will increase demand for illicit products.<sup>2</sup>

Since it is required for the FDA to consider the possibilities of illicit trade in its rulemaking, the FDA should use its considerable authority to discourage illicit trade, rather than relying on the regulated tobacco companies to voluntarily reign in illicit trade. The FDA should:

- 1) Reject any partnership with the tobacco industry
- 2) Reject industry estimates and exaggeration of illicit trade
- 3) Use FCTC Protocol on Illicit Trade as model to counter the supply side of illicit trade

**1) The FDA should reject any partnership with the tobacco industry**

International experience demonstrates that government partnerships with tobacco companies have yet to result in reducing illicit tobacco trade, mostly due to the fact that tobacco companies

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<sup>1</sup> U.S. Food and Drug Administration. Family Smoking Prevention and Tobacco Control Act. Washington D.C., United States, 22 June 2009. Available at: <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm>. Accessed 25 May 2018.

<sup>2</sup> Joossens L, Raw M. Turning off the tap: the real solution to cigarette smuggling. Int J Tuberc Lung Dis. 2003 Mar;7(3):214-22.

have benefitted from illicit trade even after these partnership deals were established.<sup>3</sup> The tobacco companies' own international data reveals that counterfeit cigarettes only make up 5-10% of the illicit trade market.<sup>4</sup>

Although the nature of the illicit tobacco market has changed substantially over time from large-scale cigarette smuggling to illegal manufacturing and counterfeiting,<sup>5</sup> international research demonstrates that tobacco companies have continued to be involved in the illicit trade and have either failed, or have not made serious efforts, to control their supply chain.<sup>6</sup> As of 2014, tobacco companies were continuing to overproduce or oversupply cigarettes knowing that they would enter into the illicit market.<sup>7</sup>

Given the fact that tobacco companies appear to significantly benefit from illicit tobacco trade, their direct and indirect involvement and ***their failure to adequately address the supply side of cigarette distribution makes the tobacco companies untrustworthy and non-credible partners.***

### ***The tobacco industry benefits from illicit tobacco trade due to tax evasion***

International experience demonstrates tobacco companies make profits when they sell to distributors regardless of whether cigarettes enter the legal or illegal market.<sup>8</sup> Tobacco companies benefit from the flow of illicit tobacco trade bypassing tariff and non-tariff barriers to trade allowing cigarettes to enter into otherwise closed or protected markets,<sup>9</sup> evading taxes and

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<sup>3</sup> OCCRP. Big Trouble at Big Tobacco 2011. Available at: [https://reportingproject.net/troubles\\_with\\_big\\_tobacco/](https://reportingproject.net/troubles_with_big_tobacco/). Accessed 20 April 2018. Solomon J. EU Probes Cigarette Deal That May Have Aided Syria. Wall Street Journal. New York City, United States. 21 August 2012; Available at: <http://www.wsj.com/articles/SB10000872396390444233104577595221203321922>. Accessed 20 April 2018.

<sup>4</sup> Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report. Tobacco control. 2014 May;23(e1):e51-61.

<sup>5</sup> Joossens L, Raw M. From cigarette smuggling to illicit tobacco trade. Tobacco control. 2012 Mar;21(2):230-4.

<sup>6</sup> Skafida V, Silver KE, Rechel BP, Gilmore AB. Change in tobacco excise policy in Bulgaria: the role of tobacco industry lobbying and smuggling. Tobacco control. 2014 May;23(e1):e75-84. Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. Tobacco control. 2014 May;23(e1):e35-43.

<sup>7</sup> Gilmore AB, Fooks G, Drope J, Bialous SA, Jackson RR. Exposing and addressing tobacco industry conduct in low-income and middle-income countries. Lancet. 2015 Mar 14;385(9972):1029-43.

<sup>8</sup> Gilmore A, McKee M. Tobacco control policy: the European dimension. Clin Med (Lond). 2002 Jul-Aug;2(4):335-42. Gilmore AB, Fooks G, Drope J, Bialous SA, Jackson RR. Exposing and addressing tobacco industry conduct in low-income and middle-income countries. Lancet. 2015 Mar 14;385(9972):1029-43.

<sup>9</sup> Gilmore A, McKee M. Tobacco control policy: the European dimension. Clin Med (Lond). 2002 Jul-Aug;2(4):335-42. Joossens L, Raw M. Smuggling and cross border shopping of tobacco

undermining price policies to reduce demand. Thus, *the FDA should reject any partnership with tobacco companies when proposing new tobacco product standards because the tobacco companies have a big financial incentive to maintain the status quo with regards to illicit tobacco trade.*

### *Tobacco industry involvement in illicit tobacco trade*

Internal documents that tobacco companies were forced to release due to litigation,<sup>10</sup> court judgements,<sup>11</sup> and their own admissions,<sup>12</sup> consistently show that they have been directly and indirectly involved in illicit trade of tobacco internationally since the 1960s. In each context smuggling enabled tobacco companies to establish demand for their brands before they began domestic manufacturing in countries to ensure that cigarettes were available cheaply, thereby stimulating consumption.<sup>13</sup>

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in Europe. *BMJ*. 1995 May 27;310(6991):1393-7. Gilmore AB, McKee M. Moving East: how the transnational tobacco industry gained entry to the emerging markets of the former Soviet Union-part II: an overview of priorities and tactics used to establish a manufacturing presence. *Tobacco control*. [Research Support, U.S. Gov't, P.H.S.Review]. 2004 Jun;13(2):151-60.

<sup>10</sup> Collin J, Legresley E, MacKenzie R, Lawrence S, Lee K. Complicity in contraband: British American Tobacco and cigarette smuggling in Asia. *Tobacco control*. 2004 Dec;13 Suppl 2:ii104-11. Lee K, Collin J. "Key to the future": British American tobacco and cigarette smuggling in China. *PLoS Med*. 2006 Jul;3(7):e228. Legresley E, Lee K, Muggli ME, Patel P, Collin J, Hurt RD. British American Tobacco and the "insidious impact of illicit trade" in cigarettes across Africa. *Tobacco control*. 2008 Oct;17(5):339-46. Nakkash R, Lee K. Smuggling as the "key to a combined market": British American Tobacco in Lebanon. *Tobacco control*. 2008 Oct;17(5):324-31.

<sup>11</sup> Government of Canada. Comprehensive settlement agreements with tobacco companies: Canada Revenue Agency 2008. Available at: <http://www.cra-arc.gc.ca/gncy/tbcc/menu-eng.html>. Accessed 20 April 2018.

<sup>12</sup> Clarke K. Dilemma of a cigarette exporter. *Guardian*. London, England.3 February 2000: Available at: <http://www.theguardian.com/bat/article/0,,191288,00.html>. Accessed 20 April 2018.

<sup>13</sup> Skafida V, Silver KE, Rechel BP, Gilmore AB. Change in tobacco excise policy in Bulgaria: the role of tobacco industry lobbying and smuggling. *Tobacco control*. 2014 May;23(e1):e75-84. Gilmore AB, McKee M. Moving East: how the transnational tobacco industry gained entry to the emerging markets of the former Soviet Union-part II: an overview of priorities and tactics used to establish a manufacturing presence. *Tobacco control*. [Research Support, U.S. Gov't, P.H.S.Review]. 2004 Jun;13(2):151-60. Joossens L, Raw M. Cigarette smuggling in Europe: who really benefits? *Tobacco control*. 1998 Spring;7(1):66-71. Gilmore A, Collin J, Townsend J. Transnational tobacco company influence on tax policy during privatization of a state monopoly: British American Tobacco and Uzbekistan. *Am J Public Health*. 2007 Nov;97(11):2001-9. Gilmore AB, McKee M, Collin J. The invisible hand: how British American Tobacco precluded competition in Uzbekistan. *Tobacco control*. 2007 Aug;16(4):239-47. van Walbeek C, Blecher E, Gilmore A, Ross H. Price and tax measures and illicit trade in the framework convention on tobacco control: what we know and what research is required. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*. 2013 Apr;15(4):767-76.

### ***Legal action against the industry on illicit trade***

In the late 1990s, tobacco companies were accused of facilitating smuggling by deliberately oversupplying brands to countries where there was no demand for them.<sup>14</sup>

In the late 1990s Canadian tobacco companies were complicit in organizing the movement of smuggled cigarettes from Canada to the United States and paid significant fines to the Canadian government in out-of-court settlements and admission of guilt fines.<sup>15</sup>

In 1998, Northern Brands, an affiliate of RJ Reynolds, pleaded guilty to charges of helping smugglers illegally re-route exported cigarettes into Canada and agreed to pay US \$15 million in criminal fines and forfeitures for its involvement in these illegal activities.<sup>16</sup>

In 2000, British American Tobacco (BAT) executive Kenneth Clarke admitted to the *Guardian* that “BAT supplies cigarettes knowing they could end up on the black market...on the basis that our brands will be available alongside those of our competitors in the smuggled as well as the legitimate market.”<sup>17</sup>

Also in 2000, BAT faced serious racketeering charges in Colombia “arising from its involvement in organized crime in pursuit of a massive, ongoing smuggling scheme.”<sup>18</sup>

In 2002, Imperial brands accounted for 55% of the 17 billion cigarettes smuggled into the UK that year.<sup>19</sup>

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<sup>14</sup> Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.

<sup>15</sup> van Walbeek C, Blecher E, Gilmore A, Ross H. Price and tax measures and illicit trade in the framework convention on tobacco control: what we know and what research is required. *Nicotine & Tobacco Research*. 2013 Apr;15(4):767-76.

<sup>16</sup> Joossens L, Raw M. How can cigarette smuggling be reduced? *BMJ*. 2000 Oct 14;321(7266):947-50.

<sup>17</sup> Gilmore A, McKee M. Tobacco control policy: the European dimension. *Clin Med (Lond)*. 2002 Jul-Aug;2(4):335-42.

<sup>18</sup> Beelman MS, Campbell D, Ronderos MT, Schelzig EJ. How smuggling helps lure generations of new smokers. *The Guardian*. London, England.31 January 2000: Available at: <https://www.theguardian.com/uk/2000/jan/31/duncancampbell>. Accessed 11 April 2018.

<sup>19</sup> Evans-Reeves K, Rowell A. Tobacco industry rallies against illicit trade – but have we forgotten its complicity? *The Conversation*. London, England.16 March 2015: Available at: <https://theconversation.com/tobacco-industry-rallies-against-illicit-trade-but-have-we-forgotten-its-complicity-38760>. Accessed 11 April 2018.

In 2004, Philip Morris International (PMI) paid the European Union US \$1.25 billion to settle claims over tobacco smuggling.<sup>20</sup>

In 2008, Canadian tobacco companies pleaded guilty and admitted “aiding persons to sell or be in possession of tobacco products manufactured in Canada that were not packaged and were not stamped in conformity with the Excise Act” between 1989 and 1994. The criminal fines and civil settlements resulted in the companies paying C \$1.15 billion, the largest ever levied in Canada.<sup>21</sup>

In 2010, BAT paid the European Commission US \$200 million to settle smuggling-related issues.<sup>22</sup>

In 2014, BAT was fined £650,000 for over-supplying its own product to Belgium.<sup>23</sup>

***Given the fact trade tobacco companies have been repeatedly found guilty in their participation in illicit tobacco trade and their partnerships with governments have yet to result in reducing illicit tobacco trade, the FDA should reject any partnership with tobacco companies.***

## **2) The FDA should reject industry estimates and exaggeration of illicit tobacco**

The FDA’s draft concept paper on illicit trade<sup>24</sup> recognizes that it is “difficult to measure existing illicit trade markets and use existing data to reliably predict future demand for illicit tobacco products.”<sup>25</sup> One of the biggest barriers to addressing and enforcing illicit tobacco trade is the availability of reliable, independent data. Due to its illegal nature, the illicit tobacco trade is methodologically difficult to measure. Those involved do not make records public, law enforcement agency data are often kept confidential and supplementary methods of estimation have limitations.<sup>26</sup>

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<sup>20</sup> Tran M. Philip Morris reaches \$1.25bn EU agreement. The Guardian. London, England. 9 July 2004: Available at: <https://www.theguardian.com/business/2004/jul/09/smoking.europeanunion>. Accessed 11 April 2018.

<sup>21</sup> Joossens L, Raw M. Progress in combating cigarette smuggling: controlling the supply chain. Tobacco control. 2008 Dec;17(6):399-404.

<sup>22</sup> European Commission. European Commission and British American Tobacco sign agreement to combat illicit trade in tobacco. Brussels, Belgium, 15 July 2010. Available at: [http://europa.eu/rapid/press-release\\_IP-10-951\\_en.htm](http://europa.eu/rapid/press-release_IP-10-951_en.htm). Accessed 11 April 2018.

<sup>23</sup> Ralph A. Fines for tobacco companies ‘fail to rein in black market’. The Times. London, England. 27 November 2014: Available at: <https://www.thetimes.co.uk/article/fines-for-tobacco-companies-fail-to-rein-in-black-market-nrd9ndpv9qb>. Accessed 11 April 2018.

<sup>24</sup> Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard. FDA. March 15, 2018 <https://www.regulations.gov/document?D=FDA-2018-N-0529-0002>

<sup>25</sup> U.S. Food and Drug Administration. Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard. Washington D.C., United States, 15 March 2018.

<sup>26</sup> Joossens L, Lugo A, La Vecchia C, Gilmore AB, Clancy L, Gallus S. Illicit cigarettes and hand-rolled tobacco in 18 European countries: a cross-sectional survey. Tobacco control. 2014

### ***Industry estimates are not accurate and unreliable***

Due to limited data on the magnitude of illicit trade, tobacco companies have commissioned reports and surveys through third party affiliates, all of which illustrate that the tobacco companies overly exaggerate the illicit trade problem. The tobacco companies use this to drive fear into policymakers and counter strict tobacco control regulations, including increased tobacco taxes and tobacco packaging and labeling regulations.<sup>27</sup>

Tobacco companies have taken advantage of the complexity of illicit tobacco trade and using their resource advantage to try to dominate every aspect of the debate. This includes controlling the data and evidence on illicit trade and using this to dominate media coverage, secure access to authorities, and promote industry messaging on illicit trade.<sup>28</sup> Many industry or quasi-industry estimates are available but should be treated with extreme caution due to lack of transparency, inadequacy of methodological details and subsequent quality of the data inputted, and the overreliance on tobacco industry data without external validation and scrutiny.<sup>29</sup>

### ***Lack of transparency***

The lack of transparency of industry reporting makes it difficult to evaluate their data. Sometimes there are no records on the sales volumes of approved contractors or from tobacco companies to ensure that the contractors were complying with anti-smuggling measures or the number of cigarettes held in tax or customs warehouses.<sup>30</sup> Tobacco companies also promote their own, ineffective, track and trace system (formerly known as Codentify, now marketed as part of Inexto Suite). This system only tracks illicit tobacco products on which no tobacco duties have been paid, including “illicit whites” aka “cheap whites” (legally sold cigarettes in one country but illegally sold in another country) and counterfeit products but does not include products

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May;23(e1):e17-23. Joossens L, Raw M. From cigarette smuggling to illicit tobacco trade. *Tobacco control*. 2012 Mar;21(2):230-4. Titeca K, Joossens L, Raw M. Blood cigarettes: cigarette smuggling and war economies in central and eastern Africa. *Tobacco control*. 2011 May;20(3):226-32.

<sup>27</sup> Smith KE, Savell E, Gilmore AB. What is known about tobacco industry efforts to influence tobacco tax? A systematic review of empirical studies. *Tobacco control*. 2013 Mar;22(2):144-53. Joossens L, Raw M. Smuggling and cross border shopping of tobacco in Europe. *BMJ*. 1995 May 27;310(6991):1393-7. Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.

<sup>28</sup> Gilmore AB, Fooks G, Drope J, Bialous SA, Jackson RR. Exposing and addressing tobacco industry conduct in low-income and middle-income countries. *Lancet*. 2015 Mar 14;385(9972):1029-43.

<sup>29</sup> Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report. *Tobacco control*. 2014 May;23(e1):e51-61.

<sup>30</sup> McKee M, Gilmore AB. European watchdog is failing to hold tobacco industry to account over smuggling. *BMJ*. 2015 Dec 29;351:h6973.

bought legally on which tobacco duties have not been paid—those purchased duty free or abroad for personal use (known as cross-border sales). Thus, this system makes it impossible to determine when cigarettes are diverted into the illegal supply chain as it is difficult to tell duplicate from real products. This is also important because the majority of the illicit market is illegal cigarettes (65-70%) and the remaining illicit market is illicit whites (25%) and counterfeit cigarettes (5%). Thus, the tobacco companies are tracking at best only 30% of the illicit market.<sup>31</sup>

### ***Inadequacy of methodological details***

The methodology and validity of tobacco industry commissioned reports and surveys are unexplained. Most tobacco industry data on illicit comes from the industry's Empty Pack Surveys (EPS), a system of collecting discarded cigarette packs to determine their authenticity, derived from Klynveld Peat Marwick Goerdeler (KPMG) reports commissioned by tobacco companies, for which the methodology is rarely available.<sup>32</sup> When the methods are revealed they change over time. For example, national data from two published industry sources show a sudden large increase in non-domestic product between 2011 and 2012 in Europe. Yet the methodology of one report changes over this period and the other provides no published methodology.

### ***Lack of external validation and scrutiny***

Independent research has consistently shown that the tobacco industry is significantly exaggerating the scale of illicit trade.<sup>33</sup> Comparing the KPMG reports with pan-European data on illicit cigarettes show that in some countries the estimates are very similar (Spain, Hungary), but the tendency is for KPMG to give larger estimates. KPMG estimates exceed the pan-European data estimates in 12 countries, with absolute differences greater than 5% or more observed in eight (Ireland 15% gap, Bulgaria 15%, Finland 12%, France 11%, Austria 8%, UK 7%, Romania 6%, Greece 5%).<sup>34</sup> Whereas EPS reports have shown sudden large increases in non-domestic products, in contrast, independent data show steady declines in nondomestic and illicit cigarette penetration from 2006 to 2012 and either a continued decline or small increase to 2013.<sup>35</sup>

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<sup>31</sup> Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report. *Tobacco control*. 2014 May;23(e1):e51-61.

<sup>32</sup> Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.

<sup>33</sup> Gilmore AB, Fooks G, Drope J, Bialous SA, Jackson RR. Exposing and addressing tobacco industry conduct in low-income and middle-income countries. *Lancet*. 2015 Mar 14;385(9972):1029-43. Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.

<sup>34</sup> Gilmore AB, Rowell A, Gallus S, Lugo A, Joossens L, Sims M. Towards a greater understanding of the illicit tobacco trade in Europe: a review of the PMI funded 'Project Star' report. *Tobacco control*. 2014 May;23(e1):e51-61.

<sup>35</sup> Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.



### ***Exaggerating and overstating the illicit tobacco problem***

Given the tobacco industry's efforts to control the data and the debate on illicit trade, they consistently overstate and exaggerate the problem.

The tobacco industry consistently claims that increased tobacco taxes will lead to an increase in illicit tobacco trade as tobacco smuggling is caused by market forces (the price differences between countries), which create an incentive to smuggle cigarettes from lower tax countries to higher tax countries.<sup>36</sup> However, tobacco industry estimates compared with a variety of independent sources show that the countries with the highest rates of smuggling are not those with the highest levels of tobacco taxes,<sup>37</sup> and that smuggling is more prevalent in "cheaper" countries, and where taxes have been reduced.<sup>38</sup>

Tobacco companies also consistently claim that if governments adopt tobacco standardized plain packaging that levels of illicit trade will increase since counterfeit cigarettes will be simpler to produce.<sup>39</sup> However, research in the UK in 2010 indicates that the pack has no impact on the decision to buy illicit tobacco. Smokers were easily able to identify counterfeit cigarettes due to the inferior quality of pack appearance (color variations, poorer quality printing, and cheaper cardboard), cigarette appearance (different color filter, different size, and additional bands), and product performance (different burn rate, smell and taste).<sup>40</sup> More importantly, smokers perceived counterfeit tobacco negatively due to the poor product appearance and performance. Thus, smokers were not fooled by counterfeiters and adamant that plain packaging would have no impact on their consumption of counterfeit cigarettes.

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<sup>36</sup> Joossens L, Raw M. How can cigarette smuggling be reduced? *BMJ*. 2000 Oct 14;321(7266):947-50.

<sup>37</sup> Skafida V, Silver KE, Rechel BP, Gilmore AB. Change in tobacco excise policy in Bulgaria: the role of tobacco industry lobbying and smuggling. *Tobacco control*. 2014 May;23(e1):e75-84. Smith KE, Savell E, Gilmore AB. What is known about tobacco industry efforts to influence tobacco tax? A systematic review of empirical studies. *Tobacco control*. 2013 Mar;22(2):144-53. Joossens L, Raw M. Smuggling and cross border shopping of tobacco in Europe. *BMJ*. 1995 May 27;310(6991):1393-7. Joossens L, Raw M. Smuggling and cross border shopping of tobacco in Europe. *BMJ*. 1995 May 27;310(6991):1393-7. Joossens L, Raw M. Cigarette smuggling in Europe: who really benefits? *Tobacco control*. 1998 Spring;7(1):66-71. Gilmore A, McKee M. Tobacco control policy: the European dimension. *Clin Med (Lond)*. 2002 Jul-Aug;2(4):335-42.

<sup>38</sup> Joossens L, Raw M. Turning off the tap: the real solution to cigarette smuggling. *Int J Tuberc Lung Dis*. 2003 Mar;7(3):214-22. Joossens L, Raw M. How can cigarette smuggling be reduced? *BMJ*. 2000 Oct 14;321(7266):947-50.

<sup>39</sup> Rowell A, Evans-Reeves K, Gilmore AB. Tobacco industry manipulation of data on and press coverage of the illicit tobacco trade in the UK. *Tobacco control*. 2014 May;23(e1):e35-43.

<sup>40</sup> Moodie C, Hastings G, Joossens L. Young adult smokers' perceptions of illicit tobacco and the possible impact of plain packaging on purchase behaviour. *European journal of public health*. 2012 Apr;22(2):251-3.



***The FDA should expect that tobacco companies will raise similar concerns to any proposed tobacco product standards; the FDA should not be overly concerned and should reject these exaggerated claims as they never materialize.***

***The FDA is correct to recognize the unlikelihood of a large-scale illicit trade problem***

We agree with several of the FDA draft paper's statements that it will be unlikely for small groups or individuals to massively produce illicit tobacco products due to the sources of tobacco and manufacturing. Domestic and international experience shows that the engineering of tobacco primarily occurs at the manufacturing level with tobacco manufactures and not at the leaf level with growers,<sup>41</sup> and that ***small producers have not been able to produce large scale counterfeit tobacco products.***<sup>42</sup>

*Sources of tobacco*

The FDA's draft paper is correct to "assume that both agricultural and manufacturing changes are possible" due to changes in tobacco product standards but that if "growing practices were irrelevant to a tobacco product complying with a standard, it is likely that no changes would take place on individual farms."<sup>43</sup>

We also agree that if tobacco manufacturers had to reduce nicotine levels through a chemical process, "the growing processes of farmers could remain unchanged, and the potential illicit trade markets would have to focus on diverting the full-nicotine tobacco prior to processing."<sup>44</sup>

*Manufacturing illicit tobacco products*

The FDA's draft paper is correct to acknowledge that while cigarettes manufactured on a large scale can contain sophisticated techniques, "the time and effort required for an individual to make cigarettes in this manner, as well as the risk of enforcement action for any distribution beyond their own personal use, may not support widespread distribution or high-volume production of illicit cigarettes."<sup>45</sup>

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<sup>41</sup> Keith D, Muniz G. Compliance Training for Small Tobacco Product Manufacturers-Domestic Establishment Inspections. Washington D.C., United States: U.S. Food and Drug Administration, November 2017. Available at: <https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM313411.pdf>. Accessed 25 May 2018.

<sup>42</sup> Drope J, Schluger N. The Tobacco Atlas: Sixth Edition. Atlanta, United States: American Cancer Society, January 2018. Available at: [https://tobaccoatlas.org/wp-content/uploads/2018/03/TobaccoAtlas\\_6thEdition\\_LoRes\\_Rev0318.pdf](https://tobaccoatlas.org/wp-content/uploads/2018/03/TobaccoAtlas_6thEdition_LoRes_Rev0318.pdf). Accessed 25 May 2018.

<sup>43</sup> U.S. Food and Drug Administration. Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard Draft for Comment. Washington D.C., United States, 15 March 2018.

<sup>44</sup> Ibid, page 6.

<sup>45</sup> Ibid, page 7.

We also agree that “the quality and consistency of the product will vary significantly with each cigarette constructed” and that “it may be difficult for average consumers to construct certain classes of products on their own, such as smokeless products that require strict controls on fermentation and aging to maintain a consistent product, and liquids commonly used in electronic nicotine delivery systems (ENDS) that require complex chemical interactions.”<sup>46</sup>

***Thus, given domestic and international experience, the FDA draft paper is correct that it will be unlikely for small groups or individuals to massively produce illicit tobacco products due to the sources of tobacco and manufacturing.***

### **3) FDA should use the FCTC Protocol on Illicit Trade as a model to counter illicit trade**

Given the lack of reliable data and lack of credibility from tobacco companies, the FDA should use the WHO Framework Convention on Tobacco Control (FCTC) Protocol to Eliminate Illicit Trade in Tobacco Products<sup>47</sup> as a model for its regulations and enforcement activities to counter illicit trade.

The protocol builds upon and complements FCTC Article 15, which addresses means of countering illicit trade in tobacco products, a key aspect of a comprehensive tobacco control policy.<sup>48</sup> The protocol was developed in response to the growing international illicit trade in tobacco products, which fuels the tobacco epidemic, undermines tobacco control policies, causes substantial losses in government revenues and contributes to the funding of transnational criminal activities.<sup>49</sup> As of May 2018, the protocol has been ratified by 35 countries and will enter into force after the 40<sup>th</sup> country ratifies.<sup>50</sup>

The protocol aims to eliminate “all forms of illicit trade in tobacco products” and emphasizes “the need to be alert to any efforts by the tobacco industry to undermine or subvert strategies to combat illicit trade in tobacco products and the need to be informed of activities of the tobacco industry that have a negative impact on strategies to combat illicit trade in tobacco products.” The protocol also highlights the importance of not allowing the tobacco industry to establish illicit trade policies by ensuring “the maximum possible transparency with respect to any interactions they [Parties] may have with the tobacco industry” when implementing tobacco control policies and that Parties “shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”

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<sup>46</sup> Ibid, page 7.

<sup>47</sup> World Health Organization. Protocol: To Eliminate Illicit Trade in Tobacco Products. Geneva, Switzerland, March 2013.

<sup>48</sup> World Health Organization. WHO Framework Convention on Tobacco Control. Geneva, Switzerland, May 2003. Available at: <http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf>. Accessed 12 November 2015.

<sup>49</sup> Joossens L, Raw M. From cigarette smuggling to illicit tobacco trade. Tobacco control. 2012 Mar;21(2):230-4.

<sup>50</sup> United Nations. Treaty Collection. Geneva, Switzerland 2018. Available at: [https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IX-4-a&chapter=9&lang=en](https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4-a&chapter=9&lang=en). Accessed 11 April 2018.

The protocol can serve as a model for the FDA to counter illicit trade of tobacco products because it aims to establish a global tracking and tracing regime to a) ensure control over the supply chain covering licensing, due diligence, record keeping, security and preventative measures, and international transit, b) cover matters concerning offences, with provisions of liability, prosecutions and sanctions, seizure payments, special investigative techniques, and the disposal and destruction of confiscated products, and c) establish enforcement cooperation and information.

### ***Supply chain control***

The FDA’s draft paper acknowledges, “Manufacturers *might be* required to maintain records related to the manufacture, processing, testing, packaging, and labeling of the product to ensure conformance with the standard.”<sup>51</sup> [Emphasis added]

The FDA’s draft paper also acknowledges it “*could* help ensure identification of the product as being in conformance with the proposed standard by requiring that the labeling of covered products contain a manufacturing code.”<sup>52</sup> [Emphasis added]

The FDA’s draft paper also recognizes the potential issues related to evading reporting requirements through “disguising a shipment: either by misreporting the contents of packages and containers, hiding illicit products within otherwise legitimate shipments, or exploiting apparent loopholes in systems such as the in-bond customs mechanism.”<sup>53</sup>

The Tobacco Control Act provides FDA with a number of authorities beyond the ability to inspect manufacturers of tobacco products, including the authority to issue recordkeeping regulations for the purpose of tracking and tracing tobacco products through the supply chain. Specifically, it directs FDA to issue regulations “regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products,” taking into consideration “which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets.”<sup>54</sup>

To maintain accurate and up to date record keeping, the FDA should **require** that tobacco manufactures report to the FDA the following:

- (a) the date of shipment from the last point of physical control of the products;
- (b) the details concerning the products shipped (including brand, amount, warehouse);
- (c) the intended shipping routes and destination;
- (d) the identity of the natural or legal person(s) to whom the products are being shipped;

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<sup>51</sup> U.S. Food and Drug Administration. Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard Draft for Comment. Washington D.C., United States, 15 March 2018.

<sup>52</sup> Ibid, page 5.

<sup>53</sup> Ibid, page 10.

<sup>54</sup> FSPTCA section 920(b).

- (e) the mode of transportation, including the identity of the transporter;
- (f) the expected date of arrival of the shipment at the intended shipping destination; and
- (g) intended market of retail sale or use.

Since the FDA has the authority, it *should* control the supply chain of illicit tobacco through due diligence and collecting information regarding its identity, including full name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, applicable tax registration numbers, copies of articles of incorporation or equivalent documents, its corporate affiliates, names of its directors and any designated legal representatives, including the representatives' names and verification of their official identification.

The FDA should partner with appropriate law enforcement and border control agencies, such as the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and allow them to implement a tracking and tracing system that would require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets and packages and any outside packaging of cigarettes. In order to determine the origin of tobacco products, the point of diversion where applicable and to monitor and control the movement of tobacco products and their legal status, the track and trace system should detail:

- (a) date and location of manufacture;
- (b) manufacturing facility;
- (c) machine used to manufacture tobacco products;
- (d) production shift or time of manufacture;
- (e) the name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer;
- (f) the intended market of retail sale;
- (g) product description;
- (h) any warehousing and shipping;
- (i) the intended shipment route, the shipment date, shipment destination, point of departure and consignee.

The FDA should require that retailers and tobacco growers, except for traditional growers working on a non-commercial basis, to maintain complete and accurate records of all relevant transactions in which they engage and that all records are:

- (a) maintained for a period of at least four years;
- (b) made available to the competent authorities; and
- (c) maintained in a format, as required by the FDA

### ***Addressing offences***

We agree with the FDA's draft paper, "if a firm had a history of violations and had promised correction in the past, but had not made the corrections, an injunction might be pursued" and that the FDA should "initiate a criminal action through FDA's Office of Criminal Investigations (OCI)" for individuals or tobacco manufactures engaging in illicit trade in tobacco.

The FDA should ensure that individuals and tobacco manufactures and growers are liable for the unlawful conduct including ensuring that criminal offenses are subjected to effective, proportionate and dissuasive criminal or non-criminal sanctions, including monetary sanctions.

The FDA should levy an amount proportionate to lost taxes and duties from the producer, manufacturer, distributor, importer or exporter of seized tobacco, tobacco products and/or manufacturing equipment.

All confiscated tobacco, tobacco products and manufacturing equipment should be destroyed, using environmentally friendly methods to the greatest extent possible to prevent the products from going right back into the market.

### ***Enforcement cooperation and information sharing***

While any kind of partnerships with tobacco companies should be immediately rejected, the FDA should engage with law enforcement agencies and North American tribes to ensure that the risk of non-conforming illicit tobacco products are prevented and or addressed immediately. This cooperation should include developing inclusive enforcement plans with the Alcohol and Tobacco Tax and Trade Bureau (TTB), and the U.S. Customs Border Protection (CBP) to make sure domestic tobacco companies, importers, and North American tribes are aware of the tobacco product standard changes, understand the public health benefits of these changes, that they are compliant, and that the enforcement agencies have the proper tools to efficiently enforce these standards.

The FDA should also cooperate with the National Association of Attorneys General (NAAG), an information sharing body, and work with them to engage state Attorneys General to promote best practices at the state level to monitor and reduce illicit tobacco trade.

The FDA should work with North American tribes to make sure they are on board for compliance with the new standards and early enforcement and to consider if they have any comments regarding any proposed changes to the tobacco products standards.

The FDA should strengthen cooperation with law enforcement agencies by arrangements for the prevention, detection, investigation, prosecution and punishment of natural or legal persons engaged in illicit trade in tobacco, tobacco products or manufacturing equipment. Assistance and cooperation into the investigation and prosecution of offenses should include the following:

- (a) records of licensing for the natural and legal persons concerned;
- (b) information for identification, monitoring and prosecution of natural or legal persons involved in illicit trade in tobacco, tobacco products or manufacturing equipment;
- (c) records of payment for import, export or duty-free sales of tobacco, tobacco products or manufacturing equipment; and
- (d) details of seizures of tobacco, tobacco products or manufacturing equipment (including case reference information where appropriate, quantity, value of seizure,

product description, entities involved, date and place of manufacture) and modi operandi (including means of transport, concealment, routing and detection).

Cooperation with law enforcement should include effective measures to:

- (a) enhance and, where necessary, establish channels of communication between the competent authorities, agencies and services in order to facilitate the secure and rapid exchange of information concerning all aspects of the criminal offences;
- (b) ensure effective cooperation among the competent authorities, agencies, customs, police and other law enforcement agencies;
- (c) cooperate in conducting enquiries in specific cases with respect to criminal offences:
  - (i) the identity, whereabouts and activities of persons suspected of involvement in such offences or the location of other persons concerned;
  - (ii) the movement of proceeds of crime or property derived from the commission of such offences; and
  - (iii) the movement of property, equipment or other instrumentalities used or intended for use in the commission of such offences.

### **Summary**

Since the FDA is required to consider the possibilities of illicit trade in its rulemaking, the FDA should use its considerable authority to discourage illicit trade, rather than rely on the regulated tobacco companies to voluntarily reign in illicit trade. In particular, the FDA should:

- 1) reject any partnership with the tobacco industry,
- 2) reject industry estimates and exaggeration of illicit problem, and
- 3) use FCTC Protocol on Illicit Trade as model to counter the supply side of illicit trade.