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# THE JURISDICTION OF THE FOOD AND DRUG ADMINISTRATION TO REGULATE TOBACCO PRODUCTS UNDER THE FOOD, DRUG, AND COSMETIC ACT: *Food and Drug Administration v. Brown & Williamson Tobacco Corporation et al.*

Alison J. Lezak\*

## I. INTRODUCTION

More than 400,000 people die prematurely each year from illnesses related to tobacco use.<sup>1</sup> In 1996, the Food and Drug Administration (FDA) claimed the authority to regulate tobacco products under the Food, Drug, and Cosmetic Act (FDCA or Act) after having denied such power since the agency's creation in 1938.<sup>2</sup> The FDA found that reducing tobacco use by minors would considerably reduce addiction and, thus, incidence of tobacco-related illness and death, since most tobacco consumers begin use before the age of eighteen.<sup>3</sup>

Accordingly, the FDA created regulations regarding tobacco products' promotion, labeling, and accessibility to minors pursuant to its power under 21 U.S.C. § 360j(e) to regulate "restricted devices."<sup>4</sup> The FDA found that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices" within

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<sup>1</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 120 S.Ct. 1291, 1298 (2000), affirming 153 F.3d 155 (4th Cir. 1998).

<sup>2</sup> *Brown*, 120 S.Ct. 1296-97. The FDCA gives the FDA jurisdiction to regulate "drugs," which includes "articles intended to affect the structure or any function of the body," and "devices." 21 U.S.C. §321. "Devices" are defined, in pertinent part, as 'an instrument, apparatus, implement, machine, contrivance...or other similar or related article, including any component, part, or accessory, ...intended to affect the structure or any function of the body.'

<sup>3</sup> *Id.* at 1297.

<sup>4</sup> *Id.* at 1299. 21 U.S.C. §360j(e) provides, in pertinent part, that the FDA may "require that a device be restricted to sale, distribution, or use...upon such other conditions as [the FDA] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [the agency] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." *Id.* at 18. Because the regulations related to the sale or distribution of tobacco products and were necessary for providing a reasonable assurance of safety, the agency determined that its regulations fell under § 360j(e).

the definitions of the FDCA.<sup>5</sup> Therefore, the agency claimed that, under the FDCA, it had the authority to regulate tobacco products as customarily marketed absent manufacturer claims of therapeutic benefit.<sup>6</sup>

Generally, a court defers to an administrative agency's interpretation of the statutes administered by the agency; however, an agency cannot employ its authority in a way that conflicts with the administrative scheme created by Congress.<sup>7</sup> Thus, under *Chevron*, a reviewing court must give effect to the unequivocal intent of Congress.<sup>8</sup> Here, the Supreme Court ruled that Congress precluded the FDA's assertion of jurisdiction to regulate tobacco products because such power conflicts with congressional intent as expressed in the overall FDCA regulatory scheme and in the tobacco-specific legislation enacted by Congress.<sup>9</sup>

## II. PROCEDURAL HISTORY

On August 11, 1995, the FDA published a proposed rule that contained several provisions restricting the sale, distribution, and advertisement of tobacco products.<sup>10</sup> On August 28, 1996, the FDA, after receiving over 700,000 submissions during the ensuing public comment period, issued the final rule: "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."<sup>11</sup>

A group composed of tobacco manufacturers, retailers, and advertisers (Respondents) brought an action challenging the FDA's regulations in the United States District Court for the Middle District of North Carolina.<sup>12</sup> Respondents moved for summary judgment, contending that the FDA lacked the authority to regulate tobacco products as customarily marketed, that the regulations exceeded the FDA's jurisdiction under 21 U.S.C. §360j(e), and that the advertising

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<sup>5</sup>*Id.* at 1300.

<sup>6</sup>*Id.*

<sup>7</sup>*Id.*

<sup>8</sup>*Id.*

<sup>9</sup>*Id.* at 1316.

<sup>10</sup>*Id.* at 1297.

<sup>11</sup>*Id.*

<sup>12</sup>*Id.* at 1299.

provisions violated the First Amendment.<sup>13</sup> The District Court denied Respondents' motion in part, holding that the FDCA authorized the FDA to regulate tobacco products as customarily marketed and that the FDA's access and labeling regulations were permissible.<sup>14</sup> However, the court also found that the regulations' advertising and promotion restrictions exceeded the FDA's authority under § 360j(e).<sup>15</sup> The District Court, which stayed implementation of the regulations that it found valid, certified an order for immediate interlocutory appeal.<sup>16</sup>

The Court of Appeals for the Fourth Circuit reversed and held that Congress did not give the FDA the authority to regulate tobacco products.<sup>17</sup> The court considered the FDCA in its entirety and determined that the FDA's regulation of tobacco would create several disparities within the regulatory scheme.<sup>18</sup> The Act requires the FDA to preclude the marketing of any "unsafe" or "dangerous" product and, thus, the FDA would have to ban tobacco products.<sup>19</sup> The Court of Appeals found this result contrary to congressional intent and concluded that this disparity showed that Congress did not intend to grant the FDA jurisdiction to regulate tobacco.<sup>20</sup>

Reinforcing this conclusion was evidence that the FDA invariably disavowed jurisdiction over tobacco before 1995 and that Congress, aware of the FDA's position, enacted tobacco-specific legislation.<sup>21</sup> In addition, the Court reasoned that Congress had considered and rejected many bills that would have granted the FDA jurisdiction to regulate tobacco and that the 1938 enacting Congress lacked intent to subject tobacco to FDCA regulation.<sup>22</sup> Thus, the court found that Congress meant to withhold the power to regulate

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<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

tobacco from the FDA.<sup>23</sup> The Government petitioned the United States Supreme Court for a writ of certiorari.<sup>24</sup>

### III. THE UNITED STATES SUPREME COURT

The United States Supreme Court considered the issue of whether, under the FDCA, the FDA had jurisdiction to regulate tobacco products as customarily marketed.<sup>25</sup> Under *Chevron v. Natural Resources Defense Council*,<sup>26</sup> a reviewing court, viewing the statutory scheme in its entirety, must determine whether Congress has specifically addressed the particular issue in controversy.<sup>27</sup> If so, the court must give effect to Congress' unequivocal, express intent; if not, the court must defer to the agency's construction of the statute if such construction is permissible.<sup>28</sup> Here, the Supreme Court found that Congress specifically addressed the question at issue and prohibited the FDA from asserting the authority to regulate tobacco products.<sup>29</sup>

A. *Considering the FDCA regulatory scheme in its entirety, Congress clearly meant to exclude tobacco products from the jurisdiction of the FDA.*

A fundamental purpose of the FDCA regulatory scheme is to safeguard public health by ensuring that a regulated product is reasonably safe and effective for its intended use.<sup>30</sup> To further this objective, the FDCA generally mandates that the FDA prohibits the marketing of a drug or device if the product's therapeutic benefit does not outweigh the potential risk of harm to the consumer.<sup>31</sup> The

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<sup>23</sup>*Id.* at 1299-1300. The Court of Appeals did not address the issues of whether the regulations exceeded the FDA's authority under 21 U.S.C. §360j(e) or whether they violated the First Amendment.

<sup>24</sup>*Id.* at 1300.

<sup>25</sup>*Id.*

<sup>26</sup>*Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 81 L.Ed. 2d 694, 104 S. Ct. 2778 (1984).

<sup>27</sup>*See Brown*, 120 S.Ct. 1297, 1300.

<sup>28</sup>*Id.*

<sup>29</sup>*Id.* at 1301.

<sup>30</sup>*Id.*

<sup>31</sup>*Id.*

FDA determined that, although tobacco products may effectively deliver pharmacological effects, such products are “unsafe” and “dangerous” when used for their intended purposes.<sup>32</sup> Thus, if tobacco products constituted “devices” within the meaning of the FDCA, the FDA would have to ban such products.<sup>33</sup>

First, the Supreme Court found that the FDA would be required to ban tobacco products because such products constitute misbranded devices under two FDCA provisions.<sup>34</sup> Tobacco products are misbranded under §352(j) because they are “dangerous to health” when used as directed.<sup>35</sup> Next, the Supreme Court concluded that no directions exist that could make tobacco safe for its intended use and, thus, tobacco products would constitute misbranded devices under §352(f)(1), prohibited from entering interstate commerce under the Act.<sup>36</sup>

Second, under the FDCA, the FDA would have to place tobacco products in the Class III category because they constitute a “potential unreasonable risk of illness or injury” and, thus, the FDA would have to ban tobacco.<sup>37</sup> The FDA argued that tobacco products are “safe” under the Act, because a ban would likely be “dangerous” due to the high level of consumer addiction.<sup>38</sup> However, under the Act, the likely therapeutic benefits of the product must outweigh the risk of harm for a product to be “safe” and, thus, the FDA did not find that tobacco products are “safe” under the FDCA.<sup>39</sup> Therefore, the Supreme Court found that the Act would require the FDA to ban tobacco products under both the misbranding and device

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<sup>32</sup>*Id.* at 1302.

<sup>33</sup>*Id.*

<sup>34</sup>*Id.* 21 U.S.C. §331(a) prohibits “the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”

<sup>35</sup>*Id.* Under FDCA §352(j) a product is misbranded “if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”

<sup>36</sup>*Id.* Under FDCA §352(f)(1), a product is misbranded “unless its labeling bears...adequate directions for use...in such manner and form, as are necessary for the protection of the public health.”

<sup>37</sup>*Id.* The FDA must put all regulated products into one of three categories, which determines the degree of regulation required to ensure reasonable safety and effectiveness; the FDA has yet to classify tobacco products.

<sup>38</sup>*Id.* at 1304.

<sup>39</sup>*Id.* at 1305.

classification provisions because it would be impossible to show such products are safe for their intended use.<sup>40</sup>

However, Congress precluded the removal of tobacco products from the market.<sup>41</sup> Since 1965, Congress has directly spoken to the issue of tobacco and health by enacting six separate statutes.<sup>42</sup> Rather than ordering a tobacco ban, Congress has regulated tobacco products in accordance with its policy of protecting “commerce and the national economy...to the maximum extent consistent with” consumers “being adequately informed about any adverse health effects.”<sup>43</sup> Therefore, the Court concluded that Congress intends that tobacco products remain on the market and, thus, a FDA ban on tobacco would clearly contravene congressional intent.<sup>44</sup>

Next, the Supreme Court found that the FDA’s construction of “safety” was implausible.<sup>45</sup> Under the Act, the FDA must weigh a product’s potential therapeutic benefit to the consumer against the likely risk of injury.<sup>46</sup> However, the FDA’s conception of safety requires that consumers’ continued tobacco use, the very problem that the FDA seeks to rectify, constitute a “probable benefit to health.”<sup>47</sup> The Supreme Court also ruled that the FDA’s conception of safety conflicts with the Act’s misbranding provision, which focuses on dangers to the consumer from using the product.<sup>48</sup> Thus, a product could be dangerous to the health of consumers when used as directed even if banning the product may harm the collective public health.<sup>49</sup>

Finally, the Court found that, under the FDCA, the FDA can

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<sup>40</sup> *Id.* at 1302-3.

<sup>41</sup> *Id.* at 1303.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 1304.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 1305.

<sup>46</sup> *Id.* Under §360c(a)(2), “the safety and effectiveness of a device are to be determined (A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

regulate “dangerous” products without prohibiting them.<sup>50</sup> However, the FDA cannot deem a product unsafe for *any* therapeutic purpose and still permit that product to stay on the market because such action conflicts with the Act’s basic goal of ensuring that every product is safe and effective.<sup>51</sup> Therefore, viewing the FDCA in its entirety, the Supreme Court ruled that Congress clearly meant to exclude tobacco products from the authority of the FDA.<sup>52</sup>

B. *Congress has ratified the FDA’s long-held position that the FDA does not have any jurisdiction to regulate tobacco products.*

The Supreme Court held that Congress’ actions constitute an effective ratification of the FDA’s position that it lacked jurisdiction to regulate tobacco.<sup>53</sup> Congress enacted six tobacco-specific statutes since 1965 in the context of the FDA’s constant statements that, under the FDCA, it did not have jurisdiction to regulate tobacco absent manufacturer claims of therapeutic benefit.<sup>54</sup> Moreover, Congress explicitly preempted any other regulation of cigarette labeling by adopting the FCLAA.<sup>55</sup> FDA tobacco regulation conflicts with the FCLAA because the FDCA requires the FDA to regulate drug and device labeling, a factor that shows Congress’ intent to adopt a regulatory scheme that precludes any administrative agency from regulating tobacco.<sup>56</sup>

In addition, while the FDA continued to disavow jurisdiction over tobacco, Congress adopted additional tobacco-specific legislation, which gradually extended the scope of its distinct tobacco regulatory scheme and proved that Congress intends to

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<sup>50</sup>*Id.* at 1305-6.

<sup>51</sup>*Id.* at 1306.

<sup>52</sup>*Id.*

<sup>53</sup>*Id.* at 1313.

<sup>54</sup>*Id.* at 1306-7.

<sup>55</sup>*Id.* at 1309. The FCLAA regulatory scheme created a ‘comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health.’ *Id.* at 50-51. Its purpose was to balance the objectives of ensuring that the public is aware of the health hazards associated with cigarette smoking and protecting “commerce and the national economy... to the maximum extent.”

<sup>56</sup>*Id.* at 1306-9.



reserve to itself the regulation of tobacco.<sup>57</sup> Furthermore, Congress, well aware of the health and pharmacological effects of tobacco use, contemplated and rejected several proposals that would have given the FDA the power to regulate tobacco products.<sup>58</sup> Thus, in effect, Congress' tobacco regulatory scheme ratified the FDA's disavowal of any jurisdiction to regulate tobacco products under the FDCA.<sup>59</sup>

Lastly, until the FDA created the regulations at issue here, it had explicitly disavowed the authority to regulate tobacco since its creation in 1938.<sup>60</sup> The FDA's former position coincided with the intent of the 1938 enacting Congress, which never even considered giving the FDA jurisdiction over tobacco products.<sup>61</sup> The Supreme Court found it very unlikely that Congress implicitly intended to subject tobacco to the FDCA considering the political and economic importance of the tobacco industry at the time.<sup>62</sup> Thus, the Court held that, Congress, through its tobacco-specific legislation, effectively ratified the FDA's clear and persistent position that, under the FDCA, it has no authority to regulate tobacco products as customarily marketed.<sup>63</sup>

#### IV. DISSENT

According to the dissent, the FDCA grants the FDA jurisdiction to regulate tobacco.<sup>64</sup> The dissent found that tobacco products are within the FDA's power under the Act to regulate "drugs" and "devices" "intended to affect the structure or any function of the body."<sup>65</sup> In addition, the dissent found that the Act's purpose of protecting public health and the Act's legislative history provide additional support for the conclusion that the FDA has the power to regulate tobacco.<sup>66</sup>

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<sup>57</sup>*Id.* 1309-10.

<sup>58</sup>*Id.* at 1312.

<sup>59</sup>*Id.* at 1313.

<sup>60</sup>*Id.* at 1308.

<sup>61</sup>*Id.*

<sup>62</sup>*Id.*

<sup>63</sup>*Id.* at 1313.

<sup>64</sup>*Id.* at 1316. Justices Breyer, Stevens, Souter and Ginsburg dissented.

<sup>65</sup>*Id.* at 1320.

<sup>66</sup>*Id.* at 1316.

Moreover, the dissent averred that the FDA's former denial of jurisdiction resulted mainly from the inability to prove the Act's "intent" requirement.<sup>67</sup> However, the FDA had since obtained evidence that manufacturers knew about the chemical effects of tobacco and that they wanted their products to produce such effects.<sup>68</sup> Thus, the dissent found that the companies "intended" their products to "affect" the body under the FDCA.<sup>69</sup>

Furthermore, the dissent found that the FDCA does not mandate a total ban on tobacco.<sup>70</sup> The Act gives the FDA discretion to choose remedies congruous with its purpose of protecting public health and, thus, does not mandate a complete product ban if, as here, a ban may pose more harm than other remedies.<sup>71</sup> In addition, the Act's misbranding and device classification provisions allow the FDA to consider the overall relative safety of a product.<sup>72</sup> Thus, the FDA could find that a product is comparatively "safe" if it would be less dangerous to make the product available, subject to regulation, than suddenly to remove it from the market.<sup>73</sup> Likewise, the Act requires a flexible construction that allows the FDA to consider human behavior and allows it remedial discretion in light of Congress' intent to protect public health.<sup>74</sup> Therefore, the dissent, finding that the Act does not require a ban, concluded that even if a ban was required, the Act would curb the agency's remedial discretion rather than its jurisdiction.<sup>75</sup>

Finally, the dissent found that the laws enacted after 1965 do not bar the FDA's power to regulate tobacco.<sup>76</sup> The dissent noted that the Court has refused to interpret the FCLAA as preempting all tobacco regulation.<sup>77</sup> In addition, although Congress did not expressly grant jurisdiction to the FDA, Congress also did not

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<sup>67</sup>*Id.* at 1329.

<sup>68</sup>*Id.*

<sup>69</sup>*Id.*

<sup>70</sup>*Id.* at 1330.

<sup>71</sup>*Id.* at 1323-24.

<sup>72</sup>*Id.* at 1323-26.

<sup>73</sup>*Id.* at 1325.

<sup>74</sup>*Id.* at 1325-26.

<sup>75</sup>*Id.* at 1331.

<sup>76</sup>*Id.* at 1326.

<sup>77</sup>*Id.* at 1327.

positively revoke such power when the FDA avowed jurisdiction.<sup>78</sup> Thus, the dissent found that the only rational interpretation of the post-1965 legislation is that Congress did not intend these laws to address the issue of the FDA's jurisdiction to regulate tobacco.<sup>79</sup>

## V. CONCLUSION

The decision of the United States Supreme Court holding that the FDA does not have jurisdiction to regulate tobacco products<sup>80</sup> constitutes a considerable victory for tobacco manufacturers. In effect, this decision bars any administrative agency from asserting jurisdiction to regulate tobacco. Thus, tobacco products will likely never face extensive regulation, much less a ban, unless Congress takes such action, which is unlikely given the adverse impact on the national economy that restrictive regulations or a complete ban of tobacco could cause. Likewise, the strong political influence of the tobacco lobby in our nation's capital will also prevent restrictive regulation of tobacco products by Congress. Therefore, tobacco products remain subject to the less restrictive and less extensive regulations promulgated by Congress.

In addition, given the political and economic importance of tobacco, the policy-making decision regarding tobacco products *should* be reserved for Congress. An administrative agency may be more willing to ban tobacco products, or at least regulate such products more strictly, because such agencies are comprised of appointed officials. Thus, since agency officials are directly accountable to the elected officials who appointed them, agency officials are likely to make policy decisions primarily based on the political preference of the appointing elected officials. However, Congress, which is accountable to the voters, should make a decision of such importance because the decision requires careful consideration not only of politics but also of a host of other factors, including economics. Congress has the vast resources and the committees necessary to conduct the thorough investigation of tobacco products necessary to protect the consumer *and* the national

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<sup>78</sup>*Id.*

<sup>79</sup>*Id.*

<sup>80</sup>*Id.* at 1316.

economy “to the maximum extent.”<sup>81</sup>

The case is also an important case for administrative law, for it indicates that the first prong of the *Chevron* test contains bite. It also indicates the willingness of the court to look at other, related statutory enactments of Congress, to interpret Congressional intent. Lastly, the case is interesting because of its view of the “mandate” contained in FDA legislation. If the FDA was correct, it was required to ban tobacco. Above and beyond visions of cigarette bootlegging, the vision that the agency had no discretion short of such a ban is an important statement about agency discretion, or the lack thereof.

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<sup>81</sup>*Id.* at 1304.

