

## FDA Gains Regulatory Authority Over Tobacco

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On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act<sup>1</sup> (the Act), giving the U.S. Food and Drug Administration (FDA) the power to regulate the tobacco industry. Passed by sizable majorities in both the House and the Senate and supported by the American Cancer Society, healthcare professionals, and even some tobacco manufacturers, the Act reverses the 2000 United States Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*,<sup>2</sup> which held the government agency lacked authority to regulate tobacco products. For decades, the agency's attempt to take on Big Tobacco has been thwarted through adverse legal decisions, lobbying efforts and unsuccessful legislative action. Now that the FDA has been given the regulatory power, some question the agency's ability to effectively govern at a time when its resources and manpower are being stretched beyond capacity.<sup>3</sup>

### Background

According to the Centers for Disease Control and Prevention, approximately 443,000 deaths are attributable to cigarette smoking each year and nearly 1,000 children become new, regular smokers every day.<sup>4</sup> Moreover, tobacco manufacturers spend about \$40 million every day to market its products, particularly to children, by promoting "enticing candy and fruit-flavored cigarettes," according to a study by the American Cancer Society Cancer Action Network.<sup>5</sup> It is widely known the lobbying power of tobacco manufacturers is highly effective, and thus, legislative efforts to regulate tobacco products have failed to yield much success.

In the late 1950s, only 44 percent of Americans believed smoking caused cancer.<sup>6</sup> That number jumped to 78 percent by 1968.<sup>7</sup> A 1964 Surgeon General report on smoking and health had a major impact on public attitudes and policy over the course of that decade. Yet, while the 1964 report concluded that "cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action," it

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<sup>1</sup> Pub. L. No. 111-31, H.R. 1256, 111th Cong. (2009).

<sup>2</sup> 529 U.S. 120, 120 S.Ct. 1291 (2000).

<sup>3</sup> See Ryan Byrnes, *Lack of FDA Resources Puts Public Health at Risk*, GAO Report Says, CNSNEWS.COM, Jan. 29, 2009, <http://www.cnsnews.com/public/content/article.aspx?RsrcID=42695>.

<sup>4</sup> Centers for Dis. Control and Prev., *Annual Deaths Attributable to Cigarette Smoking—United States, 2000-2004*, [http://www.cdc.gov/tobacco/data\\_statistics/tables/health/attrdeaths/index.htm](http://www.cdc.gov/tobacco/data_statistics/tables/health/attrdeaths/index.htm) (last updated May 29, 2009); see also Chris Silva, *FDA to Regulate Tobacco*, AM. MED. ASSOC. NEWS, June 22, 2009, <http://www.ama-assn.org/amednews/2009/06/22/gv110622.htm>.

<sup>5</sup> Chris Silva, *FDA to Regulate Tobacco*, AM. MED. ASSOC. NEWS, June 22, 2009, <http://www.ama-assn.org/amednews/2009/06/22/gv110622.htm>.

<sup>6</sup> Nat. Lib. of Med. and Nat. Inst. of Health, *The Reports of the Surgeon General: The 1964 Report on Smoking and Health*, <http://profiles.nlm.nih.gov/NN/Views/Exhibit/narrative/smoking.html>. The complete 386-page report is available at [http://profiles.nlm.nih.gov/NN/B/B/M/Q/\\_/nnbbmq.pdf](http://profiles.nlm.nih.gov/NN/B/B/M/Q/_/nnbbmq.pdf).

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

failed to provide specific recommendations.<sup>8</sup> That challenge fell to politicians. While a battle among legislators and tobacco manufacturers has raged since, substantive regulations and legislation intending to control the tobacco industry have failed to pass. Instead, incremental measures have been passed. For example, in 1965, Congress required all cigarette packages distributed in the United States to carry a health warning, and since 1970, this warning has been made in the name of the Surgeon General.<sup>9</sup> In 1970, cigarette advertising on television and radio was banned.<sup>10</sup>

In the past 15 years, the FDA has taken steps to aggressively assert its influence in the tobacco industry. Tasked with “protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics and products that emit radiation,”<sup>11</sup> the FDA launched a sizeable effort in 1996 to significantly regulate cigarettes and tobacco products, and control the marketing of those products to children and adolescents. The agency’s regulatory measure was successfully challenged legally by Big Tobacco.

#### FDA v. Brown & Williamson Tobacco Corp.

In 1996, former head of the FDA, David Kessler, launched a daring initiative to assert regulatory authority over tobacco after decades of deliberately avoiding the task.<sup>12</sup> Kessler, and the FDA, reasoned that nicotine was a “drug” within the meaning of the Food, Drug, and Cosmetic Act,<sup>13</sup> and that cigarettes and smokeless tobacco are “devices,” i.e., “combination products” (which the agency had statutory authority to regulate) designed to deliver the drug, nicotine, to the body.<sup>14</sup> In response, the agency promulgated regulations intending to reduce tobacco consumption among children and teenagers, widely believed by the FDA to be a target group of the tobacco companies.<sup>15</sup>

A group of tobacco manufacturers, retailers, and advertisers filed suit in federal court challenging the regulations as exceeding the FDA’s authority.<sup>16</sup> A threshold issue for the

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

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

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

<sup>11</sup> Kathleen Kingsbury, *FDA Regulations*, TIME, June 22, 2009, [http://www.time.com/time/specials/packages/article/0,28804,1906464\\_1906463\\_1906429,00.html](http://www.time.com/time/specials/packages/article/0,28804,1906464_1906463_1906429,00.html); Food & Drug Admin., *Centers & Offices*, <http://www.fda.gov/AboutFDA/CentersOffices/default.htm>.

<sup>12</sup> *Id.*; see also Gregory D. Curfman, M.D., et al., *Editorial: Tobacco, Public Health, and the FDA*, NEW ENG. J. MED. 10.1056, June 22, 2009, available at <http://content.nejm.org/cgi/reprint/NEJMe0905622v1.pdf>.

<sup>13</sup> 21 U.S.C. § 301 *et. seq.* (West 2009). The FDCA grants the FDA the authority to regulate “drugs” and “devices” among other things. The Act defines “drug” to include “articles (other than food) intended to affect the structure or any function of the body.” It defines “device” as an “instrument, apparatus, implement, machine, contrivance...or similar article, including any component, part, or accessory, which is...intended to affect the structure or any function of the body.” The Act also grants the FDA the authority to regulate “combination products” which “constitute a combination of a drug, device, or biological product.”

<sup>14</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125, 120 S.Ct. 1291 (2000) (JJ. Breyer, Stevens, Souter, and Ginsburg dissenting).

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

<sup>16</sup> *Id.* at 129.

United State Supreme Court was determining the appropriate framework for analyzing the FDA's assertion of regulatory authority over tobacco.<sup>17</sup>

Writing for the Court, Justice Sandra Day O'Connor said the "case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use."<sup>18</sup> Although a majority of the Court in the 5 to 4 decision expressed concern over the economic and health costs attributed to tobacco use, it refused to grant the FDA regulatory authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law."<sup>19</sup>

In a comprehensive and meticulously-written opinion, Justice O'Connor thoroughly examined FDA's proposed regulations, the statutory authority granted to the agency by Congress, as well as other federal laws and Congressional intent. For example, Justice O'Connor wrote "it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction."<sup>20</sup> She reasoned:

[A] fundamental precept of the FDCA [the Food, Drug, and Cosmetic Act] is that any product regulated by the FDA that remains on the market must be safe and effective for its intended use... That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit... In its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market... Congress, however, has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects. Thus, an FDA ban would plainly contradict congressional intent...

The Court concluded by reiterating the serious health concerns raised by tobacco use and the FDA's attempt to address the problem. "The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States," wrote Justice O'Connor.<sup>21</sup> Nonetheless, Justice O'Connor wrote, an "administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress."<sup>22</sup> The Court failed to find such power delegated to the FDA by Congress. Nine years later, the recently-enacted Family Smoking Prevention and Tobacco Control

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<sup>17</sup> *Id.* at 132.

<sup>18</sup> *Id.* at 125.

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

<sup>20</sup> *Id.* at 121.

<sup>21</sup> *Id.* at 161.

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

Act reverses the Court's decision and remedies the lack of regulatory authority conferred on the agency.

### The Family Smoking Prevention and Tobacco Control Act of 2009

One major provision of the Act establishes the Center for Tobacco Products, a unit within the FDA dedicated to carrying out the law's provisions.<sup>23</sup> Funded by user fees from tobacco manufacturers and importers,<sup>24</sup> the Center will have the authority to require that all ingredients, compounds, and additives in tobacco products be reported to the agency, and ban products found to be harmful.<sup>25</sup> Although menthol, nicotine, and cigarettes as a whole cannot be banned outright, cigarettes with fruit, mint, or other flavoring are.<sup>26</sup> Additionally, new tobacco products failing to meet FDA pre-market standards will not enter the market.<sup>27</sup> The new law also gives the FDA authority to do the following:

- require disclosure of a tobacco product's contents;
- compel the tobacco industry to research the effect of its products on consumers' health;
- prohibit terms such as "light," "mild," and "low-tar" on tobacco products;
- require warning labels to cover 50 percent of the front and rear of each pack, with the word "warning" in capital letters.<sup>28</sup>

A significant aspect of the law seeks to reduce targeting of tobacco products through marketing, advertising, and other promotional efforts to children and adolescents. Tobacco companies are thus no longer allowed to sponsor sporting events and outdoor advertising of tobacco products is no longer allowed within 1,000 feet of a school.<sup>29</sup> Whether such advertising restrictions placed on a company can survive a First Amendment legal challenge remains to be seen. Although Representative Henry Waxman said the legislation was carefully drafted to avoid such litigation, many first amendment advocacy groups expect there to be legal challenges to the Act's advertising restrictions.<sup>30</sup>

In the meantime, FDA Commissioner, Margaret Hamburg, has stated she is eager to undertake her new role. "We now have an opportunity to really make a difference with

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<sup>23</sup> Pub. L. No. 111-31, H.R. 1256, Sec. 901(e), 111th Cong. (2009).

<sup>24</sup> User fees for fiscal year 2010 are estimated to reach \$235 million and rise to \$712 million over the next 10 years. *See* Curfman, et al., *supra* note 12.

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

<sup>26</sup> Pub. L. No. 111-31, H.R. 1256, 111th Cong. (2009); *see also, e.g.* Melissa Healy, *The FDA's Tobacco Road*, L.A. TIMES, June 29, 2009, <http://www.latimes.com/features/health/la-he-tobacco29-2009jun29,0,474954.story>; Gregory D. Curfman, M.D., et al., *Editorial: Tobacco, Public Health, and the FDA*, NEW ENG. J. MED. 10.1056, June 22, 2009, available at [http://content.nejm.org/cgi/reprint/NEJM\\_e0905622v1.pdf](http://content.nejm.org/cgi/reprint/NEJM_e0905622v1.pdf).

<sup>27</sup> *Id.*

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

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

<sup>30</sup> Duff Wilson, *Tobacco Regulation Is Expected to Face a Free-Speech Challenge*, N.Y. TIMES, June 15, 2009, [http://www.nytimes.com/2009/06/16/business/16tobacco.html?\\_r=1&scp=1&sq=waxman%20tobacco%20first%20amendment&st=cse](http://www.nytimes.com/2009/06/16/business/16tobacco.html?_r=1&scp=1&sq=waxman%20tobacco%20first%20amendment&st=cse).

what is probably the No. 1 public health concern in the nation and the world,” said Hamburg.<sup>31</sup> However, some commentators note that the FDA is badly underfunded, understaffed, and needs to act more aggressively when threats to the public’s health arise.<sup>32</sup>

### Can FDA Handle Big Tobacco?

In recent months, Congress has increased the budget of the FDA to coincide with the agency’s new role in regulating tobacco, and President Obama is asking for additional funding.<sup>33</sup> However, a recent Government Accountability Office (GAO) report notes that the agency’s resources have not kept pace with “the growing demands placed on it.”<sup>34</sup>

The report noted that the FDA may only inspect about eight percent of nearly 3,300 estimated foreign drug-manufacturers subject to inspection in a given year.<sup>35</sup> “As a result, the American consumer may not be adequately protected from unsafe and ineffective medical products,” the report concluded.<sup>36</sup>

Recent health issues attributed to cookie dough, pistachios, and imported peppers – all of which the FDA is tasked to monitor – have added to the mounting concerns regarding the agency’s ability to effectively do its job.

### Conclusion

Even without adding tobacco to its list of regulatory efforts, the FDA is struggling to carry out its other responsibilities, including the safety of the nation’s food, drugs and medical devices.<sup>37</sup> The new Center for Tobacco Products will undoubtedly divert resources from other centers and may even further sidetrack oversight efforts of clinical trials and the post-market safety monitoring of medical products.

Seemingly aware of its strained resources, the FDA recently asked “all interested parties to provide information and share views” on its implementation of the new Act.<sup>38</sup> Specifically, the agency said it is interested in “comments on the approaches and actions

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<sup>31</sup> Gardiner Harris, *New F.D.A. Chief Says She’ll Toughen Enforcement Efforts*, N.Y. TIMES, June 17, 2009, <http://www.nytimes.com/2009/06/17/us/17fda.html>.

<sup>32</sup> See, e.g., Byres, *supra* note 3; Kingsbury, *supra* note 11; Chris Silva, *FDA to Regulate Tobacco*, AM. MED. ASSOC. NEWS, June 22, 2009, <http://www.ama-assn.org/amednews/2009/06/22/gv110622.htm> (“[s]ome lawmakers opposed the legislation, saying the agency is already stretched too thin to take on the added responsibility of tobacco regulation. Others questioned the propriety of having an agency dedicated to public health overseeing a product that can never be safe when used as directed”).

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

<sup>34</sup> See Byrnes, *supra* note 3.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> See Healy, *supra* note 26.

<sup>38</sup> David B. Clissold and Ricardo Carvajal, *Implementation of the Family Smoking Prevention and Tobacco Control Act: FDA Wants to Hear From You*, FDA LAW BLOG, June 30, 2009, [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2009/06/implementation-of-the-family-smoking-prevention-and-tobacco-control-act-fda-wants-to-hear-from-you.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2009/06/implementation-of-the-family-smoking-prevention-and-tobacco-control-act-fda-wants-to-hear-from-you.html).

the agency should consider initially to increase the likelihood of reducing the incidence and prevalence of tobacco use and protecting the public health.” Hopefully, the agency will be up to the task.

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