UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, MASSACHUSETTS CHAPTER OF AMERICAN ACADEMY OF PEDIATRICS, INC., AMERICAN CANCER SOCIETY, INC., AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, INC., AMERICAN HEART ASSOCIATION, INC., AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, TRUTH INITIATIVE FOUNDATION d/b/a TRUTH INITIATIVE, DR. TED KREMER, DR. JONATHAN WINICKOFF and DR. LYNDA YOUNG,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. _____

COMPLAINT

Introduction

1. This complaint is brought under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), to compel the United States Food and Drug Administration ("FDA") to promulgate a final rule implementing Section 201(a) of the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776-1858 ("Tobacco Control Act"), to require cigarette packages and advertisements to bear color graphic images and specified textual warnings.

2. The Tobacco Control Act became law on June 22, 2009. Section 201 required the FDA to promulgate its final rule "not later than 24 months after the enactment" of the Act: June 22, 2011. 123 Stat. 1845.

3. Shortly after passage of the Act, and before the FDA began rulemaking proceedings under Section 201, in August 2009 various tobacco product manufacturers and sellers brought suit in the United States District Court for the Western District of Kentucky claiming that Section 201 was unconstitutional on its face as an infringement of free speech under the First Amendment of the United States Constitution. In January 2010, the District Court held that the provisions of Section 201 were not unconstitutional on their face and denied relief. The Court of Appeals for the Sixth Circuit affirmed that decision in March 2012 and the Supreme Court declined to review the issue.

4. On November 12, 2010, the FDA commenced a notice-and-comment rulemaking proceeding under Section 201. 75 Fed. Reg. 69,524.

5. On June 22, 2011, exactly two years after the Tobacco Control Act was enacted, the FDA promulgated a final rule designating nine graphic warning labels depicting the negative health consequences of cigarette smoking as required by Section 201 and set September 22, 2012 as the time by which such warning labels would be required. Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("2011 Rule").

6. On September 2, 2011, a group of tobacco product manufacturers and sellers filed an action in the United States District Court for the District of Columbia alleging that the 2011 Rule was unconstitutional as applied because the specific required content, placement and type style of the mandated warning labels infringed their rights of free speech under the First Amendment. The complaint did not challenge the text of the warnings required by Section 201.

7. On February 29, 2012, the United States District Court for the District of Columbia found that the specific warning labels required by the 2011 Rule were unconstitutional and enjoined the enforcement of the rule. On August 24, 2012, the Court of Appeals for the

District of Columbia Circuit affirmed the judgment of the District Court and vacated the 2011 Rule. The Court of Appeals remanded the rule to the FDA and vacated the District Court's permanent injunction.

8. On March 15, 2013, Attorney General Eric Holder, in a letter to Congress, stated that, given the FDA's plan to undertake research to support a new rule mandating graphic warning labels consistent with the Tobacco Control Act, the Solicitor General had determined not to seek Supreme Court review of the Court of Appeals' ruling.

9. Although more than four years have now passed since the Court of Appeals vacated the 2011 Rule, the FDA has not even begun rulemaking proceedings to promulgate a new graphic warnings rule as required by Section 201. No proposed rule even appears on the FDA's Unified Regulatory Agenda for action during 2016.

10. By vacating and remanding the 2011 Final Rule to the FDA, the Court of Appeals restored the status quo before the 2011 Rule was issued.

11. The FDA is in violation of its nondiscretionary statutory duty to issue a final rule implementing Section 201 no later than June 22, 2011.

12. This Court should compel the FDA to comply with the agency's nondiscretionary statutory duty to promulgate a lawful graphic warning label rule under Section 201.

Jurisdiction and Venue

13. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 702-706 and, in the alternative, pursuant to 28 U.S.C. § 1361. Venue is properly within this District under 28 U.S.C. § 1391(e)(1)(c) because plaintiff the Massachusetts Chapter of the American Academy of Pediatrics, Inc. has its principal place of business in Massachusetts and the individual plaintiff pediatricians, Dr. Ted Kremer, Dr. Jonathan Winickoff and Dr. Lynda Young, all reside in Massachusetts.

Parties

14. Plaintiff the American Academy of Pediatrics ("AAP") is a professional membership organization of 64,000 pediatricians, pediatric medical sub-specialists and pediatric surgical specialists. It is incorporated under the laws of Illinois and operated exclusively for charitable and educational purposes under section 501(c)(3) of the Internal Revenue Code. The AAP's headquarters are located at 141 Northwest Point Blvd., Elk Grove Village, Illinois 60007.

15. The AAP's mission is to attain optimal physical, mental and social health and well-being for all infants, children, adolescents and young adults. To accomplish this goal, the AAP's pediatrician members in Massachusetts and elsewhere actively screen their patients for use of tobacco and provide counseling to their patients and patients' parents about the health hazards of smoking, in an effort to prevent smoking initiation and reduce tobacco smoke exposure. The AAP publishes and distributes to its members a *Clinical Practice Policy to Protect Children from Tobacco, Nicotine, and Tobacco Smoke* ("AAP Clinical Practice Policy"), which describes clinical practice recommendations to physicians on how to screen for tobacco use and counsel their patients and patients' parents, including urging children to make a commitment to being tobacco free, as well as encouraging parents to stop smoking and providing recommendations on obtaining assistance in quitting smoking.

16. The AAP expends substantial resources in providing its physician members tools to screen their patients for tobacco use and counsel their patients and patients' parents against smoking, including production and distribution of the AAP Clinical Practice Policy. The FDA's failure to promulgate a final rule under Section 201 reduces the AAP's effectiveness as a professional association in providing assistance to members because graphic health warnings would reinforce the content and importance of the physicians' counseling and enhance the success of that counseling. The individual physician members of the AAP suffer similar injury

from the FDA's failure to issue a final rule requiring graphic warnings because such warnings would make patients and their parents more receptive and responsive to the anti-smoking counseling provided by those physician-members, thus allowing the physician-members to invest less time in providing effective counseling.

17. Plaintiff the Massachusetts Chapter of American Academy of Pediatrics, Inc. ("MCAAP") is a nonprofit corporation organized under Massachusetts law. Its principal place of business is 860 Winter Street, Waltham, Massachusetts, 02451. It is separately incorporated from the AAP and operates under section 501(c)(6) of the Internal Revenue Code. The MCAAP is a membership organization with approximately 1800 members in the Commonwealth of Massachusetts.

18. As a Chapter of the AAP, the MCAAP provides assistance to its physician-members in their efforts to screen their patients for tobacco use and to counsel patients and patients' parents about the dangers of smoking, in an effort to prevent smoking initiation and reduce tobacco smoke exposure, consistent with the AAP's Clinical Practice Policy. The FDA's failure to promulgate a final rule under Section 201 reduces the MCAAP's effectiveness as a professional association in providing assistance to members because graphic health warnings would reinforce the content and importance of the physicians' counseling and enhance the success of that counseling. The individual physician members of the MCAAP suffer similar injury from the FDA's failure to issue a final rule requiring graphic warnings because such warnings would make patients and their parents more receptive and responsive to the anti-smoking counseling provided by those physician-members, thus allowing the physician-members to invest less time and expend fewer resources in providing effective counseling.

19. Plaintiff the American Cancer Society, Inc. ("ACS") is a nationwide, community-based voluntary health nonprofit organization. It is incorporated under the laws of the State of New York and operated exclusively for charitable and educational purposes under section 501(c)(3) of the Internal Revenue Code. ACS has offices across the nation, including in Massachusetts. Its headquarters are located at 250 Williams Street NW, Atlanta, Georgia, 30303. Its principal place of business in Massachusetts is located at 30 Speen Street, Framingham, Massachusetts.

20. ACS's mission is to eliminate cancer as a major health problem by preventing cancer, saving lives from cancer, and diminishing suffering from cancer through research, education, advocacy and service.

21. ACS has long been engaged in efforts to educate the public about smoking as a cause of cancer, the health benefits of quitting smoking, and the most effective ways of quitting and of helping others quit. Research conducted by ACS in the 1950s established the original scientific link between tobacco use and lung cancer and coronary heart disease. To this day, ACS actively promotes tobacco prevention and cessation programs. For example, ACS annually sponsors The Great American Smokeout, a one-day national event in which smokers are urged to quit for at least one day, as an important step toward a healthier life. ACS also sponsors education, service and counseling programs to help smokers quit. This includes collaborating with Optum in "Quit for Life," a phone-based coaching and web-based learning support service to help smokers quit, and a program called "Freshstart," a group-based face-to-face tobacco cessation program delivered by company-based facilitators. ACS has devoted substantial resources towards these anti-smoking and smoking cessation research, education, advocacy and service initiatives.

22. Timely implementation of the required graphic warning labels is essential to advancing ACS's missions with respect to research, education, advocacy and service. ACS would rely heavily on graphic warning labels to advance its work in this area.

23. The FDA's failure to issue a final rule under Section 201 makes it more difficult for ACS to educate the public about the dangers of smoking and effectively counsel smokers to quit. The absence of larger, more effective textual warnings and prominent graphic warnings on cigarette packaging and in cigarette advertising makes it more difficult for ACS to educate and counsel members of the public not to smoke. If graphic warning labels were required by a final rule promulgated by the FDA, smokers would be better informed and more motivated to quit, and the individuals assisted by ACS's cessation programs would be more receptive to undertaking the effort required to quit and persevering to overcome a strong addiction. Graphic warning labels would require ACS to expend fewer resources and the effectiveness of its programs would be enhanced.

24. The American Cancer Society Cancer Action Network, Inc. ("ACS CAN") is a nonprofit organization incorporated in the District of Columbia, with its principal place of business in Washington, D.C. Created in 2001, ACS CAN is the nonpartisan advocacy affiliate of ACS and is incorporated separately under section 501(c)(4) of the Internal Revenue Code. ACS CAN is the nation's leading cancer advocacy organization dedicated to making cancer issues a priority. ACS CAN is a membership organization, with approximately 47,000 members nationwide and over 1,000 members in Massachusetts. Its principal place of business in Massachusetts is located at 30 Speen Street, Framingham, Massachusetts.

25. Because smoking is a leading cause of lung and other forms of cancer, ACS CAN has, since its founding, been a leader in educating the public about the dangers of smoking and

advocating for policies and programs to discourage smoking initiation and help smokers quit. Through its members and volunteers, ACS CAN advocates for effective tobacco control at every level of government. ACS CAN has been an active participant in FDA tobacco regulatory proceedings since the FDA was given regulatory authority in 2009, including filing comments in the rulemaking proceeding leading to the issuance of the graphic warnings rule in 2011. ACS CAN and its members continue to devote substantial resources to educating the public about the dangers of smoking.

26. The FDA's failure to issue a final rule under Section 201 makes it more difficult for ACS CAN and its individual members to educate the public about the dangers of smoking because the public is deprived of the effective and reinforcing communication of those dangers through strong graphic health warnings. Effective graphic warning labels would therefore require ACS CAN and its individual members to expend fewer resources to educate the public about the dangers of smoking and their public education efforts would be enhanced.

27. The FDA's failure to issue a final rule requiring graphic warning labels also makes it more difficult for individual ACS CAN members who seek to educate their children and other family members about the dangers of smoking and discourage them from smoking. Because graphic health warnings more effectively communicate the dangers of smoking to children and other family members of ACS CAN members than the current textual warnings, the absence of graphic warning labels impedes the efforts of such members to ensure that their children and other family members understand the dangers of smoking and decide not to smoke.

28. Plaintiff the American Heart Association, Inc. (the "AHA") is a nonprofit corporation organized under the laws of New York with its principal place of business in 7272 Greenville Avenue, Dallas, Texas. It is a tax-exempt organization under section 501(c)(3) of the

Internal Revenue Code. Its principal location in Massachusetts is 300 5th Avenue, Suite 6, Waltham, Massachusetts, 02451.

29. The AHA provides counseling in schools, churches and hospitals to help prevent youth initiation of tobacco use and help current tobacco users to quit. This counseling involves direct contact with individuals about the consequences of smoking. Through its multi-cultural initiatives department, the AHA works with historically black colleges and universities as well as churches to ensure that strong tobacco-free policies are in place and to provide tobacco users with the resources they need to quit. Through AHA's "Get With The Guidelines" quality improvement program, the AHA seeks to ensure that hospitals are screening for tobacco use among patients and providing cessation resources when needed. One of the principal goals of AHA's programs is to ensure that the individuals who receive counseling fully understand the consequences of cigarette smoking.

30. In addition, the AHA's website provides individuals with a large array of information about the long-term consequences of smoking and strategies to promote cessation. The absence of effective graphic warning labels on cigarette packs and in cigarette advertising makes it more difficult to convince smokers of the true long-term consequences of smoking. This is particularly true with young people, who find it difficult to understand the real long-term consequences of becoming addicted to tobacco. Cigarette packs and advertising carrying graphic warnings would reinforce this message and enhance the effectiveness of AHA counseling programs, which in turn would reduce the cost of such programs to the association. The AHA participated in the rulemaking proceeding that led to the promulgation of the 2011 Rule requiring graphic warning labels.

31. The American Lung Association ("ALA") is a non-profit voluntary health organization incorporated in the State of Maine with a principal place of business in 55 W. Wacker Drive, Suite 1150, Chicago, Illinois 60601. It is a tax-exempt corporation under section 501(c)(3) of the Internal Revenue Code. Its principal location in Massachusetts is located at 14 Beacon Street, Suite 717, Boston, Massachusetts, 02108.

32. ALA's mission is to save lives by improving lung health and preventing lung disease. The prevention and cessation of the use of tobacco products is an integral part of this mission. Providing effective assistance to smokers who are trying to quit smoking is one of ALA's top priorities. ALA expends substantial resources to sponsor the award-winning Freedom From Smoking Program, which provides smokers with access to certified tobacco treatment specialists on a telephone line, 1-800-LUNGUSA, through responses to online questions, and through an online chat room through which smokers can talk with counselors about quitting. ALA's Freedom from Smoking Plus Program provides a nine-session online course to be completed over a six-week period by smokers that includes telephone and online chat support to smokers trying to quit.

33. The FDA's failure to require graphic warning labels on cigarette packs and in cigarette advertisements impedes ALA's Freedom From Smoking Program by requiring ALA to devote additional resources to educate smokers about the true consequences of smoking and to help provide the motivation for smokers to undertake the difficult task of quitting. If graphic warning labels were required, smokers would be both better informed and more motivated to quit, and the individuals ALA assists in its Freedom From Smoking Program would be better prepared for and more receptive to undertaking the effort required to quit and persevering to overcome a powerful addiction. The fact that ALA must undertake these efforts in the absence

of graphic warning labels means that ALA must expend more of its scarce resources to achieve positive results.

34. Plaintiff Campaign for Tobacco-Free Kids ("CTFK") is a tax exempt non-profit corporation under section 501(c)(3) of the Internal Revenue Code, organized under the laws of the District of Columbia. Its principal place of business is 1400 I (Eye) Street, NW, Suite 1200, Washington, D.C. 20005. CTFK works to reduce tobacco use and its deadly toll in the United States and around the world. CTFK engages in public education about the dangers of cigarettes, as well as advocating public policies and sponsoring activities to prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke. Through its youth initiatives, CTFK sponsors youth activities to educate young people about the dangers of smoking and engage them in activities designed to discourage youth from initiating cigarette use and encourage youth smokers to quit smoking. For example, CTFK sponsors Kick Butts Day, a national day of activities that engage youth to speak up against the dangers of tobacco use, generating more than 1,000 events across the United States, including many in Massachusetts. The youth participants plan and conduct events that focus attention on the deadly dangers of tobacco use and urge their peers to be tobacco-free.

35. The FDA's failure to promulgate a rule regarding graphic warning labels has undermined CTFK's activities to educate the public, and particularly young people, about the dangers of smoking. The effectiveness of CTFK's programs would be enhanced by replacing the relatively ineffective textual warnings that have been unchanged on cigarette packages for many years with the warnings mandated by the TCA, which include larger lettering, more prominent placement, more explicit text, and graphics.

36. The FDA's failure to abide by the statutory mandate to issue a final rule requiring graphic warnings on cigarette packages has undermined the effectiveness of CTFK's sponsorship of youth activities to educate young people about the dangers of smoking. It has also made it more difficult for CTFK to engage young people in activities designed to discourage youth from initiating cigarette use and encourage youth smokers to quit smoking.

37. The FDA's failure to abide by the statutory mandate has made it more difficult for CTFK's public education and youth activities to be effective in (a) giving young people an accurate understanding of the dangers of smoking, (b) discouraging initiation of smoking and (c) encouraging young smokers to quit smoking. FDA's failure to abide by the statutory mandate has therefore caused CTFK to expend more resources to achieve the objectives of its public education and youth activities than would have been necessary if the considerable public health benefits of the graphic warnings mandated by Section 201 of the Act had been realized.

38. Plaintiff the Truth Initiative Foundation, d/b/a Truth Initiative ("Truth Initiative") is a Delaware corporation created in 1999 out of the 1998 Master Settlement Agreement ("MSA") resolving litigation brought by 46 states, five U.S. territories and the District of Columbia against the major U.S. cigarette companies. It is a tax-exempt corporation under section 501(c)(3) of the Internal Revenue Code. Its headquarters are located at 900 G Street, NW, 4th Floor, Washington, DC 20001. Truth Initiative's purposes are to study and support programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use.

39. Truth Initiative supports innovative and highly successful programming to educate young people about tobacco so they make informed choices about its use and programming that encourages and assists smokers to quit. For example, Truth Initiative's

nationally recognized truth® campaign has reached hundreds of millions of teens and young adults through television, radio and print advertisements, social media, the internet, earned media, and in-person events, with information about the health effects and social costs of tobacco in order to enable young people to make informed decisions about tobacco use. Since 2008, Truth Initiative has offered a free, evidence-based, on-line smoking cessation intervention, EX®, to help adults stop smoking. EX has reached over 700,000 persons to date. Truth Initiative also conducts youth activism programs to educate low-income, minority and LGBTQ youth about the health risks of tobacco and encourage them to take an active role in helping their communities become tobacco-free.

40. Research demonstrates that graphic warnings educate the public about the health effects of tobacco and increase and enhance attempts to quit smoking. Because the FDA has failed to promulgate a final rule regarding graphic warnings on cigarette packaging and advertising, Truth Initiative has been forced to devote more funds and resources to its programs. The implementation of graphic warnings would allow Truth Initiative to spend less on, and otherwise devote fewer resources to, certain programs than it otherwise would, thereby making these funds and resources available to be used in other ways to advance Truth Initiative's corporate purposes to improve the public health.

41. Truth Initiative's truth campaign and youth education and activism programs are similarly harmed by the absence of graphic warnings. Truth Initiative must spend more funds and devote additional other resources to these programs to achieve the same results they would achieve had the graphic warnings regulation been promulgated or suffer the diminished impact of these programs. The textual warnings currently on cigarette packages are relatively ineffectual in all of these regards and provide no off-setting benefit to Truth Initiative.

42. FDA's failure to issue a rule requiring graphic warnings on cigarette packages has directly undermined Truth Initiative's ability to achieve its corporate purposes by depriving it of these and other benefits. More particularly, FDA's failure has forced Truth Initiative to choose to either spend more funds and work harder to achieve its purposes than it would have had to if the FDA had complied with the statutory mandate, or suffer the diminished effectiveness of its programs. For example, the number of individuals utilizing Truth Initiative's EX® smoking cessation program at any point in time is linked to the amount Truth Initiative is then spending on paid advertising of the program. Because graphic warnings increase smokers' intents to quit smoking as well as, at least, successful short term quitting, if graphic warnings were on cigarette packages, Truth Initiative could either spend less on paid advertising and devote fewer non-pecuniary resources to achieve the same results it currently achieves or maintain its spending level and help more smokers quit smoking.

43. Truth Initiative has spent over $200 million on just the three programs described above since June 22, 2011, the statutorily required date for the promulgation of a graphic warnings regulation. It has spent over $150 million since the date that Attorney General Holder informed Congress that the government would not appeal the D.C. Circuit's decision but would instead undertake additional research to pursue a new rule-making to mandate graphic warnings. The loss of even a small incremental benefit achieved through graphic warnings amounts to significant economic injury to Truth Initiative. The non-pecuniary loss of foregone programmatic impact is also substantial.

44. Plaintiff Dr. Ted Kremer resides in Holden, Massachusetts and is a pediatric pulmonologist licensed by the Commonwealth of Massachusetts. Dr. Kremer is the Director of Pediatric Pulmonology and Sleep Medicine at the Department of Pediatrics at UMass Memorial

Medical Center, 55 Lake Avenue North, Worcester Massachusetts 06155. As part of his regular professional practice Dr. Kremer provides medical care and advice to patients from infancy through college age and to their parents. Many of the patients suffer from pulmonary diseases such as asthma and cystic fibrosis. As part of this practice, Dr. Kremer provides advice to such patients and their parents regarding the long-term consequences of smoking. The adolescent patients Dr. Kremer treats and advises are exposed to pervasive advertising, marketing and promotion of cigarettes, which is particularly effective with adolescents and is designed to make smoking attractive. The absence of graphic warning labels on cigarette packs and advertising makes it more difficult for Dr. Kremer to communicate effectively the long-term consequences of smoking to his patients and their parents and requires the allocation of greater resources to accomplish this objective.

45. Plaintiff Dr. Jonathan Winickoff is a resident of Brookline, Massachusetts and a pediatrician duly licensed to practice medicine in the Commonwealth of Massachusetts. He works as a pediatrician at the Department of Pediatrics, Massachusetts General Hospital, in Boston and is a member of the faculty of the Harvard Medical School.

46. Dr. Winickoff specializes in the medical care of infants, children, adolescents and young adults under the age of 21. In the course of his practice, Dr. Winickoff routinely counsels patients between the ages of 10 and 21 and their parents regarding the long-term health consequences of smoking. The attitudes of these patients about using tobacco products are greatly influenced by the pervasive advertising of tobacco products and the labeling of cigarette packs by manufacturers to make the pack convey positive information about the product. The nearly invisible warnings currently required on cigarette packs do little to inform young people of the true long-term consequences of smoking. The absence of graphic warnings on cigarette

packs and in cigarette advertising impedes the effectiveness of Dr. Winickoff's practice and causes him to expend additional resources to provide effective counseling. The presence of graphic warnings accurately depicting the long-term consequences of smoking would make Dr. Winickoff's counseling more effective and would enable him to use available resources more effectively to promote the health of his patients.

47. Plaintiff Dr. Lynda Young is a resident of Worcester, Massachusetts, and a pediatrician duly licensed to practice medicine in the Commonwealth of Massachusetts. She is employed as a pediatrician at the Department of Pediatrics, University of Massachusetts Medical Center, University Campus, 55 Lake Avenue North, Worcester, Massachusetts 01655.

48. Dr. Young specializes in the medical care of infants, children, adolescents, and young adults under the age of 21 years. In the course of her practice, Dr. Young routinely counsels patients between the ages of 10 and 21 and their parents regarding the long-term health consequences of smoking. The attitudes of these patients about using tobacco products are greatly influenced by the pervasive advertising of tobacco products and the labeling of cigarette packs by manufacturers to make the pack convey positive information about the product. The nearly invisible warnings currently required on cigarette packs do little to inform young people of the true long-term consequences of smoking.

49. The presence of graphic warnings accurately depicting the long-term consequences of smoking would make Dr. Young's counseling more effective and would enable her to use her available resources more efficiently to promote the health of her patients. Accordingly, the absence of graphic warnings impedes the effectiveness of Dr. Young's medical practice and causes her to expend additional resources to accomplish its results.

50. Defendant United States Food and Drug Administration (the "FDA") is the federal agency that Congress instructed to promulgate a final rule implementing the requirements of Section 201 of the Tobacco Control Act by June 22, 2011.

Facts

The Tobacco Control Act

51. Section 201 was enacted on June 22, 2009 as part of the Tobacco Control Act, which conferred jurisdiction on the FDA to regulate tobacco products.

52. Section 201 amended Section 4 of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333, to require FDA to issue a final rule requiring cigarette packages and advertisements to bear color graphics depicting the negative health consequences of smoking not later than two years after the enactment of the Tobacco Control Act. Section 201 also mandates the use of nine specific new textual warnings (to replace the text of warnings that have been unchanged since 1984), specifies the placement of the warnings on the packages and advertisements, specifies the size of the warnings, and specifies the type size of the text to be used. Section 201(a) provides that all the changes are to take effect 15 months after the issuance of the required rule.

53. Specifically, Section 201(a) provides:

> Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).

54. Subsection (a)(1) of Section 4 of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333, as amended by the Tobacco Control Act, provides:

> It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.
WARNING: Tobacco smoke can harm your children.
WARNING: Cigarettes cause fatal lung disease.
WARNING: Cigarettes cause cancer.
WARNING: Cigarettes cause strokes and heart disease.
WARNING: Smoking during pregnancy can harm your baby.
WARNING: Cigarettes can kill you.
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
WARNING: Quitting smoking now greatly reduces serious risks to your health.

55. Subsection (a)(2) of Section 4 of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333, as amended by the Tobacco Control Act, provides:

> Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package . . . [and] shall comprise the top 50 percent of the front and rear panels of the package.

Subsection (a)(2) also specifies the type size of the textual warning.

56. Subsection (b)(1) of Section 201(a) requires the same textual warnings on all advertisements for cigarettes.

57. Subsection (b)(1) of Section 201(a) provides:

> It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

58. Subsection (b)(2) specifies the placement type size of warning labels on cigarette advertisements.

59. Subsection 201(b) provides that "[t]he amendment made by subsection (a) shall take effect 15 months after the issuance of the regulations required by subsection (a)." Thus the requirement of new textual and graphic warnings does not take effect until 15 months after the issuance of the regulation requiring graphic warnings.

60. Because the FDA has failed to issue the graphic warning regulations required by subsection (a), none of the requirements of Section 201 have been made effective either for cigarette packages or for advertising.

The Importance of Graphic Warning Labels

61. In enacting the Tobacco Control Act, Congress recognized that tobacco usage is the largest preventable cause of death in the United States and gave the FDA comprehensive authority to regulate tobacco products. The extensive statutory findings state that tobacco use causes over 400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses related to tobacco. Pub. L. 111-31, § 2(13). Virtually all new users of tobacco products are under the minimum age to purchase such products. *Id.* § 2(4). As the FDA has found, each day almost 1,000 U.S. children become new daily smokers. 75 Fed. Reg. 69,527.

62. The severity of the public health problem presented by tobacco usage caused Congress to give the FDA comprehensive regulatory authority over tobacco products that included a prohibition on the marketing of all new tobacco products unless the FDA issued an order finding that the marketing of the product was appropriate for the protection of the public health; a grant of authority to the FDA to establish product standards for tobacco products; and a broad grant of authority to the FDA to regulate the advertising, marketing, and sale of tobacco products.

63. Congress specifically found that advertising, marketing and promotion of tobacco products have been designed to attract young people to use tobacco products, that these efforts have resulted in increased use of tobacco by youth and that past efforts to deal with the consequences of the tobacco industry's advertising, marketing, and promotions had not been successful. Pub. L. 111-31, § 2(15). Congress found that children are exposed to substantial and

unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who use tobacco. *Id.* § 2(20). Congress also found that children are more influenced by tobacco marketing than are adults. *Id.* § 2(23).

64. The requirement for new and more prominent textual warnings and graphic warning labels was an integral part of the regulatory program enacted by the Congress. As the FDA has properly understood, the purpose of the warning labels is to promote greater public knowledge of the health risks of using cigarettes and to convey to the public the adverse health consequences of smoking. 75 Fed. Reg. 69,526. The warning on a cigarette package can provide a clear, visible vehicle to communicate risk at a most crucial time for smokers and potential smokers. *Id*. at 69,529.

65. Although some textual warning has been required on cigarette packs since 1966, the warnings have been very small and have appeared on the side of cigarette packages where they have been difficult to see. In addition, the text of the warnings has not changed since 1984. *Id*. As the FDA itself found, "the unchanging nature of these warnings, as well as their small size and lack of a graphic image component, severely impairs their ability to effectively communicate to customers." *Id*. As a result, the agency found, "the current warnings in the United States frequently go unnoticed or fail to convey relevant information regarding health risks." *Id*. By contrast, "large pictorial warnings graphically convey the harm and danger that tobacco use causes." *Id.* at 69,532.

66. When it promulgated the 2011 Rule, the FDA found that the addition of graphic images will have a significant positive impact on public health and that the revised textual statements will communicate more effectively. *Id.* at 69,533.

67. The 2011 Rule was based on extensive scientific evidence, including a 2007 report from the Institute of Medicine describing existing warnings as "invisible" and finding that they fail to communicate relevant information in an effective way. The FDA cited substantial evidence indicating that larger cigarette health warnings, with graphic content, would offer significant health benefits over the existing warnings. 76 Fed. Reg. 36,628-36,636.

68. The international community recognizes the comparative public health value of graphic warnings that supplement textual warnings. More than 90 nations throughout the world have imposed requirements for graphic warnings for cigarette packages. At least 22 nations have mandated graphic warnings since the Court of Appeals vacated the 2011 Rule in 2012.

A Rule Requiring Graphic Warning Label Would Not Be Unlawful On Its Face

69. Shortly after the enactment of the Tobacco Control Act, in August 2009 a group of tobacco product manufacturers and sellers filed an action in the United States District Court for the Western District of Kentucky alleging that the provisions of Section 201 were unconstitutional on their face because they infringed the freedom of speech protected by the First Amendment. The District Court rejected this claim. *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010). On March 19, 2012, the Court of Appeals affirmed this decision. *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012). The Supreme Court denied plaintiffs' petition for a writ of certiorari on April 22, 2013. *American Snuff Co. v. United States*, 133 S. Ct. 1996 (2013).

The FDA's 2011 Rule Requiring Nine Specific Graphic Warning Labels

70. Although the Tobacco Control Act specifies the precise text of the new warning labels, the placement of the warning labels on the packages and advertisements, and the type size to be used, the Act does not specify the specific graphic warnings to be required. Instead, Congress directed the FDA to promulgate a rule specifying the graphic warnings that must

accompany each of the nine new textual warnings required by the Act. In November 2010, the FDA issued a proposed rule designating 36 potential pictures and sought public comments. 75 Fed. Reg. 69,524 (Nov. 12, 2010). Plaintiffs AAP, ACS CAN, AHA, ALA, CTFK and Truth Initiative (then called "Legacy") submitted written comments on the proposed rule. After receiving public comment, the FDA selected nine of the potential pictures and again sought public comments. On June 22, 2011, at the two-year statutory deadline for completing its rulemaking, the FDA issued a final rule requiring the use of these nine specific graphic warnings. 76 Fed. Reg. 36,628.

The Court of Appeals' Decision

71. Once again, the tobacco industry sought to prevent the implementation of Section 201. This time, various tobacco product manufacturers and sellers sought review of the 2011 Rule in the United States District Court for the District of Columbia. They did not claim that Section 201 was unconstitutional on its face or challenge the statutorily mandated textual warnings, but instead challenged the specific graphic warnings mandated by the FDA in its 2011 Rule as well as the placement and type-style requirements. The District Court found that it was unconstitutional under the First Amendment, as applied, for the FDA to mandate the specific warning labels required by the 2011 Rule. *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266 (D.D.C. 2012). Its decision was affirmed by the Court of Appeals. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

72. The decision invalidating the specific warning labels specified in the 2011 Rule in no way suggested that every rule mandating graphic warnings would be unconstitutional or that the FDA is without power to comply with its statutory obligation to promulgate constitutionally permissible graphic warning label requirements under Section 201. In fact, during the course of

the litigation, the tobacco industry plaintiffs conceded that different graphic warnings label requirements could be constitutional.

73. On March 15, 2013, in a letter to Congress, the Attorney General reported the FDA's intention to undertake research to support new rulemaking proceedings on graphic warnings and stated that, in these circumstances, and after consultation with the Department of Health and Human Services and the FDA, the Justice Department had determined not to seek Supreme Court review of the Court of Appeals' ruling in the *Reynolds* case. The Attorney General noted that the Court of Appeals "did not hold the provision of the Act directing FDA to promulgate graphic-warning regulations facially invalid," but held only "that the particular graphic warnings adopted in FDA's regulations violated the First Amendment, based on the record before FDA in the rulemaking proceedings, and it remanded the matter to the agency."

The FDA's Failure to Promulgate a New Rule

74. In the four years since the Court of Appeals vacated the 2011 Rule and remanded the matter to the FDA, the agency has not commenced any curative rulemaking proceeding. Certain of the plaintiffs wrote to the FDA on November 25, 2013 and again on August 14, 2014 urging the agency to promulgate a rule requiring graphic warning labels, as required by the Tobacco Control Act. In its most recent response, more than two years ago, on September 22, 2014 the FDA declined to comment on its plans, other than to indicate that it "is undertaking research to support a new graphic warnings rulemaking consistent with the TCA." Certain of the plaintiffs wrote to FDA Commissioner Califf again on August 3, 2016 urging agency compliance with the statutory mandate on graphic warnings because of its urgent public health importance.

75. The FDA has not yet promulgated or even proposed a new rule as required by the Tobacco Control Act even though the agency said, years ago, that it would develop and issue a

new set of graphic warning labels consistent with the Act. No proposed rule even appears on the FDA's Unified Regulatory Agenda for future action.

76. The FDA has been in violation of Section 201 for more than four years. During that time, over three million Americans, the vast majority of them minors, have begun to smoke on a regular basis. Half of them will die prematurely as a result of tobacco-related disease. During the time FDA has been in violation of Section 201, almost two million Americans have died of tobacco-related disease.

77. The FDA's failure to comply with the requirements of section 201 has materially diminished the effectiveness of the overall regulatory program enacted by the Tobacco Control Act.

78. Each of the plaintiffs or their members have suffered actual and particularized injury as a result of the FDA's failure to comply with its statutory duty to promulgate a lawful rule requiring the use of graphic warning labels as required by Section 201. The only way to redress these injuries is for the FDA to promulgate such a rule.

79. Plaintiffs have no administrative remedies to pursue under the Tobacco Control Act or the Food, Drug and Cosmetic Act or any other applicable provision of law. A proceeding under 5 U.S.C. § 706(1) or, in the alternative, under 28 U.S.C. § 1361 is the only available means to compel FDA's compliance with Section 201.

80. The FDA's demonstrated unwillingness to comply with Section 201's unambiguous statutory mandate and the importance of providing the public with the health benefits of the warning labels required by Section 201 warrant the issuance of an order under 5 U.S.C. § 706(1) or a writ of mandamus compelling the FDA to promulgate a rule mandating the use of graphic warning labels that comply with Section 201.

Count I: Claim under the APA

81. The plaintiffs adopt by reference the allegations of ¶¶ 1-80 of this Complaint.

82. The Administrative Procedure Act provides a remedy to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

83. The FDA has unlawfully withheld and unreasonably delayed action on a rule to implement the graphic warning requirements of Section 201 of the Tobacco Control Act within the meaning of 5 U.S.C. § 706(1).

Count II: Claim under the Mandamus Statute

84. The plaintiffs adopt by reference the allegations of ¶¶ 1-80 of this Complaint.

85. The federal mandamus statute gives the court jurisdiction to compel an agency of the United States to perform a nondiscretionary duty owed to a plaintiff as a matter of law. 28 U.S.C. § 1361.

86. The FDA has failed to perform its nondiscretionary duty owed to plaintiffs to issue a rule under Section 201 of the Act within the meaning of 28 U.S.C. § 1361.

WHEREFORE, plaintiffs ask that the Court:

(1) Declare the FDA to be in violation of the Tobacco Control Act;

(2) Issue an order under § 706(1) of the APA or a writ of mandamus to compel the FDA to submit for the Court's review a proposed timetable for expedited rulemaking in accordance with Section 201;

(3) Issue an order under § 706(1) of the APA or writ of mandamus to compel the FDA by a date certain to complete notice-and-comment rulemaking on a new rule to implement the graphic warnings requirements of Section 201;

(4) Award plaintiffs' their attorneys' fees and costs pursuant to 28 U.S.C. § 2412; and

(5) Grant such other and further relief as the Court deems proper.

By their attorneys,

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