UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 16-cv-11985-IT

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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The plaintiffs – eight non-profit public health organizations and three physicians who are all actively engaged in efforts to reduce the use of tobacco products[1] – seek summary judgment against the United States Food and Drug Administration ("FDA") because FDA has unlawfully withheld or unreasonably delayed the promulgation of a final rule requiring color graphic warnings on cigarette packs and in cigarette advertisements. Mindful of the enormous toll on the public health that is directly attributable to the consumption of cigarettes, as well as the scientific evidence that graphic warnings substantially enhance the effectiveness of textual warnings in communicating the hazards of smoking, in the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") Congress mandated that FDA promulgate a graphic warnings rule within two years, by a date certain: June 22, 2011. While FDA initially met this deadline, the agency's 2011 rule was vacated in August 2012 when a panel of the Court of Appeals for the District of Columbia Circuit found that the specific graphic warnings FDA had

[1] 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. SOF ¶¶ 1-11.

required violated the First Amendment rights of cigarette manufacturers. Since then, FDA has allowed almost five years to pass without even publishing a *proposed* rule that would cure the defects in its 2011 rule and satisfy its Congressional mandate – or committing to any timetable for the completion of its statutorily-required rulemaking. The Court should, as a result, find that FDA has "unlawfully withheld" or "unreasonably delayed" agency action under the Administrative Procedure Act ("APA"); and if the Court makes such a finding, the Court must compel FDA to promulgate on a fixed schedule a graphic warnings rule in compliance with the Tobacco Control Act.

Statement of the Case.

The plaintiffs commenced this action by filing their Complaint on October 4, 2016. Dkt. 1. FDA filed its Answer on February 10, 2017. Dkt. 21. In accordance with the Court's Scheduling Order, Dkt. 26, the plaintiffs now seek summary judgment.

Statement of Facts.

The plaintiffs rely upon the Local Rule 56.1 Statement of Undisputed Facts ("SOF") filed with their Motion for Summary Judgment. The plaintiffs refer below to particular facts showing that they are entitled to summary judgment as a matter of law.

Argument.

Summary judgment may be granted when the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Lawsuits under the APA seeking to compel agency action that has been unlawfully withheld or unreasonably delayed are properly resolved on summary judgment. *See Oxfam America, Inc. v. United States Sec. & Exch. Comm'n*, 126 F. Supp. 3d 168,170 (D. Mass. 2015) ("*Oxfam*").

I. THIS COURT MUST COMPEL FDA TO PROMULGATE THE GRAPHIC WARNINGS RULE THE AGENCY HAS UNLAWFULLY WITHHELD.

The APA provides in stark, mandatory terms that when judicial review of administrative inaction is sought, "[t]he reviewing court *shall … compel* agency action unlawfully withheld *or* unreasonably delayed." 5 U.S.C. § 706(1) (emphasis added). FDA's continuing failure to promulgate a final rule by a specific deadline, as the Tobacco Control Act requires, is agency action "unlawfully withheld" and demands an order compelling FDA to meet its statutory obligation.

A. Failure to Promulgate a Rule by a Specific Congressionally-Mandated Deadline is Agency Action "Unlawfully Withheld" Under the APA.

When a federal agency such as FDA fails to meet a fixed statutory deadline to promulgate a rule, it has "unlawfully withheld" agency action within the meaning of the APA. *See Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 65 (2004) (when agency is "compelled by law to act within a certain time period," agency action can be ordered as unlawfully withheld); *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1190 (10th Cir. 1999) ("when an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action …"); *South Carolina v. United States*, No. 1:16-cv-00391, 2017 WL 1053844, at *8 (D.S.C. Mar. 20, 2017) ("when Congress by organic statute sets a specific deadline for agency action, neither the agency nor any court has discretion"; "the agency must act by the deadline"). This Court recently held that an agency's delay in promulgating a rule is agency action "unlawfully withheld" if the duty to promulgate the rule by a Congressionally-established deadline remains unfulfilled. *Oxfam*, 126 F. Supp. 3d at 172-173, 175 (adopting Tenth Circuit's analysis in *Forest Guardians*). *See also Tang v. Chertoff*, 493 F. Supp. 2d 148, 155 (D. Mass. 2007) (Gertner, J.) ("where agency delay violated a fixed deadline

set out in a separate statute or regulation" that would constitute "agency action unlawfully withheld").

B. Congress Established a Firm, Enforceable Deadline for FDA's Graphic Warnings Rule.

Congress could not have more plainly emphasized the importance of graphic warning labels on cigarette packages and in cigarette advertisements when it set a statutory deadline for FDA to take action. The Tobacco Control Act, enacted on June 22, 2009, for the first time gave FDA jurisdiction to regulate tobacco products. Pub. L. No. 111-31, 123 Stat. 1776-1858; SOF ¶ 14. Section 201(a) of the Act amended Section 4 of the Federal Cigarette Labeling and Advertising Act and gave FDA new power and responsibility to regulate the labeling and advertising of cigarettes. Section 201(a) is now codified as 15 U.S.C. § 1333.

The Tobacco Control Act required FDA – within two years of enactment – to issue a final rule requiring cigarette packages and advertisements to bear color graphic images depicting the negative health consequences of smoking. The statute specified the language of nine new textual warnings, gave precise instructions about their type size and placement on cigarette packs, and directed FDA to issue regulations requiring color graphic warnings by a date certain. 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).

15 U.S.C. § 1333(d). Congress thus required FDA to promulgate a final graphic warnings rule by June 22, 2011.[2]

[2] Section 201(b) of the Tobacco Control Act provides that all the textual and graphic changes are to take effect 15 months after the issuance of the required rule. 123 Stat. 1845.

"[W]hen a statute uses the word 'shall,' Congress has imposed a mandatory duty upon the subject of the command." *Forest Guardians*, 174 F.3d at 1187. Section 201's statutory deadline created an enforceable duty for FDA to promulgate its graphic warnings rule within two years. *See Norton*, 542 U.S. at 65 (a statute requiring FCC to establish certain regulations "'within 6 months' … would have supported a judicial decree under the APA requiring the prompt issuance of regulations") (citation omitted); *Sierra Club v. Johnson*, 374 F. Supp. 2d 30, 32-33 (D.D.C. 2005) (Clean Air Act deadline for EPA action created nondiscretionary duty for agency to act; failure to promulgate rule after vacatur meant that EPA's duty was "still (or again) unfulfilled"). Because "Congress clearly imposed . . . a date-certain deadline to issue a final regulation," FDA had no discretion to decide whether to withhold or delay the regulation, and its failure to comply is unlawful. *In re Paralyzed Veterans of Am.*, 392 F. App'x 858, 860 (Fed. Cir. 2010).[3]

C. FDA is Continuing to Violate the Tobacco Control Act.

Nearly eight years after the Tobacco Control Act became law, FDA has failed to fulfill its statutory duty to promulgate a graphic warnings rule, as the following undisputed facts show.

November 2010 NPRM. On November 12, 2010, just 17 months after the Tobacco Control Act took effect, FDA published a thoroughly researched and well-documented notice of proposed rulemaking under Section 201 (the "2010 NPRM"). 75 Fed. Reg. 69524; SOF ¶ 17. Explaining the need for the rule, FDA reported: "According to the nation's health experts, tobacco use remains the most important preventable cause of morbidity and premature morbidity in the United States, accounting each year for over 400,000 deaths." 75 Fed. Reg. at 69542;

[3] There is no doubt that FDA's statutory obligation to promulgate a graphic warnings rule remains in effect. The tobacco industry's facial First Amendment challenge to the graphic warnings requirements of the Tobacco Control Act has been rejected. *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), *cert. denied sub nom. American Snuff Co. v. United States*, __ U.S. __, 133 S. Ct. 1996 (2013).

SOF ¶ 20. FDA found that the textual warnings still in use today on cigarette packages and in cigarette advertisements are inadequate because, even at that time, they had not changed in more than 25 years, often go unnoticed and fail to convey relevant information in an effective manner. 75 Fed. Reg. at 69529-69531; SOF ¶ 21. In contrast, FDA found that larger, graphic warnings communicate more effectively, get consumers' attention, influence their awareness of cigarette-related health risks and reduce the prevalence of smoking. 75 Fed. Reg. at 69533-69534; SOF ¶ 22. Based upon an extensive review of the impact of graphic warning images, FDA found that its proposed graphic warnings rule would have "a significant, positive impact on public health" and generate a variety of ancillary social and economic benefits. 75 Fed. Reg. at 69543-69546; SOF ¶ 23.

June 2011 Final Rule. On June 22, 2011, exactly two years after the Tobacco Control Act took effect, FDA published a final rule requiring the use of nine graphic warning labels depicting the negative health consequences of cigarette smoking, as required by Section 201 (the "2011 Rule"). 76 Fed. Reg. 36628; SOF ¶ 25. Consistent with the Act, FDA set September 22, 2012 as the effective date of its new warning requirements. 76 Fed. Reg. at 36628; SOF ¶ 25. When it published its 2011 Rule, FDA reiterated the findings it had made in the NPRM about the need for graphic warnings. 76 Fed. Reg. at 36629-36636; SOF ¶ 26. FDA expanded its analysis of the benefits of the rule. 76 Fed. Reg. at 36705-36719; SOF ¶ 26. FDA also compiled substantial evidence that its 2011 Rule would more effectively communicate the dangers of smoking, reduce cigarette smoking rates, improve the public health, reduce medical costs and yield other social and economic benefits. 76 Fed. Reg. at 36705-36719; SOF ¶ 26.

The D.C. Circuit's 2012 Decision. On February 29, 2012, in a lawsuit brought by various tobacco product manufacturers and sellers, the U.S. District Court for the District of

Columbia held that the specific graphic warning labels required by the 2011 Rule were unconstitutional and enjoined enforcement of the Rule. *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266, 268 (D.D.C. 2012). On August 24, 2012, by a two-to-one majority, a panel of the U.S. Court of Appeals for the D.C. Circuit affirmed the District Court's judgment. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). The D.C. Circuit vacated the graphic warning requirements of the 2011 Rule and remanded the rulemaking to FDA. *Id.* at 1222. Importantly, the Court of Appeals did not hold that any rule mandating graphic warnings would be unconstitutional *per se* or that FDA lacks the constitutional authority to comply with its statutory obligation under Section 201. *Id.* at 1236.[4]

FDA's Actions Since the D.C. Circuit's 2012 Decision. In the nearly five years since the D.C. Circuit's decision, FDA has not commenced any curative rulemaking proceedings, SOF ¶ 31, and has moved at a snail's pace to comply with its statutory obligation to issue an expedited graphic warnings rule. In March 2013, in a letter to Congress, the Attorney General reported that the Justice Department had decided not to seek review of the Court of Appeals' decision and, instead, that FDA intended to undertake research to support new rulemaking proceedings on graphic warnings. SOF ¶ 32. Significantly, the Attorney General noted in that letter 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." *Id.* As years then passed with no action by FDA, various of the plaintiffs repeatedly urged FDA to take action to meet its statutory obligation, but the agency

[4] In fact, during litigation the tobacco industry plaintiffs conceded, as they must, that different graphic warning label requirements could be constitutional. SOF ¶ 28. After all, the Sixth Circuit had earlier rejected the industry's facial First Amendment challenge to the statute requiring FDA to mandate the use of graphic warning labels in *Discount Tobacco City & Lottery, Inc.*, 674 F.3d 509, as noted above (n.3).

was unresponsive, revealing only that it was "undertaking research to support a new graphic warnings rulemaking" consistent with the Tobacco Control Act. SOF ¶ 33.

On March 28, 2017, after this Court set the schedule for summary judgment, FDA invited public comment on a proposed collection of information regarding proposed revisions to the *textual* warnings Congress mandated in the Tobacco Control Act. 82 Fed. Reg. 15359; SOF ¶¶ 34-35.[5] FDA revealed that:

> [p]reliminary research has been underway since 2013. Informed by the previous court decisions on this matter, including on the First Amendment, the next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning revised textual warning statements for use with new images as part of cigarette graphic health warnings, and their potential impact on public understanding of the risks associated with the use of cigarettes.

82 Fed. Reg. at 15360. This was a surprising development, because nothing in the Court of Appeals' decision vacating the 2011 Rule required FDA to revise the statutorily-prescribed textual warnings; in fact, as the Court of Appeals noted, the tobacco companies never challenged the new textual warnings prescribed by Congress. *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1211.

FDA's "preliminary" research on revised textual warnings has apparently been underway for twice as long as Congress gave FDA to complete its entire rulemaking. Presumably, FDA will not even begin its research on new graphic warnings until it has completed this preliminary work on revised textual statements.[6] FDA has not announced any timetable for conducting its

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[5] FDA has authority under 15 U.S.C. § 1333(d) to adjust "the text of any of the label requirements" if it determines that such a change would "promote greater public understanding of the risks associated with the use of tobacco products." Congress gave FDA this authority because Congress understood the need to refresh warning statements to maintain their effectiveness. *See* 15 U.S.C. § 1333(c) (requiring plans for the "random display" and "rotation" of the required label statements). Congress never contemplated, however, that FDA would seek to change the textual warnings before they had ever been used, nor did Congress ever anticipate that FDA would delay implementing graphic warnings requirements in order to do so.

[6] FDA's March 2017 notice reveals that, according to FDA, the results of its research on the effectiveness of new textual warnings in promoting greater public awareness of the negative health consequences of cigarette smoking "will inform the Agency's development of cigarette graphic health warnings to be tested in future studies

research on new graphic warnings, developing a proposed new rule or completing its rulemaking, SOF ¶ 36, and apparently does not consider this long overdue, statutorily-mandated rulemaking to be an agency priority.[7]

D. The D.C. Circuit's Decision did not Excuse FDA from its Duty to Promulgate a Timely Graphic Warnings Rule.

The D.C. Circuit's 2012 decision did not give FDA the option to take as long as it might choose to complete curative rulemaking. While the agency cannot rewrite history and publish a new rule by June 2011, as Congress had specified, FDA has remained under a statutory obligation to complete its rulemaking within two years. "In general, remand orders only serve to 'restore the status quo ante,'" and the D.C. Circuit's decision to vacate the 2011 Rule "simply returned matters to where they stood before." *Oxfam*, 126 F. Supp. 3d at 172-173 (SEC unlawfully withheld final rule after initial rule vacated); *Independent U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 855 (D.C. Cir. 2002) (vacatur of an agency rule returns conditions to the status quo ante); *Johnson*, 374 F. Supp. at 33 (after an order vacating agency action, the agency's "duty to act is still (or again) unfulfilled" because the order merely "operated to restore the status quo ante"); *Environmental Def. v. Leavitt*, 329 F. Supp. 2d 55, 64 (D.D.C. 2004) (the vacatur of agency promulgations "restored the status quo," which "presented a situation wherein [the agency] had failed to promulgate regulations in accordance with [an] express deadline … despite its nondiscretionary, statutory obligation to do so."). As Judge Casper pointedly observed, "[w]ere the rule otherwise, an agency could take inadequate action to promulgate a

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with the goal of implementing the mandatory graphic warning label statement" consistent with statutory requirements and the First Amendment. 82 Fed. Reg. at 15360.

[7] The graphic warnings rule is not currently listed as an agency priority on FDA's "Unified Agenda" maintained on FDA's web page. SOF ¶ 37. The absence of any mention of graphic warning labels in the Unified Agenda is a strong indication that issuance of a rule requiring graphic warnings is not a priority and that no significant action is planned for the coming year.

rule and forever relieve itself of the obligations mandated by Congress." *Oxfam*, 126 F. Supp. 3d at 172. Even if the D.C. Circuit's August 24, 2012 decision reset the clock for FDA, giving the agency two more years for curative rulemaking, FDA did not commence formal rulemaking before its time ran out two years later – and even today FDA has yet to publish a proposed rule or commit to any timetable for its rulemaking.[8]

E. Because FDA has Unlawfully Withheld Promulgation of the Graphic Warnings Rule, the Court Must Compel FDA to Act.

The APA provides in § 706(1) that when agency action has been unlawfully withheld, the reviewing court "shall compel" the agency action. 5 U.S.C. § 706(1). To resolve the plaintiffs' claim of agency action unlawfully withheld, this Court must make a straightforward, binary decision: was "agency action" – in this case, a rule – "unlawfully withheld" because it was not issued by a fixed statutory deadline? If the answer is "yes," as it is in this case, the Court has no discretion to deny relief.

As the Tenth Circuit explained in *Forest Guardians*, under § 706(1) of the APA: "'Shall' means 'shall'" and therefore "courts, upon proper application, *must* compel the agency to act." 174 F.3d at 1187, 1190 (emphasis added). The Court of Appeals continued, "when Congress by organic statute sets a specific deadline for agency action, neither the agency nor the court has discretion. . . . The agency must act by the deadline. If it withholds such timely action, a reviewing court must compel the action lawfully withheld." *Id*. at 1190. Judge Casper properly followed the Tenth Circuit's lead in *Oxfam*, rejecting the government's argument that a reviewing court has discretion to deny relief when an agency has failed to take action by a

[8] Even if it were assumed, for the sake of argument, that FDA's new two-year period for agency action did not begin to run until the Attorney General advised Congress in March 2013 of FDA's intention to undertake research to support a new graphic warnings rule, that time also expired long ago. Under any conceivable interpretation, FDA has already taken far longer than Congress allowed for issuance of its graphic warnings rule.

statutorily-established, fixed deadline. *Oxfam*, 126 F. Supp. 2d at 175. Judge Casper concluded, "the equitable discretion retained by the Court here is not the discretion not to act at all, but is the discretion to order an appropriate and reasonable remedy." *Id*. at 176. *Accord South Carolina*, 2017 WL 1053844, at *15 (court must enter an order compelling agency to take unlawfully withheld agency action following failure to meet statutory deadline).

When an agency's failure to act constitutes agency action "unlawfully withheld" under § 706(1), as it does in this case, a reviewing court has no discretion to consider the hexagonal guidelines for assessing agency delay set out in *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC*"). *See Forest Guardians*, 174 F.3d at 1187-1188 (under APA § 706(1), reviewing count is required to issue injunction to compel agency to take statutorily-mandated action, and has no equitable discretion to permit noncompliance with statute); *Oxfam*, 126 F. Supp. 3d at 172-176 (APA "[Section] 702 provides that courts retain appropriate equitable jurisdiction[;] however, it does not create equitable discretion where there is none."); *South Carolina*, 2017 WL 1053844, at *8 (same). This Court is required by § 706(1) to compel FDA to issue a graphic warnings rule.

II. FDA'S FAILURE TO PROMULGATE A GRAPHIC WARNINGS RULE ALSO CONSTITUTES AGENCY ACTION UNREASONABLY DELAYED.

A. FDA has "Unreasonably Delayed" its Graphic Warnings Rule Within the Meaning of the APA.

Because FDA has "unlawfully withheld" agency action on the graphic warnings rule, there is no reason for this Court to consider whether FDA has also "unreasonably delayed" agency action. In either case, the remedy is the same: the Court must compel agency action under § 706(1) of the APA. If this Court were nevertheless to consider whether FDA's failure to promulgate the graphic warnings rule is a case of agency action "unreasonably delayed," the undisputed facts show without question that FDA has unreasonably delayed agency action.

TRAC provides that when reviewing "claims of agency delay," the Court should consider six factors to determine whether an order compelling agency action is warranted:

> (1) the time agencies take to make decisions must be governed by a "rule of reason," (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is "unreasonably delayed."

TRAC, 750 F.2d at 80 (internal quotations and citations omitted). All of the *TRAC* factors point toward a finding that FDA has unreasonably delayed its graphic warnings rule and must be compelled to take prompt action now.

As to **length of delay**: The "most important factor" under *TRAC* is the time that agencies take to make decisions. *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008). Congress's mandatory two-year deadline provides a "timetable or other indication of the speed" with which it expects FDA to proceed, and that statutorily-prescribed timetable "supp[lies] content for the rule of reason." *TRAC*, 750 F.2d at 80. FDA has delayed issuing a graphic warnings rule for much longer than Congress allowed, even after the intervening decision by the D.C. Circuit is taken into account.

Since the D.C. Circuit's 2012 rejection of the 2011 Rule, FDA has allowed nearly five years to pass without even *commencing* formal rulemaking proceedings – more than double the time Congress gave the agency to *complete* its rulemaking. This delay would be presumptively unreasonable even if Congress had not established a much shorter, definite timetable for the agency's rulemaking. *MCI Telecommc'ns Corp. v. FCC*, 627 F.2d 322, 340 (D.C. Cir. 1980) (four-year delay unreasonable; "a reasonable time" for agency decision could "encompass[ ]

months, occasionally a year or two, but not several years or a decade"); *Tang*, 493 F. Supp. 2d at 157-158 (four-year delay unreasonable); *Fund for Animals v. Norton*, 294 F. Supp. 2d 92, 113 (D.D.C. 2003) (five-year delay unreasonable); *Raymond Proffitt Found. v. EPA*, 930 F. Supp. 1088, 1099-1101 (E.D. Pa. 1996) (19-month delay unreasonable under statutory deadline to act "promptly" in light of statutory purpose and other deadlines); *Public Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983) ("*PCHRG*") (three-year delay between announced intent to regulate and issuance of notice of proposed rulemaking unreasonable where notice repeatedly postponed and issues related to environmental health).

As to **human health and welfare and nature and extent of interests prejudiced**: The third and fifth *TRAC* factors, which direct courts to consider "the nature and extent of interests prejudiced" and to find delays "less tolerable when human health and welfare are at stake," could not point more compellingly toward the need for judicial action. *TRAC*, 750 F.2d at 80. "Delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake." *PCHRG*, 702 F.2d at 1157 ("Three years from announced intent to regulate to final rule is simply too long given the significant risk of grave danger … to the lives of current workers and the lives and well-being of their offspring."). Human health and welfare are unquestionably the central issue here.

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

Congress's findings in enacting the Tobacco Control Act demonstrate the extent to which human health and welfare are at stake. Congress found 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 smoking." 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). Advertising, marketing and promotion of tobacco products have been designed to attract young people to use them, and these efforts have resulted in increased use of tobacco by youth. *Id.* § 2(15). Past efforts to deal with the consequences of the tobacco industry's advertising, marketing, and promotions had not been successful. *Id.* § 2(15). Without effective health warnings, 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).

FDA agrees. When it promulgated the proposed rule, FDA found that the addition of graphic images would have a significant positive impact on public health and that the revised textual statements would communicate more effectively. SOF ¶¶ 19-23. When promulgating the 2011 Rule, FDA cited substantial evidence indicating that larger cigarette health warnings, with graphic content, would offer significant health benefits over the existing warnings. SOF ¶ 26. Since the FDA issued its 2011 Rule, new studies have shown that graphic warnings are far more effective than FDA found when it completed its initial rulemaking. SOF ¶¶ 39-43.[9] In light of

[9] In its 2012 decision striking down FDA's 2011 graphic warnings rule, the D.C. Circuit relied heavily on FDA's analysis of the Canadian data and concluded on that basis that there was no evidence that graphic warnings labels had "directly caused a material decrease in smoking in any of the countries that now require them." *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1219. However, a subsequent study found that FDA's analysis had misinterpreted the Canadian data and that a proper analysis of that data established that implementation of graphic

the public health impact Congress expected from the administrative action it mandated, FDA's delay cannot possibly be justified. *See In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149-1150 (D.C. Cir. 1992) (six-year delay in promulgating rule regarding cadmium exposure safety standards was unreasonable; OSHA's purpose was to protect health of American workers).

In the past five years millions of Americans, the vast majority of them minors, have begun to smoke on a regular basis. Half of those who smoke for a prolonged period of time will die prematurely as a result of tobacco-related disease. During the time since the government announced that FDA would promulgate a revised set of warning labels to comply with its obligation under Section 201 of the Tobacco Control Act, approximately two million Americans have died of tobacco-related disease. SOF ¶ 38.

Since the D.C. Circuit vacated the 2011 Rule, FDA has not commenced curative rulemaking proceedings, but the global consensus that graphic warning labels are an effective means to reduce smoking has continued to grow. While FDA failed to act in the aftermath of the Court of Appeals' decision, more than 40 other countries began to require graphic warnings; more than 100 countries – but not the United States – now require graphic warning labels on cigarette packs and in cigarette advertising. SOF ¶ 44.

As to **higher or competing priorities**: Courts have sometimes declined to compel agency action unreasonably delayed when they conclude that to do so would merely reshuffle or delay equally or more important agency priorities. *See, e.g., In re Barr Labs., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991). But where a statute sets forth a "bright-line rule for agency action," "there is no room to debate – Congress has prescribed a categorical mandate that deprives [the agency]

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warnings in Canada actually had an effect on smoking prevalence 33 to 53 times larger than that estimated by FDA. Indeed, the study found that if the United States had adopted graphic warning labels in 2012, the number of adult smokers in the United States would have decreased by 5.3 million to 8.6 million, based on the Canadian experience. SOF ¶¶ 40-44. These findings further underscore the public health importance of graphic health warnings.

of all discretion over the timing of its work." *American Lung Ass'n v. Reilly*, 962 F.2d 258, 263 (2d Cir. 1992). Congress has established the controlling priorities by setting a statutory deadline, and FDA lacks discretion to reorder its work and ignore a Congressional mandate. *See Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978) ("Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.").

As to **impropriety**: The Court need not find agency impropriety in order to conclude that agency action has been unreasonably delayed. *Public Citizen Health Research Grp. v. Commission, Food & Drug Admin.*, 740 F.2d 21, 34 (D.C. Cir. 1984)**.** The plaintiffs do not assert that any improper motives have animated FDA's decision to proceed so slowly since its 2011 Rule was set aside. But there is no good reason to allow FDA to continue to ignore its duty to promulgate a timely, valid and effective graphic warnings rule, as Congress required when it passed the Tobacco Control Act.

B. Because FDA has Unreasonably Delayed Issuing its Graphic Warnings Rule, the Court Must Compel the Agency to Act.

The APA requires the Court to compel the FDA to comply with its statutory duty to promulgate a final rule because FDA has "unreasonably delayed" agency action. Under § 706(1), "the reviewing court shall … compel agency action unlawfully withheld *or* unreasonably delayed." 5 U.S.C. § 706(1) (emphasis supplied). As this Court held in *Oxfam*, 126 F. Supp. 3d at 175, "once a court deems agency delay unreasonable, it must compel agency action" (adopting Tenth Circuit's analysis in *Forest Guardians,* 174 F.3d at 1187). "To hold otherwise would be an affront to our tradition of legislative supremacy and constitutionally separated powers." *Oxfam*, 126 F. Supp. 3d at 175. Whether the Court finds that FDA's delay constitutes agency action "unlawfully withheld" or merely agency action "unreasonably

delayed," this Court must intervene to compel FDA to take the action Congress required when it passed the Tobacco Control Act nearly eight years ago.[10]

III. THE COURT SHOULD ESTABLISH A FIXED TIMETABLE FOR FDA TO COMPLETE ITS CURATIVE RULEMAKING AND RETAIN JURISDICTION TO ENSURE THAT FDA COMPLIES WITH THE COURT'S ORDER.

When an agency misses a specific statutory deadline, a court can issue "a judicial decree under the APA requiring the prompt issuance of regulations." *Norton*, 542 U.S. at 65. In such circumstances, the court may retain jurisdiction to monitor the agency's progress and ensure compliance with the court's order. *See, e.g., In re Core Commc'ns, Inc.*, 531 F.3d at 862; *Oxfam*, 126 F. Supp. 3d at 176 (citing *Nader v. FCC*, 520 F.2d 182, 207 (D.C. Cir. 1975)); *Abdi v. Chertoff*, 589 F. Supp. 2d 120, 121 (D. Mass. 2008). Although a mandatory injunction is an "extraordinary remedy, especially when directed at the United States Government . . . so too is an agency's failure to act an extraordinary circumstance 'because it signals a breakdown of regulatory processes.'" *Oxfam*, 126 F. Supp. 3d at 175 (citing *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004)).

The APA requires this Court to order FDA to promulgate a graphic warnings rule, on a fixed timetable, as mandated by the Tobacco Control Act. Where, as in this case, an agency has failed to specify a "definite time frame" for action, the court has no basis on which to evaluate the prospects for completion. *Muwekma Tribe v. Babbitt*, 133 F. Supp. 2d 30, 37 (D.D.C. 2000). Consistent with the Order entered in *Oxfam*, the plaintiffs request that the Court issue an order

[10] In their Complaint, the plaintiffs asserted separate claims under the APA and the federal mandamus statute. Complaint ¶¶ 81-86. Because the APA provides for complete relief in a case like this, the plaintiffs do not expect that the Court will need to reach their mandamus claim. If for whatever reason, however, the Court were to find that the plaintiffs cannot invoke the APA to compel FDA to take the discrete action Congress required, the Court should grant the plaintiffs the relief they seek under the mandamus statute because, as shown in this brief, they have a clear and indisputable right to relief; FDA is continuing to violate a clear duty to act; and, if relief is denied under the APA, there is no adequate, alternative remedy. *See, e.g., Cervoni v. Secretary of Health, Educ. & Welfare*, 581 F.2d 1010, 1019 (1st Cir. 1978).

requiring FDA, within 30 days of the Court's order, to propose an expedited, fixed schedule for the publication of a proposed graphic warnings rule for public comment and then a final graphic warnings rule by dates certain in accordance with Section 201 of the Tobacco Control Act. The plaintiffs further request that, after FDA submits its proposed timetable, plaintiffs be provided an opportunity to comment and, if warranted, present evidence to the Court on the appropriateness of FDA's proposed schedule. They ask that the Court then issue an order establishing specific milestones and a fixed deadline for FDA's issuance of a final rule and retain jurisdiction to ensure that FDA complies with the court-ordered rulemaking schedule.

Conclusion.

For all of these reasons, the Court should grant the Plaintiffs' Motion for Summary Judgment; find that FDA has unlawfully withheld and unreasonably delayed its graphic warnings rule; issue an order requiring FDA to submit a proposed, expedited schedule for promulgation of a final rule, to be followed by an order establishing a fixed timetable for the completion of FDA's rulemaking; and retain jurisdiction to enforce FDA's compliance.

Respectfully submitted,

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Certificate of Service

I hereby certify that this document filed through the ECF system was sent electronically to all counsel of record on April 28, 2017.

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