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 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. 1:16-cv-11985-IT

MEMORANDUM AND ORDER
September 5, 2018

TALWANI, D.J.

The Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "Act") required Defendant United States Food and Drug Administration ("FDA") to promulgate a final rule mandating color graphic warnings on cigarette packs and in cigarette advertisements by June 22, 2011. See Tobacco Control Act Pub. L. No. 111-31, § 201, 123 Stat. 1776, 1845 (2009). Plaintiffs[1] bring this action seeking a declaration that the FDA "unlawfully

[1] American Academy of Pediatrics, Massachusetts Chapter of American Academy of Pediatrics, Inc., American Cancer Society, Inc., American Cancer Society Action Network, Inc., American

withheld" or "unreasonably delayed" promulgating a final rule and an order compelling the FDA to expedite a final graphic warnings rule. Pls.' Mot. Summ. J. 2 [#27]. On the parties' cross-motions for summary judgment, the court finds that the FDA has both "unlawfully withheld" and "unreasonably delayed" agency action, and that pursuant to the Administrative Procedure Act ("APA"), the court must compel agency action. Accordingly, and as set forth below, Plaintiffs' Motion for Summary Judgment [#27] is ALLOWED and the FDA's Cross-Motion for Summary Judgment [#32] is DENIED.

I. Background

A. The Tobacco Control Act

On June 22, 2009, Congress passed the Tobacco Control Act, which conferred upon the FDA the jurisdiction to regulate tobacco products. Tobacco Control Act Pub. L. No. 111-31, 101(b), 123 Stat. 1776, 1786-87 (2009). The Tobacco Control Act directed the FDA to regulate the labeling and advertising of cigarettes, and specifically ordered the promulgation of color graphic warnings to be placed on cigarette packaging. Id. § 201. The statute required that:

> 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).

Id. § 201, 123 Stat. at 1845, codified in 15 U.S.C. § 1333(d) (2012). The Act further required the FDA to promulgate the new graphic warnings rule within two years of enactment, or by June 22, 2011. Id.

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.

B. The First Legal Challenge

Shortly after the Tobacco Control Act was enacted, a number of tobacco companies brought a facial challenge, and in 2010, the district court granted in part and denied in part cross-motions for summary judgment. Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 541 (W.D. Ky. 2010). In 2012, the Sixth Circuit rejected the facial challenge to the graphic and textual warnings for cigarette packaging, finding that the requirement passed constitutional muster as reasonably related to the government's interest in preventing consumer deception. Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 568-69 (6th Cir. 2012), *cert. denied*, 569 U.S. 946 (2013).

C. The FDA's Promulgation of a Final Rule

Meanwhile, in August 2009, the FDA formed the Center for Tobacco Products to implement the Tobacco Control Act. Tobacco Control Act Pub. L. No. 111-31, 101(b), 123 Stat. 1776, 1787 (2009). On November 12, 2010, the FDA published a notice of proposed rulemaking, setting forth a proposed rule with nine textual warnings accompanied by color graphics. Required Warnings for Cigarette Packages & Advert., 75 Fed. Reg. 69523 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141). The notice stated that the purpose of the warning labels was to "promote greater public knowledge of the health risks of using cigarettes" and to convey to the public the adverse health consequences of smoking. Id. at 69526. The notice stated further that the textual warnings in use on cigarette packages and in cigarette advertisements were "inadequate" as they "often go unnoticed" and "fail to convey relevant information in an effective manner." Id. at 69529-30. In contrast, according to the notice, "larger, graphic warnings communicate more effectively," get consumers' attention, influence their awareness of cigarette-related health risks and reduce the prevalence of smoking. Id. at 69531-33.

On June 22, 2011, the FDA published its final rule requiring the use of nine textual warnings accompanied by graphic images on cigarette packaging and advertisements. Required Warnings for Cigarette Packages & Advert., 76 Fed. Reg. 36627, 36628 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141). The FDA set September 22, 2012, as the effective date of its new warning requirements. Id.

D. The Second Legal Challenge

On August 16, 2011, a group of tobacco product manufacturers and sellers (including three of the plaintiffs in the earlier case) brought suit alleging that the graphic image warnings and the placement and type-style requirements for the corresponding textual warnings violated their constitutional right to free speech under the First Amendment. R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 845 F. Supp. 2d 266, 271 (D.D.C. 2012). The suit did not include a facial challenge and the companies conceded at oral argument that "different graphic warning label requirements could be constitutional." Pls.' App. of Supp. Evidentiary Materials ("Pls.' App.") Ex. 1, 19:21-20:16 [#30-1]. The district court held the graphic image warnings unconstitutional and enjoined enforcement of the 2011 final rule. Reynolds, 845 F. Supp. 2d at 277.

On appeal, the companies "[did] not dispute Congress's authority to require health warnings on cigarette packages, nor [did] they challenge the substance of any of the nine textual statements mandated by the Act." R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1211 (D.C. Cir. 2012), overruled in part by Am. Meat Inst. v. U.S Dep't of Agric., 760 F. 3d 18, 26 (D.C. Cir. 2014) (en banc). The issue on appeal was whether the graphic warning labels, which included the textual warning, corresponding graphic image, and the "1-800-QUIT-NOW" hotline number, violated the First Amendment. Id. The D.C. Circuit vacated the graphic

warning requirements, holding that the FDA "failed to present any data – much less the substantial evidence required under the APA – showing that enacting their proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates" – and remanded to the agency. Id. at 1222. The D.C. Circuit denied the FDA's petition for rehearing *en banc* in December 2012. Pls.' App. Ex. 2, 2-3 [#30-1].

E. The FDA's Actions in the More Than Five Years Following Remand

On March 15, 2013, in a letter to Congress, the Attorney General reported that the Justice Department had decided not to seek review of the D.C. Circuit's decision and that the FDA intended to undertake research to support a new graphic warnings rule. Pls.' App. Ex. 2, 3 [#30-1]. That same year, the FDA established a working group to develop a new proposed graphic warnings rule. Def.'s L.R. 56.1 Statement of Undisputed Material Facts & Resp. to Pls.' L.R. 56.1 Statement of Undisputed Facts ("Def.'s SOF") Attach. 1 ("Zeller Decl.") ¶ 12 [#35-1]. After the working group's "review of literature and data" to determine the correct course of action, id., the FDA decided to modify and develop new warning statements and consult with outside experts to review proposed study designs. Id. ¶ 13.

In February 2015, the FDA contracted with a communications and marketing firm to develop new graphic warning image concepts and images. Id. ¶¶ 17-18. After the firm developed initial image concepts, the firm then conducted fifty-four in-person, in-depth interviews in three locations in the United States to ascertain whether the images were understood by target audiences. Id. ¶ 19. Based on the findings, the FDA made further revisions to the image concepts. Id. ¶ 20. The FDA hired a certified medical illustrator to draw the images for further testing and estimated that each image would take up to ten working days to draw. Id. ¶ 22.

The FDA also finished the initial phase of work on the new warning statements in 2015. Id. ¶ 13.The FDA then conducted qualitative testing on the warning statements, including contracting with an outside firm with expertise in social science research to conduct testing on the statements utilizing sixteen focus groups in three locations in the United States. Id. ¶¶ 14-15. In the fall of 2015, the FDA further modified the warning statements based on the testing results. Id. ¶ 15. Corresponding Spanish-language translations and testing were completed in early 2016. Id. ¶ 16.

On March 28, 2017, the FDA invited public comment on the proposed collection of information regarding proposed revisions to the textual warnings. Pls.' L.R. 56.1 Statement of Undisputed Facts ("Pls.' SOF") ¶ 34 [#29]. As of October 2017, the certified medical illustrator had completed the images. Hr'g Cross-mots. Summ. J. Tr. 33:4-6 ("Summ. J. Hr'g Tr.") [#46].

As of January 29, 2018, the Office of Management and Budget ("OMB") approved two information collection requests. Def.'s Suppl. Filing ("Def.'s 2d Suppl.") 4 [#48]. The first request was for qualitative testing of the images, which was to be presented to 20 focus groups in four locations. Zeller Decl. ¶ 23 [#35-1]. The second request was for a quantitative study on the modified warning statements. Id. ¶ 24. Information collection for the quantitative study began on January 30, 2018. Def.'s 2d. Suppl. 4 [#48]. The recruitment of focus group participants was set to begin on February 6, 2018. Id.

F. The FDA's Anticipated Further Actions

The FDA has identified additional steps it plans to take before completing the new rule. Zeller Decl. ¶ 21 [#35-1]. The agency estimates that execution of these steps will take approximately three additional years, and "that, at the earliest, a final rule would be submitted to

the Office of the Federal Register" in November 2021. Id. ¶¶ 22-37; First Suppl. Def.'s L.R. 56.1 Statement of Undisputed Material Facts ("Def.'s 1st Suppl.") 2 [#42]. These steps include:

(1) Completing the first quantitative study on the modified warning statements and the qualitative study on the images in order to select and finalize nine health warnings with text statements and images that will be tested in the second and final quantitative study. Zeller Decl. ¶ 28 [#35-1].

(2) Conducting the second of the two quantitative studies, which includes approval from the Human Subjects Research protections board and OMB. Id. ¶ 29. This process requires two successive rounds of Federal Register notices and opportunities for public comment. Id. The FDA estimates that this will be completed in another eight months. Id.; Def.'s 1st Suppl. 2 [#42].

(3) Analyzing the results and evaluating whether the overall record supports a rulemaking to require the warnings developed and studied. Zeller Decl. ¶ 31 [#35-1].

(4) Drafting the proposed final rule, which includes review within the agency, the Department of Health and Human Services, and OMB. Id. ¶¶ 32-33. Afterwards, the FDA will submit the rule for publication in the Federal Register for an estimated sixty-day period for public comment. Id. ¶ 34.

(5) Reviewing the public comments and draft responses to prepare a final rule. Id.¶ 35. The estimate time from proposed rule to final approved form is twenty-four months. Id. ¶ 37.

II. Discussion

Plaintiffs argue that the FDA has "unlawfully withheld" agency action by failing to promulgate the new graphic warnings, or in the alternative, has "unreasonably delayed" the final

rule. Pls.' Mem. in Supp. of Mot. Summ. J. ("Pls.' Mem.") 2 [#28]. The court finds that Plaintiffs are entitled to relief under either argument.

A. "Unlawfully Withheld"

Pursuant to the APA, a court "shall . . . compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). Plaintiffs argue that because Congress established a firm, enforceable deadline for the graphic warnings rule, which the FDA failed to meet, this court should apply the Tenth Circuit's reasoning in Forest Guardians v. Babbitt, 174 F.3d 1178 (10th Cir. 1999), and compel agency action.

The Tenth Circuit in Forest Guardians held that an agency that fails to meet a non-discretionary deadline has "unlawfully withheld" action. 174 F.3d at 1191. The plaintiffs, non-profit organizations, sought an injunctive ordering the Secretary of the Interior to issue a final rule after the Secretary failed to meet the statutory deadline. Id. at 1182. The Tenth Circuit held that in failing to meet the non-discretionary deadline, the defendant "unlawfully withheld agency action and courts, upon proper application, must compel the agency to act." Id. at 1190. The court distinguished between agency actions "unlawfully withheld" and "unreasonably delayed," finding that the distinction "turns on whether Congress imposed a date-certain deadline on agency action." Id. "[I]f an agency has no concrete deadline establishing a date by which it must act, and instead is governed only by general timing provisions – such as the APA's general admonition that agencies could conclude matters presented to them 'within a reasonable time' . . . – a court must compel only action that is delayed unreasonably." Id. (citing 5 U.S.C. § 555(b)).

Oxfam America, Inc. v. United States Securities and Exchange Commission, 126 F. Supp. 3d 168 (D. Mass. 2015) adopted the Forest Guardians analysis. In Oxfam, the court further held that where an agency delayed in promulgating a new rule after the initial rule was vacated,

the vacatur "simply return[s] matters to where they stood before and that, in general, remand orders only serve to restore the status quo ante." 126 F. Supp. 3d at 172 (citing Indep. U.S. Tanker Owners Comm. v. Dole, 809 F.2d 847, 854-855 (D.C. Cir. 1987) (noting that vacatur of an agency rule returns conditions to the status quo ante); Sierra Club v. Johnson, 374 F. Supp. 2d 30, 33 (D.D.C. 2005) ("noting that 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"); Envtl. Def. v. Leavitt, 329 F. Supp. 2d 55, 64 (D.D.C. 2004) (noting that 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")) (internal citations and quotations omitted). Were the rule to be otherwise applied, the court reasoned, "an agency could take inadequate action to promulgate a rule and forever relieve itself of the obligations mandated by Congress." Id. The court concluded that in the absence of a new rule more than four years past Congress' deadline, the agency "unlawfully withheld" a new rule. Id.

Here, the FDA's duty to promulgate a rule is nondiscretionary. Pursuant to 15 U.S.C. § 1333(d), "[n]ot later than 24 months after June 22, 2009, the Secretary *shall* issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements . . . ." (emphasis added). "The Supreme Court . . . [has] made clear that when 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.

The FDA criticizes Oxfam as essentially holding that a "vacatur erases the historical fact that an agency ever acted." Def.'s Mem. in Supp. of Cross-mot. for Summ. J. ("Def.'s Mem.") 18 [#33]. This court disagrees. By finding that the FDA "unlawfully withheld" a rule, this court

is not erasing the "historical fact" that the FDA did originally issue the rule in a timely fashion. Instead, in adopting the analysis within Oxfam, the court finds that the statute and deadlines set forth by Congress continue to apply to the FDA, and the FDA must comply. In the wake of the D.C. Circuit's vacatur and remand back to the agency, it cannot be the case that the FDA has freed itself from Congressional mandates and may now take the opportunity to promulgate this rule at whatever pace it chooses. While the vacatur may reset the two-year clock, it does not negate the FDA's continuing obligation to comply with Congress' deadlines.

B. TRAC Factors

The FDA urges this court to apply the six factors set forth in Telecommunications Research and Action Center, et. al. v. Federal Communications Commission, 750 F.2d 70 (D.C. Cir. 1984) ("TRAC"), to find that the agency did not "unreasonably delay" in promulgating a final rule. Def.'s Mem. 1-2 [#33]. However, this court finds that even utilizing the TRAC factors, since remand, the FDA has "unreasonably delayed" in promulgating a final rule.

Under the first factor, the courts must consider whether the time frame agencies take to make decisions is governed by the "rule of reason." TRAC, 750 F.2d at 80; Towns of Wellesley v. Fed. Energy Regulatory Comm'n, 829 F.2d 275, 277 (1st Cir. 1987). Generally, "[t]he cases in which courts have afforded relief have involved delays of years." Id. at 277-78 (citing Potomac Elec. Power Co. v. I.C.C., 702 F.2d 1026, 1035 (D.C. Cir. 1983) (eight-year delay unreasonable); MCI Telecomm. Corp. v. F.C.C., 627 F.2d 322, 324-25 (D.C. Cir. 1980) (four-year delay unreasonable); Nader v. F.C.C., 520 F.2d 182, 206 (D.C. Cir. 1975) (ten-year delay unreasonable)); cf. Kokajko v. Fed. Energy Regulatory Comm'n, 837 F.2d 524, 526 (five-year delay not so unreasonable that "the extraordinary remedy" of mandamus is appropriate where the

record shows relatively few periods of agency inaction, the action involves economic regulation, not human health and welfare, and agency has higher priorities).

According to the second factor, "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." TRAC, 750 F.2d at 80. Here, Congress set a statutory deadline of twenty-four months, which the FDA initially complied with. 15 U.S.C. § 1333. After the Reynolds court vacated the graphic warning requirement and remanded, 696 F.3d at 1222, the FDA did not immediately turn its attention back to the graphic images; rather, the agency decided to first tackle the substance of the textual warnings, though these textual warnings were neither challenged by the tobacco companies nor found unconstitutional by the D.C. Circuit. From 2013 to 2015, the record before this court does not indicate any work on the graphic images. Instead, the working group decided to detour into developing new text, which included the creation and review of the text for accuracy, consultation with outside experts as to proposed study designs, conducting focus groups on the texts, and further revisions of the text in the fall of 2015. The FDA did not complete the testing relating to the text for three years, until early 2016.

After about two years into its detour, in February 2015, the FDA finally hired a communications and marking firm to develop new images. After initial images were designed, the marking firm conducted interviews to assess whether target audiences understood the images. This was completed in June 2016. From June 2016 to October 2017, the record indicates that the

agency performed one related task: the FDA hired one certified medical illustrator to draw images for final testing.[2]

At the January 4, 2018, hearing, this court inquired as to what further work the FDA had completed from May 26, 2017 until the date of the hearing.[3] Aside from the completion of the images by the illustrator, counsel for the FDA relayed to the court that the agency had submitted paperwork to the OMB to obtain funding for additional testing. At the time of the hearing, the FDA had not yet received a response from OMB. Summ. J. Hr'g Tr. 39:11-40:2 [#46].

After the hearing, the FDA filed its Supplemental Filing [#48], in which it acknowledged that if an agency does not hear back from OMB within sixty days, pursuant to 44 U.S.C. § 3507, approval may be inferred.[4] The FDA conceded that it did not use the non-response mechanism. Def.'s 2d Suppl. 2-3 [#48]. The FDA also confirmed that on January 29, 2018, OMB approved both information collection requests and the FDA would be able to move forward with the qualitative testing of the images and the quantitative study on the modified warning statements. Id. at 4.

Nevertheless, despite the two year schedule initially set by Congress, and the passage of more than five years since remand, the FDA asserts that its further rule-making process will take three more years – for a total of over eight years – or four times the initial amount of time set by

[2] The operations of the Center for Tobacco Products are funded by user fees paid by tobacco manufacturers. 21 U.S.C. § 387s(a). In the 2018 fiscal year alone, the amount of user fees collected reached $ 672,000,000. Id. § 387s(b)(1). These funds are available only for activities related to the FDA's regulation of tobacco products. Id. § 387s(c)(2).

[3] The May 26, 2017, date is the filing date of the Declaration of Mitchell Zeller, which outlined the remaining work to be completed by the agency before the expected graphic warning rule promulgation date of November 2021. See Zeller Decl. [#35-1].

[4] The agency may request an OMB control number which OMB "shall . . . assign[ ] without further delay," and the agency may collection information for not more than one year. 44 U.S.C. § 3507(c)(3).

Congress. Whereas the final rule was initially set to be completed by June of 2011, the FDA now represents to the court that the final rule will not be completed until one decade later, in November 2021. As justification for its extraordinary delay, the agency argues that its process "has only grown more complex, because its new rulemaking must now also be informed by the D.C. Circuit's critiques of the initial rule." Def.'s Mem. 16 [#33]. The FDA argues that "[a]gency action is often the culmination of many steps, but even so, the courts will not second-guess timelines that involve complex scientific and technical questions." Id. at 10 (internal citations and quotations omitted).

However, the D.C. Circuit's decision did not apply to the substance of the textual warnings. The FDA, of its own accord, decided to revise the texts for two years and delay work on the images until 2015. Despite repeatedly referencing the D.C. Circuit's decision as the basis for its delay, the agency's actions are neither responsive nor required by Reynolds. Moreover, even more troubling is the gaps of time where little to no work was completed on the graphic images. From 2013 to 2015, the record does not indicate any work on the graphic images. Aside from the drawings completed by the certified medical illustrator, the record does not indicate any work on the images from June 2016 to October 2017. The FDA fails the first and second factors.

This court also reviews the third and fifth factors together. Under the third factor, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." TRAC, 750 F.2d at 80. The fifth factor states that "the court should also take into account the nature and extent of the interests prejudiced by delay." Id. The graphic warning rule relates to human health, and the FDA does not dispute this fact. In enacting the Tobacco Control Act, Congress found that "[t]obacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and

approximately 8,600,000 Americans have chronic illness related to smoking." Tobacco Control Act Pub. L. No. 111-31, § 201, 123 Stat. 1776, 1777 § 2(13) (2009). "Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." Id. § 201, 123 Stat. 1776, 1777 § 2(15). "Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease." Id. § 201, 123 Stat. 1776, 1777 § 2(14). The aim of the statute is to allow the agency to regulate tobacco products and create rules that would effectively warn tobacco smokers of the health problems associated with smoking tobacco products. The end result is to decrease or prevent the number of people within the United States that are smokers. The interests prejudiced by delay are substantial.

As to the fourth factor, although the FDA states that it has "competing priorities" in its brief, the FDA has not articulated a single higher priority in its pleadings nor does the record indicate any higher priorities.[5] The FDA simply requests that this court defer to its priority choices, Def. Mem. 15, without regard to those dictated by Congress. As to the sixth factor, Plaintiffs concede that there is no impropriety on the party of the agency.

[5] In cases concerning the issue of competing priorities, the culprit is often limited resources or budget. See In re Sierra Club, Inc., 2013 WL 1955877, at *1; Forest Guardians, 174 F.3d at 1182; Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1100-01 (D.C. Cir. 2003). However, as outlined in footnote 3, the FDA does not suffer from limited resources, nor does the agency allege that limited resources are at issue here.

This court finds that in light of the timeline originally set forth by Congress, the FDA's current timeline (and work completed thus far), the human health and welfare at stake, and the lack of competing priorities enumerated in the FDA's brief, the FDA has failed the TRAC factors. At this point, this court declines to defer to the agency's timeline. See Tang v. Chertoff, 493 F. Supp. 2d 148, 155 (D. Mass. 2007) ("Nor does an agency have sole discretion to define what is a reasonable time under the APA, which would render meaningless § 706(1)'s clearly mandatory language that the 'reviewing court shall compel agency action unlawfully withheld or unreasonably delayed.'") (citing 5 U.S.C. § 706(1)). This court concludes that because the FDA has both "unlawfully withheld" and "unreasonably delayed" agency action, the court must compel agency action. 5 U.S.C. § 706(1).

C. Remedy

The remaining question is the proper time frame for the agency to act. The court orders that, no later than September 26, 2018, the FDA shall provide to this court an expedited schedule for the completion of outstanding studies, the publication of the proposed graphic warnings rule for public comment, review of public comments, and issuance of a final graphic warnings rule in accordance with the Tobacco Control Act. Plaintiffs may submit a response to the proposed schedule no later than 14 days after the FDA files its expedited schedule. The court intends to direct further action, as necessary, following review of the expedited schedule.

IT IS SO ORDERED.

Date: September 5, 2018

/s/ Indira Talwani
United States District Judge