

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

AMERICAN LUNG ASSOCIATION and )  
NATIONAL PARKS CONSERVATION )  
ASSOCIATION, )  
Plaintiffs, )  
v. ) Civil Action No. 1:12-cv-00243-RLW  
 ) (Judge Robert L. Wilkins)  
UNITED STATES ENVIRONMENTAL )  
PROTECTION AGENCY, and LISA )  
JACKSON, Administrator, United States )  
Environmental Protection Agency, )  
Defendants.  
STATE OF NEW YORK, et al., )  
Plaintiffs, )  
v. ) Civil Action No. 1:12-cv-00531-RLW  
 ) (Judge Robert L. Wilkins)  
LISA P. JACKSON, as Administrator of the )  
Environmental Protection Agency, and the )  
UNITED STATES ENVIRONMENTAL )  
PROTECTION AGENCY, )  
Defendants.

**REPLY TO DEFENDANT EPA'S OPPOSITION TO APPLICATION FOR  
PRELIMINARY AND PERMANENT INJUNCTION, AND OPPOSITION TO EPA'S  
CROSS-MOTION FOR SUMMARY JUDGMENT AS TO REMEDY**

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## INTRODUCTION

Plaintiffs American Lung Association and the National Parks Conservation Association bring this case to enforce the mandatory statutory deadline in the federal Clean Air Act for Defendants U.S. Environmental Protection Agency, *et al.* (“EPA”) to review the national ambient air quality standards (“NAAQS”) for particulate matter (“PM”). Plaintiffs took the extraordinary step of filing an Application for Preliminary and Permanent Injunction (“Application for Injunction”) because EPA’s refusal to comply with the statutory deadline means that every month thousands of people in this country will continue to suffer and die needlessly from particulate matter pollution that EPA is charged to address. EPA now urges the Court to deny Plaintiffs’ Application for Injunction but does not contest any of the merits of Plaintiffs’ motion. EPA’s only argument goes to the remedy requested. EPA’s dispute over the appropriate remedy, however, does not support denial of Plaintiffs’ application for injunctive relief. The Court therefore should grant Plaintiffs’ application for injunctive relief.

As described below, Plaintiffs nonetheless agree that the schedule in their original proposed order must now be adjusted to account for the time that has passed since Plaintiffs filed their Application for Injunction. Plaintiffs, therefore, request a schedule that would have EPA complete the overdue rulemaking by no later than December 14, 2012. As described below, this schedule is feasible and, unlike EPA’s proposed schedule, is consistent with the case law of this Court. Plaintiffs have included a revised proposed order directing EPA (1) to sign the required proposed rulemaking within 30 days of the Court’s decision in this matter and (2) to sign the required final rulemaking by no later than December 14, 2012.

## ARGUMENT

### I. Plaintiffs Are Entitled To Injunctive Relief.

The Supreme Court, in *Winter v. Natural Res. Def. Council*, outlined the four-factor test to be applied by courts in deciding whether to grant a preliminary injunction:

A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.

555 U.S. 7, 20 (2008). In their application for injunctive relief, Plaintiffs showed that there was no dispute as to the underlying merits in this case – EPA is subject to a clear mandatory deadline for reviewing the national particulate matter standards and Plaintiffs are entitled to enforce that deadline under the Clean Air Act. Applic. for Inj. at 8. EPA does not dispute its liability for failing to comply with the statutory deadline. Def.’s Mem. in Opp’n to P.’s Applic. for Prelim. and Perm. Inj. (“EPA Mem.”) at 1.

Nor does EPA dispute Plaintiffs’ demonstration that the continued delay envisioned by EPA is likely to cause irreparable harm to Plaintiffs’ members. The health effects associated with breathing elevated levels of fine particulate matter are severe, including aggravation of lung and heart disease, developmental effects in children, and death. Applic. for Inj. at 13. The extent of these impacts, as documented by Plaintiffs, is staggering. *Id.* at 14 (citing a study by EPA scientists estimating that every year between 130,000 to 320,000 deaths, 180,000 heart attacks, 110,000 emergency room visits for asthma in minors, and 18,000,000 lost work days are due to fine particulate matter pollution in the U.S.). As Plaintiffs explained, by EPA’s own assessments, new standards recommended by EPA staff over a year ago could prevent thousands of deaths every month and even more suffering from avoidable asthma attacks, heart illnesses and strokes. *Id.* at 14-15.

EPA cites cases reiterating the Court’s discretion to fashion equitable relief, *see* EPA Mem. at 14, but offers no argument to rebut Plaintiffs’ demonstration showing that the balance of equities and the public interest favor an injunction. EPA’s dispute over the remedy requested by Plaintiffs does not undermine the merits of Plaintiffs’ application. Because EPA offers no argument as to why the criteria under *Winter* have not been met, Plaintiffs’ application for an injunction should be granted.

## **II. The Court Should Order EPA To Sign A Final Rule By December 14, 2012.**

### **A. Standard of Review.**

As EPA notes, the only question for the Court is what schedule the Court should impose with its injunction. *See* EPA Mem at 14. In cases such as this where EPA has acted in direct conflict with mandatory statutory deadlines, it is well-established that courts should use their equitable authority “to set enforceable deadlines” to obtain “expeditious compliance” with the Congressional deadlines that EPA has ignored.<sup>1</sup> *Natural Res. Def. Council v. Train*, 510 F.2d 692, 705 (D.C. Cir. 1974); *see also Sierra Club v. Johnson*, 444 F. Supp. 2d 46, 52-53 (D.D.C. 2006) (applying *Train* to a violation of a nondiscretionary duty under the Clean Air Act). “The court’s injunction should serve like adrenalin, to heighten the response and to stimulate the fullest use of resources.” *Train*, 510 F.2d at 712. The test is not how long such rulemakings might take in the normal course, but what the agency is capable of achieving. Where the agency proposes to comply on a schedule that is not in accordance with a mandatory statutory deadline,

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<sup>1</sup> EPA implies that the D.C. Circuit’s refusal to set a deadline for EPA to respond to the court’s remand in *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512 (D.C. Cir. 2009) was an endorsement of the reasonableness of EPA’s proposed schedule. EPA Mem. at 20. The D.C. Circuit, however, did not apply the criteria outlined here because the question presented to the court was not whether EPA’s schedule, having missed a statutory deadline, was as expeditious as possible. The D.C. Circuit did not opine on the appropriateness of the schedule – only that, given EPA’s commitment, it was not necessary for the court to provide the extraordinary remedy of a writ of mandamus.

the agency bears a “heavy burden” to show that more expeditious compliance is impossible. *See Sierra Club*, 444 F. Supp. 2d at 53 and 58. As the *Train* court warned:

An equity court can never exclude claims of inability to render absolute performance, but it must scrutinize such claims carefully since officials may seize on a remedy made available for extreme illness and promote it into the daily bread of convenience.

*Train*, 510 F.2d at 713. Unlike other challenges to EPA decisionmaking where “the Court defers to agency expertise about appropriate rulemaking procedures, such deference is inappropriate where Congress has unambiguously expressed its intent that these regulations be promulgated by a date certain and the agency manifestly has failed to fulfill this statutory obligation.” *Sierra Club*, 444 F. Supp. 2d at 56.

The analysis of the court in *Am. Lung Ass’n v. Browner*, 884 F. Supp. 345, 348-49 (D. Ariz. 1994) is instructive. That case involved a previous EPA failure to comply with the Clean Air Act’s statutory deadline to review the national ambient air quality standards for particulate matter. *Id.* at 346. As here, the only task for the court was to fashion the appropriate equitable remedy. *Id.* As here, EPA submitted a proposed schedule for complying with the missed statutory deadline. *Id.* at 348. The court reviewed EPA’s schedule and made adjustments “to provide for only those review activities required by Congress and essential to ensuring that within the 5-year intervals, EPA standards reflect the latest scientific knowledge so as to fully protect the public.” *Id.* Applying these criteria and cuts to EPA’s proposed schedule in this case demonstrates that a much more expeditious schedule is possible.

#### **B. EPA’s Proposed Schedule Does Not Provide For Compliance As Expeditiously As Possible.**

EPA’s proposed schedule is laid out in the May 4, 2012 Declaration of Regina McCarthy, Assistant Administrator for the Office of Air and Radiation at EPA. *See* EPA Mem. Att. 1 (hereinafter “McCarthy Decl.”). Ms. McCarthy states that “EPA’s current plan is to take final

action on its review of the 2006 PM NAAQS by August 15, 2013.” McCarthy Decl. ¶ 20. Without committing to a specific date for a proposal, Ms. McCarthy implies that EPA will propose its rulemaking in August, 2012. *Id.* (explaining “EPA currently believes approximately one year from issuance of the proposal is reasonable for completion of the rulemaking process”). Ms. McCarthy states that between now and date the proposal is signed, “EPA’s next steps . . . include finishing internal review and completing interagency review pursuant to Executive Orders 12866 . . . and . . . 13563 . . .” *Id.* ¶ 18. Ms. McCarthy notes that “Executive Order 12866 provides for 90 days for interagency review.” *Id.* ¶ 18 n.1. This suggests that EPA’s internal review for the proposal must be nearly complete and that the only remaining major delay for a proposed decision is the three months built into the schedule for Office of Management and Budget (“OMB”) review under Executive Order 12866.

As Plaintiffs explained in their application for injunctive relief, this Court and others have rejected delays affording time for OMB review beyond mandatory statutory deadlines. *See* Applic. for Inj. at 9-10. As the court in *Am. Lung Ass’n* explained: “Review by the Office of Management and Budget serves no congressional purpose and is wholly discretionary. Therefore, it is not required, and the schedule shall exclude such review.” 884 F. Supp. at 349; *see also Envt’l Def. Fund v. Thomas*, 627 F. Supp. 566, 571 (D.D.C. 1986) (holding “OMB has no authority to use its regulatory review . . . to delay promulgation of EPA regulations . . . beyond the date of a statutory deadline”); *Natural Res. Def. Council v. Ruckelshaus*, Civ. A. No. 84-758, 1984 WL 6092, at \*4 (D.D.C. Sept. 14, 1984) (holding “OMB review is not only unnecessary, but in contravention to applicable law”). EPA’s response brief makes no attempt to rebut or distinguish this case law. *See* EPA Mem. at 23. At a minimum, the Court should exclude the two 90-day periods of interagency review built into EPA’s proposed schedule.

Excluding OMB review time from EPA’s proposed schedule suggests that EPA should be able to make its proposed decision by the end of May or beginning of June (*i.e.*, 90 days sooner than August 2012). EPA’s proposed schedule also includes another round of OMB review prior to issuing the final decision. *See* McCarthy Decl. ¶ 23. Excluding that time, suggests that instead of a year between proposed and final rulemaking, by EPA’s own reckoning, EPA should need only nine months. Thus, without even scrutinizing EPA’s other assumptions, EPA’s schedule should provide for a proposal by June 2012 and a final rulemaking by March 2013. As detailed below, however, a yet more expeditious schedule is possible.

EPA states that unlike all of the previous NAAQS rulemakings documented by Plaintiffs, *see* Applic. for Inj. at 11, where EPA took no more than nine months between proposed and final rulemakings (including OMB review), *this* NAAQS rulemaking is different. *See* EPA Mem. at 19; *see also* McCarthy Decl. ¶ 20. Ms. McCarthy’s declaration, however, does not support any tangible differences that make a schedule similar to prior NAAQS rulemakings “impossible.”

Ms. McCarthy first states that “a very large body of new science has been developed involving the health effects of PM” and therefore “more time and effort are needed to interpret and apply the science in the context of this rulemaking compared to the last review . . . .” McCarthy Decl. ¶ 20; *see also* EPA Mem. at 18. Ms. McCarthy’s statement is misleading in that it suggests that EPA has yet to complete its interpretation and application of the scientific evidence. This is simply not true. EPA long ago completed its work for this rulemaking to “interpret and apply [this large body of new] science.” As Ms. McCarthy explains, one of the first steps in reviewing the NAAQS is the development of an Integrated Science Assessment (previously called the Criteria Document), which “provides an evaluation and integration of the

policy-relevant science.” McCarthy Decl. ¶ 6. EPA completed this interpretation and assessment of the body of new science in December 2009. *Id.*

Following completion of the Integrated Science Assessment, EPA uses this review of the science, along with risk assessments based on this review, to develop a Policy Assessment, which “is intended to help ‘bridge the gap’ between the relevant scientific information and assessment and the judgments required of the Administrator in reaching decisions on the NAAQS.” McCarthy Decl. ¶ 12. In other words, the Policy Assessment applies the scientific evidence and risk assessments to make recommendations on policy options. *Id.* The Policy Assessment presents “EPA staff conclusions related to the broadest range of policy options that could be supported by the currently available information.” *Id.* EPA completed the final Policy Assessment over a year ago in April 2011. *Id.* ¶ 13. In other words, EPA long ago completed its work to “interpret and apply” the new scientific studies that are part of this round of review for the particulate matter standards.

Ms. McCarthy later clarifies that the reason for needing more time in this rulemaking between proposed and final rulemaking is to allow for a “provisional assessment” of any “new science that is relied upon by commenters but was published too recently to be included in the rigorously reviewed Integrated Science Assessment.” McCarthy Decl. ¶ 20. Setting aside the speculative nature of the claim, this “additional” review is not required by the statute and therefore cannot provide an excuse for delay. While new studies are constantly being published, EPA is not compelled, and traditionally has refused, to “interpret and apply” this constant stream of new science. Ms. McCarthy acknowledges that “EPA has traditionally based its decision on studies and related information included in the Integrated Science Assessment (previously Criteria Document), the Risk and Exposure Assessment, and the Policy Assessment (previously

the Staff Paper), which undergo CASAC and public review, and intends to do so in this rulemaking.” McCarthy Decl. ¶ 20; *see also* 71 Fed. Reg. 61144, 61148 (Oct. 17, 2006) (“Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the air quality criteria [document].”). Moreover, this excuse of needing more time to review new or better information has specifically been rejected as an excuse for delay where the agency has violated a statutory deadline. *See Sierra Club*, 444 F. Supp. 2d at 53-54 (explaining that courts “have rejected agency claims that additional time is needed simply to improve the quality or soundness of the regulations to be enacted” and “tend to reject as contrary to the relevant statute agency approaches to rulemaking that sacrifice the timely implementation of the statute in favor of extensive agency information-gathering and analysis”).

The final problem with Ms. McCarthy’s excuse regarding the need for a provisional assessment is that there is no explanation as to why this “screening and surveying” of the new studies cannot occur during the same time provided to the public for review. Certainly EPA has the resources and expertise to review and interpret the same body of scientific literature that commenters will be reviewing and interpreting at the same time. To the extent the Administrator would like to have this additional assessment, EPA need not wait and add this time to the schedule.

Ms. McCarthy’s second justification for needing more than the usual time between proposed and final rulemakings is that “EPA is considering a distinct secondary standard that differs from the primary standard . . . [thereby] increas[ing] the range and complexity of issues to address in this review of the secondary standard . . .” McCarthy Decl. ¶ 20; *see also* EPA Mem. at 18. Again, this statement is misleading in implying that these issues have not already been evaluated.

The Policy Assessment finalized in April, 2011, digested the relevant scientific information and made specific conclusions about the secondary standard. *See, e.g.*, EPA, Office of Air Quality Planning and Standards, “Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards” (“Policy Assessment”), at ES-2 to ES-3 (April 2011) (recommending a secondary particulate matter standard with a 24-hour averaging time and a level of 28 to 25 deciviews) (available at:

[www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf](http://www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf)) (filed herewith as Attachment 1 to Declaration of Christopher W. Hudak In Support of Plaintiffs’ Second Request for Judicial Notice (“Hudak Decl.”)).

Moreover, this situation is not unique. In the 1997 particulate matter NAAQS rulemaking, which EPA completed in seven months between proposed and final rulemakings, EPA promulgated new separate standards for fine particulate matter (“PM<sub>2.5</sub>”), including new indicators, forms and levels. *See* 62 Fed. Reg. 38652, 38679 (July 18, 1997). Indeed, when EPA staff announced the timeframes for promulgating the current rulemaking, they predicted schedules that were in line or even shorter than previous NAAQS rulemakings. *See* Applic. for Inj. at 11-12.

Plaintiffs further suspect that within EPA, separate staff will be assigned to address comments and issues related to the secondary standard. *See* Policy Assessment “Acknowledgments” (identifying the separate EPA staff who led the production of the Policy Assessment sections on the primary and secondary standards) (Hudak Decl. Att. 1). As a result, any additional resources needed to address these issues can be applied in parallel and need not consume more time than required in previous rulemakings.

Ms. McCarthy’s third and final excuse for needing more time is that “[t]his amount of time also takes into account the fact that during the same time period for this rulemaking, EPA’s Office of Air and Radiation will be working on many other major rulemakings . . .” McCarthy Decl. ¶ 20. Ms. McCarthy’s statement is not sufficient to prove that a more expeditious schedule is impossible. Ms. McCarthy does not identify how many other rules EPA is working on, whether these other rules consume the same or overlapping resources within the Agency, how the schedules of these rulemakings might be stacked to avoid conflicts, how many of these rules are mandatory, how many of these rules are voluntary and could be delayed to provide additional resources for the particulate matter NAAQS rulemaking, or why these other rules should be given higher or even equal priority to the overdue rulemaking here. As this Court explained in

*Sierra Club*:

Courts also turn a skeptical eye towards agency claims that competing regulatory priorities preclude compliance with statutorily-mandated deadlines. If Congress formulates policies and programs to meet specific problems, it may also establish their relative priority for the Nation. In such a situation, the court’s role is to enforce the legislative will when called upon to do so. EPA’s generalized complaints . . . that there are competing demands on their resources do not amount to a claim of impossibility sufficient to justify a departure from a Congressional mandate . . . [S]hifting resources in response to statutory requirements and court orders is commonplace for EPA.

444 F. Supp. at 54 (internal quotations and citations omitted).

EPA simply has not met its “heavy burden” to show that a rulemaking timetable in line with previous NAAQS rulemakings is “impossible.” In the longest of those rulemakings – the 2006 particulate matter NAAQS rulemaking – EPA provided 90 days for public comment, included OMB review, and still completed the rulemaking in nine months. In the shortest of these – the 2009 Lead NAAQS rulemaking – EPA provided 75 days for public comment, included OMB review, and completed the rulemaking in just under six months. Plaintiffs here believe, without OMB review, EPA can complete this particulate matter NAAQS rulemaking within

approximately six months by December 14, 2012.<sup>2</sup> This schedule is consistent with the key steps identified by EPA and the timeframes EPA has demonstrated to be feasible.

### **C. Plaintiffs' Proposed Deadline Of December 14, 2012 Is Possible.**

As noted above, based on Ms. McCarthy's declaration, EPA should be able to propose its rulemaking here by June if no delay is built into the schedule for OMB review. *See supra* at 5-6. Ms. McCarthy states that "EPA believes that somewhat more than 3 months is needed from the issuance of the proposed rule to have the rule published in the Federal Register, hold public hearings, and complete the public comment period."<sup>3</sup> McCarthy Decl. ¶ 23. Assuming the proposal is issued in early to mid-June, based on Ms. McCarthy's statement, the comment period should be completed by October, 2012. After the close of the public comment period, EPA must review and respond to the comments, brief senior management on the comments and potential options, make final decisions and prepare the final rulemaking package that explains these decisions. *See id.* A December 14, 2012 deadline would mean that EPA would have approximately two-and-a-half months to complete these steps.

While Plaintiffs acknowledge that their proposed schedule would be cumbersome, there is no reason to believe it is not possible with the fullest use of the Agency's resources. *See Train*, 510 F.2d at 712. In the 1997 particulate matter NAAQS rulemaking, the comment period closed on March 12, 1997. *See* 62 Fed. Reg. at 38654. EPA received over 50,000 written and oral

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<sup>2</sup> Plaintiffs, in their Application for Injunction, used this same analysis based on EPA's previous plan to propose a rulemaking in June 2012 to arrive at a final rulemaking deadline of October 15, 2012. *See* Applic. for Inj. at 10-11. Now that EPA has again revised its schedule, Plaintiffs here use Ms. McCarthy's latest statement to derive the new deadline of December 14, 2012. Because EPA has demonstrated that these declarations are not reliable commitments of Agency action, Plaintiffs have also modified their proposed order to include a deadline for EPA to sign a proposed rulemaking.

<sup>3</sup> EPA's brief states that EPA "plans to allow a 90-day period for public comment." EPA Mem. at 16 (citing McCarthy declaration). This is not, in fact, what Ms. McCarthy's declaration states. *See* McCarthy Decl. ¶ 23. But, to the extent, this is EPA's plan, there is room to save additional time in the schedule by shortening this period. *See Am. Lung Ass'n*, 884 F. Supp. at 349 (allowing for only a 60-day public comment period).

comments. *Id.* As noted above, this was a complex rulemaking promulgating for the first time separate PM<sub>2.5</sub> standards. *Id.* at 38562. What's more, EPA conducted this particulate matter NAAQS rulemaking at the same time that it was also promulgating a major new ozone NAAQS rulemaking. *See* 62 Fed. Reg. 38856 (July 18, 1997). EPA, *with OMB review*, was able to respond to all of these comments and all of the comments on the ozone proposal, make final decisions, prepare two rulemaking packages explaining the decisions, and sign the final rules four months after the close of the comment period. *See* 62 Fed. Reg. at 38711. Plaintiffs contend that, without OMB review, two-and-a-half months between the close of the comment period and completion of the rulemaking is entirely possible.

## **CONCLUSION**

The legal principle at the root of this case is about the separation of powers. Congress has dictated a timeframe for reviewing national ambient air quality standards. EPA has ignored that schedule arguing that its proposed schedule is more “reasonable” and now asks the Court to endorse its decision to flout the law. Where an agency violates a clear statutory mandate, it is up to the Court to ensure compliance with the directive of Congress. An agency may not “avoid the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better policy.” *Engine Mfrs. Ass’n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996).

In addition to this fundamental legal principle, this case is about protecting public health. Lost in EPA’s opposition to Plaintiffs’ Application for Injunction is any acknowledgement of the human costs of delay. Particulate matter air pollution kills people and causes extreme suffering among the most vulnerable. As burdensome as Plaintiffs’ proposed schedule may appear, it is nonetheless feasible and more accurately reflects the urgency of the situation.

For the foregoing reasons, Plaintiffs respectfully request the Court to grant Plaintiffs' Application for Injunction and deny EPA's Cross-Motion for Summary as to Remedy. A proposed form of order is provided herewith.

DATED: May 11, 2012

Respectfully submitted,

/s/Paul R. Cort  
PAUL R. CORT, admitted *Pro Hac Vice*  
EARTHJUSTICE  
50 California Street, Suite 500  
San Francisco, CA 94111  
Phone: (415) 217-2077  
Fax: (415) 217-2040  
[pcort@earthjustice.org](mailto:pcort@earthjustice.org)

/s/David S. Baron  
DAVID S. BARON  
D.C. Bar No. 464222  
EARTHJUSTICE  
1625 Massachusetts Avenue NW, Suite 702  
Washington, DC 20036-2212  
Phone: (202) 667-4500  
Fax: (202) 667-2356  
[dbaron@earthjustice.org](mailto:dbaron@earthjustice.org)

*Counsel for Plaintiffs*