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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
AT SAN FRANCISCO

ASBESTOS DISEASE AWARENESS ORGANIZATION, et al.,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

Case No. 19-CV-00871-EMC

ADAO PLAINTIFFS' OPPOSITION TO EPA'S MOTION TO ALTER OR AMEND THE JUDGMENT UNDER RULE 59 OR FOR RELIEF UNDER RULE 60

Date: March 18, 2021
Time: 1:30 PM
Judge: Hon. Edward Chen
Courtroom: 5, 17th Floor

STATE OF CALIFORNIA, by and through Attorney General Xavier Becerra, et al.,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants

Case No. 19-CV-03807-EMC

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PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO ALTER OR AMEND THE JUDGMENT UNDER RULE 59 OR FOR RELIEF UNDER RULE 60

INTRODUCTION

On December 22. 2020, the Court granted plaintiffs' motions for summary judgment, ruling that the denial of plaintiffs' petitions under section 21 of the Toxic Substances Control Act (TSCA) by the U.S. Environmental Protection Agency (EPA) was arbitrary and capricious and not in accordance with law.[1] The Order "directed [EPA] to amend its CDR [Chemical Data Reporting] rule . . . under Section 8(a) of TSCA) to address the information-gathering deficiencies identified herein." *Id.*

EPA has now moved to alter or modify the Judgment to eliminate this remedy. The Court should deny the motion because it impermissibly seeks to relitigate decided matters, is wrong as a matter of law, and would unacceptably defer, perhaps forever, the important remedy the Court has ordered.

EPA does not challenge the Court's determination that its petition denials were contrary to TSCA and arbitrary and capricious. However, its motion seeks to deny petitioners the relief that this determination requires under both Section 21 and the Administrative Procedure Act (APA). Instead of directing it to conduct rulemaking, EPA would convert the Order into an open-ended remand that instructs EPA merely to reexamine the petition denials, without any obligation to propose amendments to the CDR rule or indeed take any action at all. This would allow EPA to evade indefinitely its statutory "obligation to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA." Order at 35. The resulting lack of reporting would both jeopardize the public health protection demanded of EPA by TSCA and ignore the

[1] Order Granting Plaintiffs' for Summary Judgment and Denying Defendant's Cross-Motion for Summary Judgment, ADAO Case ECF No. 58, (Order) at 35.

Court's determination that "complete and adequate information is necessary to an effective assessment of risk and regulation thereof" under TSCA. Id. at 17.

Amending a judgment after its entry is "an extraordinary remedy which should be used sparingly." *McDowell v. Calderon*, 197 F.3d 1253, 1255 n. 1 (9th Cir. 1999) (en banc) (per curiam) (internal quotation omitted). A motion for reconsideration under Rule 59(e) "should not be granted, absent highly unusual circumstances, unless the district court is presented with newly discovered evidence, committed clear error, or if there is an intervening change in the controlling law." *389 Orange St. Partners v. Arnold*, 179 F.3d 656, 665 (9th Cir. 1999). As EPA acknowledges in the memorandum in support of its motion (EPA Mem. at 3), "[a] party may not use a Rule 59(e) motion to litigate old matters."

EPA has failed to overcome this deferential policy in support of maintaining judgments as entered. To begin with, briefing and argument on the cross-motions for summary judgment fully addressed the appropriate remedy if plaintiffs prevailed. EPA vigorously asserted, as it does again here, that the only permissible remedy was a bare remand of the petitions for agency reconsideration;[2] plaintiffs did not agree with this unduly constrained reading of the available remedies and asked the Court to order EPA "to quickly initiate rulemaking to require CDR reporting on asbestos."[3] The Court considered these positions and decided to grant the relief plaintiffs sought. Despite EPA's assertion now that it earlier presented only "narrow remedy arguments,"[4] its current motion merely repackages its unsuccessful plea for a limited remand order.

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[2] EPA's Combined Opposition to Plaintiffs' Motions for Summary Judgment, Cross-Motion for Summary Judgment, and Memorandum of Points and Authorities in Support Thereof, at 45-46 ("Upon finding an APA violation, the proper remedy is remand to the agency").

[3] ADAO Plaintiffs' Combined Opposition to Defendants' Motion for Summary Judgment and Reply in Support of Their Summary Judgment Motion (ADAO Mem.), at 23-25.

[4] The only new argument EPA makes is that the December 22 Order blocks it from following the normal APA rulemaking process in amending the CDR rule. EPA Mem. at 11-12. As demonstrated below. EPA misreads the Order and, in any event, its argument has no bearing on whether the

Continued on the next page

Nor has EPA demonstrated that the Court's Order suffers from the "manifest errors of law" necessary to justify amending a judgment under Rule 59(e). On the contrary, under both TSCA section 21 and the APA, the Court had ample authority to direct EPA to initiate the rulemaking it ordered.

As we show in **Part I** below, EPA erroneously persists in claiming that "there are no live TSCA claims before the Court." This is a misinterpretation of the Court's prior rulings and the plain language of TSCA. The Court's November 15, 2019 Order (ADAO Case ECF No. 43) (2019 Order) found that the APA standard of review governs where a petition seeks amendment of an existing rule as opposed to issuance of a new rule. However, it does not follow that section 21's remedies for unlawful petition denials are unavailable merely because the petition denial is subject to the APA review standard. Section 21(a) authorizes petitions to "initiate a proceeding for the issuance, *amendment* or repeal of a rule" under section 8 (emphasis added). Under section 21(b)(4)(A), if such a petition is denied, "the petitioner may commence a civil action in a district court of the United States." Such actions may seek "to compel the Administrator to initiate a rulemaking proceeding *as requested in the petition*" (emphasis added). This is the precise remedy prescribed by the Court in the December 22 Order, a remedy that is available for *all* unlawful petition denials, whether the petition sought issuance of a new rule or amendment of an existing rule.

As we demonstrate in **Part II**, EPA is also incorrect that under the APA, the only "proper remedy is vacatur of the [agency] decision and remand to the agency for reconsideration of the challenged action." EPA Mem. at 2. In this case, the Court found that the petition denial was arbitrary and capricious *and* violated EPA's obligations under TSCA. Where an agency has failed

proper remedy was a remand or a requirement to conduct rulemaking, an issue fully briefed and argued at the summary judgment stage.

to perform a statutory duty, courts have intervened under section 706(1) of the APA to "compel agency action unlawfully withheld or unreasonably delayed." In *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 77–78 (D.C. Cir. 1984) (*TRAC*), the District of Columbia Circuit held that, under section 706(l), "courts designated by statute to review agency actions may play an important role in compelling agency action that has been improperly withheld or unreasonably delayed." As shown below, both the Ninth Circuit and the D.C. Circuit have frequently relied on this principle in ordering EPA to conduct rulemaking that was legally required but the Agency failed to conduct.

The criteria for invoking this remedy articulated in *TRAC* and other cases are plainly satisfied here. As this Court has already found, EPA breached its legal duty under TSCA to obtain "reasonably available information" on asbestos use and exposure; this obligation arose when EPA initiated its risk evaluation on asbestos in 2016 and remains unfulfilled over four years later; the absence of CDR rulemaking has resulted in a final risk evaluation (FRE) that fails to adequately protect public health because it lacks necessary information on asbestos use and exposure; continued failure to obtain this information under the CDR rule would seriously weaken the risk management rulemaking and Part 2 asbestos risk evaluation that EPA recently initiated; and there is no countervailing agency interest that justifies further delay.

As we discuss in **Part III**, EPA also incorrectly asserts that the Order requires the agency to promulgate CDR amendments without satisfying the procedural requirements in the APA by "predetermining the final outcome of a *rulemaking proceeding* as opposed to directing *the initiation of a rulemaking proceeding*, as explicitly provided for under TSCA section 21(b)(4)(A)" (emphasis in original). EPA Mem. at 5. This misreads the Court's Order. The Order nowhere suggests that EPA could or should amend the CDR rule other than through normal APA notice-and-comment rulemaking. Plaintiffs expect that, consistent with the APA and the Order, EPA

would promptly propose CDR amendments, allow for public comment, consider the comments and issue a final rule with any necessary adjustments. In fact, before EPA filed this motion, plaintiffs' counsel wrote to EPA to request that it commit to dates certain by which it would comply with the Order and outlined this very notice-and-comment process as the basis for the proposed schedule.

Finally, as we demonstrate in **Part IV**, EPA's resistance to conducting rulemaking and its refusal to discuss a timeframe for complying with the December 22 Order leave the Court with no choice but to intervene to enforce its Order. An expeditious rulemaking schedule is essential here because, after issuing its final risk evaluation (FRE) on December 30, 2020, EPA has a one-year deadline to propose a TSCA risk management rule for asbestos and is simultaneously conducting a Part 2 evaluation to fill gaps in the FRE. The Court has retained jurisdiction "for purposes of ensuring compliance." Order at 36. Plaintiffs therefore request that the Court direct EPA to propose amendments to the CDR rule within 45 days of entry of the amended order and to issue a final rule within 60 days thereafter.

ARGUMENT

I. The Court's Order Directing EPA to Initiate a Rulemaking Amending the CDR Rule is Grounded in the Express Remedy Provisions of Section 21 of TSCA

EPA's position that the only permissible remedy is an open-ended remand of plaintiffs' petitions disregards the more expansive remedies explicitly authorized in section 21 of TSCA. EPA points to the Court's 2019 Order, which concluded that *de novo* review was not available in this case, and asserts that the Order somehow establishes that "there are no live TSCA claims before the Court." EPA Mem. At 11. But the November 2019 Order reached no such conclusion and the judicial remedies in section 21 expressly apply to petitions, such as those of plaintiffs, seeking amendment of an EPA rule.

Section 21 is an "unusually powerful procedure[] for citizens to force EPA's hand" by compelling

it to act against environmental threats that the agency has ignored. *Trumpeter Swan Soc. v. E.P.A.*, 774 F.3d 1037, 1039 (D.C. Cir. 2014). Section 21(a) authorizes petitions to "initiate a proceeding for the issuance, amendment or repeal of a rule" under several TSCA provisions, including section 8. Under section 21(b)(4)(A), if such a petition is denied, "the petitioner may commence a civil action in a district court of the United States." Such actions apply to denials of *all* petitions, including those which ask EPA to issue a new rule and those seeking to amend an existing rule. In both cases, the remedy provided by the statute is the same: the plaintiff may seek "to compel the Administrator to initiate a rulemaking proceeding *as requested in the petition*" (emphasis added).[5]

Section 21(b)(4)(B provides that, where a petition seeks issuance of a new rule as opposed to revision of an existing rule, the Court must make a *de novo* determination of the merits of the petition. In its 2019 Order, the Court held that the ADAO plaintiffs in this case were not entitled to *de novo review* because their petition "expressly requests the EPA to modify the CDR rule for stricter asbestos-reporting" and not issuance of a new rule.[6] 2019 Order at 11, 12. The Court then turned to the APA to define the standard of review because "TSCA Section 21 provides no express guidance of the scope of review available to denials of petitions to amend or repeal existing rules."

However, recourse to the APA's standard of review hardly means that the judicial remedies for petition denials under section 21(b)(4)(A) are inapplicable. The Court's 2019 Order did not make such a determination, which indeed would be contrary to the plain language of TSCA.[7] Moreover, it would

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[5] Note that "initiat[ion] of a rulemaking proceeding" would be necessary both to issue a new rule and amend an existing one.

[6] The Amended Complaint filed by the ADAO plaintiffs on February 19, 2019 (ADAO Case ECF No. 5) cited TSCA section 21 as the basis for the Court's jurisdiction. Thus, plaintiffs invoked section 21 to support their claims to relief under both the *de novo* and APA standards of review. The 2019 Order upholding plaintiffs' APA claims did not negate plaintiffs' reliance on section 21 as the basis for relief.

[7] The Order holds only that "[p]laintiffs' Section 21 claim for *de novo* review cannot survive and is DISMISSED with prejudice." 2019 Order at 12. It does *not* hold that the judicial remedies in section 21(b)(4)A) are unavailable if plaintiffs were to demonstrate that the denial of their petition is unlawful under the APA standard of review.

negate section 21's action-forcing purpose if a judicial ruling that the Agency's petition denial was unlawful only resulted in remand of the petition for further consideration, with no timetable for further action and open-ended discretion to deny the petition yet again.

The Court's Order directing EPA "to amend its CDR reporting rule" is the precise remedy that section 21 provides: it "compel[s] the Administrator to initiate a rulemaking proceeding as requested in the petition." Thus, the Court was well within its authority in requiring rulemaking to expand TSCA CDR reporting requirements for asbestos.

II. The APA Itself Authorized the Court to Require Rulemaking Based on its Determination that the Petition Denials Were Unlawful

The APA provides an independent basis for directing EPA to proceed with rulemaking. As the D.C. Circuit concluded in its influential *TRAC* decision, the APA "stipulates that the 'reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed . . . 706(1) coupled with section 555(b) does indicate a congressional view that . . . courts designated by statute to review agency actions may play an important role in compelling agency action that has been improperly withheld or unreasonably delayed." 750 F.2d at 76-77. *See also Public Citizen Research Group v. Commissioner, Food Drug Administration,* 740 F.2d 21, 32 (D.C. Cir. 1984). In this case, EPA's failure to conduct rulemaking as plaintiffs requested is "agency action unlawfully withheld or unreasonably delayed" under section 706(1) of the APA.

According to the Ninth Circuit, because an agency cannot be compelled to undertake an action which is not legally required, "the first step . . . is necessarily to determine whether the agency is required to act, that is whether it is under a duty to act." *Cmty. Voice v. United States EPA*, 878 F.3d 779, 784 (9th Cir. 2017). EPA claims it had no duty to act here because the "premise of the Court's Order . . . was that EPA's petition denials were arbitrary and capricious" under the APA. EPA Mem. at 6. This is untrue.

While the December 22 Order held that the petition denials were arbitrary and capricious, it also

found that EPA "has not acted in accordance with law." Order, at 35. As the Court determined, EPA's refusal to undertake rulemaking in response to plaintiffs' petitions "stands in the face of its significant statutory authority to require that this information be reported via the CDR rule and runs contrary to its obligation to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA." Id. The Order amplified this conclusion in a lengthy discussion of TSCA requirements entitled *EPA's Duty to Gather Information at the Risk Evaluation Stage* which underscores "EPA's duty to obtain 'reasonably available information' under TSCA § 26(k)." Id. at 14-17.

The Court particularized EPA's duty to obtain "reasonably available information" by examining the information gaps identified in plaintiffs' petition, the draft risk evaluation and other EPA documents, and the report of the Science Advisory Committee on Chemicals (SACC). Based on this analysis, the Court concluded that EPA lacked critical information about asbestos use and exposure that it had a legal duty to obtain under TSCA by amending its CDR rule as proposed in the petitions. Order at 34-35. It ordered EPA to discharge its "duty to gather information" on asbestos by "amend[ing] its CDR reporting rule . . . to address the information-gathering deficiencies identified herein."

In *Cmty. Voice v. United States EPA,* the Ninth Circuit conducted a similar analysis under TSCA, concluding that the:

> statutory framework clearly indicates that Congress did not want EPA to set initial standards and then walk away, but to engage in an ongoing process, accounting for new information, and to modify initial standards when necessary to further Congress's intent: to prevent childhood lead poisoning and eliminate lead-based paint hazards.

878 F.3d at 784. There was no deadline in TSCA for updating the lead standards, but the court nonetheless found that "the EPA is under a duty stemming from the TSCA and the Paint Hazard Act to update lead-based paint and dust-lead hazard standards in light of the obvious need." Id. at 786.[8]

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[8] The court also found that EPA had partially granted a rulemaking petition in 2011 but had not followed up with rulemaking in violation of the APA, which "requires agencies to 'conclude a matter presented to it' 'within a reasonable time.'" 5 U.S.C. § 555(b). Id. at 784. This was an

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Similarly, in *Pub. Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150, 1154, 1158 (D.C. Cir. 1983) (per curiam), OSHA had denied a petition for an emergency workplace standard for ethylene oxide, a dangerous carcinogen. Plaintiffs challenged the petition denial, "invok[ing] a provision of the Occupational Safety and Health Act . . .that authorizes OSHA to adopt an immediately effective temporary standard upon determining that failure to take emergency action would subject employees to 'grave danger' from exposure to a toxic substance." The D.C. Circuit emphasized the "mandatory language" in the Act requiring emergency standards, the "potentially grave danger" to workers and "the obvious need" to strengthen the current standard. Invoking the APA, it ordered OSHA to issue a notice of proposed rulemaking within 30 days and finalize the rule "on a priority, expedited basis." *See also Public Citizen Health Research Group v. Commissioner, Food & Drug Administration,* 740 F.2d at 32 ("When agency recalcitrance is in the face of a clear statutory duty or is of such magnitude that it amounts to an abdication of statutory responsibility, the court has the power to order the agency to act to carry out its substantive statutory mandates.")

Where the applicable law imposes a duty on an agency but there is no statutory deadline for complying, the courts "ascertain the length of time that has elapsed since the agency came under a duty to act ... [consider] the reasonableness of the delay ... and ... examine the consequences of the delay." *Cutler v. Hayes,* 818 F.2d 879, 897-98 (D.C.Cir.1987). Applying this standard, the Ninth Circuit and other courts have ordered agencies to undertake rulemaking or other action where the delay in carrying out a statutory duty was "unreasonable" under section 706(l) of the APA. [9] *See, e.g., Cmty.*

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alternative basis for its holding that the failure to update the lead standards was action "unlawfully withheld or unreasonably delayed" under the APA.

[9] Defendants argue that these cases "involved materially different circumstances" because they arose from petitions "seeking writs of mandamus to compel EPA actions assertedly 'unlawfully withheld or unreasonably delayed.'" EPA Mem. at 7. As explained in *TRAC,* since these cases involved the absence of agency action, a writ of mandamus in the court of appeals provided the only effective remedy for the delay and was justified in light of the court of appeal's authority to protect its jurisdiction to ultimately review the rule the agency had failed to promulgate. *TRAC*, 750 F.2d at 76 ("Because the statutory obligation of a Court of Appeals to review on the merits

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Voice v. United States EPA, 878 F.3d at 786-787 (because "EPA's delay here is into its eighth year, and EPA has not offered a 'concrete timetable' for final action", it must issue a proposed rule in 90 days and a final rule in one year); *NRDC v. United States EPA* (*In re NRDC*), 956 F.3d 1134, 1143 (9th Cir. 2020) (court found unreasonable delay after a protracted failure to respond to a petition to cancel a pesticide registration and set a deadline of 90 days for EPA to deny the petition or initiate a cancellation proceeding); *In re International Chemical Workers Union,* 958 F.2d 1144 (D.C. Cir. 1992) finding that OSHA's six year delay in finalizing a workplace standard for cadmium was "an extraordinarily long time, in light of the admittedly serious health risks associated with the current permissible levels of cadmium exposure under the twenty-year-old standards still in place" and ordering OSHA to complete the rulemaking in slightly over 5 months); *Public Citizen Health Research Group v. Com'r, FDA*, 724 F. Supp. 1013, 1014. 1022 (D.D.C. 1989) (FDA "has been lethargic in responding to and carrying out its legal obligation" to promulgate "necessary regulations" to protect users of tampons from toxic shock and must promulgate final regulations in slightly over 60 days from close of comment period); *Pesticide Action Network N. Am. v. U.S. EPA*, 798 F.3d 809 (9th Cir. 2015) (EPA directed within 70 days to issue either a proposed or final revocation rule for a pesticide or a full response to administrative petition).

The D.C. Circuit in *TRAC* has distilled the unreasonable delay analysis applied in these cases into six factors, which the Ninth Circuit has adopted. [10] As *TRAC* has described these factors:

> "(1) the time agencies take to make decisions must be governed by a rule of reason; (2)

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may be defeated by an agency that fails to resolve disputes, it may resolve claims about an agency's failure to act "in order to protect its future jurisdiction"). However, the APA remedy for agency action unlawfully withheld or unreasonably delayed is not limited to mandamus petitions in the courts of appeals and has been invoked by district courts. *See*, e.g., *Public Citizen Health Research Group v. Com'r, FDA*, 724 F. Supp. 1013. In this case, since the denial of plaintiffs' petitions comprised final agency action, the rationale for a writ of mandamus was inapplicable. Nonetheless, this Court had authority under the APA to require EPA to amend the CDR rule upon finding that EPA was in breach of its obligations and the amount of time for which EPA had failed to perform these obligations made them "unreasonable withheld."

[8] *Independence Mining Company, Inc. v. Babbitt,* 105 F.3d 502, 507 (9th Cir. 1997) (adopting the *TRAC* factors).

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> 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."

750 F.2d at 80 (citations and internal quotation marks omitted).

The first two factors strongly favor a determination of unreasonable delay here. The D.C. Circuit has noted that "a reasonable time for agency action is typically counted in weeks or months, not years" and thus a "six-year-plus delay is nothing less than egregious."[11] *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004). Here, the duty EPA failed to perform under section 26(k) -- to obtain "reasonably available information" to inform its asbestos risk evaluation -- arose in December 2016, when asbestos was selected for one of EPA's first 10 risk evaluations under TSCA section 6(b)(2)(A). TSCA section 6(b)(4)(D) directs that, within 6 months of commencing a risk evaluation, EPA must "publish the scope" of the evaluation, including the "exposures, conditions of use, and the potentially exposed or susceptible subpopulations" to be addressed. EPA cannot possibly satisfy this requirement unless, upon selecting the substance for a risk evaluation, it immediately begins to identify and obtain "reasonably available information." [12]

[11] Although the "reasonableness" of a delay in agency action is a case-specific determination, it is worth noting that courts have found delays in the range of four years or less to be unreasonable. See, e.g., *MCI Telecommunications Corp. v. FCC,* 627 F.2d 322 (D.C. Cir. 1980) (four-year delay unreasonable); *TRAC*, 750 F.2d at 81 (delays of nearly 5 years and 2 years unreasonable); *Pub. Citizen Health Research Grp. v. Auchter*, 702 F.2d at 1157 (3-year delay unreasonable).

[12] EPA's risk evaluation framework rule makes clear that obtaining "reasonable available information" is a fundamental initial step in conducting a risk evaluation. The rule provides that the risk evaluation scope under section 6(b)(4)(D) must "include a description of the reasonably available information . . . EPA plans to use" in the evaluation. 82 Fed. Reg. 33726, 33741 (July 20, 2017). While the evaluation scope may include modeling as well, the Court emphasized in its Order that " the predictive efficacy of these models is conditioned upon reliable and sufficiently comprehensive raw data inputs." If EPA fails to obtain these inputs, "EPA's models do not have the comprehensive raw data necessary to make accurate assessments that capture all 'reasonably available' data." Order at 29.

Thus, EPA has defaulted on its duty to obtain such information on asbestos for over four years. This is longer than the 3-3.5-year timetable for completing risk evaluations under TSCA section 6(b)(4)(E). Obviously, a delay that prevents EPA from performing its risk evaluation responsibilities in accordance with the statutory deadline is indefensible under the "rule of reason." Indeed, the delay will only become more egregious if EPA continues to resist amending its CDR rule for asbestos since the agency has initiated both a Part 2 risk evaluation and risk management rulemaking under section 6(c) and each is subject to statutory deadlines. An open-ended remand of plaintiffs' petitions could easily delay CDR reporting for several more years, if indeed it happens at all. The Court should not allow EPA to prolong a four-year delay that is already unreasonable.

The third *TRAC* factor—the need for expeditious agency action "when human health and welfare are at stake"—further underscores the unreasonableness of the delay in CDR reporting. As the D.C. Circuit emphasized in a case involving protection of workers from chemical risks under the Occupational Safety and Health Act, "[d]elays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake." *Auchter,* 702 F.2d at 1157. TSCA is similarly intended to prevent unreasonable risks to human health from chemical exposure and asbestos is among the most lethal substances known to man, causing an annual death toll of nearly 40,000 Americans. EPA's delay in accessing all "reasonably available information" has already resulted in a flawed FRE that understates asbestos risks. Unless EPA acts expeditiously to fill information gaps through CDR reporting, the Part 2 evaluation and the risk management rulemaking will be similarly inadequate to protect public health.

The fourth *TRAC* factor also bolsters a finding of unreasonable delay. There is no "higher or competing priority" that EPA is addressing under TSCA that would suffer if EPA were to amend the CDR rule for asbestos. These amendments would be narrow in scope and the resources required for rulemaking would be modest. In fact, receipt of CDR reports would make the Part 2 evaluation and risk

management rulemaking more efficient by filling information gaps that might otherwise necessitate complex and imprecise modeling. Moreover, because asbestos is so deadly, it is hard to imagine a higher public health priority than a robust risk evaluation and risk management rulemaking based on the best available science and information.

Finally, the fifth *TRAC* factor favors expeditious action. "[T]he interests prejudiced by delay" would be very substantial since public health protection would be compromised. By contrast, there is no countervailing interest that would be served by allowing EPA to delay CDR reporting indefinitely. In its Order, the Court carefully examined the record and cited overwhelming evidence of serious gaps in EPA's understanding of asbestos use and exposure—evidence derived from EPA's own documents, the peer review report of its scientific advisors and the draft and final risk evaluations themselves—that convincingly rebutted EPA's rationale for denying the petitions. It is hard to imagine how EPA could rationally conclude on remand that the petitions should be denied. Indeed, since the Court found that EPA's failure to require CDR reporting was not simply arbitrary and capricious but *unlawful,* a remand that resulted in a decision *not* to amend the CDR rule would violate the legal duty imposed by the Court.

In sum, the APA provided an alternative basis for ordering EPA to amend the CDR rule for asbestos to remedy the Agency's failure to carry out its information collection obligations under TSCA.

III. The Court's Order Does Not Preclude EPA From Amending the CDR Rule Through a Normal Notice-and-Comment Rulemaking under the APA

Even if the Court had authority to order EPA to amend the CDR rule, defendants claim that this directive "frustrates the purpose and intent of the APA's procedural requirements for rulemaking proceedings by depriving the public of a meaningful opportunity to participate." EPA Mem. at 11. This argument presumes that the Court ordered EPA to immediately issue final amendments to the CDR rule without taking the normal steps in the rulemaking process required under the APA. However, the

December 22 Order does not impose this requirement, or even suggest that the agency could or should act other than in accordance with APA-mandated rulemaking procedures. Thus, the Order implicitly directs EPA, in amending the CDR rule, to issue a notice of proposed rulemaking that provides an opportunity for comment, to review the comments submitted and then to take final action following consideration of these comments.

Plaintiffs do not dispute EPA's legal obligation to follow this procedure in complying with the December 22 Order. Following the APA rulemaking process, however, hardly means that EPA can decide not to *propose* amendments to the CDR rule which "address the information-gathering deficiencies identified" by the Court and fulfill EPA's obligation to obtain all "reasonably available information" on asbestos use and exposure. Order at 35-36. As discussed above, the Court had clear authority for imposing this remedy under both section 21 of TSCA and the APA. *See, e.g*., *Cmty. Voice v. United States EPA,* 878 F.3d at 788 (EPA ordered to propose regulations amending its standards for preventing harmful exposure to lead-based paint); *Public Citizen Health Research Group v. Auchter*, 702 F.2d at 1157-59 (OSHA ordered to propose an emergency workplace standard for ethylene oxide); *Public Citizen Health Research Group v. Com'r, FDA*, 724 F. Supp. at 1023 (FDA ordered to issue regulation requiring standardized tampon absorbency labeling); *Environmental Defense Fund v. E.P.A.,* 852 F.2d 1316, 1331 (D.C. Cir. 1988) (EPA required to propose rule determining which processing wastes remain within a statutory exclusion).

The Court likewise had authority to direct EPA to take final action after proposing CDR amendments consistent with the Court's order and taking public comment. Several of the decisions discussed above imposed deadlines on EPA to issue both proposed and final rules. Such final rules may differ from the proposals if evidence submitted during the comment period requires a change in course, but there is no doubt that EPA can be compelled by the Court to complete the rulemaking process.

In sum, the December 22 Order does not direct or even allow EPA to disregard normal notice-and-

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comment rulemaking when amending the CDR rule. And the Court acted well within its discretion in ordering EPA to propose CDR amendments consistent with plaintiffs' petition and the December 22 Order and then take final action. Thus, EPA has not justified amending the Order by removing its obligation to conduct rulemaking,

IV. The Court Should Set an Expeditious Schedule for EPA Rulemaking to Carry Out the Obligations Imposed by the December 22 Order

It has been two months since entry of the Court's December 22 Order and EPA has made no progress in amending the CDR rule. Meanwhile, on December 30, a week after the Order was entered, EPA issued its "Part 1: Chrysotile Asbestos Final Risk Evaluation" (FRE).[13] Predictably, the FRE reflected the many gaps and omissions in EPA's understanding of asbestos use and exposure that the Court had underscored in its Order:

> EPA declined the petition's request to collect more information about asbestos-containing articles even though the petition accurately described how little information EPA has about the quantities of asbestos-containing products in the U.S. chain of commerce and the overall consumer and occupational exposure for downstream uses of asbestos. EPA declined to collect more information about asbestos impurities without seriously analyzing whether companies had access to reasonably ascertainable third-party testing from suppliers. And EPA declined to collect more information about asbestos processors, instead relying on the type of voluntary reporting that its scientific advisors deem inadequate in the SACC [TSCA Science Advisory Committee on Chemicals] Report.

Order at 34. Thus, the FRE did not contain any new use and exposure information or address additional asbestos uses and it failed to implement nearly all the SACC recommendations for strengthening the evaluation. [14] Although the FRE determined that some asbestos conditions of use presented an

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[13] 86 Fed. Reg. 89 (January 4, 2021)

[14] https://www.epa.gov/sites/production/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf, last viewed February 18, 2021. The Court may take judicial notice of the FRE, a document available to the public online. In its Order, the Court took judicial notice of the DRE and SACC report because "[w]hether EPA has adequately assembled all reasonably available information, and what kinds of information the EPA did not possess, is at the crux of this case [and] [t]he information provided by the DRE and the SACC Report is highly probative to those questions" Order at 32 (emphasis in original). The same rationale warrants consideration of the FRE at the remedy stage of this case.

unreasonable risk of injury, it found that others did not and made no risk determinations for asbestos-containing products that it previously identified but failed to include in the evaluation. Timely CDR reporting might have produced a very different outcome.

In parallel with the FRE, EPA committed to conduct a "Part 2" risk evaluation that would assess the risks of use and disposal of "legacy" asbestos—conditions of use that the Ninth Circuit ruled in November 2019 must be included in EPA risk evaluations[15]– and would potentially address the gaps and deficiencies in the Part 1 evaluation highlighted in the SACC report.[16]

Because the Part 1 FRE found that certain asbestos conditions of use present an unreasonable risk to health, EPA also launched the risk management process required by TSCA sections 6(a) and 6(c). Section 6(c)(1) of TSCA requires EPA to propose a risk management rule within one year and to finalize it within two years of completion of a risk evaluation. This rulemaking process, which is governed by section 6(c)(3), will examine which of the regulatory options listed in section 6(a) is necessary to eliminate the unreasonable risks identified in the FRE. In assessing these options, EPA must make several technical, scientific and economic findings which require in-depth understanding of asbestos use and exposure.

The amended CDR rule required by this Court's December 22 Order will yield critical information that will inform both the Part 2 risk evaluation and the risk management rulemaking. Because of TSCA's stringent rulemaking deadlines and the time required to finalize CDR amendments and then obtain and analyze reports,[17] any delay in complying with the Court's order

[15] *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397, 425 (9th Cir. 2019).
[16] The ADAO plaintiffs have filed a petition for review of the FRE in the Ninth Circuit. *Asbestos Disease Awareness Org, et al v. USEPA*, *et al* (No. 21-70160).
[17] This includes the period (typically 120 days following promulgation) that EPA's rule provides for submitting CDR reports. 40 CFR § 711.20

will jeopardize timely reporting and once again result failure to consider all "reasonably available information."

In an effort to move forward, plaintiffs' counsel wrote to EPA counsel on January 28 to request that it commit to a date certain by which it would comply with the Order. (Attachment 1.) Specifically, the letter asked EPA to enter into a consent decree requiring the Agency to propose amendments to the CDR rule within 45 days, i.e., by Monday, March 15, 2021, and to issue a final rule within 60 days thereafter, i.e., by Friday, May 14, 2021. On February 2, EPA informed plaintiffs that it would not respond to the letter because its motion to alter or amend the judgment in this case might make the letter "moot." (Attachment 2).

Anticipating roadblocks in implementing its directives, the Court's Order expressly "retains jurisdiction for purposes of ensuring compliance." In the face of EPA's adamant refusal to initiate rulemaking, we respectfully request that the Court enforce the Order by imposing a schedule for compliance. This schedule should be as expeditious as possible in view of the lapse of two months without any action by EPA and the urgency of putting CDR reporting requirements for asbestos in place. Plaintiffs therefore urge the Court to order EPA to propose CDR amendments within 45 days of entry of its amended Order and to take final action 60 days thereafter.

This compliance schedule is realistic and achievable. The necessary CDR amendments are specific to asbestos and limited in scope, and the Court's December 22 Order provides a clear roadmap to the key elements that an amended the CDR rule should contain. Both the public and EPA will benefit if reportable information addressing the gaps in the FRE is submitted as soon as possible and can inform both risk management and the Part 2 risk evaluation.

CONCLUSION

The Court should deny EPA's motion and set a schedule for proposed and final rulemaking to

comply with its December 22 Order. A proposed order is attached.

Respectfully submitted on February 26, 2021:

/s/____________________
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3 **CERTIFICATE OF SERVICE**
4
5 I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing
6 this 26th day of February 2021 upon all ECF registered counsel of record using the Court's CM/ECF
7 system.
8
9 /s/ *Robert Sussman*
Robert M. Sussman
10 Attorney for Plaintiffs
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ATTACHMENT 1

THE COMMONWEALTH OF MASSACHUSETTS, THE STATES OF CALIFORNIA, CONNECTICUT, HAWAII, MAINE, MARYLAND, MINNESOTA, NEW JERSEY, OREGON, AND WASHINGTON, AND THE DISTRICT OF COLUMBIA

– and –

ASBESTOS DISEASE AWARENESS ORGANIZATION, AMERICAN PUBLIC HEALTH ASSOCIATION, CENTER FOR ENVIRONMENTAL HEALTH, ENVIRONMENTAL WORKING GROUP, ENVIRONMENTAL HEALTH STRATEGY CENTER, AND SAFER CHEMICALS, HEALTHY FAMILIES

January 28, 2021

By Electronic Mail
Debra J. Carfora
Brandon N. Adkins
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Re: *ADAO et al v. Environmental Protection Agency*, Case No. 3:19-cv-0871-EMC (ND Cal); *California at al v. Environmental Protection Agency,* Case No. 3:19-cv-3807-EMC (ND Cal)

Dear Ms. Carfora and Mr. Adkins:

We are writing to you in your capacity as counsel for the U.S. Environmental Protection Agency (EPA or the Agency) in the referenced consolidated matters to request that EPA commit to a date certain by which it will comply with the Court's order to amend the Chemical Data Reporting (CDR) rule to address deficiencies in asbestos reporting.

In this case, plaintiffs challenged EPA's denial of plaintiffs' petitions under section 21 of the Toxic Substances Control Act (TSCA) to amend the CDR rule to obtain information essential for the Agency's risk evaluation of asbestos. As you know, on December 22, 2020 and prior to the change of administration, Judge Chen issued an order granting plaintiffs' motions for summary judgment and denying EPA's cross-motions for summary judgment (Order). On January 5, 2021, based on this Order, Judge Chen entered Judgment in favor of plaintiffs and against EPA.

In the Order, the Court rejected EPA's rationale for denying the petitions, finding that:

> EPA's decision not to collect the information which the Plaintiffs contend should be collected via the elimination of the CDR exceptions did not come after taking a "hard look" at the value and availability of the additional information the EPA has forsaken. As noted above, EPA declined the petition's request to collect more information about asbestos-containing articles even though the petition accurately described how little information EPA has about the quantities of asbestos-containing products in the U.S. chain of commerce and the overall consumer and occupational exposure for downstream uses of asbestos. EPA declined to collect more information about asbestos impurities

> without seriously analyzing whether companies had access to reasonably ascertainable third-party testing from suppliers. And EPA declined to collect more information about asbestos processors, instead relying on the type of voluntary reporting that its scientific advisors deem inadequate in the SACC Report.

Order at 34. The Court then ruled that "the EPA has not acted in accordance with law" and "has also acted arbitrarily and capriciously." *Id.* at 35.

Based on this ruling, the Order stated that "EPA is directed to amend its CDR reporting rule pursuant to its authority under 15 U.S.C. § 2607(a)(1)(A) (i.e., under Section 8(a) of TSCA), to address the information-gathering deficiencies identified herein." *Id.* (emphasis added). The Court retained jurisdiction "for purposes of ensuring compliance." *Id.* at 36.

The Order reflects the Court's strong expectation that EPA would move expeditiously to amend its CDR rule to require reporting of the information called for in plaintiffs' petitions. The Order cites two Ninth Circuit decisions setting deadlines for EPA action unlawfully delayed in the face of citizens' petitions:

> *Cmty. Voice v. United States EPA*, 878 F.3d 779, 788 (9th Cir. 2017) (after EPA granted a petition from several organizations asking for a rulemaking to update lead-based and dust-lead hazard standards, the Ninth Circuit found that TSCA imposed a clear duty on EPA to conclude a rulemaking proceeding within a reasonable time, and it "order[ed] … that EPA issue a proposed rule within ninety days of the date that th[e] decision bec[ame] final … [and] retain[ed]jurisdiction for purposes of ensuring compliance"); *NRDC v. United States EPA*, 956 F.3d 1134, 1143 (9th Cir. 2020) (finding that EPA's delay in responding to an environmental organization's administrative petition, which requested that it cancel the registration of a dangerous pesticide used in household pet products, merited mandamus relief because it delayed the performance of its statutory duties on a crucial matter of public health).

Id. at 35-36. Consistent with these decisions and the Order, we request that EPA enter into a consent decree with the plaintiffs requiring the Agency to propose amendments to the CDR rule within 45 days, i.e., by Monday, March 15, 2021, and to issue a final rule within 60 days thereafter, i.e., by Friday, May 14, 2021.

The necessary CDR amendments should be straightforward and not require significant time and effort to promulgate. It is critical to obtain the information to be reported under these amendments as quickly as possible: EPA published its final risk evaluation (FRE) for asbestos on January 4, 2021 (86 Fed. Reg. 89), and Section 6(c)(1) of TSCA requires EPA to propose a risk management rule within one year and to finalize it within two years of the completion of a risk evaluation. The additional CDR reports to be required will provide critical information on asbestos use and exposure that will inform the risk management rulemaking. Given that EPA provides a 120-day period for submitting CDR reports, the schedule we propose would provide EPA with reportable information late in the development of the proposed rule; a longer schedule most certainly will delay reporting until *after* the proposed rule is published.

In addition, the FRE continues to suffer from the many omissions and deficiencies emphasized in the report of the Science Advisory Committee on Chemicals (SACC) and highlighted in Judge Chen's decision. These flaws render the FRE in its current form legally insufficient under TSCA. Indeed, EPA has itself recognized that the FRE is incomplete and must be supplemented.[1] Expanded CDR reporting consistent with the December 22 Order is essential to inform a sufficient FRE, and it is in the interest of EPA and the public for reportable information addressing the gaps in the FRE to be submitted as soon as possible.

We ask that you respond to the proposed rulemaking schedule in this letter by no later than Friday, February 12, 2021, so that we can consider next steps in the event we cannot reach agreement. We appreciate your prompt and careful consideration, and if you would like to discuss these matters further, please contact the undersigned.

Sincerely,

ASBESTOS DISEASE AWARENESS ORGANIZATION, ET AL.

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COMMONWEALTH OF MASSACHUSETTS

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On behalf of themselves and the States of Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, Oregon, and Washington, and the District of Columbia

[1] When EPA released the final risk evaluation, it announced that it was initiating a "Part 2" risk evaluation addressing use and disposal of legacy asbestos products as well as certain other issues left unresolved by the initial evaluation. *See* 86 Fed. Reg. at 91.

ATTACHMENT 2

From: Carfora, Debra (ENRD)
To: Goldberg, Andy (AGO); Adkins, Brandon (ENRD)
Cc: Robert Sussman; "Megan Hey"; "Liz Rumsey"
Subject: RE: ADAO et al v. Environmental Protection Agency, Case No. 3:19-cv-0871-EMC (ND Cal), consolidated with California at al v. Environmental Protection Agency, Case No. 3:19-cv-3807-EMC (ND Cal)
Date: Tuesday, February 2, 2021 4:07:34 PM

Andy,

We received your letter. I am writing to let you know that today EPA will file a motion under Rule 59(e) and Rule 60(b) to alter or amend the judgment. Because resolution of EPA's motion may moot Plaintiffs' request, we do not intend to further respond to your letter at this time.

Thanks,

DEBRA J. CARFORA, SENIOR TRIAL COUNSEL
Environmental Defense Section
Environment and Natural Resources Division
202.514.2640

From: Goldberg, Andy (AGO) <andy.goldberg@state.ma.us>
Sent: Thursday, January 28, 2021 4:50 PM
To: Carfora, Debra (ENRD) <DCarfora@ENRD.USDOJ.GOV>; Adkins, Brandon (ENRD) <BAdkins@ENRD.USDOJ.GOV>
Cc: Robert Sussman <Bobsussman1@comcast.net>; 'Megan Hey' <Megan.Hey@doj.ca.gov>; 'Liz Rumsey' <Liz.Rumsey@doj.ca.gov>
Subject: ADAO et al v. Environmental Protection Agency, Case No. 3:19-cv-0871-EMC (ND Cal), consolidated with California at al v. Environmental Protection Agency, Case No. 3:19-cv-3807-EMC (ND Cal)

Debra and Brandon:

See attached.

Thanks, Andy

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