IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

UNITED STATES COURT OF APPEALS
FOR DISTRICT OF COLUMBIA CIRCUIT
FILED
AUG 10 2001
CLERK

UNITED STATES COURT OF APPEALS
FOR DISTRICT OF COLUMBIA CIRCUIT
AUG 10 2001
RECEIVED

ing and Health (ASH)

Petitioner

No. 01-1199

THE SECRETARY OF LABOR'S RESPONSE
TO ASH's PETITION FOR A WRIT OF MANDAMUS

Action on Smoking and Health (ASH) has petitioned this Court for a writ of mandamus to the Department of Labor, the Secretary of Labor, Elaine L. Chao, and the Occupational Safety and Health Administration ("OSHA") compelling the issuance of a final rule regulating occupational exposure to environmental tobacco smoke ("ETS") within 90 days of the Court's order. The Secretary of Labor[1] responds as follows:

BACKGROUND

1. Legal and regulatory background: 1991-1996

This is the seventh time ASH has asked this Court to order OSHA to promulgate a rule regulating occupational exposure to ETS. In ASH v. OSHA, No. 89-1656 (May 10, 1991) (ASH I), this Court upheld OSHA's denial of ASH's request for an Emergency Temporary Standard under section 6(c) of the Act, 29 U.S.C. 655(c). In ASH v. OSHA, No. 91-1037 (ASH II); and

[1] The Occupational Safety and Health Act of 1970, 29 U.S.C. 651-678 (1994 & Supp. V 1999) ("OSH Act" or "Act") authorizes the Secretary of Labor to issue occupational safety and health standards to address, inter alia, toxic substances present in workplaces. 29 U.S.C. 655 (b)(5). The Secretary has delegated rulemaking authority to the Assistant Secretary for Occupational Safety and Health, who heads OSHA. In this response, the terms "Secretary" and "OSHA" are used interchangeably. A/C Elec. Co. v. OSHRC, 956 F.2d 530 (6th Cir. 1991).

NOTE: This document contains underlines and margin note not included in original document. Such additions are intended to provide emphasis and clarification for readewrs. All underlines and maring notes are added.

ASH v. OSHA, 91-1038 (ASH III) (consolidated) (January 29, 1992), this Court dismissed two more ASH petitions challenging, on various grounds, OSHA's ongoing consideration of the need for a permanent standard on ETS under section 6(b) of the Act, 29 U.S.C. 655(b). The court dismissed some of ASH's arguments on ripeness and finality grounds. It also denied the petitions to the extent they sought a writ of mandamus, holding that OSHA had not unreasonably delayed resolving whether and how to regulate ETS.

In July 1992, ASH formally petitioned OSHA to regulate ETS under section 6(b). ASH requested that ETS be regulated as a potential occupational carcinogen under OSHA's Cancer Policy, codified at 29 C.F.R. 1990.101-152 (2000), and that a regulation also address ETS's non-carcinogenic effects. On April 5, 1994, OSHA issued a Notice of Proposed Rulemaking (NPRM) proposing to regulate ETS together with other indoor air contaminants in an omnibus Indoor Air Quality ("IAQ") rulemaking. 59 Fed. Reg. 15968- 16039. OSHA found preliminarily that exposure to ETS presents a significant risk of harm to workers. The NPRM stated that the Secretary had determined that the Cancer Policy procedures were not appropriate for this rulemaking and proposed, inter alia, to prohibit smoking in all indoor workplaces except in separately enclosed areas with sufficient ventilation to contain the smoke within the designated area. 59 Fed. Reg. at 16001, 16037. The agency noted that there was no established method for quantifying exposure to ETS. It therefore concluded that it was impossible to establish a permissible exposure limit for ETS that would reflect the level at which exposure creates a significant risk of harm. 59 FR at 16001. See Benzene, 444 U.S. 607, 655 (1980).

Original OSHA Conclusion

OSHA Original ETS Testing View

OSHA based its significant risk finding principally on studies indicating that spouses of smokers face elevated health risks as a result of their exposure to ETS. See 59 FR at 15993-

OSHA Original Basis

15994. The agency determined that on average an employee's exposure to ETS at work is equivalent to the exposure experienced by a nonsmoker married to a smoking spouse. Therefore, since spouses face an elevated risk from ETS, the agency surmised that workers do as well.[2]

OSHA invited comments on all aspects of the proposal. The agency noted that if the public comments warranted, it would publish additional Federal Register notices. 59 FR at 15968.

In ASH v. OSHA, 28 F.3d 162 (D.C. Cir. 1994) (ASH IV), this Court dismissed an ASH challenge to the proposed IAQ rule. It held that issuance of the proposal had mooted ASH's claim of unreasonable delay in initiating regulatory action. 28 F.3d at 164. It also refused to reach the merits of two claims by ASH that the Cancer Policy required that ETS be regulated in a separate proceeding, apart from other IAQ contaminants. It found unripe for review ASH's claim that regulating ETS in an omnibus IAQ proceeding would violate the Cancer Policy's timetable for issuing a final rule on a carcinogen, finding that OSHA could still meet that timetable. Id. And it held that considerations of finality precluded review of ASH's argument that the Cancer Policy's substantive provisions required that carcinogens must always be regulated separately, since OSHA had not made a final decision on the scope of the rulemaking, and no legal consequences attached to the proposed rule. ASH IV, 28 F.3d at 165.

Less than a month after the decision in ASH IV, and prior to the close of the pre-hearing

---

[2] The risk assessment includes two components. The exposure assessment estimates the number of employees believed to be exposed to ETS at work. The quantitative risk assessment estimates the likelihood that each of those exposed employees will be harmed by that exposure. Those two numbers may be combined to calculate how many cases of disease and death would be prevented by reducing or eliminating exposure.

comment period in the IAQ rulemaking, ASH filed a petition renewing its challenges to the proposal. In ASH v. OSHA, No. 94-1551 (November 22, 1994) (ASH V), the Court dismissed this petition for the same reasons stated in ASH IV: OSHA could still issue a final rule within the Cancer Policy timetable, and no legal consequences attached to the inclusion of ETS in the IAQ proposal.

Public hearings on the proposed IAQ rule began on September 20, 1994, and continued through March 13, 1995. ASH did not appear at the hearing.

2. This Court's decision in ASH VI

In December 1995, prior to the close of the post-hearing comment period, ASH filed a sixth petition for review in this Court. The petition challenged OSHA's failure to issue a final rule regulating ETS. Among other things, ASH argued that OSHA had unreasonably delayed regulating ETS by failing to issue a final rule within the Cancer Policy's timeframe and that OSHA's proposed decision to regulate ETS in an omnibus IAQ rulemaking was arbitrary, capricious and violative of the Cancer Policy. Treating ASH's petition as one for mandamus, the Court rejected the unreasonable delay claim. It held that the Cancer Policy's deadlines are aspirational only and do not alter the Secretary's statutory discretion rationally to delay development of a standard at any stage of the rulemaking as priorities demand. ASH v. Department of Labor, 100 F.3d 991, 993 (D.C. Cir. 1996) (ASH VI) (citing National Congress of Hispanic Am. Citizens (El Congreso) v. Marshall, 626 F.2d 882, 888 (D.C. Cir. 1979)).

The Court also held that ASH was not entitled to relief under the principles established in Telecommunications Research & Action Center (TRAC) v. FCC, 750 F.2d 70 (D.C. Cir. 1984). It noted that practical problems had contributed to the delay, including, inter alia, budget cuts,

uncertainty about future appropriations, a huge and complex record, technological problems in assessing the levels of tobacco smoke in different settings, the novelty of the proposed method of regulation and changing agency priorities. ASH VI, 100 F.3d at 993. It also noted that, although OSHA had stated in 1995 that an IAQ standard remained one of the agency's highest priorities, additional progress on IAQ could only have come at the expense of other safety and health items on the agency's agenda. Id. at 994, citing In re Barr Labs., 930 F.2d 72, 75 (D.C. Cir. 1991).

Finally, the Court found that ASH's argument that by combining ETS with other indoor air contaminants in a single proposed standard, OSHA violated the Cancer Policy and acted arbitrarily and capriciously, "raised a policy question for the agency, not the courts." ASH VI, 100 F.3d at 995, citing American Iron & Steel Inst. v. OSHA, 939 F.2d 975, 982 (D.C. Cir. 1991). Moreover, the Court noted, OSHA had given "good, logical reasons for dealing broadly with the subject of indoor air pollutants." 100 F.3d at 995. Accordingly, the Court dismissed ASH's petition.

3. Subsequent developments in the rulemaking

Following the close of the comment period in February 1996, OSHA began reviewing the record on ETS to determine whether it was adequate to permit development of a final rule. OSHA was particularly concerned about how to resolve criticisms of the methodologies used in (1) the proposed rule's exposure assessment, the measurement of the amount of ETS actually present in workplaces and the number of workers exposed, and (2) the proposed quantitative risk assessment, the estimate of the magnitude of the health risk expressed in numbers of deaths

OSHA Concerns When Reviewing H:earing Record

caused by exposure to ETS at work.[3] OSHA also expressed concern that the record might not support the proposed finding that smoking restrictions were feasible in all sectors of the hospitality industry, such as bars and casinos.

To help resolve these issues, OSHA sponsored three workshops in which experts were commissioned to evaluate the available data on the issues of concern and to make recommendations about how these issues could be resolved. Separate workshops were held on the topics of exposure assessment, health risk assessment, and ventilation controls for the hospitality industry. At the conclusion of each workshop, the participants produced a report summarizing their conclusions, which was peer-reviewed and published. See Environmental Health Perspectives, Vol. 107, Supplement 2 (May, 1999) ("Exposure Assessment Report"), Supplement 6 (December 1999) ("Health Risk Assessment Report"); Proceedings of the Workshop on Ventilation Controls for Environmental Tobacco Smoke the Hospitality Industry, U.S. Department of Labor, Occupational Safety and Health Administration, ACGIH Worldwide, Cincinnati, Ohio (June 7-9 1998) ("Ventilation Control Report"). The Secretary intends to place these reports into the rulemaking record.

OSHA Supplemental Workshops

The ETS exposure assessment workshop was held in September 1997. It reviewed the data on the levels of ETS present in various workplaces, and addressed comments on the

[3] The Secretary's brief to this Court in ASH VI, filed in 1996, explained that substantial testimony and data had been presented on the appropriate methodology for assessing current levels of ETS in occupational settings, and on the proposed quantitative risk assessment. The brief also noted the possibility that the record might prove inconclusive on these issues, and that additional evidence would have to be gathered before a final rule could be issued. See Secretary's Response to ASH's Petition For Mandamus at 9, 10.

exposure assessment section of the proposed rule. As noted above, the proposed rule had found, preliminarily, that the level of ETS present in workplaces was, on average, equivalent to the level present in homes in which smoking occurs. See 59 Fed. Reg. 15993-15994. This finding of equivalence in the levels of ETS in workplaces and in homes was critical because, at the time of the proposal, most studies of the health effects of ETS examined the lung cancer risk to nonsmoking housewives in homes in which the husband smoked. Id. The proposal had concluded that this similarity in exposure in smoking homes and in workplaces justified using risk estimates based on residential exposures to accurately reflect occupational risks in most workplaces. 59 Fed. Reg. at 15994. However, several commenters argued that the proposal failed to account for the variability of ETS exposures in workplaces as compared to homes, or to consider whether there had been any reduction in overall ETS levels due to restrictive smoking policies in effect in many areas.

One Major Flaw In ETS Exposures

The workshop participants found that substantial additional data on ETS exposures had become available since the proposal, including some material not in the rulemaking record. Exposure Assessment Report at 309. Based on this data, the participants recognized that ETS exposures in the workplace had "sharply declined" over the last decade as a result of smoking policies implemented by employers voluntarily or to comply with state or local smoking ordinances. Id. at 310. One study cited in the report found that in general exposure levels were much lower than those in earlier studies, and that ETS levels in workplaces where smoking was restricted to designated areas were 2 to 8 times less than the levels present in facilities where smoking was not restricted. Id. at 348. The participants concluded that ETS exposures in the workplace should be re-estimated using new approaches suggested in the recent scientific

Lower Exposures Than Anticipated

literature. Id. at 310-311. OSHA would then be able to determine more reliably whether ETS exposure in the workplace is a significant hazard to workers and to evaluate the consequences of different control measures. Id. at 310.

OSHA sponsored a second workshop in July, 1998 to address the health effects of exposure to ETS in the workplace, including issues related to OSHA's proposed quantitative risk assessment. As noted above, the proposal had stated that there was no established method for quantifying exposure to ETS, so it was not possible to perform the type of dose response calculations that could determine the likelihood of illness or death at any particular exposure level, or to determine an exposure level that would eliminate significant risk. 59 Fed. Reg. 15995-15996, 16001. The participants found that by 1998, however, new approaches were available that might be used to assess the health effects of exposure to ETS at various levels in workplaces. In addition, although the participants did not address whether the proposal's residential-analogy method of quantifying risk was sound, they made clear that accurate data on ETS exposures in workplaces would be a fundamental component of such an assessment of the occupational hazard. Health Risk Assessment Report at 823.

Actual Exposure Testing Fundamentally Important

The June 1998 workshop on ventilation controls addressed the feasibility of the proposed rule in certain industry sectors. In industries where there is substantial contact between customers who smoke and workers, such as some sectors of the food, beverage and gaming industries (including bars and casinos), the proposed rule's prohibition on smoking except in separately ventilated areas may not be economically feasible. See Preface to Ventilation Control Report. The workshop panelists sought to identify feasible engineering controls that could be used in these industries to protect workers. Id. However, the panelists concluded that more

Smoking Ban Compliance By Bars May Not Be Economically Feasible For Bars

information needs to be gathered, by research or documented experience, before engineering solutions can be evaluated. Engineering Control Report, Executive Summary at 2. Accordingly, OSHA's preliminary finding that the rule is feasible in all industries to which it applies is not supported. 59 Fed. Reg. 16021.

All of these factors combined to convince the agency that the IAQ rulemaking, and particularly the portion addressing ETS, could not be concluded as quickly as had originally been hoped. Accordingly, the agency categorized the IAQ proceeding as a long-term action with no projected date for completion. 62 Fed. Reg. 21939 (April 25, 1997).

4. The future of the rulemaking

The current Administration has not yet determined the future course of the IAQ rulemaking. As explained in the latest Regulatory Agenda, the new Secretary is still developing her own regulatory priorities for OSHA. The new Assistant Secretary for OSHA was not confirmed until late last Friday, August 3, 2001. Although he has not yet had the opportunity to address all of the issues facing OSHA, he obviously will have substantial input into the development of its regulatory priorities.

Nevertheless, the background discussed in the prior sections demonstrates that it is now clear OSHA cannot proceed simply to promulgate a final rule on ETS. Evidence indicates that the assumptions underlying OSHA's original risk and exposure estimates are not valid at this time, even if they were appropriate when the proposal was issued. For example, it now appears that, contrary to the assumption in the proposal, it may be possible to perform dose-response analyses for the ETS risk assessment. This may allow selection of a permissible exposure level

New Data Suggests PEL May Be Possible

for ETS, something that was not possible at the time of the proposal. 59 Fed. Reg. at 16001. Similarly, it also appears that OSHA's critical assumption that workplace exposures to ETS are similar to spousal exposures is simply wrong.

OSHA Original Conclusions About ETS "Simply Wrong"

These problems and the others described above are significant, and correcting them will require substantial agency resources that are usually only available to a few high-priority rulemaking projects. These new analyses, moreover, would be different enough from the proposal that the Secretary believes a new risk assessment, a new opportunity for public comment, and possibly a completely new proposal, could be warranted if OSHA decides to make issuing a standard that would be upheld on review a high agency priority. Thus continuation of this proceeding is the equivalent of beginning an entirely new rulemaking. In light of this, in her development of Departmental priorities, the Secretary is considering whether such an undertaking is an appropriate use of OSHA resources and consistent with Agency priorities, or whether she should exercise her discretion to terminate the proceeding without issuing a final standard. Cf. Consumer Federation v. Consumer Product Safety Commission, 990 F.2d 1298, 1305 (D.C. Cir. 1993) (applying "highly respectful" standard of review to agency decision to terminate a rulemaking proceeding without promulgating a rule).

ARGUMENT

OSHA HAS NOT UNREASONABLY DELAYED THE RULEMAKING

A. The TRAC decision does not support issuance of a writ of mandamus

Relying on TRAC v. FCC, 750 F.2d 70 (D.C. Cir. 1984) ASH argues that OSHA's pace in the IAQ rulemaking is so unreasonably protracted as to warrant judicial intervention to compel issuance of a final rule within 90 days. ASH Petition at 7. TRAC established an analytical

framework for resolving claims of unreasonable agency delay. The Court emphasized that the exercise of equitable powers, particularly the issuance of a writ of mandamus, is an intrusive step to be taken sparingly. Id. at 79 ("In the context of a claim of unreasonable delay, the first stage of judicial enquiry is to consider whether the agency's delay is so egregious as to warrant mandamus.") See also In re Barr Laboratories, Inc., 930 F.2d 72, 74 (D.C. Cir. 1991) (respect for autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command of agency priorities through mandamus).

TRAC identified six factors to aid the Court in determining when mandamus is an appropriate remedy:

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

750 F.2d at 80 (citations omitted). As we demonstrate below, neither TRAC's rule of reason nor the remaining listed factors support issuance of a writ of mandamus in this case, and OSHA could not, in any case, complete action addressing ETS within the 90 days suggested by ASH.

1. Before the Secretary may issue a final rule regulating ETS, she must determine, on the basis of the best available evidence, that there currently exists a "significant risk" of material health impairment to employees, that the new standard is "reasonably necessary or appropriate to eliminate or substantially reduce that risk," and that compliance with the standard is feasible.

OSHA Regulatory Standards

American Textile Mfrs. Inst. v.Donovan, 452 U.S. 490, 506 (1981); Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S.607, 614-615, 639, 642-643 (1980). To make these risk findings, the Secretary typically relies upon mathematical techniques for quantifying the risk posed by the particular substance. See International Union, UAW v. Pendergrass, 878 F.2d 389, 392 (D.C. Cir. 1989) ("OSHA necessarily seeks to quantify the risk posed by each toxic threat").

To withstand judicial scrutiny, OSHA's quantitative risk assessments and feasibility findings must be carefully performed and throughly explained in each final rule's preamble. Id. at 395-396 (remanding standard because of unexplained inconsistency in OSHA's risk analysis). Moreover, OSHA must evaluate competing analytical methodologies and explain its rejection of significant contrary evidence and argument. Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1485, citing United Steelworkers of America AFL-CIO- CLC v. Marshall, 647 F.2d 1189, 1206-1207, 1272-1308 (D.C. Cir. 1980) cert. denied 453 U.S. 913 (1981).

Old ETS Risk Assessment Based On Invalid Assumptions

As explained in the background section, the Secretary now has strong indications that the proposed risk and exposure assessments are based on invalid assumptions. There is no longer any basis to believe that ETS exposure conditions in workplaces are, on average, similar to those reflected in studies of residential exposures during the 1980s and early 1990s. In fact, the evidence strongly suggests that ETS exposure levels have declined substantially in workplaces as a result of restrictive smoking policies implemented during the last decade.[4] While it is possible

[4] OSHA is not fully informed as to the breadth and nature of state and local laws restricting smoking, or of policies voluntarily implemented by private employers. According to information current through March, 1999, 45 states restrict smoking in state buildings, and 21 states restrict smoking in private worksites. In addition, 33 states restrict smoking in restaurants.

Weight Of Evidence Now Does Not Support ETS Risk As Assumed

that ETS exposures remain high in some workplaces in some industry sectors, the proposal's central finding that risk estimates based on residential exposures could be expected to accurately reflect occupational risks in most -- or even in many -- workplaces is not supported by the weight of the evidence currently available.

In addition, new risk assessment methodologies may now permit construction of the type of dose-response model that is the basis for most quantitative risk assessments, and for the establishment of permissible exposure levels for many toxic substances. And to conduct an accurate risk assessment, under any methodology, OSHA would have to obtain new data on ETS exposure conditions that would reflect the impact of smoking restrictions implemented in the last decade and would take advantage of modern risk assessment methodologies. See Exposure Assessment Report at 310-311. OSHA's analysis would also have to account for the fact that compliance with a standard may not be feasible in some of the industries where ETS exposure is highest.

Faced with the prospect of having to develop an entirely new record to determine the magnitude of the risk posed by ETS, and the appropriate means of controlling that risk, the Secretary under the prior Administration decided to downgrade the priority of the IAQ proceeding pending completion of other projects. 64 Fed. Reg. 64656. Thus, after concluding the ETS health risk assessment workshop in July, 1998, OSHA focused its resources on projects that could be completed within the Administration's remaining term. By allocating its limited resources in this manner, OSHA completed three major projects by January 19, 2001: a final Ergonomics standard; 65 Fed. Reg. 68261 (Nov. 14, 2000) (resolution of disapproval under the Congressional Review Act (5 U.S.C. 801 et seq.) signed into law on March 20, 2001, P.L.

107-5); a final Steel Erection standard , 66 Fed. Reg. 5317, and a final Recordkeeping rule, 66 Fed. Reg. 5916 (Jan. 19, 2001).

The decision not to accord a high priority to the IAQ rulemaking was rational and well within the zone of discretion granted the Secretary under the OSH Act. This Court has long recognized that section 6(g) of the Act, 29 U.S.C. 655(g), which contains the Secretary's authority to "determine[e] the priority for establishing standards," embodies the discretion not only to set regulatory priorities initially, but also to reorder priorities and defer action at any point during the rulemaking as changing circumstances require. National Congress of Hispanic American Citizens v. Usery, 554 F.2d 1196, 1199 (D.C. Cir. 1977) (OSH Act has built in flexibilities the Secretary may use, including the right to determine whether there will be a standard; to alter and change priorities even though once set; to delay hearings; to process higher priority standards more quickly than initiated ones; and to refuse to adopt any standard even though the rulemaking process has been exhausted).

The Secretary was entitled to consider whether the conclusions reached in the 1997 and 1998 workshops had substantially diminished the prospect of completing any rulemaking based on the 1994 proposal; whether, in light of the sharp decline in ETS levels in workplaces during the 1990s, continued investigation into the need for an ETS standard should be a high priority; and whether limited agency resources could be better used on other projects. The Agency's choice to assign a low priority to regulation of ETS under these circumstances did not violate TRAC's rule of reason. Cf. ASH VI, 100 F.3d at 994 (OSHA decision not to divert resources from other regulatory priorities to complete ETS rule during fiscal 1996 was not unreasonable); In re Barr Laboratories, 930 F.2d at 76 ("The agency is in a unique -- and authoritative --

position to view its projects as a whole, and estimate its resources in the optimal way. Such budget flexibility as Congress has allowed the agency is not for us to hijack.") See also In re Monroe Communications Corp., 840 F.2d 942, 946 (D.C. Cir. 1988) (court must give agencies great latitude in setting their priorities, and collecting additional cases on this point).

The Agency is also acting within its discretion in not making promulgation of a final rule on ETS a high priority at this time, and in considering whether to terminate the rulemaking without issuing a standard. The OSH Act gives the Secretary discretion to refuse to issue a final standard following an initial round of notice and comment on a proposed rule. See 29 U.S.C. 655(b)(4); National Congress of Hispanic American Citizens, 554 F.2d at 1199 (Secretary has right to refuse to adopt any standard after completion of statutory rulemaking process). While no final decision has been reached, the existing record, evaluated in light of the workshops, appears to show that current ETS exposures are much lower than assumed in the proposal, lessening the need for any federal standard, much less one that generally prohibits all smoking in all industries. Critically, there is no longer any basis to assume, as the proposed rule does, that all workers in all workplaces face an elevated health risk equivalent to that found in studies of ETS in homes during the1980s. Therefore, it is reasonable for the Secretary to consider whether to continue to commit the Agency's limited resources to investigating the hazard posed by ETS, with the prospect that a new, scaled-back proposal might be developed, or whether those resources could be better used to address other, more immediate safety and health problems.

Current ETS Exposures Are Lower Than Assumed, No Longer Any Basis To Assume All Workers Face elevated Health Risks

Whether OSHA ultimately decides to proceed toward termination of the rulemaking, or toward further fact-finding on ETS's hazards under current exposure conditions, no final decision can be reached within 90 days. As a threshold matter, the Secretary needs time to

determine, with the assistance of the new Assistant Secretary for Occupational Safety and Health, what the Agency's regulatory priorities should be in light of the safety and health threats now facing workers. Only after evaluation of competing claims on the Agency's limited resources can the Secretary decide the future of this rulemaking. National Congress of Hispanic American Citizens, 554 F.2d at 1199 (great demand for standards from working groups in hundreds of occupations and agency's limited resources necessitate stringent priority choices).

After prioritization of the rulemaking, additional work will be necessary to conclude it, with or without a final standard. A decision that a final rule regulating ETS should not be issued will still require further analysis of the available data and preparation of a Federal Register document explaining the reasons for this action. 5 U.S.C. 553(c). To promulgate a final rule regulating ETS, OSHA would have to develop a new proposal based on an assessment of the health risks existing under current exposure conditions in workplaces, provide notice and opportunity for comment, and formulate a final standard based on the new record -- that is, OSHA would essentially have to begin a complicated rulemaking anew.

2. Consideration of the remaining TRAC factors also supports OSHA's position. The second TRAC factor requires that the reasonableness of any delay must be judged in the context of the statute which authorizes the agency's action. We have explained that the OSH Act preserves the traditional agency discretion to alter priorities and defer action in the face of limited resources. Indeed, Congress explicitly recognized that the myriad hazards existing in workplaces would force the Secretary to make difficult choices as to which hazards to regulate and the order in which those hazards would be addressed. 29 U.S.C. 655(g). These considerations informed

the prior Administration's decision to defer action on the ETS rulemaking, and will guide the Secretary as she determines the future of the rulemaking in the present Administration.

The third and fifth elements of the TRAC analysis provide for differentiation between cases involving purely economic regulation and those in which human health and welfare are at stake, and for consideration of the nature and extent of interests prejudiced by delay. There is no question that the regulation of ETS involves human health and welfare and that delay in promulgating a standard bears on those interests. However, this factor alone cannot be considered dispositive because OSHA's entire docket is addressed to health and welfare issues. Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987). Judicial intervention to force agency action on ETS would limit the Secretary's ability to set priorities reflecting her expert judgment on the full range of safety and health matters before the Agency. ASH VI, 100 F.3d at 994. See also In re Barr Laboratories, 930 F.2d at 75 ("Agency officials not working on Barr's matters have presumably not just been twiddling their thumbs.")

The arguments raised by ASH in its mandamus petition do not support a contrary view. ASH's primary contention appears to be that the analysis set forth in the proposed rule conclusively establishes the need for a regulation banning or severely restricting smoking in all indoor workplaces, and that such a standard could be issued within a few months. See ASH Petition at 8-9, 14. But the proposed rule is just that -- a proposal -- and its preliminary conclusions are always subject to revision in light of newer data. Here, as we have explained above, the proposed rule appears to be based upon outdated information and methodology and its risk estimates are not supported by the weight of evidence now available. OSHA does not believe that over 74 million nonsmoking workers are exposed to ETS at work at levels equivalent

to those faced by a nonsmoking spouse of a smoker at home. See 59 Fed. Reg. 15995, 16001; ASH Petition at 16. Nor does OSHA believe that issuance of an ETS rule would prevent between 2,234 and 13,723 excess deaths annually, or anything like those numbers. See 59 Fed. Reg. 16001; ASH Petition at 14. Health risks arising from ETS exposure are likely to be concentrated in certain jobs and industries, as suggested by the ETS Exposure Assessment Report. Exposure Assessment Report at p. 310. This potential hazard is not, as ASH's Petition suggests, so egregious as to demand instant action, especially to the exclusion of all other safety and health matters before the Agency.

ETS Health Risks Are Not So Egregious As To Demand Instant OSHA Action

ASH is also wrong in suggesting that with judicial intervention, OSHA could resolve any remaining problems quickly and issue a final rule. ASH points to the ergonomics rulemaking as an example of the agency's ability to resolve complex matters quickly, and argues that OSHA could complete the rulemaking "relatively easily" if ETS were addressed separately from other indoor air contaminants. ASH Petition at 14. We demonstrate in the following section that ASH's challenge to the omnibus nature of the rulemaking does not raise a justiciable issue. Moreover, as discussed earlier, addressing ETS in a separate proceeding would not enable the Agency to shortcut the additional procedural steps, outlined above, that would be necessary to produce a legally sustainable final rule. Indeed, the ergonomics example counsels against, rather than for, judicial intervention. OSHA received substantial criticism for issuing that rule too quickly, thereby depriving interested parties an adequate opportunity to comment, and the Agency adequate time to evaluate the issues. Complaints about OSHA's rush-to-judgement were also a major factor in Congress's disapproval of the ergonomics rule under the Congressional Review Act. See e.g., 147 Cong. Rec. S1839 (March 6, 2001) (remarks of Senator Enzi).

Clearly this Court should not direct OSHA to complete another massive regulatory project with similar haste.

B. ASH's challenge to the omnibus nature of the rulemaking is not justiciable

In three previous rulings, this Court has rejected ASH's claim that OSHA has unreasonably delayed the rulemaking and violated the Cancer Policy by including ETS together with other indoor air contaminants in an omnibus proposed indoor air quality proceeding. ASH Petition at pp. 16-18. This Court has repeatedly held that the omnibus nature of the proposed IAQ rule is non-final and non-reviewable. See ASH IV, 28 F.3d at 165; ASH V, (unpublished order dated Nov. 22, 1994); ASH VI, 100 F.3d at 995. These prior rulings plainly foreclose ASH's argument here. ASH VI, 100 F.3d at 995 ("ASH's point raises a policy question for the agency, not the courts.")

CONCLUSION

Neither the OSH Act nor the Cancer Policy prescribes a mandatory timetable for completion of this rulemaking. To the contrary, as this Court recognized in ASH VI, the statute gives the Secretary broad discretion to make difficult priority choices among the competing demands on limited agency resources, and to adapt to changing circumstances affecting the need for standards. The Secretary has acted within that discretion in acknowledging that changed circumstances have impeded the agency's ability to complete the rulemaking, and may now call for termination of the proceeding. ASH has provided no basis whatsoever to question the Secretary's assessment. Accordingly, the petition should be denied.

Respectfully submitted.

HOWARD M. RADZELY
Acting Solicitor of Labor

JOSEPH M. WOODWARD
Associate Solicitor for
Occupational Safety and Health

ANN ROSENTHAL
Counsel for Appellate Litigation

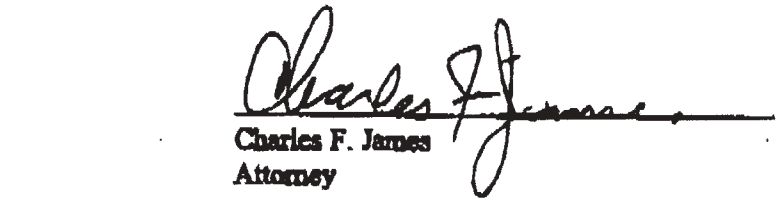
CHARLES JAMES
Attorney

U.S. Department of Labor
Office of the Solicitor
200 Constitution Avenue, N.W.
Washington, D.C. 20210
(202) 693-5454

CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of August 2001, a copy of the Secretary of Labor's Response to ASH's Petition for a Writ of Mandamus was served by overnight mail upon:

John F. Banzhaf, III
Executive Director and Chief Counsel
Action on Smoking and Health
2013 H Street, N.W.
Washington, D.C. 20006



Charles F. James
Attorney

U.S. Department of Labor
Room S-4004
200 Constitution Avenue, N.W.
Washington, D.C. 20210
(202) 693-5445