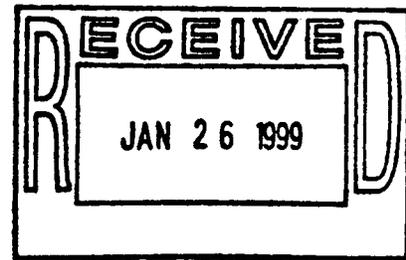




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Regulatory and Trade
Counsellors

January 25, 1999

Dr. Kenneth Olden
Director
National Institute of Environmental Health Sciences/
National Toxicology Program
111 T.W. Alexander Drive
Bldg. 101, B241
Research Triangle Park, NC 27709

Dear Dr. Olden:

Our firm, Multinational Business Services, has been actively involved in the NTP listing process for the *Report on Carcinogens*. In this capacity, we have worked on a number of chemicals and have provided analyses on NTP's adherence to and compliance with federal rules governing the formulation of regulations and related actions. In each instance, we have not addressed the underlying science, *per se*, but we have limited our analyses to procedural deficiencies in NTP's listing activities.

In a number of cases, we have suggested changes to NTP which were adopted and implemented. In other cases, NTP decided not to adopt our recommendations. In both instances, however, we are pleased that NTP gave serious consideration to our views.

Given the expertise of our firm in analyzing the procedural aspects of the listing decision process, Philip Morris Mgt. Corp. has asked us to review the actions taken on ETS. Again, as indicated above, our analyses will not address the underlying science.

The Multinational Companies

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We have found a number of deficiencies in the process and procedure related to the ETS proposed listing. Although these deficiencies are fully addressed in the enclosed memorandum, at least three shortcomings deserve mention here. These issues are as follows:

1. Failure to give substantive consideration to the International Agency for Research on Cancer (IARC) European Multicenter study of ETS exposure and lung cancer;
2. Substantial reliance on EPA's ETS risk assessment which was vacated by a federal court;
3. Failure to consider important data presented by the public in the oral testimony before the RC Subcommittee on the grounds that the data were unpublished.

1. *Failure to Incorporate the IARC European Multicenter Study of ETS Exposure and Lung Cancer into the NTP Proceeding*

The ETS Background Document does not even mention the IARC study. We assume that this is because it was published after the Background Document was prepared. However, the publication of the IARC European Multicenter study of ETS and lung cancer preceded the RC Subcommittee meeting by a number of months. The fact that the NIEHS presenter only mentioned the IARC study in passing speaks volumes about NTP's selective use of information in the listing process. This deficiency is of particular significance because (1) IARC is a major international research organization and (2) no statistically significant increase in risk was reported for ETS exposure and lung cancer.

2. *Utilization of the Vacated EPA ETS Risk Assessment*

In Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, 4 F. Supp. 2d 435, 466 (M.D.N.C. 1998), the court vacated EPA's risk assessment on ETS. Notwithstanding the foregoing, NTP's ETS Background Document relied heavily on EPA's ETS risk assessment. There is a serious legal question as to whether NTP can place substantial reliance on EPA's risk assessment after it has been vacated by a federal court. The court's order vacating EPA's risk assessment would be rendered meaningless if federal agencies could simply turn around and place substantial reliance on the risk assessment.

3. *Failure to Consider the Results of an Important Unpublished Analysis During a Recent RC Subcommittee Hearing*

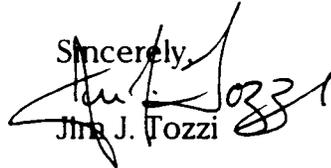
One of the cornerstones of the NTP analysis of ETS is the Wells meta-analysis. In an unprecedented move, the author assigned a zero weight to the Brownson study. The Brownson study is a major study of ETS funded by the National Cancer Institute (NCI) and has been recognized in the peer reviewed literature as an excellent scientific work. Incredibly, the Board of Scientific Counselors refused to consider an analysis of Wells' unreasonable and unsubstantiated treatment of the Brownson study on the grounds that the public commenter had not published his analysis.

Incredibly, three key studies that NTP relied upon in analyzing ETS are of disputed value. The Wells meta-analysis is questionable due to its summary dismissal of the Brownson study; the EPA ETS risk assessment has been vacated by the courts, and the 1986 IARC monograph quoted in the ETS Background Document has been rendered ripe for thorough reevaluation by the 1998 IARC study on ETS.¹

In sum, we conclude that there are very substantial deficiencies in the manner in which NTP conducted its review of ETS. The details of these deficiencies are explained more fully in the attached document. These deficiencies are magnified by the fact that we were not provided with copies of the transcript of the RC Subcommittee meeting until fifty percent of the public comment period had elapsed. Not only is this failing indefensible, but it underscores the fact that these deficiencies are so serious that there is a potential that they will taint the entire NTP process. It is for this reason that we recommend that you: (1) postpone discussion of ETS at the upcoming NTP Executive Committee meeting; (2) make available for public comment your position on the IARC study and its relevance to the current proposal, (3) permit the NTP Executive Committee to review the unpublished data and analyses that were presented by public commenters at the December 2-3, 1998 RC Subcommittee meeting, (4) adequately explain the legal basis for relying upon a risk assessment that has been vacated by a federal court or expunge use of the ETS ETS risk assessment from the record, and (5) revise the ETS Background Document, taking into consideration the foregoing, and seek public comment on the revisions.

I would welcome the opportunity to discuss this issue with you and your staff.

Sincerely,



Jim J. Tozzi

Attachment

¹ The California EPA report on ETS relied on EPA's risk assessment and the 1986 IARC monograph.

Multinational Business Services, Inc.

**UPHOLDING STANDARDS FOR DATA QUALITY IN
REGULATORY DECISION MAKING:**

**Procedural Violations in the National Toxicology Program's
*Report on Carcinogens Program***

January 25, 1999

**Multinational Business Services, Inc.
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Table of Contents

Statement of Interest	1
Introduction	1
I. The NTP <i>Report on Carcinogens</i> Program: Current Process and Statutory Requirements	2
Importance of the NTP <i>Report on Carcinogens</i> Program	2
Current Steps in the NTP <i>Report on Carcinogens</i> Program	3
Administrative Procedure Act Requirements and Public Policy Mandating Opportunity for Public Notice and Comment in Federal Agency Rulemaking	6
NTP Listing of Substances in the <i>Report on Carcinogens</i> as Rulemaking	7
Applicability of the Federal Advisory Committee Act to the NTP <i>Report on Carcinogens</i> Program	8
II. The NTP <i>Report on Carcinogens</i> Process in Action: A Success and a Disappointment	10
Boot and Shoe Manufacturing: A Procedural Success Story	10
ETS: Identified Procedural Flaws	11
FACA Shortcomings in the Current NTP Process for ETS	12
Inadequate Consideration of the IARC European Multicenter Study of ETS and Lung Cancer	13
Inconsistent Treatment of Unpublished ETS Data in the NTP <i>Report on Carcinogens</i> Process	14
Analysis of Dr. Paul S. Levy	15
Potential Consequences of Inadequate Review of Data	16

Multinational Business Services, Inc.

Use of Disparate Standard for Review of Epidemiological Studies Across Substances: Different Treatment for Diesel Exhaust Particulates and ETS	17
Consequences of NTP Reliance on EPA's 1992 ETS Risk Assessment which has been Vacated by the Courts	18
Conclusions Regarding ETS	18
Recommendations for ETS Process	19

UPHOLDING STANDARDS FOR DATA QUALITY IN REGULATORY DECISION MAKING:

Procedural Violations in the National Toxicology Program's *Report on Carcinogens* Program

Statement of Interest

Multinational Business Services, Inc. submits the following paper based upon its concerns about procedural irregularities in the National Toxicology Program's *Report on Carcinogens* process, specifically as regards the proposed listing of environmental tobacco smoke (ETS) in the *Ninth Report*. The paper will outline these procedural problems and recommend steps for their correction.

Multinational Business Services (MBS) is an international regulatory consulting firm representing clients in the public and private sectors. We have worked with a number of federal agencies on scientific policy issues related to risk assessment and risk management. In that our firm specializes in regulatory procedures which govern the development of federal rules and related actions, Philip Morris Mgt. Corp. has asked us to examine the proposed ETS listing from that vantage point.

MBS has worked with NTP on a number of potential listing/delisting decisions in the past. We understand the constraints under which NTP operates, and we look forward to continuing our cooperative work efforts.

Introduction

As both a producer of scientific research and a regulatory entity, the federal government has a duty and responsibility to ensure that the scientific data it creates and utilizes are sound in terms of quality, objectivity, utility, and integrity. One key element of ensuring data quality involves allowing the interested public opportunity for notice and comment on proposed federal regulatory actions. Public participation increases confidence in scientific/regulatory conclusions by expanding the number of parties reviewing the information in question. Public involvement also advances important policy goals such as government transparency and public right-to-know principles. Congress has signaled its approval of public involvement in the regulatory process by making strong provisions for public access to information through the Freedom of Information Act (FOIA) and the Federal Advisory Committee Act (FACA).

When the above principles are followed, the public is more assured of rational regulations based upon sound scientific understanding. When federal agencies deviate from such principles, public confidence in the regulatory process can be shaken and unintended consequences may result. *Unfortunately, the most recent actions of the National Toxicology Program (NTP) in its review of environmental tobacco smoke (ETS) for potential listing in the Ninth Report on Carcinogens seem to have violated the spirit, if not the letter, of the FOIA and FACA statutes, thereby seriously compromising the public's ability to provide meaningful comment on ETS.*

The following discussion demonstrates that while the NTP's procedures are designed to provide meaningful public involvement in the preparation of the *Report on Carcinogens*, in the case of environmental tobacco smoke, procedural violations are likely to preclude a fair review of the ETS listing proposal. Therefore, NTP should adopt the recommendations laid out in this paper to remedy these procedural defects for ETS and, in so doing, strengthen the overall NTP process.

I. The NTP *Report on Carcinogens* Program: Current Process and Statutory Requirements

The *Report on Carcinogens* is statutorily mandated by section 301(b)(4) of the Public Health Services Act, as amended. The *Report* states that it is intended for informational purposes only and, ostensibly, it is not intended as a regulatory document or to impose limitations on the production or release of any substance, or on human exposures to those substances. Initially an annual publication, the Report is now published biennially. The *Eighth Edition* was published in 1998, and the *Ninth Edition* will be finalized later this year and published in 2000.

Importance of the NTP Report on Carcinogens Program

The NTP *Report on Carcinogens* Program is charged with the important task of conducting hazard identification activities for various substances to which Americans may be exposed. Hazard identification is the first step in the risk assessment process and focuses strictly on the potential *hazard* of a substance in the technical sense, i.e., irrespective of considerations of *exposure*. The workproduct generated by NTP may be used by other federal agencies such as EPA and OSHA, which issue regulations affecting human exposures to the substances. Thus, the scientific determinations NTP makes are of considerable consequence to both the public and industry.

Current Steps in the NTP Report on Carcinogens Process

As stated in the *Eighth Report on Carcinogens*, "Continuing opportunities for public comment and participation are also an integral part of the process."¹ The following discussion lays out the steps in the process to prepare the *Report on Carcinogens*, which involves multiple levels of review of both the substances being considered for listing or delisting as well as the draft *Report* prior to publication.

(1) NIEHS/NTP Report on Carcinogens Review Committee (RG1)

The first group to review a nomination for listing or delisting in the *Report*, the RG1 Committee, is composed of in-house NIEHS/NTP scientists and serves an initial screening function. NTP issues an announcement of a proposed listing and a request for comments in the *Federal Register*. At this point, NTP publishes the proposed listings without any accompanying rationale provided for the candidate substances/processes. (This limits the quality of the first round of public comment to a certain degree.) This committee then reviews the original petition and all comments received to determine whether the petition merits further consideration.

If so, RG1 commissions the agency to conduct an independent literature search and the preparation of a Background Document on the substance. This group ultimately votes on a recommendation for the listing of the substance in question.

-- It should be noted that the RG1 Committee's meetings and deliberations are not open to the public. No meeting minutes are made available to the public, and there is no opportunity for the public to comment at meetings of the RG1 Committee.

(2) Working Group for the Report on Carcinogens

The Working Group for the *Report on Carcinogens* (RG2) is a Subcommittee of the NTP Executive Committee and undertakes its own review of the evidence, taking into account the recommendations from RG1.

-- RG2, like RG1, is composed exclusively of government officials.

-- There is no separate solicitation of public comments before the meeting of the RG2 Committee.

¹ *Eighth Report on Carcinogens*, p. 3.

- Again, it should be noted that the RG2 Committee's meetings and deliberations, like those of RG1, are not open to the public. No meeting minutes are made available to the public, and there is no opportunity for public comment at the RG2 Committee meetings.

(3) Report on Carcinogens Subcommittee of the NTP Board of Scientific Counselors

The RC Subcommittee provides the sole external peer review during the listing and delisting process. Public notices on the substances about to undergo review by the RC Subcommittee are printed in the *Federal Register*, and a request for public comment is made at that time.

- Because the panel includes non-governmental employees, the RC Subcommittee meetings are open to the public, as required by the Federal Advisory Committee Act (FACA). The public is also given an opportunity to make brief presentations on substances undergoing consideration prior to the vote on the Subcommittee's recommendation.
- Public comment on the substances is again solicited in the *Federal Register* after the RC Subcommittee meeting. In contrast to the first call for public comments, the public has an opportunity at this point to evaluate both the NTP's rationale for the proposed listing and a full summary of the scientific literature. The comments at this point are significantly more informed, meaningful, and important.

(4) NTP Executive Committee

The NTP Executive Committee², which is composed of senior federal officials or their alternates from a number of agencies, then reviews the independent recommendations of the RG1, RG2, and RC Subcommittee, as well as all public comments. The NTP Executive Committee then makes its own recommendation for listing/delisting of substances to the NTP Director.

² Agencies represented on the NTP Executive Committee include: the Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Products Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), Department of Health and Human Services (DHHS), National Institute of Health (NIH), National Cancer Institute (NCI), National Library of Medicine (NLM), and National Institute of Environmental Health Sciences/NTP (NIEHS/NTP).

- Again, it should be noted that the NTP Executive Committee's meetings and deliberations are not open to the public. No meeting minutes are made available to the public, and there is no opportunity for public comment at NTP Executive Committee meetings.

(5) NTP Director

The Director of NTP reviews the recommendations of RG1, RG2, the RC Subcommittee, and the NTP Executive Committee and makes the final working decision regarding the proposed listing or delisting. The Director then submits the *Report on Carcinogens* to the Secretary of HHS.

- The deliberations of the NTP Director are not open to the public.

(6) Secretary, Department of Health and Human Services (HHS)

The Secretary of HHS has the final opportunity to review the *Report on Carcinogens*. Once the Secretary approves the new *Report*, it is submitted to Congress, and the substances newly listed or delisted are published in the *Federal Register*, along with those listed in previous editions.

Thus, consideration of the Report on Carcinogens process reveals the key role of the Report on Carcinogens Subcommittee of the NTP Board of Scientific Counselors, as the only step in the process which provides an opportunity for public notice and comment on the candidate substances after a government body has reviewed and voted on a proposed listing. The RC Subcommittee is the primary vehicle for direct public involvement and the only opportunity for the public actually to meet the decision makers. It is, therefore, crucial that the opportunity for public involvement at this juncture be meaningful.

The most recent meeting of the RC Subcommittee was held on December 2-3, 1998 at the NIEHS/NTP facility in Research Triangle Park, North Carolina. At that time, a number of substances were considered for inclusion in the *Ninth Report on Carcinogens*.³ However, for at least one of those substances – environmental tobacco smoke (ETS) – procedural irregularities have threatened the effectiveness of the public's ability to comment, as discussed below. Steps should therefore be taken immediately to remedy this situation in order to maintain the integrity of the NTP *Report on Carcinogens* process.

³ The following substances and/or processes were considered at the December 2-3 meeting: alcoholic beverage consumption, boot and shoe manufacture and repair, diesel exhaust particulates, environmental tobacco smoke, ethyl acrylate, ethylene oxide, isoprene, methyl-t-butyl ether, nickel and nickel compounds, nickel refining, crystalline silica, and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).

Administrative Procedure Act Requirements and Public Policy Mandating Opportunity for Public Notice and Comment in Federal Agency Rulemaking

Where federal agencies engage in rulemaking, the Administrative Procedure Act assures the public a right to notice and comment. Under the APA, general notices of proposed rulemaking must be published in the *Federal Register*, and the agency must:

give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments. . . .

5 U.S.C. § 553(c). In the case of substantive rules, the required publication generally must be made not less than 30 days before the rule's effective date. *Id.*, § 553.

The rulemaking provisions of the APA were designed to promote fairness and mature consideration of agency rules of general application. The public policy behind the notice and comment procedure is both to allow the agency to benefit from the experience and input of the parties who file comments and to assure that agencies maintain an open-minded attitude toward their own rules. Chocolate Mfrs.' Ass'n of U.S. v. Block, 755 F.2d 1098 (4th Cir. 1985). Public comments ensure that the agency is provided the broadest possible base of information by those most interested, and perhaps best informed, on the subject of the rulemaking at hand. Brown Exp., Inc. v. United States, 607 F.2d 695 (5th Cir. 1979). A fundamental reason for receiving public comments is to allow for adversarial debate among the parties. An agency cannot function properly without the benefit of such comments *before* making a final decision. American Lithotripsy Soc. V. Sullivan, 785 F. Supp. 1034 (D.D.C. 1992). The requirements of the above sections of the APA are fundamental to due process. Bell Lines, Inc. v. United States, 263 F. Supp. 40 (D.W.Va. 1967).

A balanced review of the available evidence is also expected as part of government's regulatory action. Although it is appropriate for an agency decision-making body to rely on summaries of the administrative record prepared by agency staff, if those summaries are severely skewed so as to distort the record, the agency decisionmaker may breach its "statutory duty to accord 'consideration' to relevant comments submitted for the record by interested parties. Certainly, if subordinates systematically eliminated from their reports all mention of record comments adverse to the agency's final action, the consideration requirement would not be satisfied unless the decisionmakers took independent steps to familiarize themselves with withheld portions of the record." National Small Shipment Traffic Conference, Inc. v. Interstate Commerce Commission, 725 F.2d 1442, 1451 (1984). All parties to a rule-making proceeding have a legal right to have their comments, at least in summary form, considered by the agency decision-making body before it takes final action. *Id.*

Likewise, identification and availability of technical studies and data employed by an agency in deciding to propose a particular rule are integral to the APA's notice requirement. "An agency commits serious procedural error when it fails to reveal portions of the technical basis for

a proposed rule *in time to allow for meaningful commentary.*" Solite Corp. v. U.S. E.P.A., 952 F.2d 473 (D.C. Cir. 1991) (quoting Connecticut Light and Power Co. v. NRC, 673 F.2d 525, 530-31 (D.C. Cir.), *cert. denied*, 459 U.S. 835 (1982)) (emphasis added). It is clear that the public must be provided opportunity to comment on information relevant to an agency's decision in a rulemaking *before* the final rule is published. American Lithotripsy Soc. v. Sullivan, 783 F. Supp. 1034 (D.D.C. 1992).

NTP Listing of Substances in the Report on Carcinogens as Rulemaking

The courts have determined that the *Report on Carcinogens* process constitutes a rulemaking that is judicially reviewable under the Administrative Procedures Act. In Synthetic Organic Chem. Mfrs. Ass'n v. Secretary, DHHS, 720 F. Supp. 1244, 1249 (W.D. La. 1989) chemical manufacturers and sellers sought an injunction to prevent publication of an earlier edition of the *Report*. In concluding that the matter was judicially reviewable under the APA, the court held that the listing criteria stated in the *Report* constitute an agency "rule." The SOCMA court also held, moreover, that publication of the *Report* is an "agency action" even though the *Report* is informational and imposes no direct sanctions or obligations. *Id.*⁴ Finally, the court held that the agency's decision to list a given substance in the *Report* is not committed to agency discretion by law, and that Congress had therefore given the courts authority to review HHS action with respect to the *Report on Carcinogens* program. *Id.* at 1250.

The SOCMA case stands for the proposition that, where NTP has violated the terms of its own approved procedures, by, for example, foreclosing meaningful public comment where the rules provide for such comment, then the courts may intervene to correct the agency's procedural violation. The court in SOCMA specifically held that the proceedings of the NTP *Report on Carcinogens* program constitute a "rulemaking" for purposes of the APA. The provisions of the APA quoted above, thus, apply directly to the NTP proceedings which culminate in publication of the *Report*.

The SOCMA holding that NTP publication of the *Report* is an "agency action" also implies that a failure by NTP to comply with notice and comment provisions of the APA is judicially reviewable on that basis. Parties adversely affected by the action of federal agencies may, in certain situations, apply to federal courts for relief. The Administrative Procedure Act provides, in relevant part:

⁴ SOCMA, decided in 1979, clearly stands for the principle that NTP's classification of agents, substances, and mixtures as carcinogens and the subsequent publication of these classifications in the *Report on Carcinogens* constitute final agency action subject to judicial review under the APA. Recent Supreme Court cases addressing similar actions by other agencies support SOCMA's conclusions of reviewability.

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

5 U.S.C. § 702. (Emphasis added.)

In addition, agency action made reviewable by statute and final “agency action” for which there is no other adequate remedy in a court are subject to judicial review. *Id.*, § 704. A reviewing court under the APA may set aside agency action, findings or conclusions which the court determines are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(a).

Applicability of the Federal Advisory Committee Act to the NTP Report on Carcinogens Program

The Federal Advisory Committee Act (FACA) was enacted in response to an increasing practice among federal agencies to rely on non-governmental boards, commissions, councils, and similar groups to advise the agencies on diverse matters requiring scientific and other expertise or diversity of opinion. FACA places restrictions on the creation, scope, and operation of these “advisory committees” and attempts to assure that the workings of these bodies are open to public review and participation.

Only certain proceedings of the NTP *Report on Carcinogens* program fall under FACA, but the RC Subcommittee meetings are clearly covered. FACA defines “advisory committee” broadly to include “any committee, board, commission, council, conference, panel, task force, or other similar group” that is either established by statute or reorganization plan or is “utilized” by the President or an agency. 5 U.S.C. § 3(2). The definition excludes committees made up entirely of full-time federal employees, however. *Id.* Thus, although the deliberative processes and records of the RG1, the RG2, and the Executive Committee are exempt from the requirements of FACA because the committees at issue are composed solely of federal officials, the RC Subcommittee proceedings are not so exempt.

The NTP Board of Scientific Counselors, which is made up of outside scientific and technical experts, *is* a FACA committee, and is listed as an “Active Federal Advisory Committee” on the Website of the Office of Governmentwide Policy Committee Management Secretariat. Therefore, the *Report on Carcinogens* Subcommittee of the Board of Scientific Counselors is also subject to the requirements of FACA and its public participation provisions.

Thus, the RC Subcommittee, through NTP, must make certain materials available to the public under FACA (outlined below). Such materials are highly important to the public comment process, since many interested parties lack the time and/or resources to attend all committee meetings in person.

Specifically, the Act requires:

§ 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

.....

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of the matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

5 U.S.C. App. §10 (b), (c). Significantly, these sections require, for example, that the slides, written comments, review notes, and other working papers of the primary and secondary reviewers of the RC Subcommittee, as well as the minutes from the December 2-3 meeting, be made available to the public.

§ 11. Availability of transcripts; "agency proceeding"

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

5 U.S.C. App. §11 (a). The public, therefore, has a right to timely copies of the transcripts of the December 2-3 meeting of the RC Subcommittee.

Like violations of the APA, an agency's violation of FACA is judicially reviewable. See, e.g., Public Citizen v. United States Dept. of Justice, 491 U.S. 440 (1989). In order to have standing to sue under FACA, a plaintiff need only show that he or she has sought and was denied access to specific agency records available under the statute. Id. at 450.

II. The NTP *Report on Carcinogens* Process in Action: A Success and a Disappointment

Although the *Report on Carcinogens* program, like many federal activities, should be constantly reevaluating itself to make refinements which better its ability to achieve its mission and to involve the public, the program is essentially sound. In some cases, such as the recent review of boot and shoe manufacture and repair, NTP officials have responded to public comments critical of proposed listings and adopted appropriate procedural mechanisms and conclusions consistent with the limited universe of available data.

However, a number of procedural irregularities and abuses have occurred with respect to the review of another substance at the meeting – environmental tobacco smoke. This section will offer a case study of the treatment of these two different substances at the December 2-3, 1998 meeting of the NTP Board of Scientific Counselors.

Boot and Shoe Manufacturing: A Procedural Success Story

The procedural record of one recent NTP proposed listing indicates that, if given an opportunity to work correctly, the notice and comment safeguards in the NTP process can result in a scientifically supportable outcome. On February 3, 1998, NTP published a notice in the *Federal Register* requesting comments on whether it is appropriate to list boot and shoe manufacture and repair (or any other “exposure circumstances”) in the *Ninth Report*.

On March 16, 1998, comments on this proposed listing were filed on behalf of Footwear Industries of America, Inc. (“FIA”). FIA submitted two documents, one addressing the legality of listing boot and shoe manufacture and repair (or any other “exposure circumstances”) in the *Report on Carcinogens*, and the other addressing the scientific inadequacy of the data upon which NTP was relying. FIA stated, as a legal matter, that NTP was exceeding its statutory authority by attempting to list an “exposure circumstance,” rather than a “substance” as directed by the Public Health Service Act, as amended. From a scientific standpoint, FIA charged, the proposed listing was unsupported because:

- There is no evidence associating cancer with modern U.S. footwear manufacturing;
- The two IARC reports NTP was relying upon were 15 and 16 years old and did not reflect modern manufacturing practices; and
- NTP accepted IARC’s conclusions without conducting its own independent review of their findings.

NTP received the comments from FIA and proceeded to conduct its review. The first review group, RG1, recommended (five yes votes to one no vote) that boot and shoe manufacture and repair in the United States be included in the *Ninth Report* as having been formally reviewed but not formally listed due to inadequate data. The RG2 reached exactly the same conclusion by a vote of six to one.

As the NTP transcript shows, the RC Subcommittee struggled with the boot and shoe manufacturing and repair issue. There was general dissatisfaction with the relevant Background Document. While identified studies from the U.S. were often old (and hence potentially not representative of current manufacturing processes in the U.S.) and of poor quality, there was nevertheless little data demonstrating the current state of the industry and showing that the concerns of the earlier studies were no longer relevant (e.g. lack of exposure assessment information). Therefore, instead of opting for a categorization of “reviewed, but not listed due to inadequate data” (see NTP transcript p. 538), the RC Subcommittee opted instead to leave the *status quo* in place and unanimously recommended that action on the nomination of the boot and shoe manufacturing and repair process be deferred (see NTP transcript pp. 555-57). This deferral was subsequently noticed in the *Federal Register* at 63 *Fed. Reg.* 68783 (Dec. 14, 1998).

ETS: Identified Procedural Flaws

As noted at p. 2 above, a number of procedural problems associated with NTP’s review of ETS have been identified during and since the time of the December 2-3, 1998 meeting of the RC Subcommittee of the NTP Board of Scientific Counselors. These problems threaten to undermine the integrity of the scientific process and to jeopardize opportunity for meaningful public comment on the substances currently being considered by NTP. Generally, these problems include:

- Violations of FACA requirements for making materials available to the public (e.g. meeting transcripts, presenter slides, etc.) in a timely fashion.
- As with boot and shoe manufacture and repair, an acceptance of third party conclusions without independent analysis.
- Reliance by NTP upon the 1992 EPA ETS risk assessment which has been vacated by the courts.
- Failure by NTP to address certain key ETS studies as part of its Background Document, which prevented proper consideration by the RC Subcommittee.
- Inconsistent use of unpublished data in the RC Subcommittee decision making process without adequate opportunity for public comment or consideration by the Subcommittee.

- Use of inconsistent standards in assessing the science of various substances under review.

Each of these procedural deficiencies will be discussed in further detail below.

FACA Shortcomings in the Current NTP Process for ETS

Although the FACA statute does not spell out how quickly an agency must make advisory committee materials and transcripts available, the spirit of the statute clearly anticipates that this information would be provided to the public prior to an agency's undertaking additional, significant regulatory action based upon the substance of such meetings. In the present case, it should be noted that the transcripts of the December 2-3, 1998 meeting of the RC Subcommittee of the NTP Board of Scientific Counselors were only made available to the public on or about January 13, 1999. Likewise, copies of the transparencies used by the NIEHS staff presenters in summarizing the data in the various Background Documents, the written comments of the Subcommittee's Primary and Secondary Reviewers, and copies of transparencies used by other public commenters at the meeting were similarly delayed in their availability to the public.

While in other circumstances such delay might be of little consequence, unfortunately, NTP initiated a 60-day public comment period which is set to expire on or about February 12, 1999 (63 *Fed. Reg.* 68783, December 14, 1998). That clock has continued to tick, even though the important materials described above were not available until very recently.

All these materials discussed above must be made publicly available under FACA. In particular, the public's ability to adequately review and comment upon the presentation slides and other materials offered by Mr. J.L. Repace at the December 2-3 meeting is crucial to the ongoing ETS listing review process. This is so because Mr. Repace's public comment presentation seemed to carry considerable weight with the RC Subcommittee and influenced its decision. *Again, because active involvement of these agency and public presenters seemed to play such a key role in the Committee's decision processes, an adequate opportunity to examine these materials is crucial to the public's ability to provide meaningful comments on the substances under consideration.*

Delaying the public availability of these key materials until January 13th has deprived the public of a full and adequate opportunity to comment on the substances under consideration. This situation leaves the public with less than one month -- less than half of the comment period -- to review and comment on all materials relevant to the substances enumerated in the *Federal Register* notice. This is a serious defect in the NTP process which should be remedied through extension of the public comment period. Such extension of the notice and comment process would ensure that the public has adequate opportunity to review the relevant materials and provide meaningful input before the NTP Executive Committee takes action on the ETS issue.

Inadequate Consideration of the IARC European Multicenter Study of ETS Exposure and Lung Cancer

Another procedural flaw in the NTP *Report on Carcinogens* process regarding ETS involves the failure of the agency to consider a key recent ETS study produced by a leading international health research organization as part of the ETS Background Document. Specifically, the World Health Organization's International Agency for Research on Cancer (IARC) has recently published the results of a major study of ETS exposure and lung cancer in Europe (reported in the *Journal of the National Cancer Institute*, Vol. 90, No. 19, October 7, 1998). The IARC study – the largest epidemiological study on ETS exposure and lung cancer risk ever conducted in Europe – involved 12 centers in 7 countries over a period of 6 years. As the ETS portion of the NTP transcript of the December 2-3 RC Subcommittee meeting makes clear, this key IARC European Multicenter Study was published subsequent to consideration of ETS by the RG1 and RG2 Committees. (See NTP transcript, p. 178.)

The IARC study reported an odds ratio of 1.16 for reported ever-exposure to spousal ETS (95% CI = 0.93-1.44) and an odds ratio of 1.17 for reported ever-exposure to workplace ETS (95% CI = 0.94-1.45), neither of which was statistically significant. More important than the lack of statistical significance, however, was the publication's detailed analysis of potential systematic biases. Virtually all of the quantitative estimates of these biases would have resulted in a decrease in the odds ratios. However, none of these were used to adjust the reported values. The authors also reported no association between childhood exposure to ETS and lung cancer, and considered that there was no meaningful association between exposure to ETS and lung cancer in social situations or in vehicles.

The results of the IARC European multicenter study are clearly important for consideration of listing ETS in the *Report on Carcinogens* because the study: (1) was large, (2) was conducted by a major international research organization, (3) is perhaps the first publication on ETS that is sufficiently transparent to allow reasonable estimates for many biasing factors to be made, (4) produced results at variance with many researchers' expectations, in that it failed to report a statistically significant association between ETS and lung cancer, and (5) provided data that are not included in the NTP Background Document on ETS.

Again, although mention of a 1986 IARC monograph was made, no reference was made to the IARC study in the ETS Background Document, and the RG1 and RG2 Committees did not consider the IARC study in making their recommendations on ETS. Also, the point at which the RC Subcommittee became aware of the IARC study is unclear; while the study was mentioned at the December 2-3 meeting, if this was the first time the members had considered the IARC findings, such last-minute consideration of an important study is procedurally inadequate.

In light of the above, NTP should address the findings of IARC's European multicenter study in writing and carefully consider such findings in a revision of the Background Document before taking any further action on the proposed ETS listing.

Inconsistent Treatment of Unpublished ETS Data in the NTP Report on Carcinogens Process

Appendix C (Report on Carcinogens Listing/Delisting Procedures) of the *Eighth Report on Carcinogens* states, "Data used in the preparation of Section 3 through 6 of the draft document [Background Document] must come from publicly available, peer reviewed sources." Still, nothing in the *Report* precludes the relevant committees, such as the RC Subcommittee, from reviewing other sources of data, including unpublished data and the unpublished analyses of published data, at public meetings or otherwise. However, if NTP chooses to accept unpublished data as part of its considerations, it should do so in a consistent and even-handed fashion. Treatment of ETS-related information at the December 2-3, 1998 RC Subcommittee meeting demonstrated a *lack* of consistency in the treatment of unpublished data.⁵ Therefore, NTP should articulate and follow uniform procedures for the use of unpublished data and analyses in the agency's decision making processes.

NTP has failed to clarify its stance on the use of unpublished data and analyses, as reflected in the comments of Dr. Frank Mirer, one of the members of the RC Subcommittee, at the December 2-3 meeting. Dr. Mirer stated his opinion that the RC Subcommittee should not evaluate the unpublished ETS data presented during the public meeting. Consider the following statement of Dr. Mirer:

... I don't see how we can take into account unpublished data that is presented here at the last minute without – I mean, it is true we have had copies in advance, but it is simply not possible to evaluate that kind of data in the face of a proceeding of this magnitude and rapidity.

Now, in particular we had two presentations that attack the validity of several of the critical – you know, the best of the case-control studies where

⁵ The RC Subcommittee's approach to unpublished data is troubling. While NTP's Listing/Delisting Procedures clearly state that only data from publicly available, peer reviewed sources can be considered in the preparation of the sections on human studies, animal studies, genotoxicity, and mechanisms in the Background Document, there is no stated requirement that public comments consist only of published data. Yet at the RC Subcommittee meeting, although there was discussion that unpublished data should be excluded from consideration, the treatment of unpublished data was inconsistent throughout. While some presenters on ETS were questioned about whether their work had been published, e.g., Butler and Marks (NTP transcript, December 2, 1998, p. 227), others, like Repace, were not. In the public comment period on diesel exhaust particulates, Mauderly presented what he called a "back-of-the-envelope" calculation. No one on the Subcommittee made any reference to this or suggested that it not be considered because it was unpublished (NTP transcript, December 3, 1998, p. 402).

we had data presented criticizing the epidemiologic methods and the like. And I simply think we have to have some rules of the game, as at IARC, that if it is not published, it is – we can't take it into account. We can't take into account things that are presented on this kind of – in this kind of setting at this kind of speed. And that is – I mean, there is a process here and it ought to be followed.

If the people who prepared these reviews think that the studies have been particularly damaged by these presentations, they should tell us so we don't rush into something and we could defer action. But if they are not, I think we have to go forward with what has been published.

(NTP transcript, pp. 238-39)

Such an approach, for example, would result in non-consideration of the Levy analysis (discussed below), regardless of its merits. However, no efforts were made to similarly exclude the unpublished analyses of Butler or Repace. This is clearly unequal treatment.

If NTP chooses to accept such data and analyses in an effort to make more informed listing/delisting decisions, it should do so in an even-handed fashion, not accepting some data based upon its content or outcome and rejecting other data merely because it reached a contradictory result. As to Dr. Mirer's concern that there is not sufficient time to consider all presented materials, expanding the current NTP process is arguably a more rational solution to this problem than summarily excluding a portion of the relevant data and analyses. In addition, the NTP process already contains checks and balances which could handle Dr. Mirer's concerns. Since suitable mechanisms are available to assist in the evaluation of unpublished data submitted in the course of the *Report on Carcinogens* inquiry (i.e. public comment provisions), there is no need to resort to a selective exclusion of unpublished data and analyses based upon content.

Analysis of Dr. Paul S. Levy

Allow us to cite one illustrative example of the importance of unpublished data in the context of the ETS listing debate. Dr. Paul S. Levy, Professor of Epidemiology and Biostatistics at the University of Illinois at Chicago School of Public Health, provided an important public comment presentation at the December 2-3 RC Subcommittee meeting which exposed potentially serious flaws in the Wells meta-analysis relied upon by NTP in its ETS Background Document. Dr. Levy, in his re-analysis of the ETS studies, arrived at meta-analytical findings that were either not statistically significant or just barely so. While unpublished, Dr. Levy's analysis raises fundamental issues which should be addressed by NTP before moving forward with the proposed ETS listing. Consider the following:

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- Dr. Levy examined the Wells ETS meta-analysis and questioned the substantial changes made by Wells to two studies (Janerich 1990 and Reynolds 1996 (Fontham *et al.*)) which were largely responsible for the increased summary odds ratios that differ from prior meta-analyses. This is particularly striking because the Reynolds number was merely taken from a letter to a journal editor.
- Dr. Levy also questioned Wells' use of a fixed effects model rather than a random effects model in conducting his meta-analysis for ETS.
- Wells also assigned essentially a zero weight to several major studies, including the highly regarded Brownson 1992 study for which a workplace odds ratio of 0.98 (95% CI: 0.74 - 1.31) has been calculated.

The Levy analysis is extremely important, in light of the fact that the RC Subcommittee had already been asking itself whether such low relative risks, as in the ETS case, could really have any meaning. Since the relative risks in the Wells analysis are arguably already at the level of statistical background noise, the Levy analysis could seriously undermine the Wells results. Therefore, any policy of NTP which would preclude consideration of such an important analysis, merely based upon the fact that it has yet to be published, is seriously flawed.

Because the Levy analysis runs to the heart of the ETS listing action, NTP scientists should address the points raised by Dr. Levy, and the public should have ample opportunity to examine and respond to the Levy analysis before the ETS issue proceeds to the NTP Executive Committee. In this way, the Executive Committee would have the benefit of this important analysis and all of the views it engenders. Therefore, in the context of the ETS listing proposal, NTP's failure to fully consider the Levy analysis represents a procedural error.

In contrast, another public commenter at the December 2-3, 1998 RC Subcommittee meeting made an assertion that the published ETS data produced by the Oak Ridge and Covance Laboratories did not fit his scientific model. This analysis was unpublished, yet the RC Subcommittee seemed to accept this interpretation and to rely upon it in its deliberations. These examples demonstrate the inconsistent treatment of unpublished data in the *Report on Carcinogens* process.

Potential Consequences of Inadequate Review of Data

An example of such agency error and its potential outcome would be the EPA's 1992 risk assessment on ETS, which a federal court vacated last year. As the court noted in Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, 4 F. Supp. 2d 435, 466 (M.D.N.C. 1998):

In conducting the ETS Risk Assessment, EPA disregarded information and made findings on selective information; did not disseminate significant epidemiologic information; deviated from its Risk Assessment

Guidelines; failed to disclose important findings and reasoning; and left significant questions without answers.

Gathering all relevant information, researching, and disseminating findings were subordinate to EPA's demonstrating ETS a Group A carcinogen.

The finding amplifies the need for federal agencies to give full accord to all relevant scientific data. To disregard the findings of Dr. Levy in their entirety based upon lack of publication, while accepting other submissions of unpublished data, would be to stumble into the same pitfall as EPA did in the above case. NTP should take steps to avoid a similar outcome.

Thus, the importance of having strong and uniform procedures in place for the public to submit unpublished data and analyses cannot be overstated. Public comment would serve as an important quality check on such unpublished data. Therefore, in order for the public to have the ability to cross-review unpublished data, NTP should adhere closely to the letter and spirit of the APA notice and comment procedures discussed above.

Use of Disparate Standard for Review of Epidemiological Studies Across Substances: Different Treatment for Diesel Exhaust Particulates and ETS

Another major procedural inconsistency is different treatment of epidemiological studies in the Background Documents on diesel exhaust particulates and on ETS.

For ETS, three reviews are cited: the IARC 1986 review, the 1992 EPA risk assessment, and the 1997 California EPA risk assessment. However, the only review cited for diesel was the 1989 IARC publication. No mention was made of the 1998 California EPA classification of diesel exhaust as a known human carcinogen. NTP fails to make clear why CalEPA's conclusions are relevant for ETS but not for diesel.

NTP's proposed listing of ETS as a "known human carcinogen" but of diesel exhaust particulates as "reasonably anticipated to be a human carcinogen" seems very inconsistent when the following is considered. A cited meta-analysis for 29 epidemiological studies of diesel exhaust exposure reported a pooled relative risk of 1.33 (95% CI, 1.18-1.51), while EPA's meta-analysis of 11 epidemiological studies on ETS reported a pooled relative risk of 1.19 (90% CI, 1.04-1.35).

The manner in which the recent epidemiological data were summarized in the respective Background Documents also appears likely to have contributed to this inconsistency. For ETS, only four epidemiological studies (three case-control studies and one cohort study) were cited, despite the fact that more than 20 such studies have appeared since the IARC review. For the three case-control studies, the *only* odds ratios cited by NTP Background Documents were those reported at the *highest level of exposure*.

Conversely, for diesel exhaust, 14 studies (8 case-control studies and 6 cohort studies) published after the 1989 IARC review were discussed. In every case the *overall* odds ratio or relative risk was cited. Moreover, for each of the diesel exhaust studies, both strengths and weaknesses of the study were discussed. For ETS, there was no suggestion that these studies suffered from any weaknesses. Consequently, the reader who was not intimately familiar with the data would draw the conclusion that for ETS, odds ratios were considerably higher than they really were and that the cited studies were free from systematic biases such as confounding.

It seems clear that the NTP "rules of the game" should be the same for all substances under review by the agency. This is an issue not only of consistency and scientific integrity, but of fundamental fairness as well.

Consequences of NTP Reliance on EPA's 1992 ETS Risk Assessment which has been Vacated by the Courts

As noted above, the 1992 EPA risk assessment of ETS was vacated by the courts in the Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA decision, due to a number of scientific and procedural problems. However, from both the ETS Background Document and the presentation by NIEHS staff at the December 2-3 RC Subcommittee meeting, it is clear that NTP relied heavily upon the EPA ETS risk assessment in making its recommendations on ETS. NTP's reliance on a document which the courts have found to be so flawed as to necessitate its being set aside is likely to invite legal challenge and possibly raise the ire of the courts.

The *Flue-cured Tobacco* court expressed itself forcefully in its order vacating the EPA ETS risk assessment. More specifically, the court stated, "EPA's study selection ... [was] disturbing ... and ... there ... [was] evidence in the record supporting the accusation that EPA 'cherry picked' its data." Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, 4 F. Supp. 2d 435, 460 (M.D.N.C. 1998). Given the force of this decision, it is unlikely that the court would sanction use of the EPA ETS risk assessment by another agency.

Conclusions Regarding ETS

As the above paper seeks to demonstrate, the NTP *Report on Carcinogens* process constitutes a key scientific determination by the federal government for substances such as ETS. Other federal agencies rely upon the information generated by NTP in their own risk assessment and regulatory processes, and the courts have held that the NTP *Report on Carcinogens* process is agency rulemaking reviewable under the APA.

Thus, it is crucial that the NTP determinations for substances such as ETS be based upon sound science and public input. To achieve these goals, the agency should scrupulously follow the requirements laid out in FACA and the APA and maximize opportunities for public comment. Where procedural defects are identified, as with the review of ETS discussed above, they should be corrected immediately so as to ensure the validity and integrity of the process.

Recommendations for ETS Process

Based upon the requirements of the relevant statutes and the identified procedural defects in the NTP process for ETS, we recommend that NTP take the following actions:

- (1) NTP should extend the comment period for ETS so that the public has a full 60 days to comment after the transcripts of the December 2-3 meeting, the transparencies used by the NIEHS staff presenters, the written comments of the Subcommittee's Primary and Secondary Reviewers, and copies of transparencies used by other public commenters at the meeting are made publicly available. Thus, the comment period should run for 60 days, starting on January 13, 1999.
 - In this way, NTP can meet the requirements of FACA and also foster the goals of transparency and public involvement in the NTP process.

- (2) NTP should issue a notice in the *Federal Register* stating its intention to defer consideration of environmental tobacco smoke by the NTP Executive Committee, based upon the precedent in the boot and shoe manufacture and repair decision.
 - Such deferral would give NTP the opportunity to conduct further analysis of data and information, including the IARC study and the Levy meta-analysis, so that such analysis would be available to the Executive Committee for its consideration. At the same time, the public could provide the agency further comments on these studies and on the transcripts and other materials from the December 2-3 meeting of the RC Subcommittee.

- (3) NTP should adequately explain the legal basis for relying upon a risk assessment that has been vacated by a federal court or expunge use of the EPA ETS risk assessment from the record.

- (4) The ETS Background Document should be revised consistent with the foregoing, and NTP should put the document out for public comment.

- (5) After the NTP Executive Committee acts, a copy of all ETS-related materials available to the Committee at the time of their decision should be produced and made available to the public.

- (6) NTP should examine the requirements of Executive Order 12988 and adopt the substance of its provisions directing agencies to engage in mediation and other forms of dispute resolution short of formal litigation. We believe that adoption of the above stated recommendations for ETS would be consistent with the Executive Order, as a means of avoiding costly judicial review of the identified procedural defects under FACA.

