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Evaluating Public Commentary and Scientific Evidence Submitted in the Development of a Risk Assessment

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Risk assessments form the methodological basis for many public policies. A key component of the risk assessment process is the public commentary period. We conducted a case study of the California environmental tobacco smoke risk assessment to describe the contribution of the commentary to the risk assessment process. We used content analysis to examine the sources, quantity, and quality of public commentary, as well as the agency's response to the commentary. We examined the type and quality of publications cited in the commentary. Most of the comments were from critics of the risk assessment (36/44, 80%), especially tobacco industry affiliates (30/36, 83%). Critics were more likely to evoke the science evaluation criteria of study quality, reliability, and validity than were supporters. More than half the critics argued that appropriate procedures were not followed (13/23, 57%). Of the 29 commentaries on the respiratory, carcinogenic, and cardiovascular chapters, four resulted in changes to the risk assessment, such as the addition of new references or reanalysis of data. Journal articles were the most frequently cited type of reference, cited by critics (1,022/1,526 of references, 67%) and supporters (39/60, 65%). However, journal articles submitted by critics had lower impact factors than those cited by supporters (2.6 vs. 3.6, $p = 0.03$). Participation in the public input process was not balanced among all interested parties, although this may reflect different opportunities for stakeholders to participate in stages of the process. Critics and supporters of the risk assessment used different criteria to evaluate the scientific evidence, suggesting that they were socially constructing the evidence to support their positions.

KEY WORDS: Risk assessment; tobacco smoke pollution; health policy; science evaluation

1. INTRODUCTION

Risk assessment, a scientific process for evaluating the adverse effects of a substance, activity, lifestyle, or natural phenomenon, often forms the methodological basis for public policy regulating environmental hazards, particularly carcinogens.[1] In the United States, the risk assessment process typically involves reviews of the relevant literature by the appropriate government agency, preparation of a draft report, collection of written and oral public commentary, and revision of the report based on that public commentary.[1–3] The opportunity for public comment is open to anyone and there are no restrictions on the type or scope of comments. Public

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participation in the risk assessment process is important for shaping the findings of the final risk assessment, increasing public acceptability of the findings,[2] and preventing the ''capture'' of the risk assessment process by special interest groups.[4] In this article, we describe public commentary on the California risk assessment of environmental tobacco smoke (ETS) by examining the sources, quantity, and quality of the commentary and attached evidence, as well as the agency's response to the commentary.

In 1997 the California EPA (Cal-EPA) published the final report of a risk assessment entitled ''Health Effects of Exposure to Environmental Tobacco Smoke.'' The California risk assessment was the result of a collaborative effort between the Office of Environmental Health Hazard Assessment (OEHHA) and the Air Resources Board (ARB), two of the six constituent organizations of the Cal-EPA. It was written in response to a request by the ARB's Scientific Review Panel, which was created under California law to provide independent peer review of the scientific aspects of the state's toxic air contaminants and air pollution programs.[5]

The Cal-EPA risk assessment was developed over a five-year period, from 1992 to 1997. To provide a comprehensive review of the scientific data on the health effects of ETS, the process included conducting reviews of the scientific literature, public release of the reviews, collection of public comment through workshops and written commentary, scientific peer review by the Scientific Review Panel, and, finally, revision of the document based on this input.[5] OEHHA released draft chapters on each major health effect. Each release was followed by a public comment period lasting between 45 and 60 days. Draft documents were then revised in response to comments received, and updated to include critical new studies. The draft chapters were compiled as a final draft and released for public comment and review by the Scientific Review Panel in April 1997. The final report was released in September 1997 with two appendices that summarized and responded to the comments received during the public comment periods.[5] The Scientific Review Panel endorsed the report and stated that it viewed ''ETS as a toxic air contaminant'' that ''has a major impact on public health.''[5]

The public health importance of the Cal-EPA ETS risk assessment is twofold. In 1992, the U.S. Environmental Protection Agency (EPA) released a risk assessment classifying environmental tobacco smoke (ETS) as a Group A human carcinogen.[6] The California risk assessment was more comprehensive than the U.S. EPA risk assessment of passive smoking because it examined the association of ETS exposure, lung cancer, and respiratory illness, plus cardiovascular, developmental, reproductive, and childhood respiratory effects.[5] The Cal-EPA risk assessment also addressed criticisms brought by the tobacco industry against the U.S. EPA risk assessment. Specifically, the Cal-EPA risk assessment addressed methodological criticisms aimed at the science presented in the U.S. EPA risk assessment and added more recent studies.[5] Second, since the tobacco industry successfully attacked the U.S. EPA risk assessment in court, the Cal-EPA risk assessment has taken on a larger national importance.[7] Although the scientific credibility of the U.S. EPA risk assessment was upheld, the U.S. EPA risk assessment was vacated on procedural grounds. The tobacco industry had similar procedural objections to the Australian Report, ''The Health Effects of Passive Smoking.''[8] Legal challenges of risk assessments are common[3] and preparing for such challenges could influence the way that the evidence is evaluated by a regulatory agency.[9]

A defining characteristic of the risk assessment process in the United States is that it is meant to be transparent and allow for public input. [9,10] Jasanoff argues that an important prerequisite for effective risk assessment development is a ''procedural and institutional framework for decision-making that encourages participation and inspires trust.''[2] We examine several questions regarding the role of public participation in the risk assessment process. Are relevant stakeholders participating in the process? Do the participants in the process evaluate science in the same way? How does the regulatory agency incorporate the public commentary? Although science plays a major role in the development of a risk assessment, the assessment cannot be separated from issues relevant to risk management, such as economic or political considerations.[1,2,9] Therefore, we analyzed how people who supported or criticized the Cal-EPA risk assessment used scientific and other arguments in the public input process. We also examined the difference between the quantity and quality of scientific research cited to support these arguments. We postulated that different players in the public input process would use different criteria for evaluating science depending on whether they supported the risk assessment or

not.[9,10] Based on our previous analyses of the response to the U.S. EPA risk assessment,[11] we also hypothesized that there would be a strong critical response by the tobacco industry and that poor quality evidence would be cited by the tobacco industry to support arguments focused on scientific issues.

2. METHODS

2.1. Data Sources

The Cal-EPA risk assessment and appendices were obtained from OEHHA. Transcripts from all public workshops held between 1994 and 1997 were obtained through the OEHHA website (http://www.oehha.ca.gov). Copies of written commentaries received during the public comment period from March 7 to May 5, 1997 were obtained from OEHHA staff. We examined the types of arguments presented in the commentary specific to three chapters of the risk assessment: respiratory, carcinogenic, and cardiovascular effects. We focused on the respiratory and carcinogenic chapters because they expanded on the U.S. EPA risk assessment by examining cancers in addition to lung cancer and adding more recent studies. We also considered the chapter on cardiovascular disease because it had not been examined in the U.S. EPA risk assessment and recent work showed an association between ETS and cardiovascular disease. To assess the quantity and quality of the research evidence cited to support the arguments used by commentators, we examined the references submitted with the commentary as attachments or in the reference lists. We obtained 1,586 references.

2.2. Data Coding

2.2.1. Transcripts and Commentary

We coded each transcript presentation ($n = 12$) and written commentary ($n = 33$) for position toward the risk assessment and affiliation of the commentator. For the transcript presentations ($n = 9$) and commentary ($n = 29$) specific to respiratory, carcinogenic, and cardiovascular issues, we also coded for arguments presented in support of or against the risk assessment. A codebook was used that included decision rules for the coding. We developed coding categories inductively, based on initial data analysis, and in conjunction with categories used in previous, related research.[11–13] QRNUD*IST (Rev 4, Qualitative Solutions and Research Pty. Ltd., Australia) was used to facilitate data management and coding.

2.2.1.1. Position toward risk assessment. We coded all transcripts and commentaries as being in support of, critical of, or neutral (e.g., pointing out typographical errors) toward the risk assessment. The one neutral comment with its attached references was excluded from further analysis.

2.2.1.2. Affiliation. The affiliation of each transcript presenter and commentary submitter was coded into mutually exclusive categories derived from the data and based on previous research.[11,12] The categories were: (1) tobacco industry (e.g., Philip Morris); (2) government organization (e.g., EPA); (3) nonsmokers' lay organization (e.g., Americans for Non-Smokers Rights); (4) smokers' lay organization (e.g., Smokers' Rights Action Group); (5) professional or voluntary health organization (e.g., American Medical Association, American Heart Association); (6) private practice-consulting (e.g., IWG Corporation); or (7) private citizen. If two affiliations existed, one affiliation was selected based on the primary affiliation presented at the workshop or in the commentary. An individual was coded as tobacco industry affiliated if he or she was an employee of a tobacco company or an industry-affiliated organization (e.g., Tobacco Institute) or acknowledged that their presentation was prepared at the request of a tobacco company or tobacco organization. Since we relied only on verbal and written disclosures, we are likely to have underestimated the number of tobacco industry affiliated individuals.[11]

2.2.1.3. Arguments. For the transcripts and commentary, we coded and marked sections of text for specific arguments. Initial analysis showed that the workshop presentations on the respiratory, carcinogenic, and cardiovascular chapters followed a similar pattern of arguments as the written commentary. Since the written commentary was more substantive and included supportive references, we focused our analysis of the arguments on the written commentary. One section of commentary could contain multiple occurrences of a single argument. In this article, we report the number of times that an argument occurs *at least once* in a commentary. The coding scheme for arguments had two components: scientific arguments and other arguments. The scientific arguments were separated into three categories: (1) *evaluation criteria* for the

science (including the quantity, reliability, quality, or validity of the studies); (2) *measurements* (including dose-response and exposure); and (3) *methods* (including bias and confounders, biological plausibility, risk calculations, ecological fallacy, epidemiological study design, generalizability, misclassification, misconduct, misrepresentation, statistical analysis, and study selection). Arguments about how science was evaluated were often used in conjunction with more specific arguments about measurements and methods. The other arguments were separated into five categories: (1) *building issues* (including ventilation); (2) *economic* arguments (including cost to government and impact on local and national economy); (3) *ideological* arguments (including accommodation to protect health, government intrusion, prohibition, and smoker nondiscrimination); (4) *political* arguments (including political motivations and jurisdiction); and (5) *procedural* arguments (including restricted comment periods and not following guidelines). The coding categories do not indicate a supportive or critical position but rather a type of argument that can be used by either position.

2.2.2. Response to Public Commentary

To assess the contribution that the public commentary made to the risk assessment process we examined OEHHA's response to the commentary on the respiratory, carcinogenic, and cardiovascular chapters. In the appendix of the risk assessment, OEHHA summarized the commentaries by submitter and specific topic within each chapter. Due to the redundancy across commentaries, comments would often be collapsed into a single summary. We counted the number of times that OEHHA explicitly stated that a change in the risk assessment was made as a result of the commentary received and summarized the nature of the changes.

2.2.3. References

2.2.3.1. Publication type. Each citation or attached reference was verified by checking the citation electronically (e.g., Medline), or if unavailable electronically, by obtaining a print copy. To test the hypothesis that critics of the risk assessment would be more likely to cite nonpeer-reviewed, poor quality scientific publications than would supporters, we coded each reference for publication type: (1) agency/institute report; (2) book or book section; (3) commentary or hearing transcript; (4) conference presentation or symposium proceeding; (5) editorial or letter to the editor from scientific journals; (6) government report; (7) journal article; (8) unpublished data; or (9) other (dissertations, unverified reports). The bibliographic software EndNote (Version 3.0, ISI Researchsoft/Thomson Scientific, 800 Jones St, Berkeley, CA 94710) was used to manage and code the references.

2.2.3.2. Quality of journal articles. Since a large proportion of the submitted references consisted of journal articles, we assessed the quality of these articles by determining their: (1) peer-review status, (2) impact factor, and (3) year of publication. We chose these criteria because they have been shown to be good indicators of quality.[14] Many problems exist in using only one quality indicator as a measure of a journal's quality;[14,15] therefore, we chose to utilize these three measures.

Peer-reviewed publications are of superior methodological quality compared to nonpeer-reviewed publications.[16–18] Peer-review status was determined by searching electronic websites and/or library print collections for the current ''aims and scope'' description of the journal or the ''information for authors'' section of the journal. These sections were then read to identify descriptions of the journals' peer-review process. Occasionally, peer-review status was not mentioned, although other indicators, such as acknowledgment of peer reviewers, were present. We used the 1999–2000 peer-review status of the journal, possibly overestimating the number of journals classified as peer reviewed because editorial boards tend to develop more rigorous review procedures over time. The journals for which we could not find any published mention of the review process (e.g., journals no longer in print) were coded as ''unknown.''

The impact factor has been tested as a valid tool for the quality assessment of scientific journals.[19] It is based on the average number of citations that articles in a given journal receive each year during the first two years following their publication.[20] We used the 1996 edition of the *Science Citation Index*[21] to collect the impact factor of the journals in which the references were published. We chose the 1996 indices because initial examination of the citations showed that a majority of journal articles were published in 1994 or earlier. Since the impact factor is calculated based on citations from the prior two years, the 1996 indices would capture the correct impact factor for a majority of the journal articles. Citation rates and

impact factors for journals also appear to be relatively stable over at least a five-year period.[22]

We chose year of publication as our third proxy for quality because more recent articles build upon and advance the findings of prior work. This is especially important for risk assessment, as a comprehensive review of the literature should include the most recent findings. The date of publication was obtained as part of the verification process that was used to determine the publication type of the references.

2.3. Analysis

We hypothesize that critics of the risk assessment were more likely to be tobacco industry affiliated, more likely to use arguments not related to science, and less likely to cite high-quality references than supporters of the risk assessment. We used the two-tailed Fisher's exact test to test for differences in the affiliations of supporters versus critics of the risk assessment. To test for differences in the types of arguments presented by supporters versus critics of the risk assessment, we used the Pearson's chi-square statistic. To determine whether revisions of the risk assessment were more likely to occur in response to critics' arguments than supporters', we used the two-tailed Fisher's exact test to test for differences in affiliations by the number of changes in the risk assessment. We also used the two-tailed Fisher's exact test to test for differences in types of references submitted by supporters versus critics of the risk assessment. For the journal quality indicators, publication year and impact factor, we report the median with 95% confidence intervals and use the Mann-Whitney U test to test for differences by supporters or critics of the risk assessment.

3. RESULTS

3.1. Position and Affiliation

Overall, 80% (36/44) of the public transcript presentations and written commentaries were critical of the risk assessment. As shown in Table I (Part 1), the affiliations of supporters and critics of the risk assessment differed ($p = 0.0001$). Critics were more likely to be tobacco industry affiliated than supporters, while supporters were more likely to be affiliated with government and professional or voluntary health organizations. Of the 12 presentations made at the public workshops, all were made by the tobacco industry and were critical of the risk assessment.

Table I. Sources of Public Commentary by Position

Part 1: Affiliations of Hearing Presenters and Commentary Submitters

	Supportive ($n = 8$)	Critical ($n = 36$)
Affiliation		
Tobacco industry	0 (0%)	29 (64%)
Private citizen	2 (4%)	4 (9%)
Professional/voluntary health organization	2 (4%)	0 (0%)
Government organization	3 (7%)	0 (0%)
Nonsmokers' lay organization	1(2%)	0 (0%)
Private practice-consulting	0 (0%)	2 (4%)
Smokers' lay organization	0 (0%)	1 (2%)
	$p = 0.000$ Fisher's Exact Test	

Part 2: Affiliation of Commentary Submitters on Respiratory, Carcinogenic, and Cardiovascular Chapters

	Supportive ($n = 6$)	Critical ($n = 23$)
Affiliation		
Tobacco industry	0 (0%)	17 (74%)
Private citizen	2 (33%)	4 (17%)
Professional/voluntary health organization	2 (33%)	0 (0%)
Government organization	1 (17%)	0 (0%)
Nonsmokers' lay organization	1 (17%)	0 (0%)
Private practice-consulting	0 (0%)	1 (4%)
Smokers' lay organization	0 (0%)	1 (4%)
	$p = 0.001$ Fisher's Exact Test	

The tobacco industry submitted critical commentary on all chapters of the risk assessment, although the greatest number was submitted for the carcinogenic and cardiovascular chapters. Of the 33 written commentaries received on the final draft, 29 contained comments specific to the chapters on respiratory, carcinogenic, and cardiovascular issues. As shown in Table I (Part 2), critics of these three chapters were more likely to be affiliated with the tobacco industry than supporters, while supporters were more likely to be private citizens or affiliated with government and professional or voluntary health organizations ($p = 0.001$).

3.2. Arguments

3.2.1. Scientific Arguments

As seen in Table II, critical commentary was more likely to contain scientific arguments

Table II. Scientific Arguments Used in Commentaries on the Respiratory, Carcinogenic, and Cardiovascular Chapters*

	Supportive ($n=6$)	Critical ($n=23$)
Science Arguments	4 (67%)	22 (96%)
	($p=0.04$ Pearson chi-square)	
Science Evaluation Criteria	4 (67%)	21 (91%)
Quality	2 (33%)	18 (78%)
Quantity	3 (50%)	14 (61%)
Reliability	1 (17%)	16 (70%)
Validity	1 (17%)	13 (57%)
	($p=0.12$ Pearson chi-square)	
Measurements	2 (33%)	22 (96%)
Exposure	2 (33%)	15 (65%)
Dose-response	0 (0%)	5 (22%)
	($p=.0003$ Pearson chi-square)	
Methods	4 (67%)	22 (96%)
Confounding	2 (33%)	21 (91%)
Study selection	2 (33%)	20 (87%)
Statistical analysis	2 (33%)	19 (83%)
Epidemiological study design	2 (33%)	17 (74%)
Misrepresentation	2 (33%)	15 (65%)
Biological plausibility	2 (33%)	7 (30%)
Misclassification bias	1 (17%)	12 (52%)
Generalizability	0 (0%)	8 (35%)
Misconduct	0 (0%)	7 (30%)
Risk calculations	0 (0%)	7 (30%)
Ecological fallacy	0 (0%)	3 (13%)
	($p=0.04$ Pearson chi-square)	

* Categories are not mutually exclusive.

(22/23, 96%) than supportive commentary (4/6, 67%) ($p=0.04$). Critics of the risk assessment were more likely to evoke the science evaluation criteria of study quality, reliability, and validity than were supporters. For example, a document submitted on behalf of the Tobacco Institute claimed that ''the Draft [risk assessment] fails to note that virtually all studies evaluated are severely deficient in such elementary design requirements.''[23] Both critics and supporters of the risk assessment emphasized the quantity of evidence. For example, a commentary submitted on behalf of the American Heart Association argued that ''in this case a number of studies, both case control and cohort studies with different experimental designs and conducted in different areas in the U.S. and around the world support this conclusion [that ETS increases the risk of coronary heart disease].''[24]

As shown in Table II, critics of the risk assessment were more likely than supporters to use arguments about measurement issues, such as exposure and dose-response relationships ($p=0.0003$). Those critical of the risk assessment were also more likely than supporters to use arguments about the specific methods of studies included in the risk assessment ($p=0.04$). The following passage from a Tobacco Institute commentary contains scientific arguments about biological plausibility, statistics, bias and confounding, and study selection:

> The EPA Report incorrectly assumes a similarity between ETS and mainstream smoke, ignores geographical inconsistency in the spousal data, makes improper use of meta-analysis, fails adequately to control for bias and confounders, improperly analyses the available trend data, and completely disregards a substantial body of pertinent workplace epidemiologic data.[25]

As seen in Table II, the arguments about methods that were most frequently used by critics were: (1) general bias and confounding, (2) study selection, and (3) statistical analysis. The category of bias and confounding included claims of personal bias, as well as study design bias, such as recall bias. A document submitted by Philip Morris Inc. illustrates an argument about confounding: ''Other characteristics, such as family history of asthma, wood stove use, home dampness, or other indoor exposures, were apparently not considered in the study.''[26] Study selection arguments included discussion of the appropriateness of studies that were selected for inclusion in the risk assessment, as well as discussion of the criteria used to include those studies. Study selection arguments often occurred in combination with accusations of personal bias, as in this comment from a private citizen:

> Having picked your hypothesis, you carefully aimed to ''prove'' it—using carefully chosen studies—and occasionally, cannily, only *sub*-sets of studies—that seemed (or might semantically be *tickled* until they seemed) to support your hypothesis. All other studies to the contrary notwithstanding. And forget the ''notwithstanding.'' They were buried under the desk. Rugs were shoved over them. And large potted plants. [27]

Arguments about statistical analysis included discussions about correct choice of statistical tests, adjustments, and analysis, as well as what should be considered a significant level of risk.

3.2.2. Other Arguments

Although scientific arguments dominated the public input process, the commentary did contain some other arguments. As shown in Table III, critics were as likely as supporters to use other arguments

Table III. Other Arguments on Commentaries Specific to the Respiratory, Carcinogenic, and Cardiovascular Chapters*

	Supportive ($n=6$)	Critical ($n=23$)
Other arguments	3 (50%)	17 (74%)
Procedural	1 (17%)	13 (57%)
Ideological	3 (50%)	3 (13%)
Political	1 (17%)	3 (13%)
Building	1 (17%)	1 (4%)
Economic	0 (0%)	1 (4%)
	($p=0.26$ Pearson chi-square)	

* Categories are not mutually exclusive.

($p=0.26$). About half the critics questioned the risk assessment procedure, including suggesting that the risk assessment did not follow appropriate guidelines, that comments were not addressed, and that the public comment periods were too short. For example, the Tobacco Institute claimed that:

> The flawed procedure followed by OEHHA, including the Agency's failure to adequately consider comments and its refusal to give stakeholders a reasonable extension of time to comment on the Draft Report, call into question the Report's credibility and reliability.[25]

3.3. Response to Public Commentary

OEHHA prepared a written response to all commentaries they received on each of the chapters. We examined OEHHA's response to the 29 comments on the respiratory, carcinogenic, and cardiovascular chapters. Four of these commentaries resulted in change to the risk assessment, such as the addition of studies, and changes in the study summaries, data analysis, and presentation.

Of the six supportive commentaries submitted, one resulted in changes to the risk assessment. This commentary resulted in the addition of two studies discussing smoker misclassification and one epidemiological study of the association of lung cancer and passive smoking.

Of the 23 critical commentaries submitted, three resulted in changes to the risk assessment. In response to the commentary from the Tobacco Institute, OEHHA added three epidemiological studies to the risk assessment. All three of these studies established some doubt regarding the association of passive smoking and children's respiratory disease. OEHHA made several changes in the risk assessment in response to the commentary from Philip Morris. OEHHA deleted from a table a reference suggesting a causal relationship between passive smoke exposure and exacerbation of adult asthma. Two epidemiological studies that did not support claims that adult asthma is associated with ETS exposure were added. Two studies were added in response to Philip Morris's comment that "OEHHA simply does not provide any evidence to support its claims that ETS, or constituents of ETS, stimulate the sensory apparatus." Another study was added in response to the comment that conclusions about "a modulatory effect of allergy upon the irritant chemoreceptive system" was inferred by OEHHA. OEHHA moved a study from the asthma analysis to the wheezing analysis and recalculated the data, but this did not change the results. Four studies were added regarding the association of cervical cancer and passive smoking. In response to commentary from RJ Reynolds, OEHHA added four epidemiological studies of lung cancer and passive smoking.

In summary, the main contribution of the four commentaries that resulted in changes in the risk assessment was to expand the literature review for the risk assessment. The one supportive commentary resulting in changes added three new studies, while the three critical commentaries added 13 new studies. The additional studies provided by critics questioned the conclusions reached by the risk assessment, but did not change them.

3.4. References

3.4.1. Publication Type

As shown in Table IV, critics of the risk assessment submitted 25 times more references than supporters. Overall, the types of publications submitted by supporters and critics were similar ($p=0.27$), and journal articles were the most frequent publication type.

3.4.2. Quality of Journal Articles

Of the 1,586 total references, 1,061 were journal articles published in 244 different journals. Of the 244 journals, 190 (78%) had a published peer-review policy, and 54 (22%) had no peer-review policy or the policy was unknown.

As shown in Table V, both supporters and critics of the risk assessment submitted similar percentages of peer-reviewed journal articles ($p=0.36$). Journal articles submitted by supporters

Table IV. Publication Type by Position Toward the Risk Assessment

	Supportive ($n=60$)	Critical ($n=1,526$)
Type of publication		
Journal article	39 (65%)	1022 (67%)
Conference/symposium	4 (7%)	126 (8%)
Government report	6 (10%)	76 (5%)
Letter to the editor/editorial	4 (7%)	65 (4%)
Book	2 (3%)	65 (4%)
Commentary/hearing transcript	0 (0%)	76 (5%)
Agency/institute report	1 (2%)	20 (1%)
Unpublished data	(0%)	9 (0.6%)
Other	4 (7%)	65 (4%)
	($p=0.27$ Fisher's Exact Test)	

Table V. Quality Indicators for Journal Articles

	Supportive	Critical
Peer-review status	$n=39$	$n=1,022$
Peer reviewed	38 (97%)	942 (92%)
Not peer reviewed	1 (3%)	80 (8%)
Impact factor	$n=36$	$n=898$
Median	3.6	2.6
95% confidence interval	3.31–4.11	2.43–2.75
Year of publication	$n=39$	$n=1022$
Median	1993	1993
95% confidence interval	1992–1995	1990–1993

of the risk assessment had a significantly higher median impact factor compared to those submitted by the critics (3.6 vs. 2.6, $p=0.03$). Although impact factors can range from 0 to 51, there are very few journals with impact factors above 10.0, with most falling between 0.0 and 2.0. For the journals in this study, the impact factor ranged from 0.08 to 28.42. Supporters had a higher percentage of journals with any impact factor above 0 (92%) compared to the critics (88%), suggesting that more of the journals referenced by supporters were cited at least once in the scientific literature. As shown in Table V, the median year of publication was identical for journal articles submitted by critics or supporters. However, the range of dates of articles submitted by critics (1957–1997) was wider than that of supporters (1982–1998).

The journal article references contained many duplicate submissions. Overall, critics submitted 250 articles 666 times and supporters submitted three articles seven times. The majority of duplicate submissions were from critics who were tobacco industry affiliated. The most criticized studies were Brownson *et al.*[28] and Fontham *et al.*,[29] which were both cited seven times by critics. These two recent studies had not been included in the U.S. EPA risk assessment.

4. DISCUSSION

This case study of the Cal-EPA risk assessment of ETS has several findings that describe the role of public commentary in the risk assessment process. First, the tobacco industry was the main critic of the draft risk assessment. Second, critics were more likely to use scientific arguments than were supporters. Through public commentary, critics constructed the claim that the scientific evidence on which the risk assessment was based was invalid, unreliable, and methodologically flawed. Third, although the critics focused on the scientific basis for the risk assessment, they also frequently criticized the procedure that was used to conduct the risk assessment. Fourth, the public input resulted in some changes in the risk assessment.

Our observations regarding the role of public commentary in the Cal-EPA risk assessment are compatible with at least two of the four explanatory models for the risk communication process that have been proposed by Jasanoff.[2] As described below, the imperfect participation model is relevant to our discussion of the sources of commentary. The social construction model is relevant to our discussion of arguments used by supporters or critics of the risk assessment.

The tobacco industry was the primary participant in the critical public commentary, whereas public health advocates were relatively absent during the process. Thus, as described for the imperfect participation model, interests that could have participated in constructing the risk assessment were not adequately represented at a key point in the process.[2] All the participants in the public workshops were affiliated with the tobacco industry, and critics submitted nearly 20 times the number of pages of written commentary as supporters. It is possible that the public health community thought that the large body of existing scientific evidence assembled by the Cal-EPA was substantial enough to support the risk assessment without any extra input. In addition, AB 13, the California assembly bill that banned smoking in enclosed workplaces, was being debated in the California Legislature

during the risk assessment process. Many advocates may have been focusing their efforts on this bill since it would result in direct action regarding passive smoke exposure.[30,31] After AB 13 was passed in 1994, advocates might not have seen the need for the risk assessment. The absence of public health advocates in the public commentary process does not mean that they did not participate in earlier stages in the development of the risk assessment. Different levels of participation in the public input process may reflect opportunities of stakeholders to participate in various stages in the regulatory process.

The arguments used by the tobacco industry suggest that the industry critics were socially constructing the scientific evidence on the health effects of passive smoking according to their subjective views about how science should be evaluated. By the time the Cal-EPA risk assessment was drafted, a series of independent scientific consensus documents and peer-reviewed publications had established that environmental tobacco smoke (ETS) is associated with disease.[6,32–35] However, critics of the Cal-EPA risk assessment tended to focus on specific studies, rather than the body of evidence as a whole, and argued that these studies of passive smoking were invalid, unreliable, and of poor quality. They suggested that the studies were flawed by confounding, study selection bias, and statistical errors. These arguments were similar to the arguments presented by the tobacco industry on the U.S. EPA risk assessment.[11] When supporters of the risk assessment mentioned the scientific evidence, they emphasized the quantity and consistency of the studies. Thus, critics and supporters of the risk assessment differed on the criteria they used to judge the scientific evidence.

The tobacco industry criticisms were supported by large numbers of older references with low impact factors, as were the criticisms the industry submitted to the U.S. EPA risk assessment and two state indoor air regulations.[11,12,36] The quantity of commentary submitted is an indication of the overall level of public interest in the topic, as well as an indication of who is interested. Since we assume that agencies must review all of the commentaries and supporting references, large submissions could delay the process. Careful review of this material, however, could help deter future litigation. OEHHA's detailed response to each criticism suggests that the agency considered the content of each criticism and the evidence used to support the criticism, as well as the volume of commentary. Although a large number of criticisms of the scientific evidence were made by the tobacco industry, the expansion of the literature review for the risk assessment was the main change resulting from these commentaries.

Regulatory agencies often find that evidence of varying quality is submitted in response to calls for public input. All submitted articles should be subjected to a rigorous critical appraisal or methodological review before being incorporated by the regulators. However, this can be a daunting task when thousands of articles are submitted. Our use of peer-review status and impact factor as indicators of quality may be applicable to other regulatory settings where large amounts of submitted information must be reviewed.

In litigation initiated by the tobacco industry, the U.S. EPA faced charges of bias and procedural misconduct during the public input process.[11] The frequent use of procedural arguments by critics of the Cal-EPA risk assessment suggests that the tobacco industry was preparing for litigation against the Cal-EPA and OEHHA as well. It is likely that a goal of any interest group might be to establish some record of information that might be used later in the context of litigation. To date, the Cal-EPA risk assessment has not been challenged in court. OEHHA's detailed response to the public commentary could have helped deter litigation.

Since the Cal-EPA produced the risk assessment in a timely manner, the agency was apparently able to counter the imperfect participation in the process and conflicting social constructions of the evidence base. However, interviews with individuals involved in the process indicate that some of them found that responding to the issues took considerable resources and delayed the process.[37] On the other hand, if the time and effort spent in responding to public commentary deters future litigation, then active participation of special interest groups in the process could be advantageous to regulators in the long run.

To balance the input of special interest groups on future risk assessments, public health advocates could provide information to counter submissions of large numbers of criticisms that are supported by relatively low-quality scientific evidence. Public health advocates could attempt to use their limited resources more effectively by organizing their responses to calls for public commentary and emphasizing the quality of scientific evidence submitted.

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