Assessing the Evidence Submitted in the Development of a Workplace Smoking Regulation: The Case of Maryland

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SYNOPSIS

Objective. This study compared the characteristics of the basic science, biomedical, and socioeconomic literature submitted in 1993–1994 by supporters and opponents of the proposed workplace regulation of tobacco smoke developed by the Maryland Occupational Safety and Health (MOSH) Advisory Board.

Methods. The authors retrospectively analyzed 544 written publications submitted to the MOSH Advisory Board regarding the proposed workplace regulation of tobacco smoke. Outcome measures included the type and year of publication and, for journal articles, the journal's peer review policy and impact factor.

Results. Supporters of regulation submitted fewer documents (n=164) than opponents (n=380). Supporters of regulation submitted a lower proportion of conference proceedings and a higher proportion of government reports. The publications submitted to the regulators by the supporters of regulation were more recently published than the materials submitted by opponents. Journal articles represented more than half of the publications submitted; most were peer-reviewed. Supporters of regulation submitted articles from journals with higher impact factors (median impact factor 2.78) than did opponents of regulation (median 1.66; p=0.0005), and articles that were published more recently (median year of publication 1990) than those submitted by opponents (median 1989; p=0.0001).

Conclusions. Public health advocates should highlight the scientific evidence base that supports tobacco control regulations. Public health advocates should encourage and support regulatory officials' use of the criteria of peer review, impact factor, and date of publication to prioritize their review of submitted documents in order to base policy on the best available evidence.

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In 1986, the Surgeon General released another in a series of reports on the health consequences of smoking, this time demonstrating the risks of exposure to other people's tobacco smoke. This focus on involuntary exposure was followed by the 1992 Environmental Protection Agency (EPA) risk assessment that established environmental tobacco smoke as a Class A carcinogen associated with lung cancer in adults and respiratory disorders in children. The report and risk assessment fueled efforts to restrict smoking in public places; as of December 2001, 43 states restricted smoking in certain public places.

While people have choice with respect to the frequency and duration of visits to most public places, workers frequent their workplaces consistently and remain at work for considerable amounts of time. Therefore, in workplaces, the degree of "voluntariness" with respect to exposure is questionable; hence, the government protects workers through regulation and legislation. Smoking is restricted in private workplaces in 23 states³; two of those states—Maryland and Washington—restrict smoking by regulation rather than by legislation.

We focus here on the development of a tobacco control regulation, as opposed to legislation, because regulatory bodies are charged by the Administrative Procedures Act with considering "objective and unbiased scientific and economic evaluations of all significant and relevant information."4 Therefore, regulatory agencies are obligated to review and incorporate scientific findings (including the findings of basic science, biomedical, and socioeconomic research) in appropriate ways. This is in contrast to legislators, who are not bound by the Administrative Procedures Act, and thus have wide discretion on what they consider, or do not consider, when developing legislation. Regulators use three basic techniques to develop policy: informal agreements with interested parties, substantive rulemaking, and adjudication.⁵ In the case of workplace smoking restrictions, the Maryland Occupational Safety and Health (MOSH) Advisory Board used substantive rulemaking, a process by which interested parties set forth their views in written commentary to the agency and in testimony at public hearings on the regulation.

Study purpose and hypothesis

In this case study of the development of the workplace smoking regulation in the state of Maryland, we examine the quantity and quality of research evidence submitted to the MOSH Advisory Board for consideration by regulators. We focus on the evidence base because in policy making forums, representatives of the to-

bacco industry continue to contend that science has failed to demonstrate that passive tobacco smoking poses a significant risk to public health. Tobacco industry representatives dismiss epidemiologic evidence because it does not establish causality and criticize all science, except for laboratory-based documentation.⁶ Although tobacco industry representatives typically frame their censure of tobacco control efforts in terms of criticizing the underlying evidence base, public health advocates often do not rebuke the industry's criticism of the science or speak for the science that does support restriction of smoking.⁷⁻⁹ Previously, we found that critics of the EPA risk assessment of passive smoking submitted a large quantity of poor quality studies to support their criticisms.¹⁰ Therefore, we hypothesized that supporters of tobacco regulation would have submitted evidence that was qualitatively different from the evidence submitted by those opposed to restricting smoking. We evaluated the materials submitted by those for or against regulation based on three criteria: the year the study was published, whether the study was published in a journal that was peerreviewed, and the impact factor of the journal in which the study was published.

We chose these criteria because they are indicators of quality¹¹ and, taken together, they "triangulate" the measurement of quality.12 In the context of a review of the literature relevant to a regulation being developed, year of publication is a "quality" characteristic because more recent articles build upon and advance the findings of prior work, and reviews should include the most up-to-date evidence. We included peer review status as a quality indicator because the methodological quality of peer-reviewed publications is superior to the quality of non-peer-reviewed publications. 13-15 The impact factor measure was developed by Eugene Garfield¹⁶ as an indication of a journal's relative influence. An impact factor is the mean number of citations received in a particular year to articles published in the journal the preceding two years. Debate in the medical literature has alerted researchers to the problems inherent in using impact factor alone as a proxy measure of journal quality. 17-29 Therefore, in this study we used impact factor in conjunction with other measures.

Study objective

The objective of this study is to compare the basic science, biomedical, and socioeconomic literature submitted by supporters and opponents of the proposed workplace regulation of tobacco smoke developed by the MOSH Advisory Board.

METHODS

In late 1993, the MOSH Advisory Board proposed indoor air regulation banning smoking in almost all enclosed workplaces. The draft regulation was open to public comment from December 1993 to January 1994. We obtained all written commentary submitted to the MOSH Advisory Board. Of the 239 parties who submitted comments to the board, 60 attached publications as supporting evidence. For this study, we analyzed supporting evidence consisting of basic science, biomedical, and socioeconomic research publications. We excluded from analysis reports appearing in the media (newspaper and magazine articles and transcriptions of broadcasts) and trade publications; letters to the Board; pamphlets prepared by public relations firms or private nonprofit organizations; legal briefs; petitions; and copies of engineering standards. From the 60 submissions with publications enclosed, we collected 544 publications that met the criteria for inclusion in the present study.

We entered into a database each publication citation that was submitted by a supporter or opponent of regulation. Some publications were in the database more than once because they were submitted by more than one party supporting or opposing the regulation. We ran our analyses using all publications submitted, and again with duplicates within the category of supporting or opposing regulation eliminated. There were no significant differences; all conclusions remained qualitatively unchanged. Therefore, we included duplicate submissions in our analyses because the Administrative Procedures Act requires regulatory policy makers to review each and every document that was submitted. Furthermore, in a previous study, policy makers reported that they were particularly attentive to publications that were submitted more than once.9

Data coding

Position toward regulation. We coded each publication with respect to whether it was offered as evidence to support the development of the regulation or in opposition. We determined the position of the submitter by reading the whole set of materials and coding the senders' arguments as for, against, or neutral (or undetermined) toward the regulation. Materials submitted by those neutral toward the regulation were excluded from further analysis.

Type of publication. Each publication was verified by checking the citation electronically using MEDLINE or other available electronic databases or by obtaining a printed copy from the author or journal. (The list of databases consulted is available from the authors on

request.) The type of publication was coded as: journal article, editorial, letter to the editor, government report, agency report (e.g., International Agency for Research on Cancer), conference presentation or symposium proceeding, book or book section, or other.

Date of publication. Each citation in our database included the year the document was published.

Impact factor of journal articles. Of the 544 publications that met the criteria for inclusion in present study, 284 were journal articles, published in 104 journals. We obtained impact factors for these 104 journals from the 1994 editions of the *Science Citation Index* and the *Social Science Citation Index*.^{30,31} The impact factor is based on the mean number of citations that articles in a given journal receive each year for two years following publication. We chose the 1994 indices because the publications were submitted to the board during the public hearings held in 1993 and 1994.

Peer review status of journals. Each journal's peer review status was determined by collecting the published peer review policy, and by searching electronic websites and library print collections for the current "aims and scope" description of the journal or the "information for authors" section of the journal. We used the 1999 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. There were 15 journals for which we could not find any published mention of the review process (including journals no longer in print), and these were coded as "unknown." Journals coded as "unknown" and the 13 journals that explicitly stated that they did not submit manuscripts to peer review (e.g., journals composed of review articles invited by the editor) were combined for analysis.

Data analysis

Our hypothesis was that supporters of regulation would submit evidence that was more recent, and from journals that had higher impact and that were more likely to be peer reviewed. We analyzed the differences in year published and impact factor by supporters and opponents of regulation using the nonparametric Mann-Whitney U test for two independent samples. For journal articles, we compared peer review status between supporters and opponents of regulation using Fisher's Exact Test. We used the chi-square statistic to compare the relative risk of an article being peer reviewed vs. not peer reviewed for supporters of the regulation, compared with opponents. This difference in percentages is reported along with the 95% confidence interval (CI).

RESULTS

Position toward regulation

In Maryland, among the 60 parties that submitted commentary that included publications, 27 were supporters of regulation, 12 were opposed to regulation, and 21 were neutral or their position could not be determined. Publications submitted with commentaries coded as neutral or unknown were excluded from further analysis, leaving 544 publications for analysis: 30% (164/544) of the submitted publications were from supporters of regulation, and 70% (380/544) were from those opposed to the regulation. Table 1 shows the number of publications submitted by various types of supporters and opponents of the proposed regulation. Of note is that the commentary from Philip Morris, Inc. (opposed to the regulation) included 359 publications. As shown in the Appendix, some references were cited by both supporters and opponents of regulation. These references were likely to be government reports or landmark research articles on the health effects of passive smoking. Supporters of regulation cited these influential references as evidence that exposure to passive smoke should be restricted, whereas opponents cited the references to criticize them.

Table 1. Number of publications submitted, by position toward proposed regulation

Type of supporter or opponent	For regulation	Against regulation
Tobacco industry	0	372
Small business/local merchant	0	3
Health activist organization	79	0
Government (local, state, federal)	29	0
University	11	0
Individual	44	5
Other	1	0

Type of publication

As illustrated in Table 2, journal articles were the most frequently submitted type of publication. Publications submitted in support of regulation were less likely to be conference presentations or symposium proceedings (6%) than publications submitted in opposition to the regulation (30%); the 24 percentage point difference (95% confidence interval [CI] 18, 30) was significant at p<0.0001. Those in support of regulation were more likely to submit government reports (12%) than were those against the regulation (2%); the 10 percentage point difference (95% CI 4, 15) was also significant at p<0.0001.

Date of publication

The 164 scientific publications submitted to the MOSH Advisory Board in support of the proposed workplace smoking regulation were significantly more recent (median year of publication 1990; 95% CI 1990, 1992) than the 380 scientific publications submitted by those opposed to regulation (median year of publication 1989; 95% CI 1988, 1989; p<0.0001).

Journal quality indicators

Date of publication of journal articles. The year of publication for the 284 journal articles submitted to the MOSH Advisory Board ranged from 1959 to 1994. As shown in Table 3, journal articles submitted in support of the workplace smoking restriction were published significantly more recently (median year of publication 1990) than journal articles submitted in opposition to regulation (median year of publication 1989; p < 0.0001).

Journal impact factor. The Institute for Scientific Information³⁰ calculated impact factors for 76 of the 104 journals in which the articles submitted to the MOSH Advisory Board were published. Therefore, we could obtain impact factors for 241/284 (85%) journal articles. The impact factors ranged from a low of 0.048

Table 2. Type of publication, by position toward proposed regulation

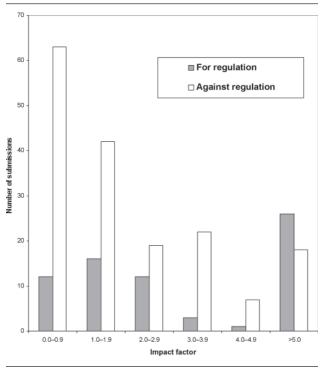
Type of publication	For regulation (n = 164)		Against regulation (n = 380)	
	Number	Percent	Number	Percent
Journal article	85	52	199	52
Editorial/letter to the editor	26	16	37	10
Government report	19	12	8	2
Agency report	15	9	9	2
Conference presentation/symposium proceedings	10	6	115	30
Book/book section	6	4	10	3
Other	3	2	2	1

Table 3. Journal qualit	v indicators.	by position	toward pro	posed regulation

Indicator	For regulation	Against regulation n = 199 publications	
Article year of publication	n = 85 publications		
Median 95% confidence interval	1990 1989 1990, 1991 1988, 198		
Journal impact factor	n = 70 publications	n = 171 publications	
Median 95% confidence interval	2.78 1.83, 4.14	1.66 1.23, 1.83	
Journal peer review status	n = 85 publications	n = 199 publications	
Percent peer-reviewed	89	85	

(American Society of Heating and Refrigeration Engineers Journal) to a high of 22.673 (New England Journal of Medicine). As illustrated in the Figure, most of the articles came from journals that had impact factors of less than 2. As shown in Table 3, the impact factors of journal articles submitted in support of regulation were significantly higher (median 2.78) than the impact factors of journal articles submitted in opposition to regulation (median 1.66; p=0.0006).

Figure. Number of journal articles submitted in support of and opposition to proposed regulation, by journal impact factor



Journal peer review status. The 284 journal articles submitted to the MOSH Advisory Board were published in 104 different journals. Of these journals, 76 (73%) had published peer review policies; the remaining 28 (27%) indicated they did not peer review articles submitted to their journal or we could not find evidence that they did. Table 3 shows that the proportion of articles from peer-reviewed journals was similar for supporters and opponents of regulation (95% CI -4, 12; p=0.44).

DISCUSSION

During the public commentary periods on the proposed smoking restriction regulation, the 27 supporters who appended scientific publications submitted fewer publications than the 12 opponents who included publications. The journal articles the supporters submitted were more recently published and were in publications with higher impact factors, suggesting that they were of better "quality."

Although opponents of regulation submitted a larger quantity of publications, they were also more likely to submit non-peer-reviewed types of publications. Those against regulation tended to submit more conference proceedings, which are less likely than journal articles to be peer reviewed and more likely to be of poorer quality. 14,32,33 Oral presentation at a meeting offers researchers a chance to receive comments and suggestions from others doing work in their field, but is not equivalent to the evaluation on the basis of clarity, originality, methodological rigor, and contribution to the emerging evidence base that peer review provides. Supporters of regulation tended to submit more government reports, some of which, such as the Surgeon General's report¹ and the EPA risk assessment,² go through peer review that typically includes a thorough assessment by a panel of experts on the topic.

About half of the materials submitted to the MOSH Advisory Board were articles published in journals, most of which were peer-reviewed. Journal articles submitted by supporters vs. opponents of regulation differed on the quality criteria we assessed. Publications submitted by supporters of regulation were published significantly more recently than publications submitted by those against regulation. The first publications on the adverse health effects of passive smoking in adults were published in the early 1980s.34-36 By the 1990s, the evidence base had progressed to a critical point at which the EPA classified passive smoke as a Class A carcinogen.² The publications submitted by tobacco industry opponents of regulation were older, most from a period when less evidence on the adverse health effects of passive smoking existed.

Furthermore, articles submitted by supporters of regulation were published in journals with higher impact factors than articles submitted by opponents of regulation. However, most journal articles submitted (regardless of position on the regulation) were in low impact journals, possibly because much of the research on the health effects of tobacco is published in low impact journals.³⁷

In an earlier analysis of the role of science-based and other arguments in the development of workplace smoking regulations, we found that opposition to the regulations came primarily from the tobacco industry, small businesses, and business organizations and appeared to be coordinated.^{7,9} There was little coordination of public health support for proposed regulations in Maryland and Washington State.⁷ Arguments about the quality of scientific evidence were used more often by those opposed to the regulations than by those in favor. Supporters emphasized the quantity of the evidence, whereas opponents criticized its reliability, validity, and quality.7 In this study, we found that the references used to support these arguments varied in quality between those who opposed or supported regulation. Because regulatory agents are required to consider all the evidence submitted to them,9 our findings suggest that researchers should emphasize that they are submitting high-quality scholarly publications to support their arguments in favor of workplace smoking regulations. High-quality research will not be able to influence health policy makers' decision-making38,39 unless public health advocates actively promote it in policy-making venues.9

Our findings also suggest criteria that regulators can use to help them sort through large quantities of information and focus on the highest quality research for the purpose of developing policy. Regulatory agencies could prioritize their review of submitted materials, with highest precedence given to the most recent peer-reviewed publications from journals with highest impact.

When reviewing tobacco industry activities in various political venues, researchers have discovered that industry representatives attempt to frame the debate within the parameters of strict cause-and-effect, limiting health evidence to the narrowest possible lab-based documentation. 4,40 In this study, we have demonstrated that although the tobacco industry representatives submitted more documents to support their arguments opposing regulation, the quality of the journal articles submitted was significantly poorer with respect to recency of publication and impact factor. This finding has implications for future state tobacco control efforts. At the time of this analysis, 23 states restricted smoking in private workplaces,41 21 by law and two states (Maryland and Washington) by regulation. The restrictions vary widely, ranging from California's law prohibiting smoking in all enclosed workplaces, even bars, to Washington State's workplace regulation prohibiting smoking in office buildings. Results of this case study show that proponents of tobacco control policies should continue to submit higher quality scientific evidence to support the push for public health regulations. Also, they should consider bringing to public attention the fact that their materials provide stronger scientific support for public health regulations than those submitted by opponents of regulation.

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APPENDIX

Articles Submitted by Both Opponents and Supporters of Regulation

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