

# Policy makers' perspectives on tobacco control advocates' roles in regulation development

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## Abstract

**Objective**—To identify, from policy makers' perspectives, strategies that enhance tobacco control advocates' effectiveness in the regulatory arena.

**Design**—Key informant interview component of a comparative case study of regulatory agencies in the USA.

**Subjects**—Policy makers involved in the development of four regulatory tobacco control policies (three state and one federal).

**Methods**—Interviews of policy makers, field notes, and deliberation minutes were coded inductively.

**Results**—Policy makers considered both written commentary and public testimony when developing tobacco control regulations. They triaged written commentary based upon whether the document was from a peer reviewed journal, a summary of research evidence, or from a source considered credible. They coped with in-person testimony by avoiding being diverted from the scientific evidence, and by assessing the presenters' credibility. Policy makers suggested that tobacco control advocates should: present science in a format that is well organised and easily absorbed; engage scientific experts to participate in the regulatory process; and lobby to support the tobacco control efforts of the regulatory agency.

**Conclusions**—There is an important role for tobacco control advocates in the policy development process in regulatory agencies.

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Tobacco control is an area in which a substantial amount of research that is relevant to public health aims has been conducted. A series of independent scientific consensus documents and peer reviewed publications established that environmental tobacco smoke (ETS) causes disease.<sup>1–6</sup> This research provided the evidence to enable federal, state, and local governments to develop tobacco control regulations to limit the public's exposure to ETS.

Through departments of labor, US national and local governments have jurisdiction to protect the health of workers. Tobacco control efforts have focused on workplace smoking restrictions because: smoking restrictions protect non-smokers from the adverse health effects of passive smoking<sup>1–6</sup>; smoking restrictions facilitate smokers' decisions to quit or

decrease consumption<sup>7–9</sup>; and those living and working in smoke-free environments are less likely to begin smoking than those exposed to smoke.<sup>10–13</sup>

Among the 23 US states that restrict smoking in the workplace, 21 states have laws that restrict smoking, and two states have regulations.<sup>14</sup> The regulations in these two states—Maryland and Washington—are more comprehensive than most laws.<sup>14</sup> A possible explanation is that regulations are more likely to be evidence based than laws because regulatory bodies are required to consider, and are more likely to base decisions on, the scientific and economic evidence submitted by interested parties.<sup>15</sup> Regulatory agencies are staffed by professionals with technical expertise on various issues who review scientific literature and draft regulations. The draft substantive rules are then published as notices to the public. In response to the draft, interested parties can submit written commentary and/or testify at public hearings. It is the task of the regulatory officials to make any necessary revisions to the draft regulation based upon the comments submitted by the interested parties. The revised final rule is sent to the agency head for approval and subsequent promulgation.

The tobacco industry is an interested party that has long understood the role of research in the regulatory process, especially with respect to tobacco control. As early as 1974 the tobacco industry began sponsoring scientific meetings and publications on the health effects of passive smoking.<sup>16</sup> The tobacco industry has used its sponsored research to respond to government requests for information on smoking restrictions or risk assessments of passive smoking.<sup>17–19</sup>

The tobacco industry's success in delaying or modifying regulation of its product points to the need for tobacco control advocates to counter the efforts of the tobacco industry in the regulatory arena. Currently, there are guides available that are written from the perspective of public health advocates.<sup>20–22</sup> We know of no guides that are written from the perspective of the people who the advocates intend to influence—the policy makers themselves. This study is an investigation of the regulatory process from the perspective of the policy makers.

We report findings from a comparative case analysis of the development of two state and one federal workplace smoking regulations, and in a third state a risk assessment of environmental tobacco smoke. This analysis of

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Table 1 Synopsis of study cases

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| State office workplace smoking regulation: Washington                   | The Washington regulation began as a comprehensive office building indoor air regulation. In August 1992, the Washington Department of Labor and Industries produced a draft regulation aimed at regulating all components of indoor air, including ETS. During November and December 1993 public commentary was collected and six hearings were held. Based on strong opposition to the other indoor air components of the proposed regulation, the director of the Department of Labor and Industries narrowed the regulation to focus only on tobacco smoke exposure. This narrower regulation was approved on 16 March 1994  |
| State enclosed workplace smoking regulation: Maryland                   | The Maryland regulation banning smoking in almost all enclosed workplaces was proposed in late 1993. It was open to public comment and hearings were held by the Maryland Occupational Safety and Health Advisory Board in December 1993 and by the Commissioner of Labor and Industry in May 1994. The regulation was approved on 21 July 1994, but later modified by the state legislature to exempt hospitality industry workplaces   |
| Federal Indoor Air Rule: Occupational Safety and Health Administration  | In April 1994, the federal US Occupational Safety and Health Administration (OSHA) published a draft comprehensive Indoor Air Regulation that included a workplace smoking ban. The public comment period and hearings were held in 1994 and 1995. The OSHA regulation remains pending.  |
| California risk assessment of environmental tobacco smoke <sup>23</sup> | Government reports, such as the US Environmental Protection Agency (EPA) risk assessment of passive smoking, <sup>6</sup> are frequently cited to support workplace smoking restrictions. However, in 1998 the federal EPA risk assessment was "vacated" by the North Carolina courts on procedural grounds. Therefore, the 1997 California risk assessment of passive smoking has policy significance since it has withstood legal challenge. Furthermore, while the federal EPA risk assessment focused on the effects of passive smoking on respiratory disease and lung cancer, the California risk assessment was the first to include the cardiac effects of passive smoking |

in-depth interviews of key participants in the regulatory process addresses the question of how the research evidence was evaluated and used by the regulatory officials. The issues discussed are significant with respect to controlling tobacco use as advocates work to counter the influence of the tobacco industry in forums where public input is taken into account. The lessons learned from this research are perhaps more important than ever for tobacco control advocates in the USA, given the recent election of a Republican President and Republican House of Representatives. Conventional wisdom has it that more tobacco control policy will be made at the state and local level, rather than at the federal level.

## Methods

### SAMPLING

We interviewed policy makers involved in the development of: workplace smoking regulations in the two states that have them (Maryland and Washington); the US federal Occupational Safety and Health Administration draft Indoor Air rule; and the California risk assessment of environmental tobacco smoke.<sup>23</sup> See table 1 for a description of these four cases.

In each of the cases the key policy makers—for example, agency administrators who directed or were responsible for the substantive rule making—were identified by contacting the designated official as delineated in the published draft of the regulation. The head of each regulatory board was asked to participate in the study, as well as the staff person responsible for administrative duties related to the process. In each of the four research sites, the regulation was subsequently challenged in court by the tobacco industry. All who were invited to participate consented to be interviewed except for those in one state agency and the federal agency for whom the

pending court cases prevented them from granting interviews. In lieu of interviews, for the state agency we were able to obtain a copy of the minutes of the board's deliberations regarding the regulation. In the federal agency, we approached those who had served on the regulatory board but no longer worked for the government, and they agreed to be interviewed. In sum, we interviewed seven policy makers from two states and one federal agency, and analysed the minutes of the policy makers' discussion from the third state. The respondents were heterogeneous with respect to background: career public administrators, scientists (and engineers), or lawyers.

### INTERVIEWS

The open ended, in-depth interviews were conducted face-to-face or by telephone<sup>24-26</sup> and ranged from 45–90 minutes. Five of the respondents permitted audiotaping, and the tapes were transcribed. Two other respondents permitted extensive note taking. The unstructured format allowed for the proffering of information that we could not have anticipated.<sup>27-31</sup> We began interviews by asking respondents to tell the story of their involvement in the process of drafting and finalising the tobacco control regulation or risk assessment. If they did not mention it in their narrative, respondents were encouraged to: compare the process of working on the tobacco control policy with other policy initiatives on which they worked; describe the role that empirical research played in their deliberations, and criteria used to evaluate the research; assess the role of tobacco control advocates and scientists in the process; and if they had advice for tobacco control advocates.

### ANALYSIS

The data consisted of interview transcriptions, detailed field notes, and deliberation minutes.

We worked inductively, not knowing the specifics of what we would find when we began the data analysis. The first author coded the data by organising it into categories on the basis of themes, concepts, or similar features. The transcripts were reviewed as comparative cases; the coding was guided by questioning how the perspectives and experiences of one official compared to the others. The first author organised the raw data into conceptual categories to create themes or concepts that were in turn used to analyse subsequent data.<sup>32</sup> The codes that were inducted from the data were used to label chunks of data (words, phrases, sentences, or whole paragraphs) by using QSR NUD\*IST software for qualitative data analysis. To document the coding process, the first author wrote analytical memos about explanations and generalisations that were grounded in the data, but moved beyond simple description. Together both authors discussed and further developed these analytical memos. Our analysis of the interview data includes the recurring ideas, reactions, and expressions found throughout the transcriptions of the interviews and the minutes of the board meeting. We present policy makers' perspectives on tobacco control advocates' roles in regulation development.

## Results

### WRITTEN COMMENTARY

Regulators are required to review the written commentary on proposed regulations. The policy makers who were part of regulatory bodies were amazed by the sheer volume of written commentary submitted with respect to ETS and indoor air regulations. As one regulatory panel member observed:

"We received like 110 000 comments, when normally we received a thousand comments of which maybe a dozen would be substantive. Here, out of 110 000 comments, probably a thousand were substantive. So we knew we were going to be in for a major battle . . . We were a small, under funded agency with very few PhDs, and we were likely to be totally swamped by the volume of information."

The policy makers' challenge was managing and evaluating this mass of technical and scientific information. They had to make judgments about how to sort through the material and decide which comments were important to consider in revising the draft regulation.

The types of documents submitted as written commentary included consultant reports, original scientific research articles, review articles, and government reports. Literature reviews or reports prepared by other government bodies were given higher weight because they were believed to have come from credible sources. This respondent explains:

"There were . . . extensive reports that we inherited from the EPA [Environmental Protection Agency], from the Surgeon General, that really satisfied, in large part, any requirement we had for a technical or scientific study . . . So, there wasn't any reason, with all that had been done, for us to reinvent the wheel. So, we relied heavily on stuff that we received from NIOSH, [National Institute of Occupational Safety and

Health] Center for Disease Control, Surgeon General, EPA."

Another strategy utilised by policy makers was to sort and rank the value of material submitted by assessing the quality by the standard of whether the document was published in a peer reviewed journal. The policy makers gave more weight to peer reviewed materials, as indicated in these minutes of a Labor Department board meeting:

" . . . [A] considerable number of Philip Morris' documents are extracts from materials distributed at various conferences and proceedings conducted around the world . . . Although the evidence does not establish the sponsorship for each proceeding, it also does not establish that the materials distributed at the proceedings are subjected to peer review to the same degree as are articles published in reputable scientific journals . . . Philip Morris also relies on extracts from various books. Here again, the board has not been advised as to the origins of the books, the sponsorship for the publication, or the extent of peer review. Philip Morris also relies on an editorial appearing in the *Journal of Smoking-Related Diseases* and upon a special report in the periodical *Consumer Research*. Such material is clearly not entitled to the same weight as articles appearing in high quality, peer reviewed journals."

Policy makers also relied on the sum or the weight of the evidence in toto. They looked for consistency accumulating over time in the literature, noting when many articles pointed to similar conclusions, as demonstrated in this passage from the Labor Board minutes:

"The Environmental Protection Agency (EPA) report is a comprehensive look at certain the health issues relating to ETS. It is an effort to synthesize the many studies relating to certain issues and determine what it is that the science as a whole, not just a few studies here and there, establishes regarding ETS."

When evaluating a document, the policy makers also considered the source of the document—that is, who submitted it. Our respondents considered all documents submitted to them, but were sceptical of materials provided by the tobacco industry, as explained by this policy maker:

"The tobacco companies had submitted boxes and boxes of paper . . . Most of those reports that were countering the EPA findings were advanced and/or financed overwhelmingly by the tobacco industry. So, they came in not as particularly credible to me from the get go because of the sources of funding that made the study possible. And I don't think they had the credibility generally . . . We were looking for more of the objective literature on the subject."

When policy makers had to resolve conflicting bodies of science, they were likely to consider government sources as more balanced, as explained by this respondent:

"In the ETS case, I sort of reviewed it all and just said, 'We are relying on the federal government whose job it is to provide us with information on safety and health'. We had all the data that were submitted and basically I said, 'I looked this over and we have to make a choice, and we're going with the federal data'."

In summary, to sort through the written material policy makers often relied upon summary reports of research, rather than original

source articles. They evaluated the relative importance of various documents by using criteria such as peer review, the overall weight of the evidence, and the source of funding for the document.

#### PUBLIC HEARINGS

When the officials were dealing with written commentary, their challenge was processing boxes of documents given limited time, resources, and expertise. In the public hearings, the challenge was how to deal with the public in public. At the hearings, a testifier's self-presentation and persuasiveness of argument was taken into account as policy makers struggled to be diplomatic, objective, and fair. For the most part, policy makers were scientists and administrators who wanted to focus on the evidence base for the regulation, as explained by this panellist:

"There were times when they [the tobacco industry] had all the irate smokers come in—I didn't want to hear it. So I just decided that I would stay home and work on the things that I needed to . . . and not get involved with those kind of things—you know, listening to "Joe Carton" complain that he wouldn't be allowed to smoke somewhere. Those were not scientific issues, but political issues, and were not really something that I would have any particular interest or expertise dealing with."

Policy makers made it clear that they would have preferred to keep the hearings focused on discussions of the scientific evidence base for the regulation. For instance, this policy maker explains difficulties with representatives of the tobacco industry:

*Board member:* "They were not reputable scientists."

*Interviewer:* "How did you assess that?"

*Board member:* "Well, the way they presented their arguments. I guess partly because they always came with mobs of lawyers. There was just this feeling that it wasn't really about the science."

As noted by this respondent, policy makers were aware that the public hearings were forums that rewarded the rhetorical tactics of lawyers, not the measured deliberations of scientists. Representatives of the tobacco industry have a long history of participation in many public hearings at the local, state, and federal levels, therefore their collective experience gave them an advantage. One policy maker explained that the Board had to be wary of red herring arguments, such as "particle equivalency levels", for which the tobacco industry attorneys argued that safe levels of tobacco smoke exposure could be maintained if employers installed smoke monitoring systems. Another policy maker noted how finely honed the tobacco industry strategies could be:

"They [the tobacco industry representatives] were giving the party line: that you could control tobacco smoke with ventilation, without ever mentioning how much ventilation was necessary. They kept saying that ASHRAE [American Society of Heating, Refrigerating and Air-Conditioning Engineers] amounts of ventilation were adequate, without ever saying that [it was a] standard based on odor control of ETS . . . [It] wasn't a health based standard, it was only based on odor control . . . [To] control the cancer

risk . . . you'd need 2000 air changes an hour. So you'd need a tornado inside the building!"

In addition to the content of a presenter's argument, often the policy maker noted the testifier's presentation of self. Below is a sample of quotes from the minutes of a Labor Board's deliberations:

"B....., whom, based on demeanor, background, and knowledge, the Board found to be a highly credible witness."

*later*

"According to R....., whom, based on demeanor, background, and knowledge, the Board also found to be a highly credible witness . . ."

*later*

"Overall, the Board found Dr B..... to be a highly credible witness. Her credentials are impressive, as is her experience, candor, and knowledge."

Without science presented in a written form, at public hearings policy makers were forced to make judgements about the testimony of a witness based on what they were given—witnesses' self presentation and argument. Being public administrators, scientists, or lawyers, policy makers operated in a work culture that gave greater weight to substantive written comments. Given that public forums did not provide the conditions that facilitated careful consideration of scientific fact, they valued oral testimony less.

#### ROLE OF TOBACCO CONTROL ADVOCATES

Our respondents had three central messages to advocates: highlight the science that supports tobacco control; present credible witnesses to counter industry attempts to discredit scientific evidence; and pay attention to the extra scientific factors that affect the policy process.

#### *Feature the science that supports tobacco control*

The policy makers interviewed did not necessarily call for more research, just better organisation and presentation of what was already available, which often seemed overwhelming to those assigned to multiple projects on various topics. Given that science supports the cause of tobacco control by defining health risks and strategies for decreasing or eliminating disease, it is important to organise and present it in formats that can be absorbed and utilised by overworked and under resourced regulators. Many of our respondents explained why they relied on government reports, literature reviews, and executive summaries, as does this policy maker:

"The summary-type documents are good. The rules for standard making say that we have to use the best available evidence and often times the evidence is scattered out there and it's a lot of work to put that together. If the scientists are providing evidence saying, 'Look, this is a comprehensive review, this is the best available evidence', then we can assure when we are working on regulations . . . that we're using the best available evidence . . . It is the best of all worlds to have review documents that are peer reviewed, summary documents of the state of the art. The best available information—where someone's already done that and we can just refer to it."

Therefore, tobacco control advocates can assist policy makers by bringing to their attention objective, high quality, systematic reviews of research evidence.<sup>33</sup>

#### *Involving scientists in public testimony*

Policy makers stressed the importance of engaging scientists who were sympathetic to the goals of tobacco control to argue for regulation. One respondent explained that it would be helpful if tobacco control advocacy groups simulated the structure and the coordination of the tobacco industry, acting in concert to identify key issues and set agendas. Policy makers wished that tobacco control advocates would organise to mirror RJ Reynolds' effort in assembling top notch scientists to look at the issues, find the gaps in the arguments, and offer critiques. They explained that often scientific advisory committees did not have the time for adequate deliberation, so it would be a great service if tobacco control advocates provided in-depth academic reviews. Furthermore, scientists should testify at public hearings, as observed by this board member:

"The testimony of activists who are not well informed can work against the effort. Emotional testimony does not help—it is a distraction from the policy issue. Better to have a few good testifiers who are groomed to know the issues. Present simple arguments and emphasize the science."

Policy makers were sympathetic to the challenges that coordination and production of relevant research summaries posed to public health advocacy groups given the limited resources typically available.

#### *Address the policy process*

Policy makers drew attention to aspects of the regulatory process that could be influenced by tobacco control advocates: resources devoted to regulatory policy making; timing of regulatory process; adherence to proper procedures; and lobbying pressure.

Tobacco control advocates can assist regulatory agencies by lobbying elected officials to ensure that the agency's resources dedicated to tobacco control policy development are protected from budget cuts. One of the Labor Boards was impacted by a change in the composition of the legislature while the regulation was being developed. The new legislature aimed to curtail agency operations by reducing the agency's budget. This resulted in cutting the staff assigned to work on the regulation to one person, slowing the process of rulemaking.

Policy makers also warned that speeding up the process was as problematic as slowing it down. Pressure to produce a regulation quickly had to be balanced against the potential that hasty proceedings would result in shoddy work that might not withstand the inevitable court challenge, as explained by this respondent:

"My guess is that it will take a year of really hard work to get the rule out . . . The problem is that if you rush to put out an inferior piece of work it won't withstand a court challenge. Regulatory bodies move at a very deliberate pace, and they have to pull people off the projects that they are working on to work on another project like the

ETS rule, and that takes time, people aren't available."

Of note is the fact that all three regulations and the risk assessment were subsequently challenged in court by the tobacco industry. Experience taught the policy makers that their best defence is to assure that the regulatory body has the resources to produce regulation that is strong enough to withstand subsequent challenge.

Furthermore, policy makers suggested that tobacco control advocates apply countervailing pressure to balance the lobbying pressure of the tobacco industry. Having tobacco control advocates involved is crucial in the framing of the debate. As public officials, regulatory agents are often under pressure from elected officials to retreat from controversial stands on public health issues. If there is no other voice in the forum besides the tobacco industry, it is difficult for policy makers to defend the tobacco control position without appearing biased. Many of the regulators expressed disappointment in the lack of participation by tobacco control advocates, illustrated by this board member's lament:

"All the public hearings, except for the first workshop, only the tobacco industry was represented . . . We didn't have anybody other than tobacco industry representatives, some of whom would make arguments that were rhetorical, such as 'There isn't evidence that smoking causes cancer, so how can you say that second hand smoke causes cancer?'"

When tobacco industry representatives claimed that there was no proof that smoking caused lung cancer, they shifted the parameters of the discussion to effectively push the considerations of the health effects of passive smoking and cancer off the table. Policy makers need public health advocates to pressure regulators to go farther so that tobacco control policies are framed as centrist and moderate within the policy debate. In this case, had the advocates been vocal that passive smoking caused cancer, it would have helped those on the board to keep the discussion focused on the regulation of ETS in the workplace.

#### **Discussion**

The purpose of this study was to suggest how tobacco control advocates could participate in the regulatory process in ways that are most likely to affect policy development. Policy makers advised advocates to continually reiterate that the impetus for tobacco control is evidence based and to highlight the science that supports it. Tobacco control advocates should not take for granted that the scientific base for regulation is understood and unchallenged. Science does not speak for itself; people must speak for science.<sup>34 35</sup>

Regulators advised that scientific research findings would be more likely to be utilised if they were presented in well organised and easily absorbed formats. Tobacco control advocates should engage scientific experts to participate in the regulatory process by submitting written summaries of the relevant literature, and testifying at public hearings.

Public health advocates are advantaged in that the science is on their side, so they do not have to raise funds to manufacture evidence to support their position. In contrast, the tobacco industry has spent billions of dollars to support research by funding bodies such as the Council for Tobacco Research or Center for Indoor Air Research, to produce data to counter the findings of non-industry funded scientists.<sup>17 36</sup>

Regulators advised that in addition to participating in the process by submitting written commentary and testifying at hearings, tobacco control advocates should also work behind the scenes in order to balance the pressure applied by industry representatives. For example, advocates could lobby legislators to ensure that sufficient resources are devoted to regulatory agencies. From the perspective of the regulators, public health advocates need to participate in the regulatory process in a manner that is at least as strong, visible, and organised as the corporate forces that oppose regulation. Tobacco control advocates need to understand the importance of the administrative record, because it is through the record that the agency demonstrates that the scientific evidence was the basis for the decision. Agencies will lose in court if they cannot point to the body of evidence in the record that supports its conclusions.

Policy makers emphasised that the best evidence must be used for regulatory policy formation. The policy makers tended to rely on government reviews and reports as sources of best evidence. Their suspicion of industry sponsored literature reviews is well founded given that industry-funded research studies and scientific publications, as well as lack of peer review, are associated with outcomes favourable to the industry sponsor.<sup>37</sup> Tobacco industry funded research tends to be of poor quality, published in non peer-reviewed formats, and associated with concluding that tobacco is not harmful.<sup>38 39</sup> However, despite concerns about the poor quality and credibility of research submitted by the tobacco industry, the policy makers emphasised that they were obligated to consider and, if necessary, respond to what was submitted. A role for tobacco control advocates and scientists is to provide the high quality, credible research needed to counter the tobacco industry research. Public health advocates can also comment on the tobacco industry's written submissions if the industry comments are filed before the close of the comment period. Thoughtful critiques of the science relied on in the tobacco industry comments can be helpful to decision makers.

Even though tobacco control advocates do not command the resources available to the tobacco industry, our findings suggest that activists can focus their efforts in ways that are likely to have impact on policy makers. For example, tobacco control advocates and academic researchers could develop an internet database containing the arguments used by the tobacco industry against smoking restriction regulations, responses to the arguments, and appropriate references—especially reviews and summary reports—to

#### What is already known on this topic

While there is research on how tobacco control advocates can counter the tobacco industry's influence on legislators, less is known about how advocates affect regulatory policy. Activists have recorded their political experiences in advocacy guides, yet to date, no one has gathered policy makers' perspectives on the tobacco control strategies that would enhance activists' effectiveness in the regulatory arena.

#### What this paper adds

This interview study of policy makers describes their perspective on how tobacco control advocates can influence the regulatory policy process and counter the force of the tobacco industry. Specifically, policy makers advised tobacco control advocates to: present science in a format that is well organised and easily absorbed; engage scientific experts to participate in the regulatory process; and lobby to support the tobacco control efforts of the regulatory agency.

support the counter arguments.<sup>40</sup> Using this strategy, tobacco control advocates could coordinate to match industry efforts to influence regulation development, as well as tailor their efforts to proffer credible review articles and summary reports.

We chose tobacco control as a case example because we hoped to provide activists with information on how to counter tobacco industry influence in regulatory policy arenas. Yet, there are enough parallels between the regulatory and legislative processes in order to generalise findings. Most legislation goes through a set of committees that can elect to hold hearings. Tobacco control advocates should participate in the hearings, trying to keep attention focused on the science that supports tobacco control. The regulatory and legislative processes are similar in that both demand that time and resources be devoted to sustain the effort: rushing legislation through the process too quickly can result in poorly constructed legislation that will be defeated; not keeping the legislation moving along may result in its dying in committee. Studies of behind the scenes efforts have found that legislators believe non-profit health lobbyists are more credible than tobacco industry lobbyists, yet also believe that they have too little contact with them.<sup>41</sup> There are many more legislators to be lobbied than regulators, and the stakes are higher for legislators in that voting is a public act. Public health advocates need to be aware of these challenges and be prepared to meet them.

We anticipate that these findings from the USA are generalisable to other nations where activists are pitted against industry, such as in the Ukraine.<sup>42</sup> Our findings indicate the importance of taking into account the challenges policy makers face, such as having to manage and respond to the volume of scientific

information submitted in writing, assessing the credibility of arguments made at public hearings, and coping with lobbying efforts from special interest groups. The World Health Organization, though not a regulatory agency, may face similar challenges in dealing with the public input when negotiating the Framework Convention on Tobacco Control.

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