


March 2001

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Sharon M. Friedman, *Risk Communication, the Hanford Thyroid Disease Study and Draft Reports*, 12 RISK 91 (2001).

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Risk Communication, the Hanford Thyroid Disease Study and Draft Reports

Sharon M. Friedman*

Introduction

Presenting the public with information about complex and controversial scientific questions that have health ramifications offers risk communication some of its greatest challenges. This task is made even more difficult when a draft, rather than a final, report of scientific findings is released to the public by a government agency, scientific organization or university before the report has undergone peer review. In particular, government agencies appear to be releasing more controversial draft reports than in the past (for example, the June 2000 release of the Environmental Protection Agency's draft final report on dioxin).¹ These draft reports present a number of complicated risk communication headaches for the government agency, the scientists involved, the reviewers to come, journalists and the public.

This paper reviews the problem-laden release of a draft final report in 1999 of a nine-year, \$18 million study by the Fred Hutchinson Cancer Research Center (FHCRC), done under contract for the Centers for Disease Control and Prevention (CDC). Some significant risk communication problems occurred with the release of the Hanford Thyroid Disease Study (HTDS) Draft Final Report,² despite the presence of a communication plan, a public advisory committee, a web site and an open information policy throughout the nine years of the study.

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¹ Environmental Protection Agency, *Dioxin Reassessment Draft Documents* (Sept. 2000), at www.epa.gov/ncea/pdfs/dioxin/dioxreass.htm.

² Fred Hutchinson Cancer Research Center, *Hanford Thyroid Disease Draft Final Report* (Jan. 1999).

Because of the controversial nature of the draft final report, risk communication problems even occurred for the committee established by the National Academy of Sciences-National Research Council (NAS-NRC) to review the HTDS draft report, both as this committee did its own evaluation and with the release of its review.³ This paper summarizes the risk communication sections of the book-length NAS-NRC committee review, which I wrote. It paraphrases and occasionally quotes from these sections without further citation. The references in this paper are to the original sources used for the NAS-NRC review.

Background on the HTDS

In 1986, the U.S. Department of Energy revealed that the Hanford Atomic Products Operations in Richland, WA, had been releasing radioactive material, in particular, radioactive iodine (I-131) into the environment over a period of years. Citizens of the region were concerned about whether Hanford releases of I-131 had led to an increase in thyroid disease in the people who lived in the area. Two years later, the U.S. Congress ordered a study by the CDC of the human health effects of exposure to I-131 released from Hanford.

The HTDS was extensive, contacting close to 5,200 people who had been born near Hanford in the period of 1940-1946. This time period was chosen because the period of greatest radiation release from the Hanford plant was 1944-47. Eventually, 3,441 people were enrolled in the study, given thorough medical exams to look for evidence of thyroid disease and questioned extensively about risk factors for thyroid disease. The investigators were able to estimate individual risk exposures for 3,190 of them.

As can be imagined, estimating radiation exposures of 50 years ago was a daunting task because of the many unknowns about people's lives, habits and diet. To help accomplish this, a complex statistical method devised previously by the Pacific Northwest National Laboratory was used to estimate the exposure received by each HTDS participant. Using rates of thyroid disease found among the participants and estimates of radiation exposure, the FHCRC investigators employed

³ Committee on an Assessment of Centers for Disease Control and Prevention Radiation Studies from DOE Contractor Sites: Subcommittee to Review the Hanford Thyroid Disease Study, Review of the Hanford Thyroid Disease Study Draft Final Report (2000).

statistical methods to determine whether there was a relationship between the rates of disease found and the estimated radiation exposures.

Announcing the Findings of the Draft Final Report

On January 28, 1999, the FHCRC investigators and the CDC released a draft final report of the study to the public. This draft had undergone internal review by CDC personnel and a few consultants, but it still had to be reviewed by the NAS-NRC committee. The prime finding of the draft final report was that there was no evidence linking radiation exposure from Hanford to the rate of thyroid disease found in the study population.

This negative finding upset many citizens of the region as did the way the information was released. Many residents, including some who were members of the study's advisory committee, thought the FHCRC investigators overstated the certainty of their results while presenting their findings to the media and the public. Here are a few examples of what the investigators said (emphasis added):

- Findings of the Hanford Thyroid Disease Study are *clear and unequivocal*.⁴
- This was *a very powerful study* because it included a large number of people estimated to have a wide range of exposures to I-131.⁵
- The design and successful completion of the study ensured *a very high probability of detecting relationships* between Hanford radiation dose and diseases under study if such relationships exist. The study *was very powerful* because⁶
- The study had *sufficient statistical power* to detect increases in thyroid disease risk that were predicted based on studies in other populations.⁷

⁴ See Scott Davis, Kenneth Kopecky & Thomas Hamilton, Letter to the Editor, *Findings of Study 'Clear and Unequivocal'*, Seattle Post-Intelligencer, Mar. 14, 1999.

⁵ See Press Release, Centers for Disease Control and Prevention, *Draft Report: Results of the Hanford Thyroid Disease Study* (Jan. 28, 1999) (quoting Scott Davis).

⁶ See Fred Hutchinson Cancer Research Center, *Questions and Answers about the HTDS Results*, HTDS Newsletter (Jan. 1999).

Because of the public furor in the Hanford region concerning the release of the draft report, CDC personnel added three communication questions to three scientific ones they had originally asked the NAS-NRC committee to answer about the HTDS draft report. First, was the material accurate and appropriate in providing guidance to the public in understanding the study findings? Second, if these messages needed to be amended, how should the revised messages best be communicated to the public? Third, with regard to release of future study reports, how can the CDC improve the public communication process?

As the designated risk communication person on the NAS-NRC committee, I worked with another committee member, Susan E. Lederer, a medical historian at Yale University, to answer these questions. We did this by seeking to reconstruct the situations that had led up to the release of the draft report, the manner in which it was released and the public response to it. To gather information, we interviewed one of the principal FHCRC investigators, six members of the communication and scientific staffs at the CDC, some citizen advisory group members and several regional journalists. We also heard from scientists, state and tribal nation officials and members of the public during a public meeting held by the NAS-NRC committee, which will be discussed later. We reviewed scientific, communication and planning documents related to the draft report and viewed past newspaper articles and citizen group web sites about the HTDS.

We found a number of communication problems with releasing the draft report, which was ironic, considering the openness and quality of the risk communication programming that had gone on during the nine years of the study. Communication efforts had included developing fact sheets, brochures, newsletters and a web site for the public and having a toll-free telephone number available. Special arrangements were made to let study participants know about the results of their clinical evaluation for thyroid disease. Communication with a federally appointed HTDS Advisory Committee was generally good for the length of the study, according to some of its members, as were relations

⁷ See Congressional Briefing Document on Hanford Thyroid Disease Study, Centers for Disease Control and Prevention, Summary of the Study and the Primary Findings (Jan. 27, 1999).

with various other citizen groups including the Hanford Health Information Network and the Hanford Health Effects Subcommittee. In fact, before the release of the draft final report, there were few complaints about communication issues related to the study.

Risk Communication Issues with the Release of the Draft Report

Some of the risk communication problems found with the report's release were generic to government draft reports in general and others were specific to the HTDS report. One generic issue concerned the audiences involved. There were many of them and they formed a fine example of what Krimsky and Plough have called the tangled web of risk communication.⁸ Regionally, they included three state governments and representatives of nine Native American nations; four major citizen groups plus some smaller ones; journalists; lawyers, litigants, consultants and potential expert witnesses for a class-action lawsuit; and many individuals in the region who themselves had or had family members who had some type of thyroid disease. Because of the secrecy about these radiation releases for many years, a number of citizens in the region said they were distrustful of the Department of Energy in particular and the federal government in general.

A major problem specific to the HTDS was that the communication plan described in the draft report was designed for a final report, not a draft.⁹ As with the communication efforts carried out during the length of the study, this plan was basically sound and aimed at getting understandable information to the public. It called for widespread distribution of a public summary and briefings by satellite of the various state agencies and citizen groups involved, among more standard media and public release strategies. This plan was approved by the HTDS Advisory Committee and widely disseminated in the HTDS newsletter. Unfortunately, it did not appear to be very flexible so that it could be implemented within a short timeframe and under different conditions.

A need to quickly issue a draft report acted as the main driver for the risk communication problems encountered, and three major factors

⁸ See Sheldon Krimsky & Alonzo Plough, *Environmental Hazards* (1988).

⁹ Telephone Interview with Scott Davis, Principal Investigator, Hanford Thyroid Disease Study (July 2, 1999).

interacted to bring this need about. First, there were numerous written requests to the director of the CDC's National Center for Environmental Health to make public the FHCRC draft turned over to the CDC on September 30, 1998. Some members of the public feared that the CDC's internal review would alter the FHCRC investigators' findings. Such fear is not surprising, given the distrust of federal government agencies prevalent in the area. Since these written messages to the director were received in early October, CDC officials said they interpreted the requests to mean the report should be made available to the public unchanged. Citizen demands to the CDC to release the report and not change it were exemplified in the minutes of a Hanford Health Effects Subcommittee meeting held in December 1998, where an individual at the meeting noted that "...if there are changes made between what Fred Hutchinson delivers and what comes out the door at CDC, I'm hoping that you have heard from this subcommittee clearly that we want to know what those changes were and the rationale for those changes."¹⁰

The second factor was that the NAS-NRC said that the credibility of its review would be compromised if the HTDS report were not publicly available when the review process began. After this communication, CDC and FHCRC officials decided on November 12, 1998 to release a draft final report at the end of January 1999. Reinforcing this decision was the third factor: a subpoena delivered during the week of November 16 from one party in a Hanford class action lawsuit that wanted release of the draft report within 30 days. Since a decision to release the report in January had already been made, the plaintiffs' attorneys, with the consent of the court, indicated they could wait until then.

The draft report was not released before January 1999 because of the need to write an understandable public summary. To help make the public summary as clear and effective as possible, the FHCRC investigators involved several focus groups, trying out various approaches to explaining very complicated technical information.¹¹

¹⁰ Transcript Excerpts, Hanford Health Effects Subcommittee Meeting, Salt Lake City, Utah (December 10-11, 1999).

¹¹ Davis interview, *supra* note 9.

Releasing a report with this type of import is not a simple task. Neither the investigators nor the CDC took it lightly. However, the relatively quick release of the draft report exacerbated some of the communication problems because there was not much time to work out details, particularly with the intervening Christmas and New Year holidays, according to one of the FHCRC investigators.¹² In preparing for the release, additional federal officials and clearances now came into the picture and took a high priority—another generic feature when releasing draft government reports. Besides those in the CDC, officials in the Department of Health and Human Services, the Department of Energy, the National Institute for Occupational Safety and Health, and the Agency for Toxic Substances and Disease Registry as well as congressional delegations from Washington, Idaho and Oregon all needed to be briefed. Clearances for the draft report through many government channels were put on a fast track and only took about two weeks, according to CDC personnel. But while these clearances and federal government briefings were occurring, officials imposed an information blackout about the report, and this led to a number of problems.

The blackout was imposed, according to CDC personnel, so that study participants and the public would know the results at the same time. However, this was an unrealistic hope, given the numbers of government groups that had to be briefed before the official public release. The more briefings scheduled ahead of an official release date and time, the greater the chance the report's findings will be leaked. (This is another generic problem with releasing draft government reports also exemplified by the leak of the results of the dioxin draft final report to *The Washington Post* in May 2000, one month before its release date.¹³)

As could have been predicted, the HTDS draft report's findings were leaked. *The New York Times* ran the story on January 27, 1999,¹⁴ which was then carried by the Associated Press wire service

¹² *Id.*

¹³ Cindy Skrzycki & Joby Warrick, *EPA Links Dioxin to Cancer: Risk Estimate Raised Tenfold*, *Wash. Post*, May 17, 2000, at A1.

¹⁴ Matthew L. Wald, *No Radiation Effect Found at Northwest Nuclear Site*, *N.Y. Times*,

and seen by reporters in the Hanford area about 8 p.m. that night. It was early enough, said one reporter, that she was able to add some local reaction about the findings to a story she had been writing about the release of the report the next day. Her newspaper also ran *The New York Times* story on the morning of January 28, before the official release of the draft report.¹⁵ The leak sent reporters, CDC and FHCRC officials scrambling. CDC personnel said they started to fax materials about the study's results to reporters at 6 a.m. EST on January 28, 1999, not waiting for the morning set of briefings for state health officers and the Northwest Tribal Nations and Indian Health Service, or the 1 p.m. briefing for four citizen groups. They also did not wait for the media briefing scheduled at 3 p.m. or the public briefing at 7 p.m. They began putting all of the draft report's findings on the web site at 3 a.m. EST, twelve hours ahead of schedule.

Besides contributing to the press leak, the blackout had an unhappy effect on the citizen groups that had been cooperating with the study, in particular, the HTDS Advisory Committee. Used to being informed about what was happening in the study, members were told in December 1998 that they would not be briefed about the study's findings until two hours before the media briefing. They were not happy with this schedule, which was followed even after the media leak. It caused serious problems for the citizen group representatives when reporters called earlier that day to ask them about a report they had neither seen nor been briefed on.

Even without the press leak, the regional briefings were a problem. Instead of the proposed satellite briefings in the original communication plan, conference calls were used to brief the tri-state health and tribal nation officials and the four citizen groups. These satisfied no one. One of the FHCRC investigators complained that these calls were too impersonal and unwieldy. He did not know who was on the other end; he could not show graphs or other illustrations, and he could only deliver an abbreviated version of the information that would be presented at the media and public briefings later in the day.¹⁶ People on the receiving end of the briefings complained that

Jan. 27, 1999, at A20.

¹⁵ Telephone Interview with Annette Cary, Staff Writer, Tri-City Herald (June 30, 1999).

¹⁶ Davis interview, *supra* note 9.

they heard a message they had not expected, had few details, had nothing in writing and could only ask general questions.

Perhaps all of these communication problems could have turned out to be relatively minor had major mistakes not occurred at the media and public briefings later that day. During these briefings, the FHCRC investigators presented an upbeat and very confident interpretation of their findings (exemplified by some of the statements cited earlier) with few, if any, qualifiers about statistical and other uncertainties that were in the study.¹⁷ In fact, the investigators were in the middle of conducting an uncertainty analysis, which was not working, when they released the draft report's findings. One of the investigators said that he did not discuss the uncertainties because they were technical and the focus groups held during the fall had said not to convey any technical information in the public materials.¹⁸

One reporter at both the media and public briefings was surprised by "how absolutely confident the Hutch [FHCRC] people were." She pointed out that subtleties and uncertainties were not discussed, nor were any problems with statistical power. She noted that scientists usually are not that positive about their studies and often make "conditional statements particularly when a study is still a draft and hasn't undergone peer review."¹⁹

However, another reporter who attended the media briefing said that even if the uncertainties in the study had been stressed, the media probably would not have emphasized them. She noted that the press "wouldn't have dwelt on the uncertainties" because the media, particularly broadcast media, do not go into all the technical details. She said that they would report only that "the bottom line is this. That's the way the media operate."²⁰

¹⁷ The media and public briefings were not taped by the CDC or FHCRC. Therefore there were no transcripts to review exactly what was said. Reports of what went on at these briefings were obtained through interviews with FHCRC and CDC personnel, citizen group members and journalists who attended.

¹⁸ Davis interview, *supra* note 9.

¹⁹ Telephone Interview with Karen Dorn Steele, Staff Writer, The Spokesman-Review (June 30, 1999).

²⁰ Cary interview, *supra* note 15.

It is hard not to question whether the public dismay with the report's release would still have come about if the message had been different. The main message — no link between radiation exposure and prevalence of thyroid disease — was not expected by most people in the region. Given previous positive findings of the Nevada Test Site, Chernobyl and other radiation exposure studies and the documented radiation releases from Hanford, a positive association was expected, according to local journalists and some citizens.

In this situation, with an audience very concerned about perceived high rates of thyroid disease in the population — an audience reported to have little trust in government agencies — great care should have been taken to deliver the HTDS results sensitively and tactfully. Delivering unpopular risk messages is itself risky. It has to be done delicately, with careful thought about how it will affect an audience expecting an opposite result. Varied audience responses have to be evaluated and planned for. Sensitivity needs to be shown to audience health concerns and fears. For the HTDS draft report, implications for individuals and families who had suffered from thyroid disease should not only have been explained but also highlighted. Instead the FHCRC investigators said that people in the region should be relieved that no link had been found between the releases and thyroid disease. They emphasized the statistical group effect, not the outcome for individuals.

Several months later in early May 1999, when the CDC held two poorly attended public meetings on the draft final report, it softened the tone of the message about the results, saying that there may be individuals in the overall population at Hanford who were exposed to radiation and did develop thyroid disease because of their exposure.²¹

In the public outcry that followed the January 28 release of the draft final report, many people asked why the CDC had not acted earlier to modify the overly positive tone of the investigators in both the draft report and the briefings. Some people in the region said that the FHCRC investigators were contractors and that the CDC was ultimately responsible for what was said about the study. They charged that the CDC had done a disservice to the people of the region. This is an important and complex question that involves agency-contractor

²¹ See Centers for Disease Control and Prevention, *Summary of the Preliminary Results — The Hanford Thyroid Disease Study Draft Final Report* (May 1999).

relations, academic freedom and responsibilities to the public. It becomes even more complicated if one remembers that in October and again in December 1998, citizens had urged the CDC not to alter the report as it came from the investigators. If CDC officials had requested a modified tone about the findings, they could have been accused of altering the FHCRC investigators report, said one CDC staff member.

CDC officials said that the main message was decided by collaboration between them and the FHCRC investigators after a number of discussions. Several CDC staff members noted that they had concerns that some of the messages were too strong, but after struggling with some of the language, decided to leave it as drafted by the investigators because of public pressure not to alter the report.

Despite some sensitivity to problems with language in the draft report, CDC personnel also showed some insensitivity to people and families with thyroid disease when they announced at the public briefing on January 28 that they would recommend a change in plans for medical monitoring of people in the region. No matter what reasons officials gave — including a report by the Institute of Medicine questioning the value of medical monitoring — the public linked this action to the announced results of the HTDS. And although the CDC took pains to point out to the public and the media that the HTDS report was a draft and would undergo peer and public review, the agency appeared to be basing policy decisions on it already. Even if the decision regarding medical monitoring was correct, discussing it at the same time that the HTDS draft final report was released was a mistake that hurt the CDC's credibility.

Risk Communication and the NAS-NRC Review Committee's Report

As mentioned earlier, evaluating the HTDS draft report also created risk communication problems for the NAS-NRC committee. It immediately found itself being criticized by citizen groups for holding its initial meetings in Atlanta and Augusta, rather than in Washington State. Concerned about its own credibility with both the scientific community and lay persons, particularly citizens in the Hanford region, the committee worked with selected members of the citizen groups and scheduled an open meeting in Spokane in June 1999 to hear all sides —

both scientific and public — concerning what was in the report itself and the manner in which the draft report had been released.

There was widespread notification about the public meeting to interested persons, citizen groups and government officials in three states. The meeting itself was structured to solicit comments from technical experts and laypersons on four specific and very contentious topics: thyroid dosimetry and uncertainty; other evidence and contextual information related to Hanford exposures; statistical power and study design; and communication. There were fourteen invited presentations for the four sessions, with each topic discussed for at least an hour, with an additional half-hour for public comment. These sessions were followed by an open-microphone period where anyone could bring any topic to the committee's attention. Those attending the meeting were encouraged to make oral statements and to provide written questions and comments to the committee. Written submissions from those who could not attend the meeting also were invited. (In its report, the NAS-NRC committee included an appendix that responded to selected comments made by the public at this meeting.) Sixty people from three states came to the meeting, including members of the press.

When, after nine months of review and writing, the NAS-NRC committee's report was ready for release, the committee tried not to get entangled in the same risk communication problems that had plagued the HTDS draft report. Believing that the public was the prime audience to hear its findings, the committee only held one advanced briefing for a small number of CDC staff members before the day of the report's release. Members of the congressional delegations were briefed on the same day as the public.

There was widespread notification in the Hanford region about a combined public and media briefing to release the report including articles in the major newspapers plus advertisements inviting people to attend. Three members of the NAS-NRC committee traveled to Spokane to release the report and answer questions from the media and the public at the briefing. Reporters from other locations could listen to the briefing, call in questions and then later interview the committee members by phone. The NAS-NRC also issued a news release and put it on its web site at the time of the public briefing. The next day, the

three committee members briefed a major CDC advisory body in Washington, DC. These arrangements appeared to work well: the NAS-NRC report got a fair amount of media coverage, people in the Hanford region and elsewhere seemed pleased, and there were no leaks.

Some of the NAS-NRC Committee's Major Findings

The NAS-NRC report presented a number of findings. Of the major scientific ones, the committee found that the HTDS study methods were of high quality, but it noted that considerable uncertainties existed in some of the information. The committee felt that the clinical examinations and laboratory studies were performed with scientifically valid methods and that the investigators were correct in emphasizing analyses of the radiation effect rather than comparisons with another population. It did not think that comparing the HTDS study group with some unexposed general population would be useful. However, it was concerned that the results of the study were reported — and interpreted — in black and white terms of whether a statistical test was passed or failed. It recommended that confidence limits be provided throughout the report to allow readers to judge how large a radiation effect might be consistent with the data.

Importantly, the committee said the HTDS investigators probably overstated the strength of their finding that there was no radiation effect. The committee felt that the assumptions used by the investigators to estimate the needed sample size and to calculate statistical power were incorrect because they did not acknowledge that exposures could be estimated only very imprecisely. This meant that the ability of the study to detect a negative effect was decreased.

Responding to the first communication question posed by the CDC about whether material in the HTDS draft report was accurate and appropriate in providing guidance to the public in understanding the study, the committee said that the written public materials and the oral statements made by the FHCRC investigators were accurate in representing what was in the draft report, but that they were sometimes inappropriate and misleading because they overstated the certainty or statistical power of the study and the conclusiveness of the negative findings, while not reporting any of the uncertainties.

Concerning the CDC's second communication question about how revised messages should best be communicated to the public, the committee noted that some revision had already occurred through CDC efforts at public meetings in May 1999 and in other written materials that made more of an effort to explain that no epidemiological study could determine "whether an individual person's thyroid disease is or is not caused by Hanford radiation exposure."²² The committee recommended that a new detailed but flexible communication plan be developed for the release of the final report. It said it was imperative that messages from the final report take into account the various audiences being addressed and show concern and sensitivity for the people in the region who suffer from thyroid disease. Any changes made to the draft final report must be clearly outlined and explained, including why they were made, what group suggested that they be made, and what impact they had had on the final results. Every reasonable effort must be made, the committee said, to present the full picture of the study results, including all the uncertainties and other problems. It suggested that FHCRC and CDC personnel work together on wording public messages about the final study findings, but that different interpretations between the investigators and CDC personnel should be offered to the public.

Responding to the final communication question posed by the CDC about how to improve the release of future study reports, the committee noted that trying to maintain a blackout during multiple briefings — particularly in Washington, DC — is something that the CDC should reconsider when a controversial report of great public interest is involved. It recommended that the CDC simplify its briefing procedure and that citizen groups who have long been involved in and supportive of a study be given high priority in the briefing process. The committee recommended that, if possible, one large briefing be considered when releasing controversial reports, using satellite or less expensive web transmission to reach all interested parties. It also suggested sending out both draft and final reports a few days early to journalists under an embargo so that the reporters could have a chance

²² *Id.*

to read through these usually lengthy and technical reports and develop informed questions.

Finally, the committee recommended that a workshop be held to discuss the risk communication issues that arise with releasing unreviewed draft reports to the public. The groups it recommended inviting to such a workshop included experts in risk communication, journalists, nongovernmental scientists who had worked on CDC studies, and members of citizen groups who had served on CDC advisory committees. It felt that while releasing draft scientific reports may appear to serve the information needs of the public, this action also has the potential to cause confusion and to undermine the credibility of researchers and government agencies, particularly if well-publicized findings of the draft are changed significantly in the final report. Of course, keeping information from the public can also create serious problems. The committee wanted the workshop group to evaluate the advisability of publicly releasing draft reports before external peer review and, because some releases of draft reports may be required by law or contract, to develop suggestions on how to do so effectively.

However, developing such suggestions would be somewhat difficult even if such a workshop were held. Much is still unknown about the impact of draft reports. For example, how do audiences respond to their release--do they perceive them as final information? How do members of the public use and respond to risk-related messages in draft reports? Do they act on them? How should government agencies discuss levels of scientific uncertainties in draft reports? Are there alternative ways in draft reports of addressing public concerns about highly controversial health issues such as the Hanford site and thyroid disease?

The HTDS situation has shown that releasing draft reports about important and controversial health issues without external peer review adds another dimension to the complexity that is inherent in risk communication. Given the increasing tendency of government agencies to release draft reports, it is important for members of the risk communication community to contemplate the issues that this practice brings to our field.



