Review of Studies of Possible Toxic Effects from Past Environmental Contamination at Fork Detrick: A Letter Report

ISBN
978-0-309-25486-1

29 pages
8 1/2 x 11
2012

Committee to Review Studies of Possible Toxic Effects from Past Environmental Contamination at Fort Detrick; National Research Council

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A Letter Report

Committee to Review Studies of Possible Toxic Effects from Past Environmental Contamination at Fort Detrick

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS **500 Fifth Street, NW** **Washington, DC 20001**

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This project was supported by Contract No. W81K04-06-D-0023 (CLIN 4001AB) between the National Academy of Sciences and the U.S. Army. The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

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Printed in the United States of America.

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500 Fifth Street, NW
Washington, DC 20001

February 24, 2012

COL Allan Darden
Commander
U.S. Army Garrison
Fort Detrick
810 Schreider Street
Fort Detrick, MD 21702-5000

Dear COL Darden:

At the request of the U.S. Army, the National Research Council established the Committee to Review Studies of Possible Toxic Effects from Past Environmental Contamination at Fort Detrick. The committee was charged to evaluate independently the scientific and methodologic quality and rigor of two studies: a public-health assessment conducted by the Agency for Toxic Substances and Disease Registry and a cancer investigation conducted by the Maryland Department of Health and Mental Hygiene and the Frederick County Health Department. Enclosed is the committee's letter report on its evaluation of those studies and answers to questions posed by the Army.

Sincerely,

John C. Bailar III, MD, PhD, *Chair*
Committee to Review Studies of Possible Toxic Effects from Past Environmental Contamination at Fort Detrick

INTRODUCTION

Fort Detrick is an active U.S. Army installation that includes six noncontiguous land parcels in Frederick, Maryland. Fort Detrick's Area B is about 399 acres and includes a solid-waste landfill and waste-disposal areas, an animal farm (for research purposes), a former shooting range, an explosives-storage facility, and open fields that have been used for research activities. Area B was established around 1946 as a proving ground for the Army's biologic-weapons program and was used to bury wastes, such as biologic materials, test animals, radiologic tracer materials, and chemical-agent containers (EPA 2008; ATSDR 2009). Historical documents indicate that drums containing perchloroethylene (PCE), trichloroethylene (TCE), and other organic solvents were buried in Area B. Fort Detrick's Area B groundwater was added to the U.S. Environmental Protection Agency (EPA) National Priorities List on April 9, 2009. The site was referred to EPA by the state of Maryland because it sought a long-term approach to protecting drinking-water sources. The Agency for Toxic Substances and Disease Registry (ATSDR) is required by law to conduct public-health assessments of all sites listed on EPA's National Priorities List. Currently, Area B groundwater contamination is being addressed by a remedial investigation and a feasibility study to select appropriate remedies.

CHARGE TO THE COMMITTEE AND ITS APPROACH

The U.S. Army requested that the National Research Council convene a committee to conduct an independent expert review of possible toxic effects of past environmental contamination at Fort Detrick (see Attachment A for biographic information on the members). The scope of the study is delineated below:

> An ad hoc committee will review the available investigations into possible toxicologic effects from past environmental contaminants at the U.S. Army's Fort Detrick. The study will focus on contamination of the drinking-water supply wells in Area B of Fort Detrick, and the possibility of a cancer cluster in the surrounding community. The reports to be reviewed include an assessment conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) in 2009, and the interim and final reports of an ongoing cancer assessment by the Maryland Department of Health and Mental Hygiene and the Frederick County Health Department (MDHMH/FCHD). The committee will assess the scientific and methodologic quality and rigor of these studies and, if appropriate, will consider options for additional study to address concerns about illnesses that might have resulted from past exposures to groundwater contaminants.
>
> The committee will address the following questions and points for each of the reports:
>
> - Are the reports scientifically sound and of high quality?
> - Are the assumptions valid and reasonable?
> - Are the conclusions valid?
> - Identify any limitations
> - Identify any data gaps
> - Assuming no additional data or data sources are available, identify whether any evidence-based conclusions could be reached concerning adverse health effects resulting from exposure to groundwater contaminants before 1992.
> - Assuming no additional data or data sources are available, what further studies would be recommended, if any?
> - Identify effective ways to communicate the results of the review to the stakeholders and to address their health concerns (with a focus on cancer).

- Make recommendations on specific actions to address deficiencies as identified above.

The committee held three meetings to gather data and address its task. At an open public meeting held on May 16, 2011, in Frederick, Maryland, Army representatives provided a historical overview of the environmental contamination at Fort Detrick (Craig 2011) and discussed the scope of the committee's task. ATSDR scientists discussed that agency's 2009 public-health assessment (Evans and Markiewicz 2011), and a representative of the Maryland Department of Health and Mental Hygiene (MDHMH) briefed the committee on the preliminary findings of its cancer investigation (Mitchell 2011a). The committee also was briefed on the data-collection efforts of the Kristen Renee Foundation (Pisani 2011a) and the Community Technical Advisory Committee sponsored by the Frederick County Health Department (FCHD) (Brookmyer 2011). During an open-microphone session, the committee heard the concerns of community members directly. A second open meeting was held on June 1, 2011, to get a detailed presentation of the conceptual site model that was developed by an Army contractor to estimate the contamination of Area B groundwater (Zondlo 2011). A final meeting was held on October 26, 2011, to learn about the findings of the Maryland cancer-investigation report released on October 3, 2011 (Mitchell 2011b). At that meeting, a representative of EPA gave a presentation on the agency's vapor-intrusion database and provided guidance on how such data might be used to assess whether vapor intrusion was a pathway of human exposure to PCE and TCE in the past (Dawson 2011). In addition, the Kristen Renee Foundation provided its perspective of the cancer cases in the communities surrounding Fort Detrick (Pisani 2011b).

During the meetings, residents raised concerns about several activities at Fort Detrick and the risks that they might pose to the surrounding community. They included contamination of groundwater in Areas A and B, the disclosure that field experiments with Agent Orange had been conducted, and the potential risk posed by a release event at one of the high-containment laboratories at the fort. It was evident that many in the community tended to lump these activities together and expected the committee's study to address all of them. However, the committee was constituted to address only the concerns about risks related to groundwater contamination in Area B; it was not charged or constituted to evaluate exposures that might have occurred in Area A, potential exposures to Agent Orange, or risks posed by pathogens studied at the biocontainment laboratories.

The committee is aware of research efforts that are under way, including those of the Kristin Renee Foundation, members of the FCHD Community Technical Advisory Committee for the Cancer Cluster Investigation, and a graduate student at the University of Maryland. It was beyond the committee's charge to critique those efforts. The focus of this report is an evaluation of the studies by ATSDR and by MDHMH and FCHD. The report reflects the consensus of the committee and has been reviewed in accordance with standard National Research Council review procedures (see Attachment B).

In the assessments that follow, it should be kept in mind that the objectives of the two studies were different. The ATSDR study was focused on determining whether past exposures to contaminants of Area B groundwater posed a public-health threat. ATSDR evaluated the likelihood of adverse health effects by comparing estimates of exposure to PCE and TCE with health-based reference values of those chemicals; it did not examine data on specific health outcomes in the communities around Fort Detrick. In contrast, the MDHMH–FCHD study was designed to characterize cancer incidence in the communities surrounding Fort Detrick and to determine whether the cancer-incidence data indicate unusual patterns; it did not collect or evaluate exposure information.

THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY PUBLIC-HEALTH ASSESSMENT

ATSDR (2009) conducted a public-health assessment (PHA) for Area B groundwater at Fort Detrick. The assessment had two major components: estimates of exposures to specific contaminants and

estimates of the potential adverse health effects of the exposures. Those aspects are briefly summarized below, and the summary is followed by the committee's answers to the questions that it was asked to address.

Exposure Assessment

To estimate potential human exposure to drinking-water contaminants, ATSDR considered the sources of the contamination, pathways by which the groundwater could have been contaminated, routes by which people could have been exposed, and possible contaminant concentrations. It considered PCE and TCE to be the groundwater contaminants of concern because they were detected at concentrations higher than EPA's maximum contaminant level for these solvents in drinking water (5 ppb) in off-site wells. The source of the contamination was probably buried drums known to contain PCE, TCE, and other solvents in Area B-11 (USACE 1998; EPA 2008). A conceptual site model of Area B illustrated how the solvents could have migrated from the waste pits to down-gradient wells and surface waters (Shaw Environmental, Inc. 2008). People might have been exposed by ingestion, inhalation, or skin contact. ATSDR estimated that adults and children may have been exposed to PCE at 0.00097 and 0.0021 mg/kg per day, respectively, and to TCE at 0.0011 and 0.0024 mg/kg per day, respectively. Those estimates were calculated on the basis of the highest concentrations of PCE (17 ppb) and TCE (19 ppb) measured in off-site wells and some assumptions about the exposures. For example, one worst-case assumption was that exposure was for 24 hours/day over 40 years (circa 1955–1992), and another was that all water consumed was from wells contaminated at the highest concentrations measured. Standard estimates of water-intake rates and body weights of adults and children also were used.

Public-Health Implications

ATSDR's PHA concluded that past exposure to PCE and TCE in contaminated water around the Area B site was unlikely to have produced any harmful health effects, including cancer. That conclusion was drawn by comparing the estimated doses of PCE and TCE to which adults and children might have been exposed with health-based comparison values, including EPA's reference doses (RfDs) and ATSDR's minimal risk levels (MRLs). For PCE, the RfD was 0.01 mg/kg per day on the basis of hepatotoxicity in mice and weight gain in rats (EPA 1988), and the acute ingestion MRL was 0.05 mg/kg per day on the basis of hyperactivity in mice (ATSDR 1997a). The estimated doses of PCE from the contaminated drinking water in Area B (0.00097 mg/kg per day for adults and 0.0021 mg/kg per day for children) were lower than both those comparison values.

The RfD for TCE used by ATSDR as a comparison value, 0.0003 mg/kg per day (EPA 2001), was based on effects on the liver, kidneys, and developing fetus of laboratory animals. The MRL for acute ingestion of TCE was 0.2 mg/kg per day on the basis of developmental and behavioral changes in mice (ATSDR 1997b). The estimated doses of TCE from the contaminated drinking water in Area B (0.0011 mg/kg per day for adults and 0.0024 mg/kg per day for children) were lower than ATSDR's MRL and higher than EPA's RfD. ATSDR did not consider the latter case to be of great concern, because the RfD had a total uncertainty factor of 3,000 (that is, the dose to which laboratory animals were exposed was reduced by a factor of 3,000).

ATSDR used an EPA cancer slope factor for PCE from 1987 (0.05 per mg/kg per day) and a range of cancer slope factors proposed for TCE from 2001 (0.02–0.4 per mg/kg per day) to calculate excess cancer risks for a 40-year period. The estimated excess cancer risk was approximately 2.8×10^{-5} for PCE and ranged from 1.2×10^{-5} to 2.5×10^{-4} for TCE. ATSDR concluded that those estimates fell within the range of no apparent (1×10^{-5}) to low (1×10^{-4}) increased risk.

Answers to Charge Questions about the Agency for Toxic Substances and Disease Registry Public-Health Assessment

Is the report scientifically sound and of high quality?

ATSDR was faced with the difficult challenge of evaluating past public-health risks associated with groundwater contamination in the absence of historical environmental-monitoring data. The scientific soundness and quality of the conclusions that can be drawn from such studies are questionable because of the inherent weakness of the available exposure data that can be used to verify estimates of past exposure. Although ATSDR acknowledged the limitations of its exposure assessment, the committee judged that the agency's decision to conclude that past exposures were *unlikely* to produce any harmful health effects does not capture the scientific uncertainty about exposures that occurred before 1992. Other limitations of the assessment include ATSDR's use of outdated health-based reference values to screen for potential health risks posed by exposure to PCE and TCE and its inadequate consideration of the vapor-intrusion pathway. All those factors (described in more detail below) undermine the scientific soundness of the assessment.

What are the limitations? Are the assumptions valid and reasonable?

Scientists must often make assumptions when interpreting data or making predictions in the absence of complete information. The major limitation of ATSDR's Area B groundwater assessment is that few off-site environmental data from before 1992 were available. Without adequate data, it is impossible to quantify reliably the exposures that might have occurred in the past or to determine when exposures began. Thus, ATSDR made the following assumptions about exposure: (1) the only contaminants of concern were PCE and TCE, (2) there was no drinking-water contamination before 1992 that was greater than that found in 1992, (3) only the residual contaminants present in Area B-11 waste pits affected the groundwater quality of down-gradient residential wells, (4) exposure to the contaminants was continuous over 40 years, and (5) exposure to the solvents from all routes (ingestion and noningestion) was assumed to be double the ingested dose. Each of those assumptions is considered below.

1. ATSDR's assessment assumed that only the contaminants measured above drinking-water standards in off-site groundwater in 1992 (PCE and TCE) should be evaluated for their possible health effects. Data presented in Tables 1 and 2 and Appendix B of the PHA suggested to ATSDR that it is unlikely that other organic contaminants exceeded drinking-water standards in 1992. Thus, the risk characterization implicitly assumes that only PCE and TCE migrated beyond the boundaries of Area B at concentrations greater than the comparison values. The geology of the area is highly heterogeneous karst, terrain that has landforms and hydrology that make aquifers vulnerable to contamination. Given such properties and the effects of seasonal variations in precipitation and the resulting recharge through karst, the validity of that assumption is difficult to assess without substantial site-characterization efforts.
2. ATSDR assumed that the maximum detections of PCE and TCE (17 and 19 ppb, respectively) in 1992 were the highest concentrations of those chemicals that had been present during the preceding 40 years. In the absence of contrary evidence, the committee sees no reasonable alternative to the assumption. However, as discussed below, high concentrations of contaminants were detected in 1997 in surface waters after disturbances at waste pits, and substantial release events in the past cannot be ruled out.
3. ATSDR assumed that only the residual contaminants in Area B-11 affected the groundwater quality in down-gradient residential wells. It assumed that some of the anomalies, such as short-term increases in PCE and TCE concentrations observed in Robinson Pond (Box Spring) in April 1997, did not affect the groundwater quality and reflected temporary disturbances caused by excavation operations at

the Area B-11 waste pit. ATSDR's report documented that the PCE concentration in 1997 increased from 0.54 ppb in April to 20,000 ppb in October and decreased to 0.87 ppb in November. TCE concentrations followed a similar pattern, with an increase from 4.5 ppb to 5,000 ppb and then a decrease to 11 ppb during the same period. However, if excavation operations resulted in the release of pure-phase PCE and TCE from buried drums, it is unclear why such a dense nonaqueous-phase liquid (DNAPL) release would result in a sharp signal at Box Spring. In subsurface systems, dissolution of contaminants from a pure DNAPL is a slow, mass-transfer–limited process (see Abriola 2005; Clement et al. 2004; Detwiler et al. 2009; Schaefer et al. 2009). Therefore, one would expect a DNAPL spill to yield a complex contaminant response rather than a well-defined, sharp contaminant pulse. Dickson and Thomson (2003) provided experimental data that showed that DNAPL dissolution in their fracture system could have several mass-transfer–limited dissolution stages, including a pseudosteady stage, a transient stage, and a tailing stage. In their experiment, only about 8% of the initial volume of DNAPL was removed during the pseudosteady stage. Even after the passing of about 560 and 2,600 fracture volumes of water, only about 10-60% of the initial trapped DNAPL mass could be flushed out from the fracture system. The study summarized the complexities involved in characterizing mass-transfer–limited DNAPL dissolution processes in fractured-rock systems. Schaefer et al. (2009) showed that PCE dissolution rates might be substantially lower in rock fractures than in unconsolidated porous media because the effective interfacial area per unit volume of DNAPL in rock fractures can be lower than that in sands. At Fort Detrick, there are few historical water-quality monitoring data and source-fracture characterization data available to permit full understanding of the source-receptor relationship between the spill site and Box Spring (about a mile away), where the temporary pulse response was observed. More field-scale studies (such as a tracer transport study) could lead to improved understanding of this source-receptor relationship and the associated transport pathways.

4. ATSDR assumed that exposures to contaminants in the drinking water were continuous (24 hours/day, 365 days/year) for 40 years. A 40-year exposure was assumed because disposal practices at the B-11 waste pits began in around 1955 and alternative water supplies were provided in 1992 that would have ended any exposures. The alternative water supply in some cases was bottled water. However, in such cases, residents would have continued to use well water for hygiene and household purposes, and this would have continued their exposures by inhalation and dermal absorption. Furthermore, we cannot be sure that the residents used bottled water exclusively for drinking and food preparation. Thus, the exposure could have been longer. It is also possible that the exposure was shorter, inasmuch as there is no evidence that the groundwater was immediately contaminated in 1955. In the absence of adequate historical information, accurate estimates of exposure duration are not possible. Exaggerated estimates of the duration of human exposure offset to some degree any underestimation of the average concentrations of PCE and TCE in drinking water. Overall, the committee concluded that the assumption that exposures were continuous for 40 years probably sets an upper bound on exposures; actual exposures probably were lower.

5. No data are available on the concentrations of PCE and TCE that volatilized into the air from water during cooking and other household activities or on the amounts that were inhaled or absorbed through the skin during showering or bathing. To address that gap, ATSDR assumed that the inhalation and dermal routes of exposure to water from off-site wells resulted in doubling of the ingested dose in dwellings. Although it is well established that both inhalation and dermal exposure can be important in assessing exposure to volatile organic compounds, support for doubling the ingested dose is needed. Published estimates of the contribution of inhalation and dermal exposure to overall exposure to volatile organic compounds have ranged from 2 to 10 times the ingested dose (for example, see McKone 1989; Weisel and Jo 1996; Haddad et al. 2006; ATSDR 2008), and there are inconsistencies in how other PHAs have accounted for the other pathways (for example, see ATSDR 2008). Regardless of the value used, the assumptions result in unavoidable uncertainty. However, the uncertainty of the exposure estimates could be conveyed by using upper and lower statistical bounds.

Limitations in the health-assessment portion of ATSDR's report were associated with the health-based reference values. ATSDR used outdated reference values (MRLs, RfD, and cancer slope factors) to determine the public-health implications of its estimated exposures to PCE and TCE. The PHA was produced in December 2009, more than a decade after most of the reference values were established. In the absence of current reference values from ATSDR or EPA,[1] alternatives should have been considered. For example, EPA's Office of Solid Waste and Emergency Response recommends the use of California's 2001 PCE cancer-toxicity values in the absence of relevant values in EPA's Integrated Risk Information System (OSWER Directive No. 9285.7-75, June 12, 2003). Other ATSDR assessments have followed that recommendation. A 2006 ATSDR health consultation used an oral-cancer slope factor for PCE of 0.54 per mg/kg per day (in contrast with the 0.05 per mg/kg per day used by ATSDR in the Fort Detrick assessment) on the basis of values established by the California Environmental Protection Agency (CalEPA 2001).[2] Furthermore, ATSDR's assessment did not consider cancer slope factors for inhalation (EPA 1991; Washington State Department of Ecology 2004) or whether the cancer risks associated with PCE and TCE should be summed to determine total cancer risk (EPA 2009).

ATSDR calculated an MRL for a specific route and duration of exposure and did not extrapolate for duration of exposure. The MRLs for PCE and TCE were established for *acute* ingestion (1–14 days) and have not been updated since 1997. In its PHA, ATSDR used the acute MRLs to screen for potential adverse health effects. Thus, the PHA assumed that acute-exposure guidelines are relevant for assessing risks posed by longer (chronic) exposure (assumed by ATSDR to be 40 years). That assumption is not valid, because such acute-exposure guidelines are based on short-exposure experiments, which do not adequately test effects that might result from sustained exposures. ATSDR acknowledged that limitation but used the acute MRLs in the absence of long-term values. It is important that ATSDR did not discuss the implications of the assumption, namely, that using exposure guidelines for short-term exposure will underestimate the risks associated with long-term exposure and that exposure guidelines based on short-term exposures are therefore less protective of public health.

Have exposure pathways been adequately considered?

It is unclear in the PHA whether analysis was sufficient to rule out routes of exposure other than from drinking water adequately. For example, the PHA eliminated the surface-water pathway as a source of exposure because there was no direct human-receptor contact with the water of Box Spring at or near the time of highest documented concentrations (October 1997) inasmuch as the spring was not a source of drinking water and other types of exposure to the spring would have been incidental. That is an acceptable argument, but it would have been a worthwhile exercise to describe some possible incidental surface-water exposure routes and provide a rationale for discounting them.

ATSDR's conclusion that the vapor intrusion was not an exposure pathway of concern for Area B groundwater is not supported by current EPA science and policy. The current concentrations of TCE immediately adjacent to Area B and the historical concentrations of PCE and TCE in drinking-water wells on the edge of a residential subdivision exceed current EPA screening concentrations of 1 ppb for PCE and 1.8 ppb for TCE (personal commun., H. Dawson, EPA, Oct. 26, 2011). EPA recently lowered its TCE screening concentration after the release of its final toxicologic review of TCE in support of summary information in the Integrated Risk Information System in September 2011 (EPA 2011). Thus, the committee supports the Army's plan to conduct a site-specific vapor-intrusion remedial investigation

[1]In 2011, EPA issued an updated RfD for TCE of 0.0005 mg/kg per day, which is slightly higher than the RfD used in ATSDR's assessment (0.0003 mg/kg per day) (EPA 2011). EPA also issued a slope factor of 0.05 per mg/kg per day, which is within the range of slope factors used by ATSDR (0.02-0.4 per mg/kg per day). On February10, 2012, EPA issued an updated RfD for PCE of 0.006 mg/kg per day, which is much lower than the RfD used in ATSDR's assessment (0.01 mg/kg per day) (EPA 2012). EPA also issued a slope factor of 0.002 per mg/kg per day, which is more stringent than the slope factor used by ATSDR (0.05 per mg/kg per day).

[2]The California Environmental Protection Agency has since released toxicity values for TCE (CalEPA 2009).

initially at one on-post building and five off-post buildings at the southeast corner of Area B (Shaw Environmental, Inc. 2010). Furthermore, reported concentrations of volatile organic compounds in groundwater beneath the subdivisions southeast of Area B when coupled with the uncertainty about whether historical concentrations might have been higher than available measurements suggest that vapor intrusion could have been a problem in the years after the construction of those homes in the subdivision starting in the late 1980s but before the retreat of the known plume in the late 1990s. (See Conceptual Site Model [Shaw Environmental, Inc. 2008] for data on plume retreat.)

Because the TCE and PCE plumes were not delineated throughout that period, it is not possible to know how many homes might have been affected by vapor intrusion. But it is possible to place an upper bound on community exposure by recognizing that relatively few homes are in the area and that the exposure, if any, is unlikely to have lasted much more than 10 years. (The committee was informed that the subdivisions at the southeast edge of Area B were constructed around 1986 or later.) The committee does not draw any conclusions about the health effects of potential vapor-intrusion exposures. Rather, it finds that ATSDR ruled out such exposures with insufficient justification.

Are the conclusions valid?

According to ATSDTR's standard protocol and language in its PHAs (ATSDR 2005; see Attachment C), five types of conclusions could have been drawn by ATSDR about the public-health risk from Area B groundwater: (1) an urgent public-health hazard, (2) a public-health hazard, (3) an indeterminate public-health hazard, (4) no apparent public-health hazard, and (5) no public-health hazard. ATSDR concluded that past exposure to PCE or TCE via contaminated drinking-water wells was "unlikely to produce any harmful health effects, including cancer". After reviewing ATSDR's assessment and its guidelines for drawing conclusions, the committee judged that the available information supported a conclusion that the groundwater posed an *indeterminate public-health hazard*.

An indeterminate public-health hazard is "the category used in ATSDR's public health assessment documents when a professional judgment about the level of health hazard cannot be made because information critical to such a decision is lacking" (ATSDR 2005). The committee judged that the available measurements of PCE and TCE in the groundwater of Area B were inadequate for forming reasonable estimates of past exposure. The lack of that critical information makes the uncertainties associated with the PHA too great to support a judgment about the likelihood of a public-health hazard.

What are the data gaps?

For the purposes of this review, "data gaps" refers to information that is missing but could be generated or collected to improve the quality of an assessment. That includes information on the toxicology of PCE and TCE and the extent of contaminant migration.

As noted above, outdated reference values were used in the PHA, and more up-to-date alternatives could have been used. It does not appear that consideration was given to potential risks from combined exposure to PCE and TCE. Those solvents have similar metabolites that target the same organs (NRC 2006, 2009), so exposure to both might increase risk. However, the lack of reliable exposure data is the greatest limiting factor of the PHA, so redoing the assessment with more current reference values and toxicologic information would not be a worthwhile exercise.

There are gaps in the data regarding the potentially exposed population. The PHA notes that two residences were found to have had high concentrations of PCE (17 ppb) and TCE (19 ppb) in their well water in 1992. Given the uncertainty about past exposures, the risk assessments might apply to a larger number of residents, including anyone who ever lived in a home that had a private well that was within the off-site plume southeast of Area B.

To determine which homes are within the plume, a historical delineation of the plume boundary is necessary. That leads to a third critical data gap: the extent of contaminant migration. Without historical off-site sampling data, past plume-migration patterns would have to be inferred from trace dye studies and modeling of groundwater movement. Such hindcast-modeling efforts have several inherent limitations (NRC 2009; Clement 2011); if such exercises are undertaken, their scope should be limited to the simplest model possible that would complement the available data. Emphasis should be placed on field work to collect more site-characterization and biogeochemical data before complex modeling efforts are pursued.

The Army's Fort Detrick Area B Work Plan (Shaw Environmental, Inc. 2010) proposes new dye tests and additional monitoring, which would help to fill some of these data gaps.

Can evidence-based conclusions be drawn?

As noted above, the committee concluded that the strongest evidence-based conclusion that can be drawn from the PHA is that contamination of Area B groundwater presented an *indeterminate* public-health hazard. The population most likely to have been affected by the contaminated groundwater appears to be residents of homes that were served by private water wells southeast of Area B. The number of residences affected appears to be relatively small. The lack of adequate groundwater measurements before 1992 makes it impossible to reconstruct the past exposures of those residents with sufficient scientific certainty to support any conclusions about the likelihood that adverse health effects resulted from the exposures.

MARYLAND CANCER-CLUSTER INVESTIGATION

MDHMH and FCHD conducted a study to determine whether the incidence of cancer in the community surrounding Fort Detrick is higher than that in the rest of Frederick County or in Maryland as a whole. The study first focused on three census tracts (roughly corresponding to the area within 1 mile of Fort Detrick's fence line) and considered cancer cases that had been reported to the Maryland Cancer Registry in 2000-2007. A progress report of the study issued in October 2010 (MDHMH/FCHD 2010) indicated that the number of cancers in the three census tracts around Fort Detrick was not statistically different from the expected number of cases based on data from Frederick County. The total number of all cancers and lymphoma was statistically higher than expected on the basis of Maryland data. The study was later expanded to include an additional seven census tracts around Fort Detrick (corresponding roughly to a 2-mile buffer around the fort) and Cancer Registry data from 1992–2008 (MDHMH/FCHD 2011a; Mitchell 2011a). The later analysis revealed no excess occurrence of cancer.

A summary report of the findings of the study was issued on October 3, 2011 (MDHMH/FCHD 2011b). Box 1 presents the major findings of the investigation, which found no evidence of a cancer cluster in Frederick County. MDHMH and FCHD plan to continue to review cancer-incidence data as they become available. The agencies will follow up on the observed increase in cancers from 2001 to 2006 and examine which types of lymphoma contributed to the increase in lymphoma rates and the ages at onset of each of the subtypes.

Answers to Charge Questions about the Maryland Cancer Investigation

Is the report scientifically sound and of high quality?

The analyses of cancer incidence rates in Frederick County and the selected census tracts were in general scientifically sound and of high quality, given the typical limitations of cancer-surveillance data from state registries. Cancer incidences in Frederick County, Maryland, and the United States were

compared, and standardized incidence ratios (SIR) were generated to compare cancer incidence in the selected census tracts with incidences in Frederick County and Maryland. MDHMH and FCHD used standard methods for analyzing the data and presenting the results. The retrospective geocoding of the pre-2001 cancer-incidence data permitted a more comprehensive and powerful analysis of the data. The committee also found that MDHMH and FCHD did a good job of keeping the community well informed throughout the process.

The committee identified some ways in which enhanced data presentation and analysis would facilitate the interpretation of the study, including the following:

- A summary of the populations of Frederick County and Maryland is presented in Table 1 of the MDHMH and FCHD report (MFDHMH/FCHD 2011b). It would be helpful to see such data on the 1990, 2000, and 2010 censuses from the U.S. Census Bureau, from which the denominator data were obtained. Summary measures similar to those presented in Table 1 for the state, county, and specific census tracts, if available, would greatly improve a reader's ability to interpret the study results.

BOX 1 Findings of the Investigation of Cancer Concerns in Frederick County, Maryland (MDHMH/FCHD 2011b)

- Compared with Frederick County, there were no statistically significant increases in all cancers or in specific types of cancer in the three census tracts that constitute an area of 1-mile radius around Fort Detrick for the period 1992-2008.
- Compared with Maryland as a whole, lymphoma was slightly increased in the same period (1992-2008). There were no increases in any other cancers or in all cancers compared with the state as a whole.
- When another seven census tracts were added to the original three, expanding the buffered area around Fort Detrick to about a 2-mile radius, there were no significant increases in all cancers or in specific types of cancer around Fort Detrick in the period 1992-2008 compared with Frederick County or the state as a whole.
- According to an earlier analysis, the age-adjusted rate of all cancers in Frederick County had increased from 2001 to 2006 compared with both Maryland and the United States. The increase is unlikely to be related to environmental exposures in the Fort Detrick area. If cancer occurrences were affected by environmental exposures decades ago, the effect would be less likely to show up in a narrow range of time than to be spread out over many years. Analysis of the cancer rates in the three census tracts closest to Fort Detrick in 2000-2007 did not show significant increases in the cancers of greatest concern compared with either Frederick County or the state.
- Analysis of potential space–time "clustering" using the SaTScan program[a] showed no significant clusters when specific cancer diagnosis groups were compared with all cancer in the 10 census tracts and Frederick County in 1992-2008.
- There was no significant difference in the ages at diagnosis of cancers in specific diagnostic groups in people who lived close to Fort Detrick (within the 10 census tracts immediately surrounding the installation) compared with people in Frederick County as a whole.
- Examination of the reports by the citizens in the community showed that although there was some correspondence between those on the citizen list and those registered with the Maryland Cancer Registry, the disparity between the two data sources was sufficiently high that the citizens' reports of cases could not be used directly as a case-finding source.

[a]SaTScan is statistical software used to analyze spatial, temporal, and space-time data. It can be used to explore whether disease clusters are present over space, over time, or over space and time.

- The analysis compared specific census tracts with the whole of Frederick County. Although that is not an unusual approach, the 10 census tracts account for a large proportion of the county population. (To compare a part with a whole that contains it also requires a different form of statistical analysis that is based on p values.) An analysis that compared the census tracts surrounding Fort Detrick with the remainder of Frederick County would more clearly describe any differences in cancer rates between the census tracts and the rest of the county.
- The committee supports MDHMH's and FCHD's intent to conduct a more detailed analysis of the increase in lymphoma and of the specific cancers that contributed to the temporary increase in cancer rates in Frederick County. Consideration might also be given to analyzing rarer cancers, which may be related to environmental exposures. For example, renal-cell carcinoma is associated with exposure to TCE (EPA 2011). A large proportionate increase in some uncommon cancers (by site or histologic type) might be less important numerically than a small increase in a common form but much easier to detect because of the lower background rate. Describing the occurrence of uncommon cancers, ones that do not fit conveniently into broad categories, will give the public a more complete accounting of the cancer burden in the community. It is likely, however, that most of the categories will have too few occurrences for a useful statistical analysis.
- The analysis of geographic and temporal clustering with SaTScan software is appropriate for exploring potential cancer patterns throughout Frederick County over time. The method takes advantage of available individual-level address information on cancer cases. However, using all cancers as a denominator assumes that the spatial and temporal distribution of the underlying population is proportional to the density of cases, which might not be true for all areas or periods. Sensitivity analyses using alternative denominator distributions (such as only melanoma cases) could be conducted as a followup. In addition, a space-only analysis could be considered for examining geographic trends independent of time.

Put more simply, MDHMH and FCHD used appropriate statistical software to determine whether there was a cancer cluster, but the analyses used data on the total number of all cancers that occurred in Frederick County each year for comparison without considering any changes in the demographics of the populations over time. Thus, it was assumed that the characteristics of the population changed in proportion with that reflected in the total number of cancers. That might not be true for all areas or periods, and it would be helpful to explore this issue or use other types of comparisons if further analyses are performed.

Are the assumptions valid and reasonable?

Most of the assumptions used in the analysis were reasonable and valid. The analysis and interpretation were based on assumptions that are standard for cancer-registry data—all cases that occur in the state are ascertained, the ascertainment of the cancers is consistent across time and the population, the diagnosis of cancer (by site and type) is consistent across the population, and the population is adequately characterized. Although it is arguable that no cancer registry can meet all those assumptions in a strict sense, the analysis presented by MDHMH and FCHD has considered them appropriately.

The one assumption that might be useful to revisit pertains to the population. The analysis assumed that the population of Frederick County, the specific census tracts, and Maryland changed equally over time. Data from the U.S. Census indicate that Frederick County grew much faster than Maryland between the 2000 and 2010 censuses (by 19.5% vs 9%) (U.S. Census Bureau 2010). Because the population of Frederick County grew faster, the rates of cancer in the county and census tracts are most likely overestimated in the report. The extent of the overestimation depends on the size and age structure of the population and could affect the interpretation of the SIRs, especially for lymphoma.

Are the conclusions valid?

Given the potential limitations above, the conclusion that the total cancer rates in Frederick County and the selected census tracts are not different from those in Maryland is appropriate. Likewise, the conclusion that the rates of lymphoma are greater in the three census tracts than in Maryland also appears to be valid with the proviso noted earlier regarding likely underestimation of the population denominator. MDHMH and FCHD identified potential next steps to clarify those results. The committee agrees that further characterization of the rates of lymphoma by subtype and a more detailed exploration of the temporary increase in the rate of all cancers (in 2001–2006) in Frederick County are warranted. Whereas the number of cases of lymphoma by subtype and the total number of 2001–2006 cases in the Maryland Cancer Registry may not be sufficient to provide definitive findings, the additional analyses could be valuable in addressing community concerns regarding experience of cancer in the vicinity of Fort Detrick, and they would render the MDHMH–FCHD report more complete in its analysis of pertinent cancer data. Because of the limitations inherent in cancer-cluster investigations, no study will be able to provide definitive findings, regardless of the number of cases.

MDHMH and FCHD drew no conclusions about the relationship between exposures at Fort Detrick and the rates of cancer in the surrounding community (MDHMH/FCHD 2011b). That is appropriate given the limitations of the exposure data and the small population exposed.

MDHMH and FCHD also examined mean ages at diagnosis of cancer in the selected census tracts, the county, and the state by cancer type. Overall, there did not appear to be significant differences in ages at diagnosis when the selected census tracts were compared with the county, but differences in ages between census tracts and the state were not statistically tested. Because median ages for bone and endocrine cancers differed by 6 years between the selected census tracts and the state, the committee suggests that further exploration of subtypes of those cancers according to ages at diagnosis be considered by MDHMH and FCHD as part of followup analyses.

MDHMH and FCHD considered incorporating cancer cases collected by citizens into its investigation. The agencies attempted to link the cancers reported in the community study to the cases in the cancer registry, but found that the community-reported cases constituted a nonsystematic sample of cancer-registry cases during 1992–2008. Many community-reported cases could not be incorporated into the study, because they were diagnosed before 1992 or after 2008, some had no reported diagnosis date, some were missing identifying information, and others could not be used for additional reasons. The committee agrees with the MDHMH and FCHD decision not to include the citizen data in the analysis.

What are the limitations and data gaps?

The limitations pertaining to this type of analysis have largely been characterized in the MDHMH–FCHD report. The committee identified two other limitations that might be addressed to improve any later analysis of the data. The assumption of a constant increase in population over time in all geographic regions could be addressed by using intercensus estimates of population of the county. Those data are available and should be used to characterize the rates and SIRs properly. In addition, MDHMH and FCHD devoted a substantial section of their report to discussion of environmental issues near Fort Detrick, although these had no role in the rest of the report, given the nature of the data and methods of analyses used in the study.

Can evidence-based conclusions be drawn?

The well-conducted analysis of cancer-registry data by the MDHMH–FCHD investigation neither supports nor refutes an association between Area B groundwater contamination from Fort Detrick and the

occurrence of cancer. There is little evidence to characterize exposures of people living in the selected census tracts in an etiologically relevant period. As mentioned elsewhere in this report, proximity of residence to Fort Detrick does not equate to exposure.

ADDITIONAL STUDIES POSSIBLE BUT NOT RECOMMENDED

The committee was asked to consider whether additional studies should be performed that would be helpful in addressing the question of whether any health outcomes might be related to contaminated groundwater in Area B. The committee explored the possibility of conducting two studies—cancer-mortality studies, parallel to the MDHMH-FCHD incidence studies, and a retrospective study of vapor intrusion. The committee considered approaches for conducting such studies and what information they could contribute. After careful consideration, *the committee has decided that these studies should not be conducted*. The discussion below documents the committee's consideration of each study and why it believes that they should not be performed.

Cancer-mortality studies might supplement incidence studies because they could provide information on cancers that are substantially affected by variations in screening programs and diagnostic standards over time and space. Use of data from cancer-screening programs can appear to increase incidence by finding and reporting borderline or benign lesions that would not progress to clinical cancer. Mortality data on such cancers could help with interpreting incidence data, although mortality studies might be influenced by variations in the success of medical treatment. Sites for which mortality studies might add to what we know about incidence include prostate, breast, thyroid, and large bowel. However, no unusual incidence of cancer at these sites was found in the MDHMH-FCHD study. Thus, the committee does not recommend cancer-mortality studies, because the results are unlikely to add to conclusions based on the incidence studies.

It would be possible to construct a study to develop a more complete picture potential vapor-intrusion exposures in the residential subdivision to the southeast of Area B, but the committee believes that the difficulty of achieving useful results outweighs the potential usefulness. The following are features of such a study and difficulties in achieving useful results:

- Use known information about groundwater flows and contamination data to model past off-post groundwater plumes of PCE and TCE in Area B. Because of the karst geology at the site, such estimates would be highly uncertain.
- Use indoor radon sampling in homes above the modeled plume to determine whether pathways exist between the subsurface and living spaces (EPA 2002; ITRC 2007; Dawson 2011). This would place an accurate upper bound on the number of homes structurally susceptible to vapor intrusion. It would be an upper bound because cracks and holes in foundations or floors might have opened after vapor concentrations receded.
- Identify the people who live or lived in the homes susceptible to vapor intrusion and conduct a health survey. Depending on turnover of occupancy, this could be difficult, expensive, and time-consuming. Because exposure would have begun only after the homes were built and people moved in, less than 25 years ago, it is possible that any cancers potentially initiated by the exposure have not yet been manifested. Even in the best of circumstances, such a study would generate uncertain or questionable results. Because other factors could contribute to any illness or condition, the results would have little value. The cleanup of the plume (and possible mitigation of the small number of buildings still above the plume) will continue regardless of health findings.

Although the two studies described above would add to the information base about possible adverse effects of exposure from Fort Detrick, the committee concludes that unless measurement data from the past are discovered, the increased knowledge would not be useful in assessing hazards. Reasons for that include the very small population subjected to known releases, the relatively low and poorly

documented concentrations in those releases, the time elapsed since exposure began, and the lack of a "fingerprint" cancer that is specific to the chemical exposures in question.

COMMUNICATING RESULTS TO STAKEHOLDERS

This committee was charged with identifying effective ways of communicating results of its review to stakeholders and addressing their health concerns. Many stakeholders in the Fort Detrick area may be skeptical of any health review that does not associate health outcomes, such as cancer, with contaminant releases from Fort Detrick. Their skepticism results from the complexity of such reviews, limitations and data gaps, and, in a portion of the population, a general mistrust of Fort Detrick. This has led some groups to perform their own analyses and to draw their own conclusions. For example, the Kristen Renee Foundation refers to "over 600 families that have been affected with cancers and diseases that are linked to [exposures to TCE, PCE, and Agent Orange]" (Kristen Renee Foundation/Fighting for Frederick Mail Survey). However, although some people in the community might have ingested, inhaled, or otherwise come into contact with these compounds, the exposure data are too sparse to determine whether there was widespread exposure in the past.

The committee believes that the underlying reason that many Fort Detrick neighbors consider the Army responsible for their ailments is a legacy of mistrust. Many in the community accept the need for secrecy in some operations at the fort for reasons of national security, but they generally do not believe that information about the release of hazardous substances should be concealed. Some citizens tend to be suspicious when the Army says that it cannot find records associated with the facility's early operations. The committee recognizes that the Army, particularly in recent years, has made a great deal of information available, but some of the historical data are still difficult to find and hard to interpret.

Furthermore, Fort Detrick has been associated with some programs, such as the development of biologic weapons and the testing of herbicides for military use, that are of concern to the community. Its current mission of biologic defense adds to public concern because the laboratories on the fort handle infectious agents that can cause serious or lethal diseases, so research performed with them must be contained in specialized laboratories. Finally, the Federal Bureau of Investigation's conclusion that the U.S. Army Medical Research Institute for Infectious Diseases at Fort Detrick was the source of the 2001 anthrax letters (DOJ 2010) heightened concern that the fort poses a threat to local health and safety. As testimony at the committee's public meetings indicated, people tend to combine all those concerns.

Against that backdrop, it might be difficult for people suffering from cancer or other serious diseases and their families to accept scientific findings that do not confirm their fears. Moreover, when faced with scientific findings indicating that the available data are insufficient to link contaminant releases to nearby illnesses, it is natural for people affected with cancer, their relatives, and friends to seek the collection of more data. However, as the committee found, it is unlikely that additional study will establish such a link and, for the types of chemical releases reported at Fort Detrick, extremely unlikely that individual causality can ever be proved. Health screening does not appear to be warranted unless new information that documents past exposure (before 1992) to unusual concentrations of contaminants in groundwater is discovered.

To help members of the Frederick County community to sort through the evidence of possible links between Army activities and public health, the committee suggests first that all parties recognize that risk depends on the existence of completed exposure pathways (simple proximity to Fort Detrick does not in itself impart increased risk). Geologic analyses indicate that groundwater contaminants from Area B migrated off site in the southeast direction; therefore, the primary exposure pathway is toward homes in this area that have drinking-water wells. A substance cannot cause disease in the absence of plausible pathways. It is not possible to infer or refute the existence of pathways on the basis of the existing epidemiologic evidence.

Second, it is important to disentangle the various concerns of Fort Detrick neighbors. The committee heard concerns about groundwater contamination, tests performed with Agent Orange, and

research being conducted in high-containment laboratories. Those are distinct activities and involve different agents of concerns and pathways of exposure. It is important for it to be clear that the results of the present review pertain only to groundwater contamination in Area B.

Third, agencies conducting health evaluations should be careful not to overstate the evidence. For example, the ATSDR PHA found it unlikely that Area B groundwater contamination caused off-post health effects. The present committee judges that the exposure data are inadequate for ruling out health consequences of possible past exposures and that a more appropriate conclusion would have been that the groundwater presented an *indeterminate* public-health hazard.

Fourth, more information about health experiences in general could put some health findings into context. For example, the committee heard testimony from some citizens who believed that multiple cases of cancer in a neighborhood constitute clear evidence of an environmental cause. However, cancer as a class of diseases is fairly common. The American Cancer Society estimates that one in two men and one in three women will develop cancer during their lifetimes (ACS 2010). The cancer incidence in the neighborhoods near Fort Detrick, at least since 1992, appears to be typical of rates seen in Maryland and in the United States as a whole. Another important message is that the types of health effects linked to PCE and TCE in the toxicologic and epidemiologic literature are not specific to those chemicals; the occurrence of a particular health problem is not necessarily indicative of an environmental exposure to them. Such a specific link has been found for only a few environmental agents. (For example, a rare form of cancer, mesothelioma, is caused by exposure to asbestos. Because no other causes of that disease have been found, the development of mesothelioma in the lung is a "fingerprint" cancer that indicates exposure to asbestos.)

In sum, the tendency of many people in the Fort Detrick area to hold the Army responsible for their cancers and other diseases is primarily a function of distrust based on Fort Detrick's known activities, and its secrecy about them, over the last several decades. It is likely that some citizens and their families will continue to question even the most careful, authoritative explanations of the limitations of health studies. To communicate the results of health evaluations to community stakeholders in the Fort Detrick area effectively, the Army and the health agencies should

- Focus on evidence, including the geographic boundaries of plausible human exposures to groundwater contaminants, that is easily comprehensible and helps to put findings into context.
- Ensure that evidence in support of conclusions is publicly available while clearly acknowledging that the absence of documented health effects does not necessarily prove that there is no increased risk associated with exposure.
- Engage in activities, beyond health reviews, that build trust with the community. For example, more public engagement might be considered for Fort Detrick's Installation Restoration Program beyond public representation on the Restoration Advisory Board. The 2009 listing of Area B on EPA's National Priorities List might make this easier.

CONCLUDING STATEMENT

Members of the public who live near Fort Detrick are concerned about releases of carcinogens and other hazards that might affect their health. Such releases in Area B have been documented, and the committee recognizes that there are legitimate concerns about health effects of them, but the investigations to date have not demonstrated exposures to high concentrations of contaminants or unusual incidences of cancer. Thus, the question arises whether additional research could lead to the identification of additional toxic exposures or adverse health effects.

A central focus of the committee's deliberations was the question of what research would serve the public interest and whether recommending research projects that are unlikely to be informative might be harmful to the public by raising false hopes, by shifting resources away from efforts with a greater likelihood of useful outcome, or by diverting attention from other approaches to dealing with possible

environmental-contamination problems. The obstacles to direct identification of health effects of toxic releases from Fort Detrick are formidable, and several important data gaps cannot be overcome with additional research. Thus, no further historical studies of cancer or other health outcomes in the vicinity of Fort Detrick appear to be indicated, because it is extremely unlikely that any such studies would yield information about whether past exposure to groundwater contaminants from Area B at Fort Detrick is related to health outcomes in the surrounding community. Some followup steps can be taken to enhance the MDHMD-FCHD study, but they are unlikely to change the overall findings.

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DEFINITIONS OF SELECTED TERMS

Exposure: Contact with a substance by ingesting it, breathing it, or touching it with the skin or eyes.

Exposure assessment: A determination of how people come into contact with a hazardous substance, how often and for how long they are in contact with it, and how much of it they are in contact with.

Hazard: A source of potential harm from past, current, or future exposures.

Minimal risk level: An Agency for Toxic Substances and Disease Registry estimate of daily human exposure to a hazardous substance at or below which the substance is unlikely to pose a measurable risk of harmful noncancerous effects.

Reference dose: Defined by the Environmental Protection Agency as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population (including sensitive groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Generally used in noncancer health assessments.

Risk: The probability of adverse effects of exposure to an environmental agent.

Slope factor: Defined by the Environmental Protection Agency as an upper bound, approximating a 95% confidence limit, on the increased cancer risk posed by lifetime exposure to an agent. It is usually expressed in units of proportion (of a population) affected per mg/kg per day and is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks of less than 1 in 100.

Standardized incidence ratio: The ratio of the number of observed cancer cases in a study population to the number expected in a standard population. If the ratio is greater than 1.0, it is said that there are excess cancers in the study population.

ATTACHMENT A

Committee to Review Studies of Possible Toxic Effects from Past Environmental Contamination at Fort Detrick

Members

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Biographies of the Committee

John C. Bailar III is professor emeritus at the University of Chicago. He is a retired commissioned officer of the U.S. Public Health Service and worked for the National Cancer Institute for 22 years. He has also held academic appointments at Harvard University and McGill University. Dr. Bailar's research interests include assessing health risks posed by chemical hazards and air pollutants and interpreting statistical evidence in medicine with an emphasis on cancer. He has served as chair or a member of numerous committees of the National Academies, including current service on the Committee on the Analysis of Cancer Risks in Populations near Nuclear Facilities. He received his MD from Yale University and his PhD in statistics from American University. Dr. Bailar was elected to the Institute of Medicine in 1993.

Bruce H. Alexander is a professor in the Division of Environmental Health Sciences of the University of Minnesota School of Public Health. His research interests are in applied occupational and environmental epidemiology, epidemiologic methods, and global health. His current research includes respiratory health and community exposure to asbestos-contaminated vermiculite; mortality, cancer incidence, and respiratory health in taconite production workers; health effects of occupational exposure to fluorochemicals; health effects of ionizing radiation in the medical field; and injuries in farm families. Dr. Alexander was a member of the National Research Council Committee on Tetrachloroethylene. He received his MS in environmental health from Colorado State University and his PhD in epidemiology from the University of Washington.

Prabhakar Clement is a professor of environmental engineering and Arthur H. Feagin Chair of Civil Engineering at Auburn University. Before joining the university, he worked as a senior research engineer at the Pacific Northwest National Laboratory for 6 years and then as a senior lecturer in the Department of Environmental Engineering at the University of Western Australia for 3 years. His research interests are in modeling of water flow and reactive-contaminant transport in groundwater systems, bioremediation of contaminated aquifers, numerical modeling of environmental processes, water-quality modeling, and optimal design of treatment systems. He is a member of the Groundwater Quality Committee of the American Society of Civil Engineers (ASCE), and was a member of the National Research Council Committee on Contaminated Drinking Water at Camp Lejeune. He has served as the associate editor of various journals, including *Ground Water*, *Vadose Zone Journal*, *Journal of Contaminant Hydrology*, and ASCE's *Journal of Hydrologic Engineering*. Dr. Clement received his master's degree in physics from American College, Madurai University, his MTech in environmental sciences and engineering from the Indian Institute of Technology, Bombay, and his PhD in civil engineering from Auburn University. He is a registered professional civil engineer.

Mary E. Davis is a professor in the Department of Physiology and Pharmacology of the West Virginia University Health Sciences Center. Her research interests are in the toxicology of environmental and occupational pollutants, including water-disinfection byproducts, halogenated solvents, and arsenic. She is particularly interested in mechanisms of toxicity in the liver, kidneys, and vascular system. Dr. Davis was treasurer of the Society of Toxicology and is a former president of the society's Allegheny-Erie Regional Chapter. She has served on the U.S. Environmental Protection Agency Science Advisory Board and the editorial boards of *Toxicology* and *Toxicology and Applied Pharmacology*. She was a member of the National Research Council Committee on Assessing Human Health Risks of Trichloroethylene and the Committee on Tetrachloroethylene. She received her PhD in pharmacology from Michigan State University.

Judith B. Klotz is an adjunct associate professor at the University of Medicine and Dentistry of New Jersey School of Public Health and holds the same appointment at the Drexel University School of Public Health. Previously, she was program manager of the cancer surveillance and environmental epidemiology programs at the New Jersey Department of Health and Senior Services. Her research interests are in epidemiologic studies of cancer incidence and reproductive outcomes, gene–environment interactions, evaluation of biologic exposures to environmental contaminants, and the application of health risk assessment and epidemiology to public policy. Dr. Klotz was a member of the National Research Council Committee on Fluoride in Drinking Water. She received her MS in genetics from the University of Michigan and her DrPH in environmental health sciences from the Columbia University School of Public Health.

Leonard M. Siegel is executive director of the Center for Public Environmental Oversight, a project of the Pacific Studies Center that facilitates public participation in the oversight of military environmental programs, federal-facility cleanup, and brownfield revitalization. He is one of the environmental movement's leading experts on military-facility contamination, community oversight of cleanup, and the vapor-intrusion pathway. For his organization, he runs two Internet newsgroups: the Military Environmental Forum and the Brownfields Internet Forum. Mr. Siegel also serves on numerous advisory committees. He is a member of the Interstate Technology and Regulatory Council's Permeable Reactive Barrier Work Team, the Department of Toxic Substances Control (California) External Advisory Group, California's Brownfields Revitalization Advisory Group, and the Moffett Field (formerly Moffett Naval Air Station) Restoration Advisory Board. He has also served on several committees of the National Research Council, including the current Committee on Future Options for Management in the Nation's Subsurface Remediation Effort and Committee to Review Risk Assessment Approaches for the Medical Countermeasures Test and Evaluation Facility at Fort Detrick, Maryland. Mr. Siegel majored in undergraduate physics at Stanford University.

Verónica M. Vieira is an associate professor in the Department of Environmental Health at the Boston University School of Public Health. Her research interests are in spatial analysis methods, exposure modeling, and cancer epidemiology. She has extensive knowledge of geographic information systems, groundwater modeling, cluster detection methods, and persistent environmental contaminants, including tetrachloroethylene, perfluorooctanoic acid (PFOA), and polybrominated diphenyl ethers. She is involved in a multiuniversity community health project, which involves historical reconstruction of PFOA exposures of people living near a chemical plant in the mid-Ohio valley, and in the Boston University Superfund Research Program, in which she works on applying disease mapping to various health outcomes, including cancer, birth outcomes, and rheumatoid arthritis. Dr. Vieira received her MS in environmental engineering from Stanford University, and her DSc in environmental health from Boston University.

ATTACHMENT B

Reviewer Acknowledgments

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of the independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of the report:

Henry Anderson, Wisconsin Division of Public Health
James Bruckner, University of Georgia
Thomas Burke, Johns Hopkins Bloomberg School of Public Health
Lewis Goldfrank, New York University School of Medicine
Linda McCauley, Emory University
Kurt Pennell, Tufts University

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by Georges Benjamin, of the American Public Health Association. Appointed by the National Research Council, he was responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the author committee and the institution.

ATTACHMENT C

ATSDR Public-Health Conclusion Categories

Category 1: Urgent Public Health Hazard

This category is used for sites where short-term exposures (<1 year) to hazardous substances or conditions could result in adverse health effect that require rapid intervention.
This determination represents a professional judgment based on critical data which ATSDR has judged sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete; in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information[a] indicates that site-specific conditions or likely exposures have had, are having, or are likely to have in the future, an adverse impact on human health that requires immediate action or intervention. Such site-specific conditions or exposure may include the presence of serious physical or safety hazards, such as open mine shafts, poorly stored or maintained flammable/explosive substances, or medical devices, which upon rupture, could release radioactive materials.

Category 2: Public Health Hazard

This category is used for sites that pose a public health hazard due to the existence of long-term exposures (>1 year) to hazardous substances or conditions that could result in adverse health effects.
This determination represents a professional judgment based on critical data which ATSDR has judged sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete; in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information[a] indicates that, under site-specific conditions of exposure, long-term exposures to site-specific contaminants have had, are having, or are likely to have in the future, an adverse impact on human health that requires one or more public health interventions. Such site-specific exposures may include the presence of serious physical, such as open mine shafts, poorly stored or maintained flammable/explosive substances, or medical devices, which upon rupture, could release radioactive materials.

Category 3: Indeterminate Public Health Hazard

This category is used for sites when a professional judgment on the level of health hazard cannot be made because information critical to such a decision is lacking.

Criteria

This category is used for sites in which *critical* data are *insufficient* with regard to extent of exposure and/or toxicologic properties at estimated exposure levels. The health assessor must determine, using professional judgment, the "criticality" of such data and the likelihood that the data can be obtained and will be obtained in a timely manner. Where some data are available, even limited data, the health assessor is encouraged to the extent possible to select other hazard categories and to support their decision with clear narrative that explains the limits of the data and the rationale for the decision.

Category 4: No Apparent Public Health Hazard

This category is used for sites where human exposure to contaminated media may be occurring, may have occurred in the past, and/or may occur in the future, but the exposure is not expected to cause adverse health effects.

This determination represents a professional judgment based on critical data which ATSDR has judged sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete; in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information[b] indicates that, under site-specific conditions of exposure, exposures to site-specific contaminants in the past, present, or future are not likely to result in adverse impact to human health.

Category 5: No Public Health Hazard

This category is used for sites that, because of the absence of exposure, do NOT pose a public health hazard.

Criteria

Sufficient evidence indicates that no human exposures to contaminated media have occurred, no exposures are currently occurring, and exposures are not likely to occur in the future.

[a]Such as environmental and demographic data; health outcome data; exposure data; community health concerns information; toxicologic, medical, and epidemiologic data.
[b]Such as environmental and demographic data; health outcome data; exposure data; community health concerns information; toxicologic, medical, and epidemiologic data; monitoring and medical management plans.
Source: ATSDR 2005.