

NATIONAL  
ACADEMIES

Sciences  
Engineering  
Medicine

# The National Academies' Role in Implementing the PACT Act

*Presentation to the PACT Act Research Symposium*

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# Outline

- The National Academies of Sciences, Engineering, and Medicine
- Sections of the PACT Act that pertain to the National Academies
- General overview of major reports on post 9/11 veterans that have examined associations between toxic exposures and health outcomes
  - Types of evidence considered
  - Criteria used to assess each publication
  - Categories of association
- How researchers can help contribute to the evidence used in NASEM reports

# The National Academies

The National Academy of Sciences was originally chartered by the U.S. Congress in 1863 as an independent non-governmental institution.

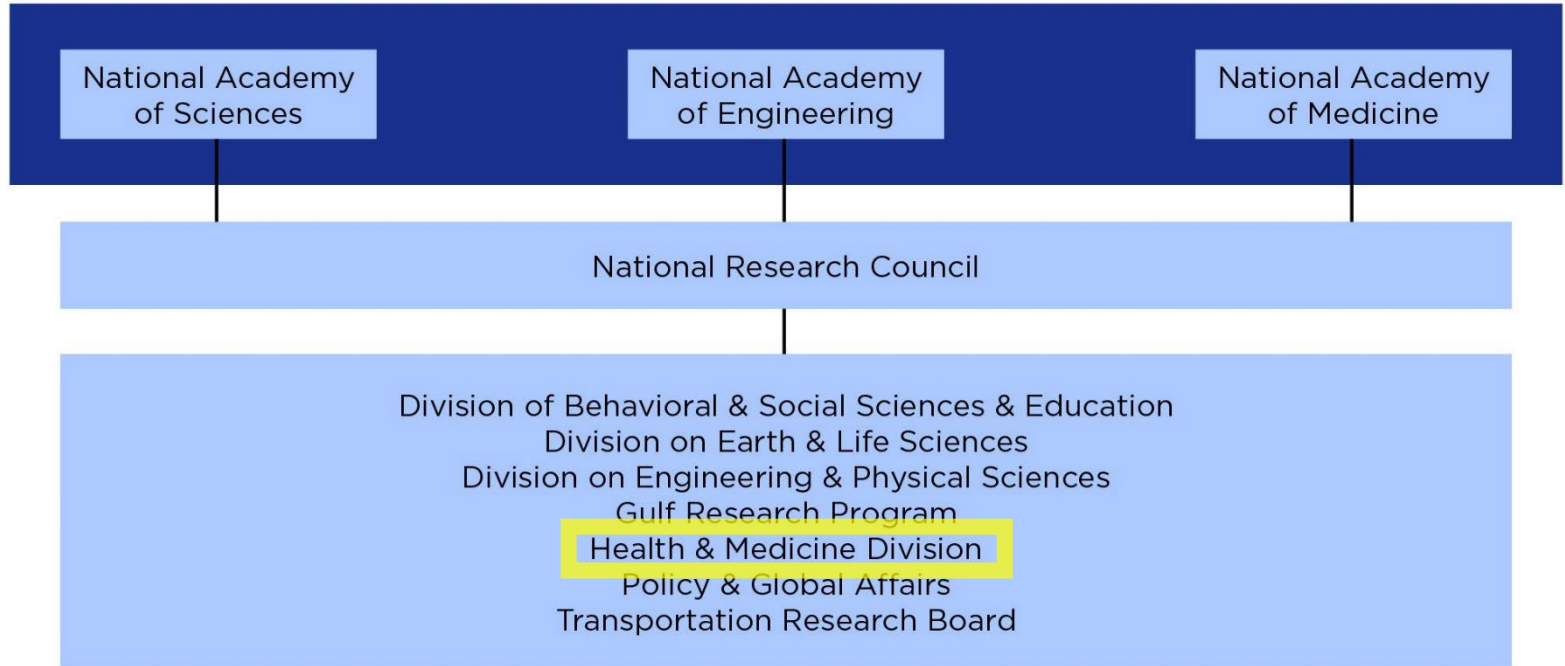


“[T]he Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art”.

– *U.S. National Academy of Sciences Charter*

# The National Academies

## National Academies of Sciences, Engineering, and Medicine



# The PACT Act and the National Academies

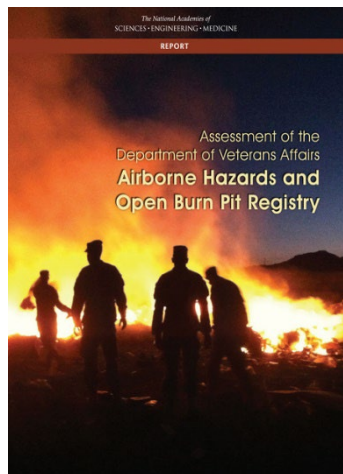
- Section 202 § 1176: Agreement with the National Academies of Sciences, Engineering, and Medicine concerning toxic exposures
  - 5-year agreement to review and evaluate the scientific evidence regarding associations between diseases and toxic exposures
  - The Academies shall conduct an assessment of the implementation by VA of the process established under subchapter VII of chapter 11 of title 38 (the presumption decision process)
- Section 506: Study on Health Effects of Waste Related to Manhattan Project on Certain Veterans
- Section 507: Study on Toxic Exposure and Mental Health Outcomes



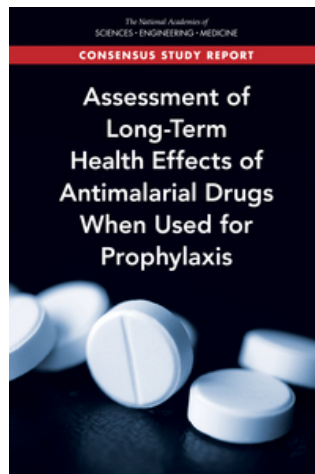
# Previous National Academies reports that have examined associations between toxic exposures and health outcomes



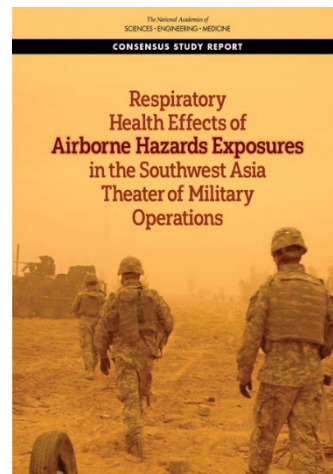
2011



2017



2020



2020



2022

# Methods and considerations when examining evidence of an association

- Depending on the question of interest, different types of evidence and information may be used to inform a conclusion on the strength of evidence of associations between toxic exposures and health outcomes
- Evidence may include
  - comprehensive literature searches (human, animal, toxicologic),
  - original data collection or analysis,
  - supplemental sources (e.g., invited presentations from subject matter experts, information requests to an agency, site visits, government reports, information from public attendees)

# Methods and considerations when examining evidence of an association

- The process used by each committee is not formulaic, however, certain basic standards are applied. For example, when reviewing epidemiologic studies, committees will consider the following:
  - Study design
  - Sample size and representation of the population of interest
  - Appropriateness of comparison group(s)
  - Quality of exposure assessment
  - Quality of outcome assessment
  - Confounding and Effect modification
  - Magnitude and precision of the estimate



# Categories of association

## **Sufficient Evidence of an Association**

A positive association between the exposure and the outcome must be observed in studies in which chance, bias, and confounding can be ruled out with reasonable confidence. For example, the committee might regard evidence from several small studies without known bias and confounding and that show an association that is consistent in magnitude and direction to be sufficient evidence of an association. Experimental data supporting the biologic plausibility of an association strengthen the likelihood of an association but are not a prerequisite and are not enough to establish an association without corresponding epidemiologic findings.

## **Limited or Suggestive Evidence of an Association**

The evidence must suggest an association between the exposure and the outcome in studies of humans, but the evidence can be limited by an inability to confidently rule out chance, bias, or confounding. Typically, at least one high-quality study indicates a positive association, but the results of other studies could be inconsistent.

## **Inadequate or Insufficient Evidence to Determine Whether an Association Exists**

Any health outcome is placed in this category before enough reliable scientific data have accumulated to promote it a category above or to move it to the category of limited or suggestive evidence of no association. In this category, the available human studies may have inconsistent findings or be of insufficient quality, validity, consistency, or statistical power to support a conclusion regarding the presence of an association. Such studies might have failed to control for confounding factors or might have had inadequate assessment of exposure. This category is the default or starting point for any health outcome.

## **Limited or Suggestive Evidence of No Association**

This category was originally defined for health outcomes for which several adequate studies covering the “full range of human exposure” were consistent in showing no association or reduced risk with an exposure of interest at any concentration, with the studies having relatively narrow confidence intervals.

# How researchers can help contribute to the evidence used in NASEM reports

Focusing on peer-reviewed publications,

- Study design
- **Sample size and representation of the population of interest**
- **Appropriateness of comparison group(s)**
- **Quality of exposure assessment**
- Quality of outcome assessment
- **Confounding and effect modification**
- Magnitude and precision of the estimate