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Report to the Chairman, Committee on Health, Education, Labor and Pensions, U.S. Senate

September 2008

INDOOR MOLD

Better Coordination of Research on Health Effects and More Consistent Guidance Would Improve Federal Efforts





Highlights of GAO-08-980, a report to the Chairman, Committee on Health, Education, Labor and Pensions, U.S. Senate

Why GAO Did This Study

Recent research suggests that indoor mold poses a widespread and, for some people, serious health threat. Federal agencies engage in a number of activities to address this issue, including conducting or sponsoring research. For example, in 2004 the National Academies' Institute of Medicine issued a report requested by the Department of Health and Human Services (HHS) summarizing the scientific literature on mold, dampness, and human health. In addition, the Federal Interagency Committee on Indoor Air Quality supports the Environmental Protection Agency's (EPA) indoor air research program. With respect to the health effects of exposure to indoor mold. GAO was asked to report on (1) the conclusions of recent reviews of the scientific literature, (2) the extent to which federal research addresses data gaps, and (3) the guidance agencies are providing to the general public. GAO reviewed scientific literature on indoor mold's health effects, surveyed three agencies that conduct or sponsor indoor mold research, and analyzed guidance issued by five agencies.

What GAO Recommends

GAO recommends that EPA use the interagency committee on indoor air to (1) help guide federal research priorities on indoor mold and (2) help agencies better ensure that their guidance to the public does not conflict, among other things. In commenting on a draft of our report, EPA agreed with our recommendations.

To view the full product, including the scope and methodology, click on GAO-08-980. To view the survey results, click on GAO-08-984SP. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

INDOOR MOLD

Better Coordination of Research on Health Effects and More Consistent Guidance Would Improve Federal Efforts

What GAO Found

In general, the Institute of Medicine's 2004 report, and reviews of the scientific literature published from 2005 to 2007 that GAO examined, concluded that certain adverse health effects are more clearly associated with exposure to indoor mold than others. For example, the Institute of Medicine concluded that some respiratory effects, such as exacerbation of pre-existing asthma, are associated with exposure to indoor mold but that the available evidence was not sufficient to determine whether mold and a variety of other health effects, such as the development of asthma, cancer, and acute pulmonary hemorrhage in infants, are associated. While the reviews GAO examined generally agreed with these conclusions, a few judged the evidence for some health effects as somewhat stronger. For example, the American Academy of Pediatrics concluded in 2006 that a plausible link exists between acute pulmonary hemorrhage in infants and exposure to toxins that some molds produce. In addition, the 2004 Institute of Medicine report identified the need for additional research to address a number of data gaps related to the health effects of indoor mold.

The 65 ongoing federal research activities on the health effects of exposure to indoor mold conducted or sponsored by EPA, HHS, and the Department of Housing and Urban Development (HUD) address to varying extents 15 gaps in scientific data reported by the Institute of Medicine. For example, many of the research activities address data gaps related to asthma and measurement methods, while other data gaps, such as those related to toxins produced by some molds, are being minimally addressed. Further, less than half of the ongoing mold-related research activities are coordinated either within or across agencies. This limited coordination is important in light of, among other things, the wide range of data gaps identified by the Institute of Medicine and limited federal resources. The Federal Interagency Committee on Indoor Air Quality could provide a structured mechanism for coordinating research activities on mold and other indoor air issues by, for example, serving as a forum for reviewing and prioritizing agencies' ongoing and planned research. However, it currently does not do so.

Despite limitations of scientific evidence regarding a number of potential health effects of exposure to indoor mold, enough is known that federal agencies have issued guidance to the general public about health risks associated with exposure to indoor mold and how to minimize mold growth and mitigate exposure. For example, guidance issued by the Consumer Product Safety Commission, EPA, the Federal Emergency Management Agency, HHS, and HUD cites a variety of health effects of exposure to indoor mold but in some cases omits less common but serious effects. Moreover, while guidance on minimizing indoor mold growth is generally consistent, guidance on mitigating exposure to indoor mold is sometimes inconsistent about cleanup agents, protective clothing and equipment, and sensitive populations. As a result, the public may not be sufficiently advised of indoor mold's potential health risks.

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Abbreviations

CDC	Centers for Disease Control and Prevention
DOE	Department of Energy
EPA	Environmental Protection Agency
ERMI	Environmental Relative Moldiness Index
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HUD	Department of Housing and Urban Development
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration

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United States Government Accountability Office Washington, DC 20548

September 30, 2008

The Honorable Edward M. Kennedy Chairman Committee on Health, Education, Labor and Pensions United States Senate

Dear Mr. Chairman:

Mold is a general term for certain microorganisms that thrive in damp conditions and are regularly found in indoor air and on materials and surfaces, such as walls. While indoor mold was considered largely a nuisance as recently as 25 years ago, scientific and medical research is now suggesting that mold poses a widespread and, for some people, serious health threat.² The presence of moisture is the primary factor leading to mold growth indoors. In the wake of Hurricanes Katrina and Rita in 2005 and the extensive flooding of homes that followed, the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) concluded that "excessive exposure to mold-contaminated materials can cause adverse health effects in susceptible persons regardless of the type of mold or the extent of contamination." A variety of health effects have been directly linked to exposure to indoor mold, although the connection to many of the more severe effects, such as acute lung hemorrhaging in infants, remains inconclusive.

Several components and products of mold may cause disease. Mold grows as a mass of microscopic filaments, fragments of which may cause adverse health effects. In addition, the spores that mold releases to reproduce, along with certain components of mold's cell walls, may also cause adverse health effects. Mold products—for example, allergens, volatile

¹In this report, we use the term "mold" to refer to the large number of species of fungi.

²National Institute of Environmental Health Sciences, "A Spreading Concern: Inhalational Health Effects of Mold," *Environmental Health Perspectives* (June 2007).

³Department of Health and Human Services, Centers for Disease Control and Prevention, *Mold Prevention Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods* (Atlanta, 2006).

gases that often create a musty odor, and toxins released by certain types of mold under certain conditions—can also cause disease. An example of a toxin-producing mold is *Stachybotrys chartarum*, which produces multiple toxins that may suppress the functioning of immune cells.

Mold may affect human health through a number of routes and mechanisms. While inhalation is generally the most common route of exposure for mold in indoor environments, exposure can also occur through ingestion (for example, hand-to-mouth contact) and contact with the skin. The roles of these routes of exposure in causing illness are unclear. Once exposure occurs, health effects may arise through several potential mechanisms, including allergic (or immune-mediated), infectious, and toxic. It is not always possible to determine which of these mechanisms is associated with a specific health outcome.

Although federal agencies are engaged in a number of efforts to address indoor mold, there are no federal or generally accepted health-based standards for safe levels of mold in the air or on surfaces. According to EPA officials, the lack of federal regulation of airborne concentrations of mold indoors is largely due to the insufficiency of data needed to establish a scientifically defensible health-based standard. Another factor is the lack of scientific consensus regarding how best to measure these concentrations. The presence of mold in homes and workplaces has led to numerous lawsuits. For example, highly publicized cases involving mold include a Texas homeowner's successful multi-million-dollar lawsuit against an insurance company related to mold contamination. Moreover, mold contamination at the Walter Reed Army Medical Center, where soldiers returning from Iraq are being treated, received significant media coverage.

In 2001, recognizing the need for credible and comprehensive information on the health effects of exposure to indoor mold, HHS commissioned the National Academies' Institute of Medicine to review the available scientific literature on the links among mold, dampness, and human health. In 2004, the Institute of Medicine issued its report, which made a variety of recommendations for research aimed at better understanding the health

⁴The National Academies comprises four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

risks of exposure to indoor mold.⁵ Currently, a number of federal agencies conduct mold-related research or provide guidance to the public on health effects associated with exposure to mold and on ways to mitigate such exposure. These federal agencies include the Environmental Protection Agency (EPA); the Department of Housing and Urban Development (HUD); the Consumer Product Safety Commission; the Federal Emergency Management Agency (FEMA); and HHS and a number of its entities, such as CDC and the National Institutes of Health (NIH). In 1983, a congressional committee directed the establishment of the Federal Interagency Committee on Indoor Air Quality to coordinate federal indoor air quality research. The research on indoor mold is a small component of indoor air research activities, and it is conducted or sponsored by a number of different entities within and across agencies. EPA serves both as the executive secretary of the interagency committee and as a co-chair; other federal departments and agencies participate as co-chairs and members.

You asked us to determine (1) what recent reviews of scientific literature have concluded about the health effects of exposure to indoor mold; (2) the extent to which federal research addresses data gaps related to the health effects of exposure to indoor mold; and (3) the guidance key federal agencies are providing to the general public on the health risks of exposure to mold, minimizing mold growth, and mitigating exposure to mold, and the extent to which the guidance is consistent. For the first objective, we analyzed the 2000 and 2004 Institute of Medicine reports, Clearing the Air: Asthma and Indoor Air Exposures and Damp Indoor Spaces and Health. We also analyzed 20 reviews of the scientific literature on the health effects of exposure to indoor mold that were published from 2005 to 2007; we did not review individual studies. To obtain information on federal research related to the health effects of exposure to indoor mold, we conducted two surveys of officials at EPA, HHS, and HUD from November 2007 to May 2008. We focused on these agencies because of their past and current research activities on the health effects of mold. We used one survey to (1) identify research activities related to the health effects of indoor mold ongoing as of October 1, 2007, and (2) determine the extent to which these research activities address the 15 data gaps

⁵Institute of Medicine, *Damp Indoor Spaces and Health* (Washington, D.C.: The National Academies Press, 2004).

⁶Institute of Medicine, *Clearing the Air: Asthma and Indoor Air Exposures* (Washington, D.C.: National Academy Press, 2000).

identified in the 2000 and 2004 Institute of Medicine reports related to the health effects of exposure to indoor mold. We also used this survey to identify the extent to which these activities were coordinated both within and across agencies. We conducted a second survey of these agencies to collect basic information regarding their mold-related research activities completed from January 1, 2005, to September 30, 2007. Overall, we received information on 107 research activities from 37 EPA, HHS, and HUD officials. Summaries of the research activities conducted or sponsored by EPA, HHS, and HUD are provided in a supplement to this report (see GAO-08-984SP). We also examined the extent to which the Federal Interagency Committee on Indoor Air Quality has been used to coordinate federal research activities related to the health effects of exposure to indoor mold. To evaluate guidance documents issued to the public by federal agencies, we focused on the five federal agencies primarily responsible for providing information to the general public on health risks and minimizing and mitigating exposure to contaminants, including mold—the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD. Our review focuses on the health effects and guidance to the general public related to indoor mold in homes and does not address occupational exposures or technical guidance documents targeted to specialized audiences such as medical professionals. Appendix I provides a more detailed description of our scope and methodology. We conducted this performance audit from January 2007 to September 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

In general, the Institute of Medicine's 2004 comprehensive report, as well as reviews of the scientific literature published from 2005 to 2007 that we examined, concluded that certain adverse health effects are more clearly associated with exposure to indoor mold than others. For example, the Institute of Medicine's report said that certain respiratory effects, such as nasal congestion and the exacerbation of pre-existing asthma, are associated with exposure to indoor mold but that the available evidence was not sufficient to determine whether associations exist between mold and a variety of other health effects, such as the development of asthma, rheumatologic and other immune diseases, cancer, acute pulmonary hemorrhage in infants, and reproductive effects. While the more recent scientific reviews we examined generally concurred with these

conclusions, a few of the reviews judged the available evidence for some of these health effects to be somewhat stronger. For example, the American Academy of Pediatrics concluded in 2006 that a plausible link exists between acute pulmonary hemorrhage in infants and exposure to certain toxins that some molds produce. Conclusively associating exposure to mold with certain health effects is challenging, according to the Institute of Medicine's 2004 report, because available studies have been of insufficient quality, consistency, or rigor. Two key research issues contribute to this difficulty: (1) the lack of standardized, quantitative methods of measuring exposure to mold and (2) the difficulty in determining which of several disease-causing agents in damp indoor environments may be responsible for the adverse health effects. In this regard, the 2000 and 2004 Institute of Medicine reports and the more recent reviews we examined identified the need for additional research to address these and other uncertainties related to the connection between exposure to indoor mold and adverse health effects. For example, the 2004 Institute of Medicine report concluded that there is a need for research to determine the health effects of long-term exposure to the toxins that some molds can produce.

The 65 ongoing federal research activities on the health effects of exposure to indoor mold conducted or sponsored by EPA, HHS, and HUD address to varying extents 15 gaps in scientific data reported by the Institute of Medicine. These gaps relate to the need to better define any association between a wide range of specific potential adverse health effects and exposure to indoor mold. Of the 65 research activities, nearly 60 percent address asthma, and more than half address measurement methods—that is, sampling and exposure assessment methods for indoor mold. Some other important data gaps are being minimally addressed. For example, 5 of the 65 research activities examine the effects of human exposure to molds that produce toxins that may cause a number of adverse health effects, and only 1 relates to acute pulmonary hemorrhage in infants—a rare but life-threatening condition that may be caused by exposure to mold. Further, identifying and coordinating research priorities, and efforts to achieve them, are particularly important given the wide range of research needs identified by the Institute of Medicine reports, the number of federal entities involved in conducting research on mold, and limited federal resources. However, federal officials reported that fewer than half of their ongoing research activities have involved coordination either with other units in their agencies or other federal agencies. For example, of the 36 ongoing research activities related to sampling and measurement methods, only 14 are being coordinated to some extent. Further, in many cases, research activities were only

coordinated within the agency conducting or sponsoring the research. Moreover, although the Federal Interagency Committee on Indoor Air Quality could provide a structured mechanism for coordinating research activities, it does not serve this function. That is, instead of selecting specific topics and tasks to advance scientific knowledge in the area of indoor air quality—such as reviewing and prioritizing agencies' ongoing and planned research in particular areas—the agendas for the committee meetings are largely driven by the interests of the agencies' individual committee representatives.

Despite the limitations of current scientific evidence in establishing clear associations and causal linkages between a number of adverse health effects and exposure to indoor mold, enough is known that federal agencies have issued guidance to the general public about health risks associated with exposure to indoor mold, how to minimize mold growth, and how to mitigate exposure. For example, a majority of the 32 guidance documents we reviewed issued by the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD describe some common adverse health effects, such as asthma attacks and upper respiratory tract symptoms. However, the guidance documents inconsistently identify some other health effects that may be less common. For example, only 6 of the 32 documents warn that exposure to mold can lead to hypersensitivity pneumonitis, a relatively rare but potentially serious allergic reaction. In addition, most of the guidance documents offer consistent strategies for minimizing the growth of indoor mold—for example, keeping areas dry and promptly addressing moisture sources, such as leaks or spills. Finally, a majority of the documents also address mitigating exposure to indoor mold, including directions for cleaning up mold and protective clothing and equipment to wear while doing so. However, the guidance is somewhat inconsistent about which cleaning agents to use—for example, some documents recommend using bleach, a biocide that is toxic to humans, if the mold growth is due to floodwater; some recommend bleach regardless of the cause of the mold; and others recommend using detergent. Finally, most of the documents warn that certain populations may be more sensitive to mold than others, but only two provide specific recommendations about the varying levels of protective clothing and equipment (such as gloves, respirators, and eye and skin protection) that such populations should use under various circumstances. As a result of some of these omissions and inconsistencies, the public may be at risk of unnecessary exposure to indoor mold.

To better ensure that federal research on the health effects of exposure to indoor mold is effectively addressing research needs and efficiently using scarce federal resources, we are recommending that EPA use the Federal Interagency Committee on Indoor Air Quality to both (1) help guide federal research priorities on the health effects of indoor mold and coordinate information sharing on this topic and (2) help agencies better ensure that their guidance to the public provides sufficient information on health effects of exposure to indoor mold, and how to minimize it, and does not conflict among agencies. We provided a draft of this report to the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD for the agencies' review and comment. EPA generally agreed with our recommendations regarding its use of the Federal Interagency Committee on Indoor Air Quality. With the exception of FEMA, the agencies also provided technical comments that we incorporated into the report, as appropriate.

Background

Moisture is the primary factor leading to indoor mold growth. To grow indoors, mold also needs temperatures above freezing levels—from 32 to 130 degrees Fahrenheit—and organic matter. The nutrients upon which mold feeds are provided by house dust and many surface and construction materials, such as wallpapers, textiles, wood, paints, and glues. Because the appropriate temperature and necessary nutrients are common in homes, mold growth can rapidly occur indoors when excessive moisture or water accumulates as a result of, for example, floods and other natural disasters; building design or construction flaws; and poor building maintenance practices, such as not repairing leaking plumbing. Moist conditions indoors may also foster the growth of other organisms capable of causing adverse health effects, including bacteria, cockroaches, and dust mites.

Mold growth may be particularly severe following natural disasters such as hurricanes and flooding. The extent of the flooding after Hurricanes Katrina and Rita in 2005 led to conditions supporting widespread mold growth. Unlike other hurricane-impacted areas, where residents could access their buildings relatively quickly after the flood event, many residents in New Orleans were unable to access buildings for several weeks because of prolonged flood inundation. According to a CDC survey, an estimated 46 percent of homes in New Orleans and surrounding areas had visible mold growth. Widespread indoor mold contamination can cause adverse health effects in returning residents and make it more difficult to rehabilitate houses for reoccupation. For example, in 2006 the Army Corps of Engineers noted that because of mold problems caused by the extensive flooding, many residences that did not require demolition

would nonetheless need to be gutted—stripping the walls down to the studs—before they could be renovated.⁷

The Institute of Medicine has identified four possible levels of connection between indoor mold and adverse health effects: sufficient evidence of a causal relationship, sufficient evidence of an association, limited or suggestive evidence of an association, and inadequate or insufficient evidence to determine whether an association exists. According to HHS, establishing a causal relationship with adequate certainty requires several types of evidence, including (1) epidemiologic associations, (2) experimental exposure in animals or humans that leads to the symptoms and signs of the disease in question, and (3) reduction in exposure that leads to reduction in the symptoms and signs of the disease. HHS officials said that more data are needed to establish a causative association between exposure to mold and some illnesses because the vast majority of the studies conducted to date have been only epidemiologic.

The federal government has responded to the uncertainty surrounding the health effects of exposure to indoor mold by, among other things, sponsoring reviews of the available scientific evidence. Committees of the National Academies' Institute of Medicine have produced two reports in the past several years that relate to the health effects of exposure to indoor mold. For a 2000 report requested by EPA, Clearing the Air: Asthma and Indoor Air Exposures, the Institute of Medicine assembled a multidisciplinary committee to examine the relevant research pertaining to asthma and the indoor environment, including, among many other issues, the possible impact of indoor mold on asthma prevalence. For its 2004 report requested by the CDC, Damp Indoor Spaces and Health, another Institute of Medicine committee reviewed the scientific literature to determine the connections among damp indoor spaces, microorganisms such as mold, and a variety of human health effects. This committee used a uniform set of categories to summarize its conclusions regarding the evidence of association between various health outcomes and exposure to indoor dampness or the presence of mold or other agents in damp indoor environments. While research in this field continues to evolve, both reports made recommendations for additional research related to mold

⁷GAO, Hurricane Katrina: EPA's Current and Future Environmental Protection Efforts Could Be Enhanced by Addressing Issues and Challenges Faced on the Gulf Coast, GAO-07-651 (Washington, D.C.: June 25, 2007).

and other areas that remain relevant—that is, the data gaps have not been resolved.

In addition to sponsoring reviews of the available scientific evidence, federal agencies have the opportunity to share information on various aspects of indoor air quality, including mold, through the Federal Interagency Committee on Indoor Air Quality. Title IV of the Superfund Amendments and Reauthorization Act of 1986 directed EPA, among other things, to disseminate the results of its indoor air quality research program and establish an advisory committee consisting of other federal agencies.⁸ EPA serves as the executive secretary of the Federal Interagency Committee on Indoor Air Quality, which fulfills this advisory role. The committee is co-chaired by EPA, the Department of Energy (DOE), the Consumer Product Safety Commission, the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA). Other federal departments and agencies participate in the committee as members. In 1991, we recommended that the Administrator, EPA, work with other members of the committee to clearly define in a charter the roles and responsibilities of the agencies participating in the committee in order to strengthen interagency coordination of indoor air research. However, EPA has not implemented this recommendation.

Although federal agencies are engaged in a number of efforts to address indoor mold, there are no federal or generally accepted health-based standards for safe levels of mold, its components, or its products in the air or on surfaces. In fact, neither EPA nor OSHA has established health-based standards for airborne concentrations of mold or mold spores indoors. Similarly, NIOSH has not set recommended exposure limits for indoor mold or mold spores. Further, according to EPA officials, the lack of federal regulation of airborne concentrations of mold indoors is largely attributable to the insufficiency of data needed to establish a scientifically defensible health-based standard. EPA officials also emphasized that the agency lacks the authority to establish airborne concentration limits for mold indoors. Legislation to require EPA to take action with respect to indoor mold has been introduced in Congress in the past but was not enacted. For example, the proposed United States Toxic Mold Safety and

⁸Pub. L. No. 99-499, Title IV, §§ 401 to 405 (1986).

⁹GAO, Indoor Air Pollution: Federal Efforts Are Not Effectively Addressing a Growing Problem, GAO/RCED-92-8 (Washington, D.C.: Oct. 15, 1991).

Prevention Act, most recently introduced in Congress in 2005, would have directed EPA to promulgate standards for preventing, detecting, and remediating indoor mold growth, among other things.

The presence of mold in homes and workplaces has led to numerous lawsuits alleging personal injury or property damage. To obtain a judgment that mold has caused personal injury, an individual must persuade the court that the type of mold at issue is capable of causing the individual's condition and that the mold actually caused the condition in the specific case. Litigants generally use expert witness testimony in an attempt to prove or disprove these points in court. Courts use different standards to judge whether such testimony is admissible. In some states, courts will admit such testimony only if it is in accord with generally accepted consensus of the relevant scientific community. In other states and in the federal courts, judges independently evaluate the reliability of the evidence by weighing several factors, only one of which focuses on the views of the relevant scientific community. Many state courts use a mixture of these two methods.

Insurance companies are frequently defendants in mold litigation, and in response to the rise in cases early in the decade, many began changing their policies to specifically exclude mold-related injuries and property damage from coverage. For example, many insurance policies now contain language stating that the insurance company "will not pay for loss or damage caused by or resulting from … rust, corrosion, fungus, decay," and other conditions. As of 2006, the insurance regulatory agencies in 40 states had approved mold-related exclusions.

Partly in response to a significant increase in mold litigation in the early part of this decade, states began enacting legislation to address various aspects of the mold problem. For example, in 2001 California enacted the Toxic Mold Protection Act, which requires the state's Department of Health Services to establish permissible mold exposure limits for indoor air. ¹⁰ In addition, in 2003, Texas passed legislation requiring a mold remediation contractor to certify to a homeowner that the mold contamination identified for the project had been remediated as outlined in the mold management plan or remediation protocol. Further, the Texas law requires owners selling property to provide buyers with copies of each

 $^{^{10}\}mbox{According}$ to CDC officials, it is not yet possible to establish mold exposure limits for indoor air.

mold remediation certificate issued for the properties the 5 preceding years. Examples of other state legislative responses to mold issues include laws

- requiring landlords to disclose to tenants information about the health hazards associated with exposure to indoor mold;
- prohibiting litigation against a real estate agent acting on behalf of a buyer or seller who has truthfully disclosed any known material defects;
- establishing licensing requirements for individuals involved with mold assessment and remediation; and
- creating a group to study the effects of toxic mold.¹¹

Many Studies Associate Indoor Mold with Adverse Health Effects but Cite the Need for Additional Research While the 2004 Institute of Medicine report, and reviews of the scientific literature published subsequently, have found evidence associating indoor mold with certain adverse health effects, the evidence supporting an association between mold and other health effects remains less certain. Two factors, in particular, pose challenges for those attempting to determine the health effects of exposure to indoor mold: valid quantitative methods of measuring exposure are lacking, and a wide variety of other potential disease-causing agents are likely to be present in damp indoor environments, along with mold. According to the Institute of Medicine and recent reviews of the scientific literature, further research is required to advance the understanding of the relationships between dampness, indoor mold, and human health.

While Mold Is Associated with Certain Adverse Health Effects, Evidence for Others Is Less Certain

The 2004 Institute of Medicine report, *Damp Indoor Spaces and Health*, found sufficient evidence of an association between exposure to indoor mold and certain adverse health effects—that is, an association between the agent and the outcome has been observed in studies in which chance, bias, and confounding factors can be ruled out with reasonable confidence. These health effects include

¹¹Information on state laws comes from data assembled by the National Association of Mutual Insurance Companies (NAMIC) at www.namic.org.

- upper respiratory tract symptoms, including nasal congestion, sneezing, runny or itchy nose, and throat irritation;
- exacerbation of pre-existing asthma;
- · wheeze;
- cough;
- hypersensitivity pneumonitis in susceptible persons; and
- fungal colonization or opportunistic infections in immune-compromised persons.

Of these health effects, the upper respiratory tract symptoms associated with allergic rhinitis are the most common, according to the American Academy of Pediatrics. 12 In addition, the association between indoor mold and exacerbation of asthma symptoms is a particularly significant public health concern because asthma is the most common chronic illness among children in the United States and one of the most common chronic illnesses overall, according to the Institute of Medicine's 2000 report, Clearing the Air: Asthma and Indoor Air Exposures. Importantly, mold can affect certain populations disproportionately. For example, the 2004 Institute of Medicine report found sufficient evidence of an association between exposure to the mold genus Aspergillus and serious respiratory infections in people with severely compromised immune systems (such as chemotherapy patients and organ transplant recipients). This report also found sufficient evidence of an association between exposure to indoor mold and hypersensitivity pneumonitis—a relatively rare but potentially serious allergic reaction—in susceptible persons. In addition to these more established health effects, this report also found limited or suggestive evidence of an association between indoor mold and lower respiratory illness (for example, bronchitis and pneumonia) in otherwise healthy children.

Most of the 20 reviews of the scientific literature published from 2005 to 2007 that we examined generally agreed with the conclusions of the 2004

 $^{^{12}\}mbox{L.J.}$ Mazur, J. Kim, and Committee on Environmental Health, American Academy of Pediatrics, "Spectrum of Noninfectious Health Effects From Molds," Pediatrics, vol. 118, no. 6 (2006).

Institute of Medicine report. However, two of the reviews characterized the relationship between exposure to indoor mold and certain of the above health effects more strongly. The American Academy of Pediatrics stated in its 2006 report that epidemiologic studies consistently support causal relationships between exposure to mold and upper respiratory tract symptoms and exacerbation of pre-existing asthma. The American Academy of Pediatrics also said that epidemiologic studies support a causal relationship between exposure to mold and hypersensitivity pneumonitis in susceptible persons. Moreover, a 2007 meta-analysis sponsored by EPA and DOE found that building dampness and mold are associated with increases of 30 percent to 50 percent in a variety of health outcomes, such as upper respiratory tract symptoms, wheeze, and cough. The authors concluded that these associations strongly suggest these adverse health effects are caused by dampness-related exposures.

According to the 2004 Institute of Medicine report, the evidence of an association between exposure to indoor mold and a variety of other health effects, however, is inadequate or insufficient—that is, the available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence of an association. The health effects for which there is inadequate or insufficient evidence of an association with indoor mold include

- acute idiopathic pulmonary hemorrhage in infants;
- airflow obstruction in otherwise-healthy persons;
- cancer;

 $^{^{13}}$ Two of the reviews focused primarily on clinical cases encountered by the authors. For a list of the studies we reviewed, see appendix II.

¹⁴The authors of this report acknowledged that, because of the presence of other potential disease-causing agents indoors, it is not possible to definitively attribute a causal relationship to any one specific agent in indoor environments.

¹⁵A meta-analysis uses statistical methods to combine data from different but comparable research studies, in order to provide a quantitative summary estimate on the size and variability of an association.

¹⁶W.J. Fisk, Q. Lei-Gomez, and M.J. Mendell, "Meta-analyses of the associations of respiratory health effects with dampness and mold in homes," *Indoor Air*, vol. 17, no. 4 (2007).

- chronic obstructive pulmonary disease;
- development of asthma;
- fatigue;
- gastrointestinal tract problems;
- inhalation fevers not related to occupational exposures;
- lower respiratory illness in otherwise-healthy adults;
- mucous membrane irritation syndrome;
- neuropsychiatric symptoms;
- reproductive effects;
- · rheumatologic and other immune diseases;
- shortness of breath; and
- · skin symptoms.

Most of the recent reviews of the literature we examined generally concurred with these Institute of Medicine conclusions as well, although a few found a somewhat stronger relationship between indoor mold and certain of the health effects listed above. For example, a 2007 review concluded that dampness and exposure to indoor mold can exacerbate or may cause shortness of breath, among other health effects. ¹⁷ In addition, other reviews differed in their conclusions regarding the link between exposure to indoor mold and acute idiopathic pulmonary hemorrhage in infants, the sudden onset of pulmonary hemorrhage in a previously healthy infant. This condition was reported among a group of infants from the same part of Cleveland, Ohio, in the 1990s and attributed by some researchers to exposure to indoor mold. Five of the reviews we examined contained conclusions about acute idiopathic pulmonary hemorrhage in infants and children. Two concluded that mold has not been proven to

¹⁷J.M. Seltzer and M.J. Fedoruk, "Health Effects of Mold in Children," *Pediatric Clinics of North America*, vol. 54, no. 2 (2007).

cause this condition. ¹⁸ However, a third review—the American Academy of Pediatrics 2006 report—said that although a causal relationship has not been firmly established, a variety of studies have provided some evidence that such a relationship is plausible. The fourth review said that the association between acute idiopathic pulmonary hemorrhage in infants and children and mold is strong enough to justify removing them from moldy environments or cleaning up these spaces, ¹⁹ and the fifth review reiterated this recommendation. ²⁰

Some of the health effects for which the evidence remains unclear (for example, fatigue and acute idiopathic pulmonary hemorrhage in infants) have been attributed to reactions to toxins, or "mycotoxins," that can be produced by certain types of mold that grow indoors. The reviews we examined were largely consistent in their interpretations of the evidence for the role of mycotoxins in relation to adverse health effects. The Institute of Medicine reported in 2004 that (1) exposure to mycotoxins can occur via inhalation, contact with the skin, and ingestion of contaminated food and (2) research on Stachybotrys chartarum (a species of indoor mold that can produce mycotoxins) suggests that effects in humans may be biologically plausible. However, the report also noted that the effects of chronic inhalation of mycotoxins require further study and that additional research must confirm the observations on Stachybotrys chartarum before a more definitive conclusion can be drawn. Among the more recent reviews we examined that specifically addressed mycotoxins, five reached a similar conclusion—that is, that the current evidence is inconclusive or

¹⁸A. Habiba, "Acute idiopathic pulmonary haemorrhage in infancy: Case report and review of the literature," *Journal of Paediatrics and Child Health*, vol. 41, no. 9-10 (2005); and S.C. Susarla and L.L. Fan, "Diffuse alveolar hemorrhage syndromes in children," *Current Opinion in Pediatrics*, vol. 19, no. 3 (2007).

¹⁹T.G. Nuesslein, N. Teig, and C.H. Rieger, "Pulmonary haemosiderosis in infants and children," *Paediatric Respiratory Reviews*, vol. 7, no. 1 (2006).

²⁰R.A. Etzel, "Indoor and outdoor air pollution: Tobacco smoke, moulds and diseases in infants and children," *International Journal of Hygiene and Environmental Health*, vol. 210, no. 5 (2007).

limited.²¹ However, one review suggested that it is likely that mycotoxins play some role in building-related disease, including exacerbation of pre-existing asthma.²² On the other hand, another recent review cast doubt on the health effects of mycotoxins in one set of circumstances—specifically, the review concluded that it was improbable for mycotoxins to cause negative health effects through a toxic mechanism when individuals inhale mycotoxins in nonoccupational settings (such as homes). This review, however, explicitly stated this conclusion did not address adverse health effects of mycotoxins that may be caused by immune-mediated mechanisms or stem from exposure in occupational settings or by ingestion.²³

Two Key Factors Pose Challenges for Determining the Health Effects of Exposure to Indoor Mold

According to the 2004 Institute of Medicine report, two key issues largely contribute to the scientific data gaps regarding the relationship between mold and adverse health effects: (1) valid quantitative methods of measuring exposure are lacking, and (2) a wide variety of potential disease-causing agents are likely to be present in damp indoor environments, which makes it difficult to link health effects with specific agents. Without standardized, quantitative methods to measure exposure, it is difficult to compare exposure levels across studies or between individuals with and without symptoms of adverse health effects. This makes it challenging to draw valid and consistent conclusions on the health effects of indoor mold.

No single or standardized method to measure the magnitude of exposure to mold has been developed. Consequently, researchers use a variety of methods to assess exposure, each of which has advantages and disadvantages. For example, most studies use an indirect method to assess

²¹In addition to the 2006 American Academy of Pediatrics review and Seltzer and Fedoruk (2007), A.T. Borchers, C. Chang, C.L. Keen, and M.E. Gershwin, "Airborne Environmental Injuries and Human Health," *Clinical Reviews in Allergy & Immunology*, vol. 31, no. 1 (2006); K.-M. Lai, "Hazard Identification, Dose-Response and Environmental Characteristics of Stachybotryotoxins and Other Health-Related Products from *Stachybotrys*," *Environmental Technology*, vol. 27, no. 3 (2006); and J.M. Portnoy, K. Kwak, P. Dowling, T. VanOsdol, and C. Barnes, "Health effects of indoor fungi," *Annals of Allergy, Asthma & Immunology*, vol. 94, no. 3 (2005).

²²B.B. Jarvis and J.D. Miller, "Mycotoxins as harmful indoor air contaminants," *Applied Microbiology and Biotechnology*, vol. 66, no. 4 (2005).

²³R.K. Bush, J.M. Portnoy, A. Saxon, A.I. Terr, and R.A. Wood, "The medical effects of mold exposure," *The Journal of Allergy and Clinical Immunology*, vol. 117, no. 2 (2006).

exposure—occupant questionnaires about the presence of dampness or mold in a building—according to the 2004 Institute of Medicine report. Other exposure assessment methods include personal monitoring, which involves measuring agent concentrations with monitors carried by individuals, and quantifying biologic response markers in bodily fluids. Another method of exposure assessment is to collect environmental samples of indoor air, dust, or building materials such as wallboard and quantitatively analyze the presence of mold (or its components or products) in the samples. In addition to the various methods that can be used to collect and analyze samples, environmental sampling for mold is complicated by the fact that concentrations of mold (particularly in the air) can vary over time and across an indoor environment. Moreover, many newly developed sampling methods are not commercially available or well-validated.

The second issue contributing to limitations in the understanding of the relationship between mold and a number of adverse health effects is the variety of potential disease-causing agents—including many species of mold and other biological agents, such as bacteria or dust mites—that are likely to be present in damp indoor environments. The number of such agents makes it difficult to know which ones are specifically responsible for the adverse health effects attributed to these environments. For example, of the approximately 1 million species of mold, there are about 200 species of mold to which humans are routinely exposed, although not all of these are commonly identified in indoor environments, and not all types pose the same hazards to human health. The mold genus Alternaria, for instance, which has been found in moldy building materials, has been linked to severe asthma. Furthermore, several different components or products of mold, such as mycotoxins, may function as disease-causing agents in indoor environments. The release of these mold components or products varies with environmental and other factors, and the individual roles they may play in adverse health effects are not fully understood. People are also exposed to mold in outdoor environments, where the concentrations, while they vary considerably, are usually higher than those found indoors. While the specific species of mold that grow indoors may differ from those found outdoors, the potential for outdoor exposure further complicates efforts to determine the relationship between adverse health effects and indoor exposure to mold.

In addition to mold, damp indoor areas can support other biological agents that may result in adverse health effects, including bacteria, dust mites, cockroaches, and rodents. Dust mites, for example, are known to cause the development of asthma. Damp conditions may also lead to potentially

harmful chemical emissions from building materials and furnishings. For example, excessive indoor humidity may increase the release of formaldehyde, a probable human carcinogen, from building materials such as particle board. Exposure to formaldehyde has been linked to some of the same health effects that have been attributed to indoor mold, such as wheezing, coughing, and exacerbation of asthma symptoms, as well as more severe effects.

Additional Research Is Needed to Better Address Uncertainties Related to the Connection between Health Effects and Exposure to Indoor Mold

The 2000 and 2004 Institute of Medicine reports and other recent reviews of the scientific literature have identified numerous areas where further research is required to advance the understanding of the relationships between dampness, indoor mold, and human health. 24 Specifically, the health effects of the components and products of mold require further study. The effects of mycotoxins in particular remain poorly understood, partly because most of the toxicologic studies on mycotoxins have examined the acute (or short-term) effects of high levels of exposure to mycotoxins in small populations of animals. To address these limitations, the 2004 Institute of Medicine report recommended that studies be conducted to help determine, among other things, (1) the effects of chronic (or long-term) exposures to mycotoxins via inhalation and (2) the dose of mycotoxins required to cause adverse health effects in humans. This report also recommended research on a particular species of toxinproducing mold, Stachybotrys chartarum, and on the relationship between mold and dampness and acute idiopathic pulmonary hemorrhage in infants. In its 2000 report, the Institute of Medicine also called for additional research related to mold particles as allergens and research to evaluate the association of dampness and mold with the development of asthma. As can be expected as research progresses over time, some of the more recent reviews we examined made additional or more specific research recommendations related to mycotoxins and other components and products of mold. A number of lawsuits alleging serious health effects as a result of exposure to indoor mold have involved exposure to mycotoxins, underscoring the need for additional research in this area.

In addition, research to develop, improve, and standardize methods for assessing exposure to mold is a high priority for understanding the health

²⁴Although our review focuses on the research needs directly related to indoor mold and human health, the 2000 and 2004 Institute of Medicine reports identified a variety of other research needs related to dampness, mold, and buildings.

effects of mold, according to the Institute of Medicine's 2004 report. Specifically, the report recommends additional research to validate and refine existing exposure assessment methods for mold, including procedures for collecting and analyzing environmental samples. Such research would facilitate comparison of results within and across epidemiological studies and help better define the relationships between mold and adverse health effects. In addition, improved methods for measuring exposure to specific components of mold would help efforts to study the roles of these agents in causing adverse health effects.

The 2004 Institute of Medicine report also identified the need for additional research on mold mitigation strategies and measures to prevent or reduce dampness, the growth of indoor mold, and exposure to mold. These strategies could include remediation activities, building renovation, and changes in building operation or maintenance practices. For example, research is needed to develop standardized, effective cleanup methods to mitigate mold growth after flooding and other catastrophic water events. In addition, the 2004 Institute of Medicine report recommended research to assess how effectively personal protective equipment, such as gloves, safety goggles, and respirators, reduces exposure to mold during mitigation activities. Research in these areas is important to help ensure that (1) mold mitigation actually improves unhealthy conditions in indoor environments and (2) protective equipment used during remediation successfully reduces the amount of mold to which workers and building occupants are exposed.

²⁵Other methods to protect building occupants and workers may involve containment efforts to control the dispersal of mold through the building during remediation, which can disturb building materials and release mold (particularly its spores) into the air.

Federal Research
Activities on the
Health Effects of
Indoor Mold Address
Data Gaps to Varying
Degrees; Limited
Planning and
Coordination of the
Activities May Reduce
Their Ability to Close
Data Gaps

Federal research activities address gaps in scientific data on the health effects of indoor mold identified by the Institute of Medicine to varying degrees, with a large number focusing on two areas in particular—asthma and measurement methods. The impact of this research portfolio may be reduced, however, by limited planning and coordination.

Federal Research Activities on Mold Largely Address Asthma and Measurement Methods

EPA, HHS, and HUD officials reported that they were conducting or sponsoring 65 mold research activities as of October 1, 2007: HHS reported 43 ongoing research activities; and EPA and HUD reported 15 and 7, respectively. The Institute of Medicine's 2000 and 2004 reports identified a number of gaps in the research needed to more clearly delineate any association between exposure to indoor mold and a number of adverse health effects. 26 As shown in appendix III, these gaps may be grouped into 15 broad categories.²⁷ Agency officials reported that most of the individual federal research activities address 2 or more of the 15 data gaps. Collectively, the agencies indicated that their research activities address all of the 15 data gaps to varying extents—the number of research activities addressing individual gaps ranged from 1 to 32 (see app. III). Moreover, EPA, HHS, and HUD officials reported that 75 percent of their mold research activities address at least one of five particular data gaps three of which relate to asthma, and two of which relate to sampling and measurement methods. These five data gaps are as follows:

²⁶Clearing the Air and Damp Indoor Spaces and Health.

 $^{^{27}}$ We aggregated the research needs on the health effects of exposure to indoor mold that were identified in the 2000 and 2004 Institute of Medicine reports into 15 groups of related needs.

- Identify environmental factors that either lead to the development of asthma or precipitate symptoms in subjects who already have asthma using good measures of fungal exposure.
- Determine the association of dampness problems with asthma development and symptoms by researching the causative agents (e.g., molds, dust mite allergens) and documenting the relationship between dampness and allergen exposure.
- Advance the understanding of specific bioaerosols (small airborne particles) in relation to asthma by studying the epidemiology of buildingrelated asthma in problem buildings where there are excess chest complaints among occupants in comparison to buildings where there are not complaints; or provide exposure-response studies of many building environments and populations.
- Improve sampling and exposure assessment methods for mold and its
 components (for example, by conducting research that will lead to
 standardization of protocols for sample collection, transport, and analysis
 or developing or improving methods of personal airborne exposure
 measurement, DNA-based technology, or assays for bioaerosols, etc.).
- Develop standardized metrics and protocols to assess the nature, severity, and extent of dampness and effectiveness of specific measures for dampness reduction.

Overall, agency officials reported that 38 of the ongoing projects—or nearly 60 percent—address asthma. In this respect, the federal mold research portfolio for EPA, HHS, and HUD, ongoing as of October 1, 2007, appears to be weighted toward addressing research gaps identified in the Institute of Medicine's 2000 report, *Clearing the Air: Asthma and Indoor Air Exposures*. The research activities federal officials reported as addressing one or more of the asthma-related research gaps include studies using animals. For example, one focuses on gestational exposure in mice to mold extracts and the effect this exposure has on the development of allergy or asthma in adult life; one assesses in mice the relative allergenic potency of molds statistically more common in water-damaged homes; and another is developing animal models (using mice and rats) to evaluate the pulmonary inflammatory response to mold products collected from indoor dust samples from buildings where people have reported respiratory symptoms and from buildings with no reported health

complaints.²⁸ Other asthma-related research activities are aimed, for example, at better understanding the relationship between respiratory symptoms and exposure to water-damaged homes in posthurricane New Orleans and at evaluating the respiratory health of staff and students attending schools that expose them to varying degrees of dampness.²⁹ (Summaries of the 65 research activities conducted or sponsored by EPA, HHS, and HUD are provided in a supplement to this report—see GAO-08-984SP.)

Many of the projects that address asthma also address sampling and measurement methods. Research that provides high-quality, consistent methodologies for sampling and measuring mold is essential to progress in evaluating the health effects of exposure to mold. For example, the Institute of Medicine reported in 2004 that evidence of an association between exposure to mold and 15 specific health effects is inadequate or insufficient to permit a conclusion regarding the presence of an association because of the insufficient quality, consistency, or statistical power of the available studies. This report, *Damp Indoor Spaces and Health*, identified the need for standardized metrics and protocols. The Institute's earlier 2000 report that focused on asthma had previously identified the need to improve exposure assessment methods for mold.

Overall, EPA, HHS, and HUD reported 36 research activities that address sampling and exposure assessment methods or standardized metrics and protocols. While a number of the research activities address these measurement methods as part of investigations focusing on specific health effects or other issues related to indoor mold, several focus solely or primarily on developing measurement methods. For example, HHS's NIOSH is working to develop biomarkers of mold exposure to lead to objective, standardized measures of exposure to support reproducible and comparable analyses in health studies, including large-scale epidemiological studies.³⁰ HHS's National Institute of Environmental

 $^{^{28}}$ These studies are titled "The Effect of Gestational Exposure to Mold on Allergy Induction in a Mouse Model," "Study of Putative Asthmagenic Molds," and "Development of an Animal Model to Evaluate the Contribution of the Fungal Product, β -glucan, on the Pulmonary Inflammatory Potential of Indoor Dust Samples."

²⁹These studies are titled "Health Effects of Exposure to Water-Damaged New Orleans Homes Six Months After Hurricanes Katrina and Rita" and "Building-Related Asthma Research in Maine Public Schools."

³⁰This research activity is titled "The Development of Monoclonal Antibody-Based Immunodiagnostics for Fungal Hemolysins as Potential Biomarkers of Fungal Exposure."

Health Sciences has three separate studies: (1) evaluating available biomarkers of exposure and effect for specific molds that may cause systemic toxicity, (2) developing tests for allergenic mold species and toxin-producing molds found in water-damaged homes that can be used to objectively assess mold exposure in buildings, and (3) testing the feasibility of a flexible and low-cost measurement method for allergens, including mold. Another example of ongoing research focusing on mold identification is HHS's CDC work to develop and validate DNA-based methods for identification and fingerprinting medically important molds because "the absence of a robust species/strain identification scheme has hampered the rapid identification of novel species and the associated burden of disease."

EPA and HUD also reported working on DNA-based assessment methods. Specifically, agency officials reported ongoing work using, in part, a DNA-based method for analyzing 36 species of mold that EPA developed, patented, and has licensed commercial laboratories to perform. Working with HUD, EPA used this method to develop a standard sampling and analytic process that then led to the development of the Environmental Relative Moldiness Index (ERMI) scale for U.S. homes. According to EPA, this index provides a simple, objective evaluation of the mold burden in a home. EPA reported ongoing epidemiological studies using the ERMI scale aimed at determining if the ERMI values can be used to understand the risk of asthma or related respiratory symptoms.³³

While most of the 65 ongoing research activities involving indoor mold are addressing asthma and critical data gaps in sampling and measurement methods identified in the 2000 and 2004 Institute of Medicine reports,

³¹These studies are titled "Toxicology Studies of Mold Exposures," "Fluorescent Multiplex Array for Indoor Allergens (which is using enzyme immunoassay and multiplex array technology)," and "Aptamer-Based Microarray for the Detection of Environmental Allergens."

³²While HHS did not classify this ongoing research, "Study on Identification and Typing (Fingerprinting) Medically Important Fungal Organisms Using DNA," as meeting the data gaps on sampling or measurement methods identified by the Institute of Medicine reports, we believe that the information from this research activity has the potential to address important measurement gaps.

³³These research activities are titled "Study on Asthma and Environmental Factors, Which Included an Application of the ERMI Index" and "Determining the National Distribution of Selected Contaminants (Including Mold) in the Residential Environment (i.e., the American Healthy Homes Survey)." The ERMI scale can describe the mold burden in any home on the basis of its relative position compared with the entire U.S. housing stock.

some other important data gaps identified in the 2004 report are being studied to a lesser degree than the gaps identified in the 2000 report. Notably, of the 15 data gaps identified in these reports, agency officials reported that only 9 research activities address to some extent 3 of the gaps identified in the 2004 report that follow.³⁴

- Research the relationship between mold and dampness and acute pulmonary hemorrhage or hemosiderosis in infants.
- Determine the effects of human exposure to *Stachybotrys chartarum* in indoor environments.
- Determine, for mycotoxins, the dose required to cause adverse health
 effects in humans via inhalation and skin (dermal) exposure; techniques
 for detecting and quantifying mycotoxins in tissues; or the effects of longterm (chronic) exposures to mycotoxins via inhalation.

Officials from EPA, HHS, and HUD reported only one research activity examining the relationship between mold and dampness and acute pulmonary hemorrhage or hemosiderosis in infants—a rare but serious health condition whose relation to exposure to indoor mold remains unsettled, as discussed earlier. This research is aimed at developing quantitative biomarkers for the toxin-producing mold species Stachybotrys chartarum—a mold that has been implicated in cases of acute pulmonary hemorrhage in infants—to facilitate epidemiological and other studies examining mold-related health effects.³⁵ Sponsored by HHS's National Institute of Environmental Health Sciences, this research will support but does not directly address the 2004 Institute of Medicine's recommendation for research on the relationship between mold and dampness and acute pulmonary hemorrhage in infants. Specifically, the Institute of Medicine report concluded that the role of Stachybotrys chartarum in cases of acute idiopathic pulmonary hemorrhage in infants that had been studied remained controversial and encouraged HHS's CDC to pursue surveillance and additional research on the issue to resolve outstanding questions because this condition has serious health consequences. The Institute of Medicine further stated that epidemiologic and case studies should take a broad-based approach to gather and

³⁴One of the nine research activities is addressing two of the three data gaps to some extent. To avoid double counting, this research activity is counted once.

 $^{^{35}}$ This study is titled "Study on Biomarkers for Exposure to $Stachybotrys\ Chartarum$."

evaluate information on exposures and other factors that would help identify the causes of acute idiopathic pulmonary hemorrhage in infants, including dampness and agents associated with damp indoor environments and environmental tobacco smoke, among others. According to CDC officials, the agency is not currently conducting either epidemiological or case studies on acute pulmonary hemorrhage in infants.³⁶

Five research activities that federal agencies reported were addressing the toxin-producing mold species *Stachybotrys chartarum* were: part of two studies on asthma; a study to develop tests for allergenic mold species and toxin-producing molds found in water-damaged homes and a study to develop quantitative biomarkers to assist epidemiological and other research examining mold-related health effects (both discussed above as also addressing other data gaps); and a follow-up study analyzing archived serum and house dust samples for *Stachybotrys chartarum* and related mycotoxins in the context of the clinical symptom profiles previously gathered on the study participants.³⁷

The research gap on the health effects of exposure to mycotoxins—toxins that can be produced by certain types of mold and may potentially cause adverse health effects—is being addressed to some extent by four research activities, according to agency officials. One of the activities will assess the potential for molds found in damp or water-damaged buildings to cause nervous system or systemic toxicity. A second activity aims to develop improved sensors for detecting mycotoxins in contaminated food and feed to support proper remedial actions.³⁸ A third activity is using an animal model to understand the disease pathogenesis of hypersensitivity

³⁶According to a CDC official, from January 2004 to June 2005, the agency undertook a "chart review" of pulmonary hemorrhage designed to determine if existing computerized information sources (such as hospital discharge and vital statistics data) or other information could be used for national surveillance of acute pulmonary hemorrhage in infants. After evaluating hospital records in six cities, CDC's preliminary conclusions are that national data sets are not reliable for this purpose and that local data sources should be used instead.

³⁷These studies are titled "Head-off Environmental Asthma in Louisiana," "Relative Potency of Mold Extraction in a Mouse Model," "Fluorescent Multiplex Array for Indoor Allergens," "Study on Biomarkers for Exposure to *Stachybotrys Chartarum*," and "Urban Moisture and Mold Program-Continuation Project."

³⁸These activities are titled "Toxicology Studies of Mold Exposures" and "Allosteric DNAzyme Sensors for Practical Detection of Mycotoxins."

pneumonitis—a relatively rare but potentially serious allergic reaction in susceptible persons that can, in its chronic form, result in permanent lung damage. Lastly, a fourth activity is a study of the mechanistic indicators of childhood asthma that uses air, biologic and clinical measures as well as molecular biology, chemistry, and gene technologies to identify factors that affect individual susceptibility to asthmatic responses. EPA reported that while this study is not directed at mold per se, the secondary data being collected could address some other research activities that the Institute of Medicine reports identified as relating to sampling and exposure assessment and mycotoxins, among others.

Finally, EPA and HHS reported they had completed 42 mold-related research activities between January 1, 2005, and September 30, 2007. In general, these activities address topics such as asthma and sampling and measurement methods, reflected in the portfolio of agencies' ongoing research activities. Information on the recently completed research activities is provided in a supplement to this report (see GAO-08-984SP).

Limited Planning and Coordination of Research Activities May Affect Their Ability to Close Data Gaps on the Health Effects of Exposure to Indoor Mold While the information on research activities relating to the health effects of exposure to indoor mold provides some insight into the extent to which federal agencies are addressing scientific data gaps identified by the Institute of Medicine in 2000 and 2004, the extent to which these ongoing research activities will effectively advance scientific knowledge in these areas is not clear. Specifically, the research is not guided by an overarching strategic plan or entity that would help agencies work together to identify their research priorities on the health effects of mold. Instead, agencies generally determine independently which research activities they will support using a variety of criteria. This lack of clearly articulated, common research goals is exacerbated by the limited intraand inter-agency planning and coordination of research activities among federal agencies. Specific information that highlights planning and coordination limitations follows.

Selection criteria for research the agencies sponsor are not always linked to identified data gaps. Several EPA, HHS, and HUD officials

³⁹This study is titled "The Role of Neutrophils in Hypersensitivity Pneumonitis."

⁴⁰This study is titled "Mechanistic Indicators of Childhood Asthma (MICA) Study."

⁴¹HUD did not report any completed mold-related research activities during this time frame.

indicated that selection of priorities for research can be based on various considerations, including agency expertise in a particular area or input from external stakeholders. For example, both HHS and HUD officials noted that ideas for research priorities can come from former grantees.

A key planning document that several EPA officials reported consulting is now outdated. Specifically, the agency's 2005 *Program Needs for Indoor Environments Research* document, which outlines the agency's research needs for the indoor environment and mold, among other topics, reflects input from the Institute of Medicine's 2000 report but not the more recent 2004 report, which also identified a number of important data gaps. EPA officials told us that the agency's research related to asthma and mold's health effects has been a priority, in part, because this topic was identified in the 2000 Institute of Medicine report, *Clearing the Air: Asthma and Indoor Air Exposures*.

Some officials stated that the 2004 Institute of Medicine report on indoor mold has not influenced their research priorities on this topic. While officials at HHS's NIOSH reported that the Institute of Medicine's 2004 report had a "major impact" on what indoor environmental quality research their institute conducts, HHS officials from two of the National Institutes of Health noted that this report did not affect their institutes' internal priorities in this area. One official stated that while the publication of this report did not change any of their internal priorities, it may have encouraged external interest in mold research.

The process that NIH uses to fund outside research may also limit the extent to which identified data gaps are addressed. Specifically, federal officials from three different NIH institutes⁴³ that sponsored 29 of the 65 ongoing research activities as of October 1, 2007, reported that 19 were unsolicited—that is, they were initiated by investigators outside the institutes.⁴⁴ Most NIH-funded research is initiated by such investigators. These investigators submitted research proposals that were of interest to

 $^{^{42}\}mathrm{EPA}, Program\ Needs\ for\ Indoor\ Environments\ Research,\ EPA\ 402-B-05-001\ (March\ 2005).$

⁴³These are the National Institute of Environmental Health Sciences; the National Heart, Lung, and Blood Institute; and the National Institute of Allergy and Infectious Diseases.

⁴⁴One of the 29 research activities was funded partly by an unsolicited grant and partly by a solicited cooperative agreement. We considered this activity as both unsolicited and solicited.

them and thus were not necessarily responsive to specific agency priorities. Along these lines, officials at one institute said they generally fund indoor mold research only because of outside investigators' interest. Unsolicited proposals are ranked for funding through a rigorous peerreview process for, among other things, scientific merit and the significance of the research. While the specific topic of the research is considered in light of its potential impact on public health during peer review, NIH officials said that specific gaps identified in the Institute of Medicine's report may well have a lower significance relative to the three institutes' many other scientific priorities. That is, while the three institutes do solicit research on areas considered to be priorities, studies on the health effects of exposure to indoor mold have generally not been in this category.

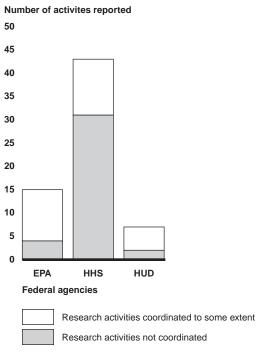
Less than half of the agencies' 65 ongoing research activities are being coordinated, either within or outside their agencies.

Specifically, in responding to our survey of ongoing research activities involving the health effects of indoor mold, EPA, HHS, and HUD reported that 28 of their 65 research activities are being coordinated (see fig. 1). In other work, we identified practices that agencies should use when coordinating their activities, including (1) defining and articulating a common outcome, (2) identifying and addressing needs by leveraging each others' resources, and (3) agreeing on agency roles and responsibilities.⁴⁶ Especially when agencies are conducting research activities addressing the same data gap, coordination is important to ensure inappropriate duplication of efforts does not occur and to best leverage limited federal resources. Even in these cases, however, a significant number of activities are not being coordinated. For example, of the 32 EPA, HHS, and HUD research activities seeking to identify which environmental factors, such as mold, contribute to the development or exacerbation of asthma, federal officials reported that 18 activities are not being coordinated. Similarly, agencies are not coordinating on 22 of 36 research activities related to sampling and measurement methods.

⁴⁵An NIH official said that after the peer-review process is completed, proposals are given a merit score, which is based on factors such as the qualifications of the researcher and the level of innovation and significance of the research. Funding is then allocated to research activities in priority order based on this ranking.

⁴⁶GAO, Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

Figure 1: Coordination of Ongoing Federal Mold Research Activities within the Agency or among Other Federal Agencies, as of October 1, 2007



Source: GAO analysis of EPA, HHS, and HUD survey data.

Note: HHS officials reported coordinating three research activities with external organizations only. These activities are listed as not coordinated in this figure.

Further, the coordination activities reported by federal officials vary widely. In some cases, the federal officials we surveyed reported internal and external coordination on a specific research activity. For example, an EPA official noted that his unit conducted one of its research activities in conjunction with another unit within the agency, provided updates regarding the activity to another unit, and collaborated with another federal agency to write papers based on this research. Coordination was more limited in other cases. Specifically, in many cases, research activities were only coordinated within the agency—and often, with only one other unit within the agency. For example, one NIOSH official reported that, for one activity, his unit coordinated with another unit within NIOSH by supplying certain instruments.

Importantly, while agencies sometimes coordinate on individual research activities, we did not identify any sustained efforts to coordinate agencies'

indoor mold research priorities. In the few instances in which officials reported that they coordinated with others on research priorities, it appeared that these partnerships did not specifically address mold-related priorities. For example, while EPA officials told us that they recently met with officials from HHS's CDC to discuss mutual research opportunities related to the indoor environment, these meetings did not address mold research priorities.

Federal agencies are not using the existing Federal Interagency Committee on Indoor Air Quality as a forum to coordinate their research activities on indoor mold. As discussed earlier, EPA serves as the executive secretary of the Federal Interagency Committee on Indoor Air Quality. We found that the committee addresses federal research activities on indoor air quality on an informal basis. For example, our analysis of the minutes of the 11 committee meetings from February 2005 to February 2008 shows that agency priorities related to indoor air quality research, which could include research on mold, were discussed only a few times. In one case, EPA officials described how their agency had developed its research needs on indoor environments, which it published in a document later in 2005 titled Program Needs for Indoor Environments Research. In this case, EPA was not seeking input from other agencies on research needs and priorities but rather was informing other agencies of decisions EPA had made. Moreover, EPA, HHS, and HUD officials who participate in committee meetings told us that they had not discussed or sought input on their agency's mold-related research priorities during committee meetings. Further, according to committee meeting minutes, the information agency officials share at committee meetings regarding their mold research is limited to describing selected ongoing activities and issues related to their funding. When mold-related research was discussed during the 3-year period we reviewed, it was usually to provide an update on the status of some individual research projects. In several instances, officials also used the meetings to advertise the availability of funding for research on indoor air quality issues, which could include research on mold, or to announce the funding of moldrelated research.

Currently, the committee holds 2-1/2 hour meetings in person and by conference call three times a year that interested parties outside the federal government can access. The agendas for the meetings are based on input to EPA from member and nonmember agencies who propose topics they would like to discuss. According to officials from one of the participating agencies, the Consumer Product Safety Commission, the Federal Interagency Committee on Indoor Air Quality had more

substantive discussions in the past on research projects, funding, and which research priorities needed to be addressed than it does now.

The role of the Federal Interagency Committee on Indoor Air Quality has changed over time. Established in response to congressional committee direction in 1983, the committee, according to an EPA report, 47 was to (1) coordinate federal indoor air quality research; (2) provide for liaison and the exchange of information on indoor air quality research among federal agencies, and with state and local governments, the private sector, the general public, and the research community; and (3) develop federal responses to indoor air quality issues. According to a 1988 report on the structure and operation of the committee, the committee comprised 16 member agencies and was co-chaired by EPA, the Consumer Product Safety Commission, DOE, and HHS. This report noted that considerable agreement existed among member agencies that the primary role of the committee was to coordinate federal indoor air activities. Further, coordination activities were specified to include joint project planning and implementation; contributions to and review of member agency indoor plans, reports, and publications; communication on technical and nontechnical issues and activities; and advising on, and fostering multiagency participation in, indoor air program and research activities of individual agencies. The committee met quarterly and had standing work groups covering indoor air quality research areas to address a diverse range of indoor air quality research issues, such as radon, formaldehyde, and allergens and pathogens (which include molds). The work groups, which are no longer active, were to coordinate research activities in these areas and identify future indoor air quality research. EPA used the committee to coordinate air quality research and assist in implementing the indoor air quality research and development program established by Congress in 1986. For example, in 1989 and 1999, EPA used the committee to help it develop two reports that identified the individual research activities on indoor air quality that federal agencies were conducting. EPA has taken the lead in directing committee activities in the past, such as chairing meetings, and this role continues today.

⁴⁷EPA, Report to Congress on Indoor Air Quality: Volume I: Federal Programs Addressing Indoor Air Quality, EPA/400/1-89/001B (August 1989).

Federal Guidance to the General Public Identifies Various Health Effects Associated with Exposure to Indoor Mold, as well as Strategies to Limit It, Some of Which Are Inconsistent The Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD guidance documents we reviewed identify health effects associated with indoor mold in a residential setting but sometimes omit less common but serious health effects. Most of the guidance documents recommend similar strategies for minimizing mold growth. While guidance documents that discuss mold mitigation offer consistent advice about detecting mold, some provide conflicting information about cleaning agents and the appropriate level of protective equipment individuals need when mitigating mold in their homes.

Federal Guidance Cites Various Adverse Health Effects of Exposure to Indoor Mold but in Some Cases Omits Less Common but Serious Effects A majority of the 32 documents we reviewed that provide guidance to the general public on the health effects of indoor mold in their homes—issued by the Consumer Product Safety Commission, EPA, FEMA, HHS, ⁴⁸ and HUD—identify asthma and upper respiratory tract symptoms as potential health effects. In addition, many of these federal guidance documents cite unspecified allergic symptoms and skin symptoms, such as dermatitis, rashes, and hives. The six adverse health effects the Institute of Medicine found to be associated with indoor mold in 2004 are included in the 32 guidance documents to varying extents. However, all six adverse health effects are included in only two guidance documents, although a majority of the guidance was issued after the publication of the 2004 Institute of Medicine report. ⁴⁹

Further, only a few of the 32 guidance documents discuss adverse health effects associated with mold that are less common but serious. Such health effects include opportunistic infections or fungal colonization in immune-compromised individuals and hypersensitivity pneumonitis, a relatively rare allergic reaction in susceptible persons characterized by

⁴⁸All the HHS guidance documents we reviewed were issued by CDC.

⁴⁹The six adverse health effects identified by the Institute of Medicine are the exacerbation of asthma symptoms, upper respiratory tract symptoms, cough, wheeze, hypersensitivity pneumonitis, and opportunistic infections and fungal colonization in immune-compromised individuals.

fever, chills, dry cough, and a flulike feeling that can, in its chronic form, result in permanent lung damage. Because these less common but potentially serious adverse health effects are infrequently cited in the guidance documents, some individuals consulting these guidance documents may not take appropriate precautions when they are exposed to indoor mold. Table 1 identifies the potential adverse health effects cited in 6 or more of the 32 guidance documents we reviewed. (App. V provides a list of the guidance documents we reviewed and information on how to access them.)

Table 1: Potential Adverse Health Effects of Exposure to Indoor Mold Cited in Six or More Guidance Documents, by Federal Agency

	Number of documents reviewed, by agency					
Potential adverse health effects of exposure to indoor mold	CPSC ^a (2)	EPA (12)	FEMA (8)	HHS (6)	HUD (6)	Total number of documents citing the health effects
	Number of documents citing the health effects					
Asthma, asthma triggers, or asthma symptoms (such as episodes or		11	c	4	6	27
attacks)	2		6	4	6	
Upper respiratory tract symptoms ^c	2	4	6	6	5	21 ^t
Eye symptoms ^d	2	3	6	6	5	20 ^t
Skin symptoms ^e	1	2	5	5	4	16 ^t
Allergies or allergic reactions (symptoms not otherwise specified)	0	7	4	3	1	15
Wheeze	1	1	5	5	2	13 ^t
Cough	2	2	4	2	2	10 ^t
Difficulty breathing or trouble breathing	1	1	3	2	4	10 ^t
Infections (including those affecting people who have chronic lung disease)	0	1	3	6	0	10
Adverse effects to the nervous system	1	1	3	0	4	8'
Shortness of breath	1	1	3	3	0	7 ^t
Fungal colonization or opportunistic infections in immune-compromised individuals	0	1	0	5	1	6'
Hypersensitivity pneumonitis	1	4	0	2	1	6'

Source: GAO analysis of selected federal guidance.

Notes: Other health effects stemming from exposure to indoor mold, including fatigue, fever, dizziness, and gastrointestinal tract problems, are cited in five or fewer guidance documents. Health effects of exposure to indoor mold that are cited in only one document include aches and pains, lung irritation, and death.

^aConsumer Product Safety Commission.

^bThe sum of the guidance documents does not equal the total number of guidance documents citing the health effect because two documents, "Healthy Indoor Air for America's Homes" and "The Inside Story: A Guide to Indoor Air Quality," were issued by multiple federal agencies.

^cSymptoms can include nasal congestion, sneezing, runny/itchy/stuffed up nose, throat irritation, and sore throat.

Symptoms can include redness, watery eyes, irritation, and burning.

°Symptoms can include dermatitis, itching, rashes, hives, and irritation.

'Symptoms can include headaches, memory loss, and mood changes.

Moreover, most of the federal guidance documents we reviewed describe populations that may be particularly sensitive to indoor mold. However, few of the documents identify all of the populations that should take extra precautions to limit exposure to indoor mold. According to an HHS guidance document, these populations include the immune-compromised as well as those with asthma, chronic lung diseases, and allergies to mold. Immune-compromised individuals include organ transplant recipients, HIV patients, individuals with leukemia or lymphoma, and those undergoing cancer chemotherapy or other immunosuppressant drug therapies. HHS also recommends "due caution" for children, pregnant women, and the elderly who are exposed to indoor mold. Although some of the guidance documents identify several of these populations, some list only one or two. As a result, individuals consulting these guidance documents, especially those who are particularly vulnerable to mold exposure, may not be fully apprised of the risks associated with such exposure.

We recognize that the guidance documents we reviewed may address health effects and particularly sensitive populations in varying levels of detail because of differences in purpose and intended audience. For example, several EPA guidance documents targeted toward particular populations, such as teens, the elderly, and people with low literacy levels, are limited in their scope and level of detail. In contrast, HHS's document, *Mold Prevention Strategies and Possible Health Effects in the Aftermath*

of Hurricanes and Major Floods, ⁵⁰ which is targeted to the general public as well as to public health officials, includes a detailed discussion of numerous potential health effects that may result from exposure to indoor mold. Although not all guidance documents need to provide a comprehensive list of all of the potential health effects of exposure to indoor mold, the information provided should be sufficient to alert the public about potential adverse health effects of exposure to indoor mold, highlight specific populations that are particularly vulnerable to such exposure, and not conflict among documents.

Guidance on Minimizing Indoor Mold Growth in Homes Is Generally Consistent

Most of the 32 guidance documents issued by the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD that we reviewed describe how to minimize indoor mold growth in the home. These documents generally advise that residents reduce indoor moisture or humidity levels, and their recommendations for doing so are generally consistent. A majority of these guidance documents recommend that residents keep areas dry and address moisture sources, such as leaks or spills. Some of the guidance documents also recommend managing specific sources of moisture or humidity by, for example, preventing water from entering the house, ventilating and cleaning kitchens and baths to reduce moisture buildup, and repairing and insulating pipes. In addition, a majority of the documents recommend promptly drying wet items. Nearly half of the documents that provide more specific recommendations note that porous items, such as carpets, must be dried within 48 hours to avoid the growth of mold and say that if more than 48 hours have elapsed, these items should be discarded.

A number of the guidance documents that address strategies to minimize indoor mold growth also advise residents to maintain indoor relative humidity within specific ranges because high relative humidity can lead to water condensation on indoor surfaces, such as walls and windows, which can support mold growth. However, we note that the humidity ranges specified by the guidance documents vary. For example, while all the guidance documents that address relative humidity recommend maintaining it at 60 percent or below, one FEMA document recommends maintaining the relative humidity below 40 percent, and three guidance

⁵⁰Department of Health and Human Services, Centers for Disease Control and Prevention, Mold Prevention Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods (Atlanta, 2006).

documents issued by HHS recommend a relative humidity range between 40 percent and 60 percent.⁵¹ Such differences in guidance to the public could cause some confusion about this aspect of minimizing indoor mold growth.

Guidance on Mitigating Exposure to Indoor Mold Is Sometimes Inconsistent about Cleanup Agents and Protective Clothing and Equipment A majority of the guidance documents we reviewed provide information to the public about mitigating exposure to indoor mold. Many of the documents agree that if mold can be either seen or smelled, it should be removed. Recommendations on detecting mold are broadly consistent with information in a 2001 EPA report on mold mitigation in schools and commercial buildings, which is cited by a number of the guidance documents as a resource for mitigation of residential mold growth. 52-53 Further, the eight guidance documents that discuss sampling or testing to measure the quantity or type of mold in the indoor environment advise against it in most circumstances because the results of such testing may not be useful. For example, one of these documents explains that no standardized method exists either to measure the magnitude of exposure to mold or to relate a particular level of exposure to adverse health effects. Another guidance document notes that it is generally not necessary to determine the species of mold present.⁵⁴ Finally, many of the guidance documents that discuss mitigation note that if the mold is extensive (for example, if it covers more than 25 square feet) or if it is found in the heating or air conditioning systems, residents should consult further guidance, such as EPA's Mold Remediation in Schools and Commercial Buildings, or hire a professional contractor.

⁵¹Department of Homeland Security, Federal Emergency Management Agency, *Dealing with Mold and Mildew in Your Flood Damaged Home* (Washington, D.C., 2005). Department of Health and Human Services, Centers for Disease Control and Prevention, *Mold Questions and Answers: Questions and Answers on* Stachybotrys chartarum *and other molds* (Atlanta, 2004); *Facts About Mold And Dampness* (Atlanta, 2005); and *Molds in the Environment* (Atlanta, 2005).

⁵²EPA, Mold Remediation in Schools and Commercial Buildings (Washington, D.C., June 2001).

⁵³Guidance documents typically referred readers to this report if mold removal exceeds 10 square feet, although it also addresses mold cleanups of less than 10 square feet.

⁵⁴As discussed earlier in this report, however, litigants attempting to show that exposure to indoor mold has resulted in adverse health effects generally need to demonstrate to courts that a specific species of mold caused a specific adverse health outcome.

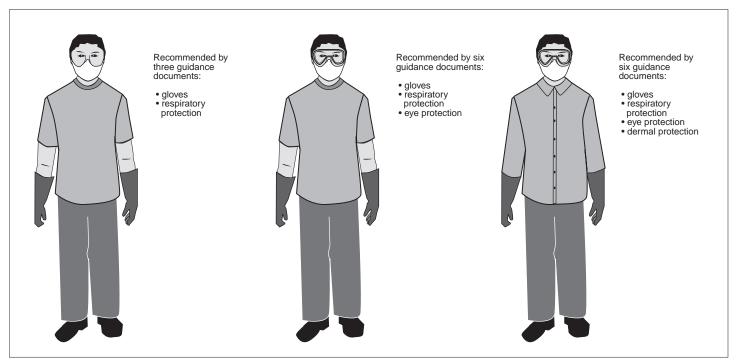
While a majority of the guidance documents we reviewed discuss how to remove mold once a problem has been identified, there is some inconsistency about which cleaning agents to use. For example, two guidance documents recommend using detergent to clean mold. On the other hand, HHS's Mold Prevention Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods advises that bleach may be warranted if the mold growth is due to floodwater, which can be contaminated. Another guidance document, issued by EPA, also advises that bleach be used when individuals who are particularly susceptible to adverse health effects from mold, such as those who are immunecompromised, are exposed to indoor mold. In contrast, six of the guidance documents we reviewed, including several of the HHS documents, recommend the use of bleach irrespective of certain populations or whether the mold growth is due to flooding. According to EPA's 2001 report on mold mitigation, mold growing on hard (nonporous) surfaces should be scrubbed with water and detergent and then vacuumed. 55 This report recommends using bleach only in limited circumstances—such as when immune-compromised individuals are present—because bleach, a biocide, is toxic to humans. These differences among guidance documents could lead to confusion among the general public about the safest and most effective way to remove mold. For example, if bleach is not necessary in most instances, using it unnecessarily could lead to avoidable problems, since bleach itself is a hazardous substance that can generate toxic fumes if it is mixed with ammonia-based cleaners.

In addition, many of the guidance documents we reviewed discuss using personal protective equipment while removing mold but, in some cases, recommend different levels of protection for the general public as well as for certain populations that may be more sensitive to mold exposure. For example, as figure 2 shows, the guidance documents provide inconsistent recommendations for the general public about wearing respiratory protection, eye protection, and skin (dermal) protection (such as long-sleeved shirts and long pants) for cleanups of limited mold contamination. ⁵⁶

⁵⁵EPA. Mold Remediation.

 $^{^{56}}$ The smallest areas addressed by guidance documents we reviewed vary from up to 10 square feet to up to 100 square feet.

Figure 2: Varying Levels of Personal Protection for Cleaning Limited Mold Contamination, as Recommended by Selected Federal Guidance



Source: GAO analysis of selected federal guidance.

Note: The guidance variously defines "limited" mold contamination as areas ranging from up to 10 square feet to up to 100 square feet.

In addition, although 26 guidance documents caution that certain populations may be more sensitive to mold, only 2 of them, issued by HHS in 2005 and 2006, provide specific recommendations about the varying levels of personal protection that such populations should use under various circumstances. The HHS documents state that, when inspecting or assessing damage, individuals with certain lung diseases should wear respirators, while healthy individuals need no special protection for these tasks. However, these documents warn that individuals with "immunosuppression," such as those undergoing cancer treatment or those who have leukemia or lymphoma, should wear a respirator, gloves, and safety goggles when inspecting or assessing damage. Further, those with "profound immunosuppression"—such as those with HIV infection—should avoid all exposure to mold.

Guidance documents also provide inconsistent information about the types of respiratory protection to use when cleaning up mold. Of the 15 guidance documents that recommend the use of respiratory protection during cleanup, 6 list items such as dust masks, which do not protect against mold because it can pass through them. Nine of the documents suggest "N-95 respirators," which filter 95 percent of airborne particles and can protect against inhaling mold. Moreover, only 3 of the guidance documents recommending the use of N-95 respirators discuss the need for proper fit—which could impact their effectiveness, according to the HHS's NIOSH, the federal agency that approves these respirators. Furthermore, only 1 guidance document, issued by HHS, warns that respirator use may not be appropriate if an individual has a pre-existing medical condition that makes it difficult to breathe while wearing a respirator.

A number of agency officials said they revisit the content of their guidance documents following significant new scientific discoveries or in response to events such as major flooding or hurricanes. We note that in the past few years, important updated information on the health effects of exposure to indoor mold and ways to protect against unnecessary exposure has been provided in three documents: the Institute of Medicine's 2004 report and two HHS guidance documents on mold issued in 2005 and 2006 in the aftermath of the hurricanes and major floods on the Gulf Coast. Nevertheless, some of the guidance documents we reviewed do not yet reflect important updated information that these publications provide. Overall, despite the useful information provided in the federal guidance we reviewed, some omissions and inconsistencies could cause some individuals to be exposed to indoor mold unnecessarily.

Conclusions

While the current research activities on indoor mold conducted or sponsored by EPA, HHS, and HUD address identified health-related research gaps to varying degrees, these activities are largely uncoordinated within and across agencies, and many are generated by independent researchers rather than by agency solicitations for specific research. This limited coordination contributes to the lack of standardized, quantitative methods for measuring exposure to mold that has impeded

⁵⁷Department of Health and Human Services, Centers for Disease Control and Prevention, Mold Prevention Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods (Atlanta, 2006) and Population-Specific Recommendations for Protection From Exposure to Mold in Buildings Flooded After Hurricanes Katrina and Rita, by Specific Activity and Risk Factor (Atlanta, 2005).

the advancement of knowledge about health effects and may result in unnecessary duplication of research efforts. Without more systematic coordination of planned and ongoing research activities, future research may not be prioritized to best fill data gaps or be of sufficient quality and consistency to more definitively support conclusions about any associations to indoor mold and adverse health effects. Specifically, the Institute of Medicine was unable to associate a number of adverse health effects with exposure to mold because the available studies were of "insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence of an association."

An existing interagency committee—the Federal Interagency Committee on Indoor Air Quality—could provide an effective vehicle for enhancing the coordination of research activities. As the executive secretary and cochair, EPA guides the activities of this committee, which was established in response to congressional direction to, among other things, coordinate federal indoor air quality research and foster information sharing among, for example, federal agencies and the public. While the committee provides a forum for informal information sharing, it has not been used in recent years to support systematic coordination of federal research priorities or agendas for indoor air research. Since the Federal Interagency Committee on Indoor Air Quality was established in the 1980s, significant advances in communications technologies, such as the Internet, have transformed the exchange of information—for example, through Web pages and hyperlinks to documents and Web sites. These communications advances can facilitate the coordination among federal agencies, state and local governments, the private sector, the research community, and the general public that the Federal Interagency Committee on Indoor Air Quality was established to accomplish.

Overall, the federal guidance documents we reviewed that provide information to the general public about the health effects of exposure to indoor mold, ways to minimize mold growth, and safe and effective methods for cleaning up provide generally useful information. However, some documents do not sufficiently advise the general public about some potentially serious health effects, and others provide inconsistent information about cleaning agents and appropriate protective gear. Regarding protective gear, some documents do not provide information about how populations that are particularly vulnerable to adverse health effects should protect themselves. In fact, populations with certain immunosuppression conditions should avoid exposure to mold but many guidance documents do not state this. As a result, the public may not be sufficiently aware of the health risks they or their family members may

face, and they may also be confused about how to approach cleaning up mold in their homes.

Recommendations for Executive Action

We recommend that the Administrator, EPA, use the Federal Interagency Committee on Indoor Air Quality to accomplish the following two actions.

- Help articulate and guide research priorities on indoor mold across
 relevant federal agencies, coordinate information sharing on ongoing and
 planned research activities among agencies, and provide information to
 the public on ongoing research activities to better ensure that federal
 research on the health effects of exposure to indoor mold is effectively
 addressing research needs and efficiently using scarce federal resources.
- Help relevant agencies review their existing guidance to the public on indoor mold—considering the audience and purpose of the guidance documents—to better ensure that it sufficiently alerts the public, especially vulnerable populations, about the potential adverse health effects of exposure to indoor mold and educates them on how to minimize exposure in homes. The reviews should take into account the best available information and ensure that the guidance does not conflict among agencies.

Agency Comments and Our Evaluation

We provided the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD with a draft of this report and the related supplement (GAO-08-984SP) for the agencies' review and comment. In its response, EPA generally agreed with our recommendations that it use the Federal Interagency Committee on Indoor Air Quality to, among other things, help articulate and guide research priorities on indoor mold across relevant federal agencies and help relevant agencies review their existing guidance to the public on indoor mold to better ensure that it sufficiently alerts the public about the potential adverse health effects of exposure to indoor mold and educates the public on how to minimize exposure in homes. In commenting on the draft report, HUD and the Consumer Product Safety Commission also generally supported our recommendations to EPA. FEMA did not provide comments on the report, and HHS's comments did not address our recommendations to EPA. The Consumer Product Safety Commission, EPA, HHS, and HUD also provided technical comments on our report, and HHS provided a technical comment on the supplement; their comments were incorporated, as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Acting Chairman, Consumer Product Safety Commission; Administrator, EPA; Administrator, FEMA; Secretary, HHS; Secretary, HUD; and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.

John B X fel

Sincerely yours,

John B. Stephenson Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

The objective of this review was to assess federal agencies' activities to minimize and mitigate the health effects of exposure to indoor mold. Specifically, we examined (1) what recent reviews of the scientific literature have concluded about the health effects of exposure to indoor mold; (2) the extent to which federal research addresses data gaps related to the health effects of exposure to indoor mold; and (3) what guidance key federal agencies are providing to the public on the health risks of exposure to mold, and on minimizing and mitigating that exposure, and the extent to which the guidance is consistent. Our review focuses on the health effects and guidance to the general public related to indoor mold in homes and does not address occupational exposures or technical guidance documents targeted to specialized audiences, such as medical professionals and emergency response workers.

To determine what recent reviews of the scientific literature have concluded about the health effects of exposure to indoor mold, we primarily relied on the findings in the National Academies' Institute of Medicine comprehensive report issued in 2004, Damp Indoor Spaces and *Health.* To identify more recent reviews of the health effects of exposure to indoor mold, we conducted a literature search. We searched for reviews and meta-analyses, rather than individual studies, published in English in 2005, 2006, and 2007, primarily using PubMed, a bibliographic database service of the U.S. National Library of Medicine. We conducted 19 different searches of PubMed using combinations of the following search terms: mold, exposure, health, indoor, glucan, microbial volatile organic compounds, mycotoxins, ergosterol, hemolysins, fungal extracellular polysaccharides, fungal/hyphal fragments, allergens, stachybotrys, acute ideopathic pulmonary hemorrhage, acute pulmonary hemorrhage and infants, and hemosiderosis. As part of these searches, we used PubMed's Clinical Queries option to find Systematic Reviews, which cover a broad set of articles that build consensus on biomedical topics. We also conducted a search for reviews and meta-analyses using the search strategy "mold AND (exposure OR indoor OR health)" in 15 other databases providing comprehensive worldwide coverage of scientific and technical journals on relevant topics. We reviewed the abstracts of all search results and obtained copies of the publications for which no abstracts were available, unless the available information indicated that the publication was unrelated to our review. We evaluated the relevance of the abstracts and publications and identified those that addressed the health effects of exposure to indoor mold and its constituents or products, excluding those that addressed dietary exposures, exposures in industrial or agricultural settings, publications focused on yeasts, case studies of mold in particular locations, and any publications that were clearly not

meta-analyses or reviews of the scientific literature. Twenty of the reviews met our criteria (see app. II for a list of these reviews). To assess the credibility, reliability, and methodological soundness of these publications, a senior GAO analyst with a doctorate in epidemiology reviewed each of the publications and any additional methodological information obtained from the authors and considered such factors as the bibliographies of evidence cited, the journals in which the articles were published, and the extent to which they are primary authors of other relevant articles. We did not examine the references cited by these studies as part of our analysis. Some of the reviews may be based on primary sources (for example, epidemiologic studies), while others may also be based on sources that are themselves reviews of the scientific literature (for example, the 2004 Institute of Medicine report). We concluded that all 20 reviews were sufficiently reliable for the purposes of this report.

We also used the 2004 Institute of Medicine report to help identify areas where additional research is needed to address scientific data gaps primarily related to the health effects of exposure to indoor mold other than asthma, as well as the institute's 2000 report, *Clearing the Air: Asthma and Indoor Air Exposures*, which focused on gaps related to asthma. We conducted in-depth reviews of these reports, including their methodology and conclusions, and we summarized the research needs they identified related to the health effects of exposure to indoor mold.

To obtain information on federal research related to the health effects of exposure to indoor mold, we conducted two surveys of officials at the Environmental Protection Agency (EPA), the Department of Health and Human Services (HHS), and the Department of Housing and Urban Development (HUD) from November 2007 to May 2008. We used one survey to (1) identify research activities related to the health effects of indoor mold ongoing as of October 1, 2007, and (2) determine the extent to which these research activities address the 15 data gaps identified in the 2000 and 2004 Institute of Medicine reports related to the health effects of exposure to indoor mold. Respondents completed a survey for each individual research activity ongoing as of October 1, 2007. We also used this survey to identify the extent to which these activities were coordinated both within and across agencies. We conducted a second survey of these agencies to collect basic information on their mold-related research activities completed from January 1, 2005, to September 30, 2007. Overall, we received information on 107 research activities from 37 EPA, HHS, and HUD officials. We received responses to our surveys from all relevant officials and agency entities. Summaries of the research activities

conducted or sponsored by EPA, HHS, and HUD are provided in a supplement to this report (see GAO-08-984SP).

We surveyed officials at EPA, HHS, and HUD because of these agencies' past and current participation in mold research. Specifically, we identified these agencies based on federal reports to Congress summarizing efforts to improve indoor air quality and interviews with federal officials involved in this research, among other things. We took a number of steps to ensure that our surveys would obtain reliable information from the appropriate agencies and officials regarding federal research activities on the health effects of exposure to indoor mold. For example, to ensure that we sent surveys to all agency officials involved in indoor mold-related research activities, we provided audit liaisons and agency respondents with a list of the units and officials in their agencies that we had identified as being relevant. We also asked audit liaisons to verify that we had not omitted any relevant units within their agencies and confirm whether other agency officials identified during our interviews as potentially involved in indoor mold-related research activities were involved with relevant activities. When an audit liaison identified a new agency respondent involved in indoor mold-related research activities, the individual was provided with copies of our surveys. (See app. IV for information on the units we contacted at these agencies.) We pretested our survey questions by sending them to two researchers from EPA and the National Institutes of Health (NIH) and incorporating their feedback into the final surveys. To increase the response rate, we followed up with agency officials to obtain responses from all relevant parties. We also performed a series of reliability tests on the data we received, including (1) examining agency submissions to exclude any that were either duplicates or did not meet our criteria and (2) checking for missing data or discrepancies. When we identified discrepancies or inconsistencies in the data, we followed up with relevant agency officials. In addition, we interviewed EPA, HHS, and HUD officials to determine the extent to which they coordinate their research projects and their priorities for mold-related research. To assess the extent to which the Federal Interagency Committee on Indoor Air Quality has been used to coordinate federal research activities related to the health effects of exposure to indoor mold, we reviewed relevant reports and the minutes of committee meetings dating from February 2005 to February 2008, and we interviewed EPA and other officials involved with the committee.

To determine what guidance key federal agencies are providing to the general public on the health risks of exposure to indoor mold, and on minimizing mold growth and mitigating exposure to mold in their homes, and the extent to which the guidance is consistent, we focused our review on the five federal agencies that provide information to the general public on health risks and minimizing and mitigating exposure to contaminants, including mold. The guidance we reviewed includes fact sheets, brochures, booklets, and Web pages. Specifically, we reviewed guidance on the health effects of mold in a residential setting issued by the Consumer Product Safety Commission, EPA, HUD, HHS, and the Federal Emergency Management Agency (FEMA) that was identified primarily through online searches of federal Web sites and interviews with relevant program officials.² We selected guidance to the general public that addresses health effects associated with indoor mold using a nonprobability sample. We did not include technical documents targeted to specialized audiences, such as medical professionals or emergency response workers.⁴ Of the 78 guidance documents that met our initial criteria, we selected 32 for detailed review on the basis of their content, purpose, and the extent to which they specifically addressed indoor mold. (In some cases, the documents broadly address indoor air contaminants but only briefly mention mold.) Specifically, of the 34 mold-related guidance documents FEMA issued to the general public responding to specific disasters since 2004, we selected 8 for our review; we excluded the other 26 because they contain essentially similar information. Further, we included in our review the 8 guidance documents issued by the Consumer Product Safety Commission and HUD that address health effects associated with indoor mold; however, we excluded some guidance documents issued by EPA and HHS primarily because they were similar to, and thus duplicative of, other documents already included in our review. We provided agency officials with an opportunity to review our list of

¹We use the term guidance to describe non-binding communications agencies issue to the public for educational purposes.

²We considered guidance to be issued by an agency if the agency is identified as its author or the guidance displays the agency's logo. Guidance documents can be sponsored by multiple federal agencies, and some of the guidance we reviewed was also sponsored by agencies other than those mentioned above, such as the Department of Agriculture.

³Nonprobability samples cannot be used to generalize or make inferences about a population. In this instance, we cannot generalize the results of our review of federal guidance to all federal guidance to the general public on the health effects of indoor mold issued by the Consumer Product Safety Commission, EPA, FEMA, HHS, and HUD.

⁴For example, we examined guidance from the Occupational Safety and Hazard Administration of the Department of Labor, but excluded it from our analysis because the mold-related information in this guidance was tailored to an occupational and professional context only.

Appendix I: Objectives, Scope, and Methodology

guidance documents and suggest additional documents for inclusion in our review. We added relevant documents, as suggested. (See app. V for the guidance documents included in our review.) Additionally, we interviewed officials from the five agencies issuing the guidance to determine their procedures for developing and issuing guidance documents. The guidance documents we analyzed are publicly available and can be accessed through the agencies' Web sites.

We conducted this performance audit from January 2007 to September 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Recent Reviews of the Health Effects of Mold

The following list of recent reviews of the health effects of mold includes two Institute of Medicine reports and 20 other reviews.

Borchers A.T., Chang C., Keen C.L., and M.E. Gershwin. "Airborne Environmental Injuries and Human Health." *Clinical Reviews in Allergy and Immunology*, vol. 31, no. 1 (2006): 1-102.

Bush R.K., Portnoy J.M., Saxon A., Terr A.I., and R.A. Wood. "The medical effects of mold exposure." *The Journal of Allergy and Clinical Immunology*, vol. 117, no. 2 (2006): 326-33.

Douwes J. "(1—>3)-Beta-D-glucans and respiratory health: a review of the scientific evidence." *Indoor Air*, vol. 15, no. 3 (2005): 160-9.

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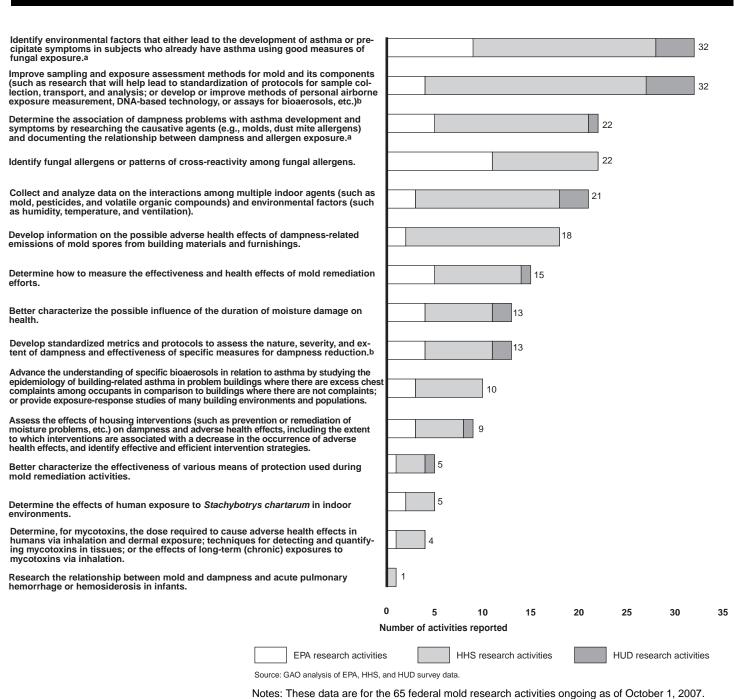
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Appendix III: EPA, HHS, and HUD Ongoing Research Activities Addressing Data Gaps Identified by the Institute of Medicine



Federal officials reported which of the data gaps identified by the 2000 and 2004 Institute of Medicine reports their research activities are addressing. Each activity can address multiple data gaps.

Appendix III: EPA, HHS, and HUD Ongoing Research Activities Addressing Data Gaps Identified by the Institute of Medicine

In fact, many of the activities are reported to address three or more gaps. Summaries of the 65 research activities conducted or sponsored by EPA, HHS, and HUD are provided in a supplement to this report (GAO-08-984SP).

Agency officials reported that eight federal mold research activities currently being conducted do not directly address any of the data gaps identified by the 2000 and 2004 Institute of Medicine reports. Some of these studies were directed at medical treatments and others were focused on other potential causes of asthma. For example, one study is evaluating whether chronic rhinosinusitis is induced by an abnormal immune response to mold and therefore whether an anti-fungal agent will be an effective treatment of the disease. Another study is developing and validating DNA-based methods for identification and fingerprinting medically important fungi. Several of these research activities focused on asthma. For example, two studies, one of children in El Paso and another of children in Detroit, are primarily focused on the role of residential proximity to roadways in the development of childhood asthma but also collected data on indoor exposures, including home dampness and the presence of visible molds. Another study being conducted is designed to test the hypothesis that asthma control in low income, urban adolescents and young adults can be improved with the addition of exhaled nitric oxide as a marker for treatment guidance to conventional asthma management guidelines; a secondary purpose of this study is to examine the role of allergy to molds in influencing the effectiveness of the asthma management plan.

^aAsthma data gaps identified by the 2000 and 2004 Institute of Medicine reports.

^bMeasurement methods data gaps identified by the 2000 and 2004 Institute of Medicine reports.

Appendix IV: Federal Agency Program Offices Contacted Regarding Their Mold-Related Research

We obtained information on federal research related to the health effects of exposure to indoor mold from three key agencies—EPA, HHS, and HUD. We obtained and analyzed information and interviewed program managers and other officials responsible for research at these agencies. Following are the offices, centers, and other program units we surveyed regarding their mold-related research.¹

Environmental Protection Agency

Office of Air and Radiation

- Office of Radiation and Indoor Air
 - Indoor Environments Division
 - Radiation and Indoor Environments National Laboratory
 - National Air and Radiation Environmental Laboratory

Office of Research and Development

- Office of the Assistant Administrator
- National Health and Environmental Effects Research Laboratory
 - Experimental Toxicology Division
 - Human Studies Division
- National Exposure Research Laboratory
 - Microbiological and Chemical Exposure Assessment Research Division
- National Risk Management Research Laboratory
 - Air Pollution Prevention and Control Division
- National Homeland Security Research Center
- National Center for Environmental Research
- National Center for Environmental Assessment

Office of Prevention, Pesticides, and Toxic Substances

- Office of Pesticide Programs
 - Antimicrobials Division
 - Field and External Affairs Division
 - Special Review and Reregistration
- Office of Pollution Prevention and Toxics
 - Environmental Assistance Division

Office of the Administrator

- Office of Children's Health Protection and Environmental Education
 - · Child and Aging Health Protection Division

¹We contacted at least one person in each program office. Officials in some of the program offices listed in this appendix responded that they were not conducting or sponsoring any mold research. In addition, some of the officials we contacted involved with indoor mold research had left their agencies; their offices are not represented in this appendix.

Appendix IV: Federal Agency Program Offices Contacted Regarding Their Mold-Related Research

Office of Solid Waste and Emergency Response

Department of Health and Human Services

Centers for Disease Control and Prevention

Office of Chief Science Officer

Coordinating Office for Terrorism Preparedness and Emergency Response

Coordinating Center for Health Information and Service

• National Center for Health Marketing

Coordinating Center for Infectious Diseases

- National Center for Immunization and Respiratory Diseases
 - Influenza Coordination Unit

Coordinating Center for Environmental Health and Injury Prevention

- National Center for Environmental Health
 - Division of Environmental Hazards and Health Effects
 - Air Pollution and Respiratory Health Branch
 - Division of Emergency and Environmental Health Services
 - Lead Poisoning Prevention Branch
- Agency for Toxic Substances and Disease Registry
 - Division of Health Assessment and Consultation
 - Cooperative Agreement and Program Evaluation Branch
 - Division of Health Studies

National Institute for Occupational Safety and Health

- Office of the Director
 - Office of the Associate Director for Science
 - Office of Extramural Coordination and Special Projects
- Health Effects Laboratory Division
 - Pathology and Physiological Research Branch
 - Allergy and Clinical Immunology Branch
- Division of Surveillance, Hazard Evaluations, and Field Studies
 - Hazard Evaluations and Technical Assistance Branch
 - Industrywide Studies Branch
- Division of Respiratory Disease Studies
 - Field Studies Branch
 - Laboratory Research Branch

Appendix IV: Federal Agency Program Offices Contacted Regarding Their Mold-Related Research

National Center for Zoonotic, Vector-Borne, and Enteric Diseases

- Division of Foodborne, Bacterial and Mycotic Diseases
 - Mycotic Diseases Branch

National Institutes of Health

National Human Genome Research Institute

Office of Population Genomics

National Institute of Allergy and Infectious Diseases

- Division of Clinical Research
- Division of Microbiology and Infectious Diseases
- Division of Allergy, Immunology, and Transplantation
 - Office of Program Planning, Operations and Scientific Information
 - Asthma, Allergy and Inflammation Branch

National Heart, Lung, and Blood Institute

- Division of Lung Diseases
- Division for the Application of Research Discoveries

National Institute of Environmental Health Sciences

- Office of the Director
- Division of Extramural Research and Training
- Division of Intramural Research
 - National Toxicology Program
 - Environmental Diseases and Medicine Program
 - Clinical Research Program
- Office of Translational Research

Office of the Assistant Secretary for Health

Office of Public Health and Science

- Office of the Surgeon General
- Commissioned Corps of the U.S. Public Health Service
 - Chief Professional Officer
 - Medical
 - Environmental Health
 - Health Services
 - Scientist

Office of the Assistant Secretary for Administration and Management

Program Support Center

- Federal Occupational Health
 - Environmental Health Services

Appendix IV: Federal Agency Program Offices Contacted Regarding Their Mold-Related Research

Department of Housing and Urban Development

Office of the Assistant Secretary for Policy Development and Research

- Office of Deputy Assistant Secretary for Research, Evaluation, and Monitoring
 - Affordable Housing Research and Technology Division

Office of Healthy Homes and Lead Hazard Control

Policy and Standards Division

Office of Public and Indian Housing

- Office of Public Housing Investments
 - Office of Capital Improvements
- Office of Native American Programs
- Real Estate Assessment Center
 - Physical Inspection Quality Assurance Division

Office of Housing

- Office for Regulatory Affairs and Manufactured Housing
 - Office of Manufactured Housing Programs

Appendix V: Selected Publicly Available Federal Guidance Related to Mold

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Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

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