

# Exposure Registries

## Overview and Utility for Nanomaterial Workers

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**Objective:** This article provides the background for consideration of exposure registries to address potential disease risks in nanomaterial workers.

**Methods:** The history of exposure registries is reviewed with a focus on their purpose and criteria for establishment. **Results:** A rationale is presented for developing registries of nanomaterial workers, and unresolved obstacles and challenges are identified. These include issues on inclusion criteria, funding, potential for legal risks, access to data, confidentiality of business information, privacy, and workers' expectations. **Conclusion:** If society is to gain the benefits from nanotechnology, it must take precautions and demonstrate care for those, such as workers, who may be most at risk of adverse effects. Establishing exposure registries is a part of such a precautionary and caring approach.

Innovations in nanotechnology have generated hundreds of diverse nanomaterials with novel properties and unknown potential to enhance or harm human health. Current toxicology studies in animals indicate hazards, which may be present for exposure to certain types of engineered nanomaterials.<sup>1,2</sup> Whether adverse health effects will result from occupational exposures to nanomaterials throughout their life cycle may not be known for years. Therefore, pragmatic and effective measures are needed to (1) preserve essential data elements for future epidemiologic evaluation, (2) establish mechanisms for early identification and communication of health hazards, and (3) protect employee health among workers potentially exposed to nanomaterials. This article explores the potential for exposure registries of nanomaterial workers to meet these growing needs.

The uncertainty that characterizes the hazards and risks of occupational exposure to engineered nanomaterials is a legitimate concern to workers, employers, and entrepreneurs. Because of their remarkably small size, nanoparticles may be difficult to detect unless using advanced aerosol monitoring equipment; they may move and disperse in unusual ways and therefore may be encountered and unwittingly inhaled or absorbed. For workers, these uncertainties can be reflected in the extent to which effective controls are implemented and recognized in their workplaces, and whether they realize that they have a right to know about occupational hazards. For employers, the uncertainty can result in inadequate protection of the workforce and inefficient or inappropriate use of control resources. These impacts on workers and employers leave entrepreneurs and investors in nanotechnology concerned about its growth potential and future liabilities. In the end, society could feel an adverse impact

not only in the workplace and production but also in limitations to obtaining the potentially significant benefits of nanotechnology.

To address these uncertainties, government agencies and others have advocated precautionary approaches to workplace control of nanomaterials.<sup>3-7</sup> Nevertheless, further assurance of worker health and safety is warranted because the degree of compliance with precautionary guidance is unknown, as is the degree to which such guidance is effective across the large number of scenarios characterized by workplace types, nanomaterials types, and business sectors.<sup>8</sup> Although it is yet unknown the extent to which any nanomaterials currently being used or produced may pose health risks to humans, an argument can be made in support of examining the issues relevant to establishing nanomaterials workers registries, which in effect can be viewed as occupational exposure registries, even though actual exposures to any specific material, as well as any potential hazards of that material, remain unknown.<sup>8</sup>

Generally, an exposure registry is a system for collecting and maintaining in a structured record, comparable information on persons with known or suspected occupational or environmental exposure to a hazardous substance.<sup>9,10</sup> The ultimate purposes of exposure registries are to provide services and feedback to registrants and facilitate the development of new scientific knowledge. Exposure registries are not warranted in every situation in which uncertainty about hazards and risks is an issue. This is because exposure registries may have unintended consequences and high costs to workers, employers, and society, which on balance would vitiate the rationale for their establishment. A registry would be warranted if it meets established criteria or rationale, but in the case of nanotechnology workers with unknown exposures and unknown hazards, there might be good reasons to consider registration of nanotechnology workers. While no widely sanctioned set of criteria exist for occupational exposure registries, the history and use of occupational exposure registries provide a basis for determining their applicability to nanomaterial workers.

### HISTORY OF EXPOSURE REGISTRIES

Exposure registries have been used for more than 50 years to help to identify and evaluate occupational and environmental health problems.<sup>9,11,12</sup> They have often been used to identify workers and residents exposed to known hazards (eg, kepone, 2-naphthylamine, beryllium, lead, benzene, Agent Orange, ionizing radiation), but in other cases, they have been established to address exposure to suspected hazards (eg, World Trade Center dust, Gulf War/Operation Iraqi Freedom, and tremolite asbestos). In addition, exposure registries have been established in which the hazard is known, but the actual exposure of risk is not (eg, Three Mile Island). While exposure registries are not epidemiologic studies per se, they form the basis for such studies by helping to identify populations potentially exposed to materials of known or unknown hazard and possibly at increased health risks. They also serve to provide a structured, orderly approach to identifying and maintaining communication with workers exposed to known or suspicious hazards.<sup>9</sup>

Because of the need to track and follow-up individuals over long time periods between exposure and various resultant chronic diseases, the registration of workers based on their exposures to

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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chemical and physical agents can be efficient.<sup>9,10,13,14</sup> The forerunner of contemporary exposure registries is the long-term follow-up of atomic bomb survivors that began in 1950, which involved the registration and prospective study of the populations of Hiroshima and Nagasaki.<sup>15</sup> One component of this effort to trace atomic bomb survivors, the Life Span Study, was organized to include 100,000 individuals who were followed to determine the long-term effects of radiation exposure.<sup>9</sup> Similarly, the National Dose Registry of Canada was established in 1951, which contains dose records of people who are monitored for occupational exposure to ionizing radiation.<sup>16</sup>

Radiation dose registries for monitoring occupational exposure continue to be the most widely developed registries in the world.<sup>16–18</sup> One survey identified 21 of the 28 European countries, with a central registry for recording dose data from occupational radiation exposure. In North America, there is the National Dose Registry of Canada, which was established in 1951 ([http://www.hc-sc.gc.ca/ewh-semt/occup-travail/radiation/regist/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/occup-travail/radiation/regist/index_e.html)). In the United States, there is no central radiation dose exposure registry but there are various ad hoc registries that exist as a function of prospective epidemiologic studies of workers exposed to ionization radiation.<sup>18,19</sup> The US Department of Energy, Nuclear Regulatory Commission, and Department of Defense records of workers and/or soldiers may continue *de facto* or explicit exposure registries.

Registration of exposed persons is a standard procedure in public health for addressing some infectious disease exposures, as well as for following patients treated with various therapeutics.<sup>13</sup> For example, in the early 1950s, the notifying, following, and screening of individuals at risk of thyroid cancer due to therapeutic thymus irradiation constituted an exposure registry.<sup>20</sup> There is also a long history of registries for outcomes in women exposed to drugs in pregnancy.<sup>21</sup>

A classic example of an environmental exposure registry was the Michigan polybrominated biphenyl follow-up registry established in 1976.<sup>22</sup> About 4600 persons were initially enrolled, interviewed, and studied for acute and subacute adverse health outcomes. This represents the ideal in exposure registries because the exposure occurred over a relatively short period; polybrominated biphenyl is toxic to animals both acutely and chronically, is persistent for a lifetime, and is measurable.<sup>9</sup>

In the occupational health field, a number of explicit or *de facto* registries have been established. Workers exposed to aromatic amines have been followed by corporations or government agencies and have been screened for bladder cancer.<sup>23,24</sup> The National Institute for Occupational Safety and Health maintained for various times registries of workers exposed to kepone, dibromochloropropane, and dioxin. In addition to these formalized registries, *de facto* exposure registries have been created in the lists of surviving members of retrospective cohort mortality studies compiled by scientific investigators.<sup>25</sup> These lists, the results of vital status determinations, inherently constitute registries; however, the registrants are not aware of their risks or membership in such *de facto* registries.<sup>9,26</sup>

Various pieces of legislation, in addition to the Occupational Safety and Health Act of 1970, have supported the establishment of exposure registries. These include the Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (Public Law 95-623) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 (Public Law 96-510). The Health Services Research, Health Statistics, and Health Care Technology Act mandated that the National Center for Health Statistics (NCHS) study the issues in establishing a federal system to assist in locating individuals who have been or may have been exposed to hazardous substances, determining the effect of such exposures on their health, and helping them obtain access to appropriate medical care and treatment.<sup>9,27,28</sup> There were five recommendations in the study that were pertinent to the establishment or operation of exposure registries:

1. Develop adequate documentation of data files and computer programs that have widespread research utility.
2. Improve the timeliness of epidemiologic studies of exposed populations.
3. Develop improved risk assessment methodologies and analytical technology for the detection and monitoring of hazards in the environment.
4. Institute efforts for coordinating environmental and health monitoring programs and for expanding the study of population subgroups that display an unusually high or low incidence of disease-specific morbidity or mortality.
5. Study the resource requirements involved in establishing a network of coordinated screening and diagnostic services for individuals with suspected exposure to hazardous substances.

Public Law 95-623 also mandated the study of incidence, prevalence, distribution, and effects of environment-related disease in populations. Subsequently, a report was released that presented a plan for these studies. The report described the major data collection systems within the environmental health area and discussed problems inherent in using this database to associate human health effects with environmental exposures.<sup>9</sup>

In 1980, exposure registries were mandated by the legislation that created the CERCLA, often referred to as “Superfund.” The CERCLA also created a new agency of the Public Health Service, the Agency for Toxic Substances and Disease Registry (ATSDR). This agency is required to implement the health-related authorities of the act, among which is the requirement, “in cooperation with the States, establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances.”<sup>29</sup>

The top priorities for registries for the ATSDR included the following:

1. Persistent, measurable levels of hazardous agents in which animal studies or other evidence predict significant adverse effects in humans, or
2. Hazardous agents for which current methods exist to prevent an adverse outcome; or
3. Persons with outcomes of interest, where measurements of exposure to hazardous agents are available.<sup>29</sup>

In another document entitled “National Registry Proposal,” ATSDR in 1987 provided an interpretation of when an exposure registry should be established. “The ultimate purposes of a registry of persons exposed to toxic substances are to provide service to registrants and to facilitate the development of new scientific knowledge. Besides identifying and keeping track of exposed persons, a registry should coordinate the clinical and research activities that involve its registrants. Since many researchers may propose using registrants as study participants, the registry should be the focal point of coordination. By maintaining a comprehensive data base on all exposed persons, a registry should try to collect information that satisfies multiple needs. Besides playing an important role in assuring uniformity and quality of the collected data, a registry should ensure that data collection is not duplicative in studies in order to reduce the overall burden to exposed or potentially exposed persons.”<sup>30</sup>

This document also proposed criteria for when a registry should be established, who should be included, levels of follow-up, and when follow-up of a registry cohort should be terminated.<sup>9</sup> Subsequently, the National Exposure Registry was created, and a ranking scheme was developed by ATSDR to select substances for which specific subregistries would be developed.<sup>31,32</sup> The National Exposure Registry established four general subcategories: volatile organic compounds; dioxins; heavy metals; and radioactive materials (<http://www.atsdr.cdc.gov/substances/ToxChemicalClasses.asp>).

The most recently established exposure registry is the World Trade Center Health Registry, which was established in 2003 by the New York City Department of Health and Mental Hygiene, and enrolled more than 40,000 persons exposed in the World Trade Center disaster.<sup>33</sup> Registry eligibility included workers and residents and was triggered by a person's location on September 11, 2001, and included those who were involved in subsequent rescue, recovery, clean-up, and other activities at the World Trade Center site or the World Trade Center recovery operation on Staten Island, New York. The World Trade Center Health Registry criteria involved exposure (or its surrogate location), and the registry was established to document physical and mental health effects.<sup>34</sup>

Overall, exposure registries have been a useful tool of public health to address situations of uncertainty regarding hazards and risks. When used as a basis for medical screening, registries have generated useful clinical, psychosocial, and epidemiologic data and have been a source of aid to workers and residents at risk.<sup>35</sup> The cost of maintaining such registries has not been widely reported in the literature but appear to be extensive.<sup>10</sup> Nevertheless, the costs of formal epidemiologic investigations—both in monetary terms and in terms of the lost informational value where historical reconstructions of cohorts and exposures estimates are required—can be enormous, but having an exposure registry in place may help to limit the costs of epidemiologic research.

## RATIONALE FOR DEVELOPING REGISTRIES OF NANOMATERIAL WORKERS

As summarized previously, exposure registries have traditionally been implemented among groups of people exposed to known or suspected hazards. Although the extent to which any nanomaterials currently being produced or used actually are hazardous, the health risks they may pose to humans remains unresolved. However, on the basis of preliminary findings, an argument based on good occupational health practice can be made in support of establishing a nanomaterials worker exposure registry.<sup>2,3,8</sup>

The overall objectives for nanoworker registration, depending on intended use, include standardization and preservation of essential employee materials, and work history records in anticipation of future epidemiologic research efforts. However, timing may be the most critical issue, as it has been shown in other industry sectors that historical data collection is extremely difficult to do accurately, especially where the necessary records are not standardized or worse, have not been preserved. The rationale for developing a nanoworker registry includes the following aspects.

First, the nanotechnology platform represents a broad and rapidly expanding capacity for the development of and applications for new nanomaterials. The rate at which materials are developed and commercialized for a wide range of beneficial applications that enhance quality and performance of consumer products, improve medical diagnosis and treatments, reduce energy consumption, and expedite environmental remediation is likely to far outpace our ability to understand potential hazards and control risks. Therefore, the need to identify, follow, and evaluate large groups potentially exposed to specific types of nanomaterials is growing. Because risks remain unknown, we do not know which, if any, diseases or conditions may be associated with nanomaterial exposures. Therefore, formal epidemiologic studies may be impractical or difficult to conduct.

Nevertheless, even without knowing the disease outcomes that might become of interest, the identification and enumeration of members of potentially exposed cohorts could occur immediately. Because basic personnel/administrative records routinely generated and maintained by most businesses, research organizations, and government (especially branches of the military in the United States) typically serve as the starting point for forming epidemiologic study

cohorts, these data should be readily obtainable and could be easily preserved for future research purposes.

Second, in the event that toxicological or early epidemiologic research or cluster investigations find health effects with exposure to certain types of nanomaterials, an exposure registry can facilitate the identification of the most relevant industries and employees that might be impacted and minimize the otherwise protracted process of identifying and enumerating an appropriate cohort to evaluate for risks. Establishment of a broad-based exposure registry now can substantially reduce the time and effort required in the future to identify, enumerate, and track individuals occupationally exposed to specific types of nanomaterials in response to an urgent or focused need. Because the data on potentially exposed workers will be derived from many companies (including academic research laboratories, start-up and pilot facilities, manufacturing, and production companies) and geographic regions and countries, identification and development of industry-wide cohorts for epidemiologic studies would be possible. Should serious health effects be associated with a certain type of nanomaterial, the registry would allow rapid identification of relevant occupational subgroups that would be most efficient to evaluate further.

Through the registry, communication of hazards, risks, and necessary warnings; recommendations for primary prevention (ie, engineering controls), industrial hygiene monitoring, and personal protective equipment use; and targeting of medical surveillance, all will be enhanced. Again, because a registry would include workers with similar potential exposures across many (possibly including very small) employers, relevant groups of workers and their employers—based on their registered workplaces and exposures—may be identified and contacted with the most recent and relevant information.

Fourth, while the generation of new science and more effectively protecting the health of the registered population are the two basic purposes of exposure registries, participating companies and institutions will also benefit. Participation is consistent with other well-established company-based health promotion and product stewardship efforts, and registration can be viewed as an extension of both. Through registry participation, companies will have the capacity to provide current and former employees with longitudinal reports on their nanomaterial exposure as they are generated or available. Evaluation of registry data further will allow corporate health and safety officials to track the nature of nanomaterial exposure among the workforce over time, evaluate potential trends in individual and aggregate data, and compare company patterns to aggregated and anonymized data from other companies in the same or related industry sectors. Employer obligations for communication of new science and any necessary hazard and risk warnings may be enhanced and expedited through a registry, as relevant recipients of information of specific interest or importance can be readily targeted.

## UNRESOLVED ISSUES—OBSTACLES AND CHALLENGES

Despite the compelling arguments favoring the establishment of some form of nanotechnology worker registry, there remain several challenges and unresolved issues. Many of these were recently explored with participants in three panel discussion groups at the Exposure Registries session at the Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research Conference, July 21–23, 2010, at the Keystone Conference Center, Keystone, Colorado. Highlights from each group are structured under several thematic questions and summarized later.

### Which Nanomaterial Workers Should be Registered?

Answering this question from a traditional perspective of exposure registries would depend on the degree of hazard and exposure

by the type of nanomaterial and whether epidemiologic studies were anticipated. However, for many, if not most nanomaterials, both the degree of hazard and the level of exposure likely remain unknown. The early findings of pulmonary fibrosis in animals exposed to various carbon nanotubes would suggest that workers exposed to them might be good candidates to be in exposure registries.<sup>36,37</sup> Even at the limit of quantification ( $7 \mu\text{g}/\text{m}^3$ ) for organic carbon, there have been estimates of risk of pulmonary fibrosis as 1 of 1000 over a working lifetime.<sup>38</sup>

Before deciding more broadly which workers should be registered, defining who constitutes a “nanotechnology worker” will need to be determined. Several options are possible, including characterizing workers by industry sector, type of exposure, or materials handled or by job tasks performed. Inclusions of end users or “transients” through the industry pose an additional challenge to defining a nanoworker as well and may be deferred for later inclusion. In addition, worker mobility and inclusion of the international workforce are potential obstacles that could be alleviated in part through a web-based, secure system. With these above stated issues and uncertainties, the simplest option would be to enroll nanomaterial workers in registries based on a case-by-case basis and where possible dependent on: 1) whether nanomaterial exposure is likely, 2) whether it is reasonably anticipated that the exposure is hazardous and that an epidemiologic study would be conducted, or 3) whether a specific medical screening of exposed workers might be recommended.

### What Information Should be Required to be Maintained?

Registration focused on identification of workers manufacturing or manipulating nanomaterials is of primary interest, with specific exposure levels identified of secondary concern. Particularly, if an epidemiologic study is possible or under consideration, unexposed as well as exposed workers in the nanomaterial manufacturing or similar facility will be important to include. In the early stages of registry development, fact and duration of employment may be all the information that is available, and whether this limited amount of information is adequate for either epidemiologic or screening purposes is an issue requiring further discussion. As workers are registered, however, some consistency in the information obtained would facilitate evaluation, particularly for epidemiologic study—even if not all data are collected immediately.

As employment classification as a nanotechnology worker is relatively new (and may not be explicit)—though expanding rapidly—information maintained at this point in time could be as basic as “yes/no” employment in a facility in which nanomaterials are manufactured and/or used. Prospectively, more information could be added, especially if the registry was web based that could be easily modified. Practical issues of the kinds of data to be immediately captured should surpass the need for perfect data collection. As mentioned earlier, exposure levels, measurements, etc, eventually would be ideal to include—especially if quantitative risk estimation efforts were anticipated. Nevertheless, these kinds of data are likely premature to require, and their absence does not preclude more rudimentary registry functions (including the identification of critical data gaps) to proceed. Thus, flexibility in required content could be critical to initiating data collection. Initially, it may be important to collect data on individuals with a reasonable probability of exposures, regardless of whether this is definitively known, as well as those who perceive that they have been exposed.

### How Will the First Registrants be Included?

Once the core data elements of a nanoworker registry are determined, the next challenge will be how to recruit and register the first participants. As noted, some employers already have a registration system through the employment records maintained. If these records could be centralized, such information might provide the

basis for adding new member companies. If the registry is to include individuals either working independently or as part of a company or institution that chooses not to participate at the institutional level, alternative recruitment approaches will be needed, including communication of the availability and objectives of the registry—and which incentives would be in place to ensure future registrants.

### Who Should Manage the Registry?

Most exposure registries have been managed by government agencies, in part, because they involve more than one company, a company that is no longer in business, or residents related to a specific environmental exposure. This does not preclude that a company or consortia can manage a registry. In any case, worker input is an important component. In some ways, employee rosters and related occupational safety and health data are *de facto* exposure registries. It may be advisable, given that the focus is an emerging technology with broad potential societal benefit that a tripartite (business, labor, and government) oversight structure be considered. Such a group can provide the overall guidance for a registry and reflect the needs of various stakeholders.

An oversight committee or other similar structure can also manage other of the issues listed later, including measures to protect worker’s privacy, employers’ confidential business information, and interest in accessing registry information, which is likely to be diverse, depending on the purpose for requesting access. Ultimately, legal ownership of the data may pose some important obstacles, as the source information for a registry would include individuals and employers.

### Who Should Fund the Registry?

Generally, industry and government should fund registries, since they represent both public health and corporate areas of responsibility. Employers have the responsibility for providing a safe and healthy workplace, and government has the responsibility to provide employers with the necessary information and determine that they are meeting their responsibilities. While employers are not mandated by law to establish registries, they are mandated to maintain components such as records, health and safety information, and a workplace free of hazardous exposures. Moreover, the support (or establishment) of an exposure registry for nanomaterial workers may demonstrate good product stewardship and risk management practice.

While logistically more complicated, there are some clear advantages to having broad support for a registry, that is, multiple funding sources. These include a reduced budgetary burden to any one funding agency, a broader and potentially more diverse collection of perspectives for oversight, more parties with a vested interest in its successful use, and greater probability of sustainability across economic and political turns. In addition to government and major corporate sponsors, other sources of financial support may include company membership fees, user fees, and grants for start-up (as initial costs are expected to be greatest).

### Is There a Legal Risk to Employers?

Whether a registry poses a legal risk to employers may depend on its purpose—the semantics of “registry” and “exposure” may have legal implications administratively. Such questions do require the input and consideration of the legal community. Nevertheless, it could pose more of a risk for employers not to consider, including their employees in a registry. Supporting a registry is also a good liability-reducing practice because it provides enhanced defense against claims of corporate indifference or inaction; in the event, a particular nanomaterial is found to cause harm. Medical directors would likely find utility in a registry to protect workers and provide immediate feedback of new knowledge. Such proactivity on

the part of employers would hopefully prove to be beneficial and not a liability.

Apart from occupational health and safety benefits, companies may actively reduce or avert legal liability by looking for, identifying, and controlling occupational health hazards. In the event in which litigation arises, participation in the registry will provide an enhanced defense against claims of corporate indifference or inaction. Exposure registration may also help to document whether or not exposures to specific materials were likely to have occurred, and if so, when, where, or under which workplace circumstances they would have occurred.

### Would Employees Have Undue Expectations of Service?

Whether employees would have undue expectations is a difficult issue to address, without a fully conceptualized registration process implemented. The employer's approach to communicating "up front" the goals and expectations—as well as the limitations and rationale for participation—would hopefully instill reasonable expectations on the part of employees. Incentives and disincentives for participation, if clarified and communicated appropriately at the onset, would also provide a framework for what employees may or may not expect. No doubt some reasonable disclaimer will need to be part of any registry, specifically indicating that the registry serves research and communication purposes and does not replace or reduce other obligations of the employer and the employee to uphold high standards for occupational health and safety.

### Would Employers' Confidential Business Information be in Jeopardy?

As indicated previously, a management structure that was designed to oversee the registry would provide a mechanism to protect confidential information. The challenge to constructing a registry of those working with nanomaterials is to maintain information on the individuals' employment history, with adequate record of tasks and types of materials handled, rather than to elaborate the complex utilization or inherent "uniqueness" of a particular material.

### Can the Privacy of Workers' Records be Maintained?

Again, the advantage to an oversight team to manage the registry would be to maintain the workers' privacy, as well as the employers' confidential business information. In addition, it will be important not only to ensure privacy but also to avoid inducing anxiety or any negative stigma attached to participation.

Nevertheless, because the primary function of a registry is to preserve and enhance the ability to link information, including individually identifiable data, from various sources, the potential always exists for breach of confidentiality or even misuse of personal identifying information. These aspects must be taken very seriously if a registry is to be trusted and ultimately to be effective in recruiting and retaining participants that provide valid and complete information.

The challenge, however, would be for workers who were highly mobile and how to track them among the various nanomaterial workplace settings—which could be as diverse as a university laboratory, start-up company, or large corporation. How to maintain linkages through the individual's career and maintain private information may pose a challenge; however, in the age of high technology, it should be possible.

### Who Would Have Access to the Registry?

The answer to this question is critical to determining the long-term success of the registry. It will be inevitable that researchers will want to use the registry to identify increased risks among nanotechnology workers and to evaluate the potential relationship between risks and exposures. This is a mandate for governmental researchers.

While such research interests should be of broad interest, manufacturers of nanomaterials may prefer that they (or their scientists) play a major or even exclusive role in conducting or overseeing the research. As active participants in the registry, companies reasonably should expect access to the data for research purposes, especially because these employers have primary responsibility for their employees. On the contrary, many research interests are academically based, and these investigators may or may not have a vested interest in the research findings. Should these groups also expect to have open access to the data (especially if it is wholly or even in part funded publically)?

It is clear that different potential users would have different expectation for accessing registry data—and would require different utility—and once developed, ideally, all would have access. Once again, central and multidisciplinary management might facilitate review and control of database access and use. The design, and guidance for access, should envision all types of users.

Use of the registry for dissemination of information to nanotechnology workers (or a subset of targeted because of the nature or location of their work) also poses challenges. The proper balance between open access to a nanomaterials registry and adequate protections against misuse and dissemination of scientifically unsound or potentially disturbing information will need to be struck.

While answers to all of these questions may not be available, the overall scientific and public health rationale for establishing a nanotechnology workers registry is sound, and the approaches and methodologies required for a minimally functional registry are straightforward and readily available. The ultimate challenges to establishing a registry of nanotechnology workers, however, may have more to do with important political and legal obstacles rather than scientific or occupational health concerns. Nevertheless, further refinement of a blueprint for a nanotechnology worker registry, continued dialogue with the stakeholders, and initiation of modest pilot and feasibility phases may lead to stronger acceptance of and participation in a full-scale registry in the future.

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