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before
The Subcommittee on Healthcare and Technology Joint Hearing with Committee on Science, Space, & Technology Subcommittee on Investigations & Oversight on
"How the Report on Carcinogens uses Science to Meet its Statutory Obligations, and its Impact on Small Business Jobs"

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Chairwoman Ellmers, Ranking Member Richmond, Chairman Broun, Ranking Member Tonko, and Members of the Subcommittees, I appreciate your inviting me to testify on "How the Report on Carcinogens uses Science to Meet its Statutory Obligations, and its Impact on Small Business Jobs." My name is Faye Grimsley, Associate Professor of Global Environmental Health Sciences, Tulane University School of Public Health and Tropical Medicine. I am on special leave from Tulane this semester and currently appointed as Yerby Visiting Associate Professor, Department of Environmental Health, Harvard School of Public Health.

My testimony today will focus on the following:

1) The overall process of the National Toxicology Program's Report on Carcinogens
2) The impact of the Report on Carcinogens on Jobs
3) Why the National Toxicology Program is Important to Public Health

Process of the NTP's Report on Carcinogens

The Report on Carcinogens (RoC) is prepared by the National Toxicology Program Director, and then submitted through the Secretary of Health and Human Services (HHS) to Congress and public every 2 years. The Report on Carcinogen Process involves 4 major steps: 1) Nomination and Selection of Proposed Substances, 2) Scientific Review of Selected Substances, 3) Preparation of Draft Specific Substance Profiles for Peer Review, and 4) Preparation and Release Draft Report on Carcinogens. The process involves a number of peer reviews first by Expert Panel, second by Interagency Scientific Review Group, thirdly the NIEHS/NTP Scientific Review Group, and final review by the NTP Board of Scientific Counselors. Comments from the public are solicited during steps 1-3 of the process. When the Expert Panel meets to review background documents and NTP Board of Scientific Counselors meets to review draft substance

profiles the public is invited to attend. Closed meetings are held when listing or removal status recommendations are made for selected substances. Although there are a number of closed meetings to discuss and recommend listing status of specific substances, the review process is transparent and open to the public for criticisms and opinions during the review process.

The 12th RoC, the latest edition, was published on June 10, 2011. The 13th RoC is under development. For each listed substance, the RoC contains a substance profile, which provides information on: 1) Cancer studies that support the listing—including those in humans, animals, and on possible mechanisms of action; 2) Potential sources of exposure to humans; and 3) Current Federal regulations to limit exposures.

NTP and Other Carcinogen Classifications and Reports: There are several other agencies, programs, and organizations that test and list agents based on carcinogenicity. Agents are classified/categorized using a criteria based on evidence of carcinogenicity. The NTP list chemicals in two categories, Known to Be Human Carcinogen or Reasonably Anticipated to be Human Carcinogen. The Twelfth Report on Carcinogens include 54 profiles for substances listed as known to be human carcinogens and 186 profiles for substances listed as reasonably anticipated to be human carcinogen. NTP categories are similar to other published carcinogen listings such as the International Agency for Research on Cancer (IARC), which is the most widely used and referenced system for classifying carcinogens, has 5 categories: Group 1- Carcinogenic to humans; Group 2A- Probably carcinogenic to humans; Group 2B- Possibly carcinogenic to humans; Group 3-Unclassifiable as to carcinogenicity in humans; and Group 4- Probably not carcinogenic to humans. In the past 30 years, the IARC has evaluated the cancer-causing potential of more than 900 likely candidates, placing them into one of the above groups. Only a little over 100 are classified as "carcinogenic to humans."

The EPA uses a rating system similar to that of IARC when describing the cancer-causing potential of a substance and has 5 categories: Group A- Carcinogenic to humans; Group B- Likely to be carcinogenic to humans; Group C- Suggestive evidence of carcinogenic potential; Group D- Inadequate information to assess carcinogenic potential; and Group E- Not likely to be carcinogenic to humans. The American Conference of Governmental Industrial Hygienist (ACGIH) assigns each chemical or agent to one of the following 5 categories for carcinogenicity: A1 - Confirmed human carcinogen; A2 - Suspected human carcinogen; A3 - Confirmed animal carcinogen with unknown relevance to humans; A4 - Not classifiable as a human carcinogen; and A5 - Not suspected as a human carcinogen.

NTP Description: The National Toxicology Program is an entity within the National Institute of Environmental Health Sciences (NTP). The program's physical offices and laboratories are located in Research Triangle Park, North Carolina. The Program was established in 1978 under the Carter Administration and has undergone transformation to align with changing institutional priorities and public health needs. The program is known and recognized as a national and international authority on testing chemicals and agents which are toxic and may

pose a threat to the health of the public and specific worker populations. The process used for testing is based on applying scientific toxicology principles and is an interagency program with collaborative efforts among various health and regulatory agencies across the United States. Agencies include but not limited to the Centers for Disease Control and Prevention (CDC)/ National Institute for Occupational Safety and Health (NIOSH), and National Center for Toxicological Research (NCTR) of the Food and Drug Administration (FDA). The NTP has four main goals: 1) to coordinate toxicology testing programs with the federal government; 2) to strengthen the science base in toxicology; 3) to develop and validate improved testing methods; and 4) to provide data information to health and regulatory agencies, medical and scientific communities, and the public.

Impact of NTP RoC Process on Jobs

According to NIOSH and published literature, it is well-documented that associations between occupational exposures and cancer exist, it is estimated that approximately 20,000 cancer deaths and 40,000 new cases of cancer each year in the United States are attributable to occupation; additionally, it is estimated that less than 2% of chemicals in commerce have been tested for carcinogenicity.

From an environmental health scientist point of view, the NTP process is a valuable resource of information and is often cited and referred when carcinogenic information is needed. Any chemical substance listed by the RoC will impact the health of workers and the public. The review process should consider what impact this will have on businesses of all sizes. Whenever new regulations or standards are introduced, use of state –of- the art technologies and practices to protect worker health may be beyond resources of small businesses. Small entities often have limited resources. Agencies charged with health safety of the public and workers should anticipate and provide assistance and resources to these entities to relieve any additional strain of compliance. In 2006, small firms with less than 500 employees accounted for 99% of the 26.8 million businesses in the United States.

Most health and safety personnel regardless of company size, would agree that additional requirements are involved when new chemicals are designated as a carcinogen or potential carcinogenic agent, but the benefits of knowing that readily available lists of carcinogenic chemicals relieves some of the burden of identifying one category of toxic substances which workers have a potential for exposures and adverse health effects is needed. According to Cherry, “There is a need to set exposure limits so that there is a balance between the risks that workers are exposed to and the costs of averting these risks.”

Why the NTP is Important to Public Health

A concern from workers and communities regarding chemicals and substances which cause or is associated with cancer is still voiced around the world. Keeping workers safe from harmful agents is a daunting and challenging job. Development of exposure limits and carcinogenic classifications is even more challenging. The American Cancer Society reference and list chemicals from the International Agency for Research on Cancer (IARC) and U.S. National Toxicology Program (NTP) and emphasizes that testing and determining if something can cause cancer is difficult. Cancer is caused by a number of environmental factors and exposures from lifestyle (e.g., tobacco use), workplace chemicals, household chemicals, pollution and medical treatments.

With more and more chemicals being developed and used by society and in the workplace, databases that contain toxicity and health and safety information developed by the NTP process and others will continue to be used by a number of companies, organizations, and agencies for toxicity assessment and decision making to address public health issues. Given the thousands of chemicals that need to be tested, and resources allotted, there are limitations to how many chemicals can be tested by carcinogenic agencies, in 1998 the NTP had resources and the capacity to consider and evaluate only 10-20 compounds. Since inception, The NTP has evaluated more than 2,500 substances for adverse health effects related to general toxicity, reproductive and developmental toxicity, genotoxicity, immunotoxicity, neurotoxicity, metabolism, respiratory illnesses, and carcinogenicity. The primary means of research and testing are performed using rodent models in short-term studies for up to thirteen weeks and long-term studies for up to two years.

The NTP is recognized by the American Public Health Association (APHA) as one of the agencies that play a role in protecting the public's health from harmful chemical exposures. The NTP coordinates the toxicological research efforts across 5 agencies (ATSDR, CDC-NCEH, FDA, NIOSH, and NIEHS) within the Department of Health and Human Services (HHS). A chemical safety responsibilities matrix developed by the APHA identifies the NTP as playing a key role in protecting workers and researching chemicals.

When workers and community members are unaware of the potential toxic health hazards in their work environment and communities, this makes them more vulnerable to injury and diseases. It is important to provide them with information and references to assist in anticipating and recognizing hazards and the health effects associated with carcinogens in the workplace and community. If a chemical or agent lacks toxicological and carcinogenic data, it is difficult to conduct exposure assessment in public health and worker populations which makes it difficult to respond to affected populations concerns and fears of long-term health effects

and outcomes. For example, in the aftermath of Hurricane Katrina, the public was very concerned about the copious amounts of mold exposure and potential health effects. The NTP played an instrumental role in gathering knowledge and coordinating potential research questions that could help address the impact of mold and mycotoxin exposures and health effects.

The NTP Process has played a role in in the field of public health specifically in the areas of occupational hygiene and environmental health. One important aspect of protecting workers and the health of communities is conducting public health and exposure assessments to determine the hazard of the chemical and to determine the amount present.

For example, when the ATSDR conduct public health assessments to identify possible harmful exposures and to recommend actions needed to protect public health, toxicological data used to determine potential health effects in these public health assessments is compiled mainly from the ATSDR's toxicological profiles and other compilations of toxicological data including resources such as the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) database, International Agency for Research on Cancer (IARC) Monographs, and National Toxicology Program (NTP), as well as some non-governmental resources and textbooks. According to the ATSDR, public health assessments differ from the more quantitative risk assessments conducted by regulatory agencies, such as EPA. When conducting public health assessments, ATSDR considers the same environmental data as EPA, but focuses more closely on site-specific exposure conditions, specific community health concerns, and any available health outcome data to provide a more qualitative, less theoretical evaluation of possible public health hazards.

When environmental health scientists, industrial hygienists, occupational safety and health professionals, and other public health practitioners conduct an exposure assessment, information is needed to evaluate potential toxicity of chemicals. Information from several agencies and organizations are used as resources for this toxicity evaluation, these include the Occupational Safety and Health Administration (OSHA), American Conference of Governmental Industrial Hygienist (ACGIH), National Institute for Occupational Safety and Health (NIOSH), American Industrial Hygiene Association (AIHA), Environmental Protection Agency (EPA), National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), Material Safety Data Sheets (MSDS), and Agency for Toxic Substance Disease Registry (ATSDR).

In summary, potential exposures from chemicals can occur in workplaces, homes and communities. Scientists have the daunting task of combining and assessing data from laboratory studies and information from human population epidemiologic studies to determine

a substance's cancer causing ability. Systematic processes are needed to assess toxicity and hazards associated with these chemicals. There is a need for more research and testing given the number of chemicals used by individuals on a daily basis. The NTP is one of many organizations, agencies, and programs that are aware of the public's concern related to chemicals that can cause or likely to cause cancer. The NTP report on carcinogen review process uses a scientific approach to gather and synthesize data, to make decisions that is in the best interest of the public's health, and to provide documents and reports that can be used to assist with identifying health hazards and disease prevention. The NTP should continue to solicit feedback and respond to input from interested stakeholders who may be affected by recommendations related to carcinogen classifications. Given the limitations of oversight sometimes placed on federal agencies, the NTP is uniquely positioned to lead various types of reviews and investigations of chemicals that are of concern across different aspects of public health.

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