

Why GAO Did This Study

The nation remains vulnerable to terrorist and other threats posed by CBRN agents. Medical countermeasures—drugs, vaccines, and medical devices—can prevent or treat the effects of exposure to CBRN agents, and countermeasures are available in the SNS for some of these agents. Children, who make up 25 percent of the population in the United States, are especially vulnerable because many of the countermeasures in the SNS have only been approved for use in adults. HHS leads the federal efforts to develop and acquire countermeasures.

GAO was asked about efforts to address the needs of children in the event of a CBRN incident. This report examines (1) the percentage of CBRN medical countermeasures in the SNS that are approved for pediatric use; (2) the challenges HHS faces in developing and acquiring CBRN medical countermeasures for the pediatric population, and the steps it is taking to address them; and (3) the ways that HHS has addressed the dispensing of pediatric medical countermeasures in its emergency response plans and guidance, and ways that state and local governments have addressed this issue. To address these objectives, GAO reviewed relevant laws, agency documents, and reports, and interviewed HHS officials, industry representatives, and subject-matter experts. GAO also reviewed a stratified sample of emergency response plans from seven state and seven local governments, based on geographic location and population size, to assess how these governments address pediatric dispensing.

View [GAO-13-438](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

NATIONAL PREPAREDNESS

Efforts to Address the Medical Needs of Children in a Chemical, Biological, Radiological, or Nuclear Incident

What GAO Found

According to the Department of Health and Human Services (HHS), about 60 percent of the chemical, biological, radiological, and nuclear (CBRN) medical countermeasures in the Strategic National Stockpile (SNS) have been approved for children, but in many instances approval is limited to specific age groups. In addition, about 40 percent of the CBRN countermeasures have not been approved for any pediatric use. Furthermore, some of the countermeasures have not been approved to treat individuals for the specific indications for which they have been stockpiled. For example, ciprofloxacin is stockpiled in the SNS for the treatment of anthrax, plague, and tularemia, but is not approved for these indications. Countermeasures may be used to treat unapproved age groups or indications under an emergency use authorization (EUA) or an Investigational New Drug (IND) application submitted to the Food and Drug Administration (FDA).

HHS faces a variety of economic, regulatory, scientific, and ethical challenges in developing and acquiring pediatric CBRN medical countermeasures. High costs and the high risk of failure associated with testing and research of pharmaceutical products on children, difficulties in meeting regulatory requirements for approving CBRN countermeasures, and scientific and ethical obstacles to safely evaluating countermeasures for children all pose challenges to developing pediatric countermeasures. Despite these challenges, HHS has taken steps to focus agency efforts on the pediatric population, adapt pediatric formulations from existing medical countermeasures, and prepare and review materials for EUAs and INDs in advance of public health emergencies.

HHS addresses dispensing of pediatric medical countermeasures in more than half of its 12 response plans and in its guidance, and seven state and seven local government plans that GAO reviewed included details about pediatric dispensing. Seven of the 12 HHS plans include information about pediatric medical countermeasures; however, HHS officials stated that these plans are intended to provide guidance for emergency response at the federal level, and not at the state or local levels, which is where dispensing would occur. CDC and FDA also provide guidance on pediatric dispensing that state and local governments can use in their planning. For example, CDC developed guidance about receiving, distributing, and dispensing contents from the SNS to help state and local emergency management and public health personnel plan for the use of countermeasures from the SNS. Response plans for all 14 of the state and local governments that GAO reviewed also included details about dispensing to the pediatric population during an emergency. For example, these seven states and seven local governments all adopted some version of a “family member pick-up” policy—sometimes referred to as a “head of household” policy—which would allow adults to pick up medicines for other family members, including children, during an event.

In commenting on a draft of this report, HHS concurred with our findings. HHS emphasized that the needs of the pediatric population have been a priority for HHS and that the department is continuously progressing in this area.