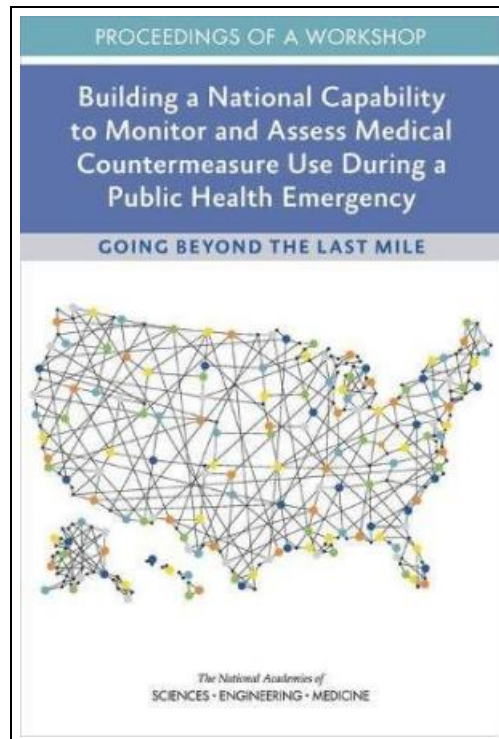


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(Eliseo Rippin)

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National Academies Press, United States, 2018. Paperback. Condition: New. Language: English . Brand New Book. During public health emergencies (PHEs) involving chemical, biological, radiological, or nuclear threats or emerging infectious diseases, medical countermeasures (MCMs) (e.g., drugs, vaccines, devices) may need to be dispensed or administered to affected populations to help mitigate the human health impact of the threat. The optimal MCMs determined for use during an emergency might be U.S. Food and Drug Administration (FDA) approved but used in unapproved ways (e.g., in a new age group or against a new agent); FDA approved using animal models because human efficacy testing is not ethical or feasible; or not yet FDA approved for any indication. As part of the United States (TM) scientific and research preparedness enterprise, there is an imperative to go a oebeyond the last milea of MCM dispensing and administration to build and maintain a national capability to monitor and assess the use of MCMs (e.g., safety, compliance, clinical benefit) after they have been dispensed during PHEs. To further the discussion on this need, the Board on Health Sciences Policy of the National Academies of Sciences, Engineering, and Medicine hosted a 2-day public workshop, Building a National Capability to Monitor and Assess Medical Countermeasure Use in Response to Public Health Emergencies. The workshop, sponsored by FDA, was held on June 6a 7, 2017, in Washington, DC. Workshop participants discussed the roles and efforts of the federal government and of relevant stakeholders with an interest in building and maintaining a national PHE MCM active monitoring and assessment capability. This publication summarizes the presentations and discussions from the workshop.



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