Responsibility for responding to homeland terrorist attacks and other emergencies begins at the local level and is grounded in collaboration between the private and public sectors. The federal government is ready, at a state's bidding, to assist communities quickly and in powerful ways—supplying pharmaceuticals, trained personnel, equipment, and other resources. Effective response also requires the cooperation of individual health care professionals at the local level. Among those professionals whose participation is vital are pharmacists, who possess science-based knowledge and clinical acumen and are also widely accessible. The September 11th attacks in New York City and Washington, D.C., and the subsequent bioterrorist threat posed by anthrax challenged our nation's medical disaster-response system in unparalleled ways. Although the system rose to the occasion, there is ample room for improvement.

These are among the key points that emerged from an executive session on emergency preparedness and the pharmaceutical supply chain that was convened by the American Society of Health-System Pharmacists (ASHP) in Bethesda, Maryland, on November 9, 2001. The session brought together more than 35 representatives from federal public health and preparedness offices, pharmaceutical manufacturers, wholesalers, group purchasing organizations, academic health-science centers, community hospitals, and health organizations. The objectives of the session were to

1. Conduct an open, honest, noncompetitive review of the readiness of the pharmaceutical supply chain (and related decision-support and drug information mechanisms) related to projected demands on the system in the face of homeland terrorism, while considering all aspects of the supply chain, from procuring raw materials for use in manufacturing to the delivery of finished products and information to patients;
2. Identify significant vulnerabilities in the pharmaceutical supply chain and steps that should be considered to remedy those vulnerabilities;
3. Identify means to communicate the session's deliberations—particularly any vulnerabilities that are noted—to appropriate public and private offices.

This document summarizes the discussions that took place at the executive session. It gives an overview of the federal emergency response system, summarizes participants' remarks concerning the strengths and vulnerabilities of the nation’s medical emergency-response system, and offers recommendations for improving this system. The opinions expressed at the meeting were candid and forthright. Given the diversity of the participants' backgrounds, a consensus on all issues was not expected. Nonetheless, as discussions proceeded, a shared resolve to work collaboratively and in new ways to meet the challenges posed by the threat of homeland terrorism was strikingly clear.

Federal emergency response system

Three participants in the executive session, representing the Office of Public Health and Science, Department of Health and Human Services (DHHS), Office of Emergency Preparedness, and the National Pharmaceutical Stockpile (NPS) program of the Centers for Disease Control and Prevention (CDC), described the systems, resources, and personnel involved in the nation’s federal emergency response system. These presentations created a common context for the day’s discussions and informed participants of the roles of these programs in handling the events of September 11th and thereafter.

An understanding of federal resources and how to access them is
Emergency preparedness and pharmaceutical supply

Hospital beds. DHHS has contracts with civilian hospitals to identify beds that may be used in emergency situations. The core of the hospital-bed supply is DVA, which has 7500–9000 beds that can be made available. Military aircraft are available to transport patients to hospitals in other cities, if necessary.

Pharmaceutical supplies. Emergency pharmaceuticals and other products that cannot be supplied at the local level are available to local public health departments through NPS, which was created in 1999. (The Federal Emergency Response Plan does not have to be activated to request assistance from NPS.) One key component of this program, which is managed by CDC, are “push packages,” which are stored in secure locations across the United States and can be delivered within 12 hours of the federal decision to deploy the supplies. The push packages contain pharmaceuticals, i.e., supplies, airway supplies, emergency medications, bandages, and wound dressings. Among the medications included are ciprofloxacin, doxycycline, gentamicin, dopamine, albuterol, lorazepam, morphine, atropine, diazepam, and pralidoxime. The quantities of antibacterials supplied are substantial; for example, one push package contains enough antibiotics to treat 50,000 persons for anthrax for 60 days. The quantities of other emergency medications are smaller. Most of the drug products are not in unit dose form and must be repackaged onsite. The push packages include counting machines, volumetric devices, packaging and labeling machines, and written patient and provider information. A CDC technical advisory team accompanies each push package that is deployed. The push packages are transported by aircraft and tractor-trailers. CDC has permission from the Federal Aviation Administration (FAA) to transport push packages on aircraft if regular commercial air travel has been suspended.

Medical assistance teams. OEP directs the deployment of Disaster Medical Assistance Teams (DMATS), which are groups of medical personnel and logistic staff trained to provide emergency medical care. Principally a local resource, DMATS can be activated and deployed at other sites when needed. There are 98 DMATS stationed throughout the country. Each is sponsored by a local organization, such as a hospital or public health department. DMATS are equipped to sustain themselves for up to 72 hours after deployment. There are three specialized forms of DMATS: Disaster Mortuary Operational Response Teams (DMORTs), Veterinary Medical Assistance Teams (VMATs), and National Medical Response Teams.

Metropolitan Medical Response System. Another component of OEP’s national disaster program is
the Metropolitan Medical Response System (MMRS). MMRS operates under contracts between DHHS and cities. It is a process or tool that OEP uses to bring together disparate agencies in the public and private sectors that share responsibility for emergency preparedness and response. Each project is led by a steering committee that includes representatives of local police and fire departments, hospitals, professional organizations, community and state agencies, and federal partners. Each MMRS site must produce 12 documents outlining its plan for responding to local emergencies in a coordinated manner. The plans must cover the spectrum of disaster-response functions, ranging from the acquisition of local caches of pharmaceuticals and equipment to the development of protocols for postevent surveillance.

MMRSs are key to a community’s first-response strategy. Ninety-seven MMRSs have been funded, and 23 others are slated for funding within the next year. One goal of MMRS is to enable cities to learn from each other. For this reason, a summary of lessons learned and best practices will be published and made available on MMRS’s Web site.

**Strengths of the pharmaceutical supply chain**

As participants began to tackle the session’s first objective—the readiness of the current pharmaceutical supply chain—the many strengths of the current system emerged.

Faced with a crisis of any dimension, hospital pharmacy managers routinely solve problems by calling their drug distributors or other hospitals. Distributors, in turn, have developed their own disaster-preparedness programs. They have internal electronic networks and are accustomed to responding quickly to unanticipated demands. Through the efforts of the Food and Drug Administration (FDA), health-professional organizations, and individual pharmacists, who monitor prescription and nonprescription drug sales patterns, drug supplies are monitored on an ongoing basis. Distributors have implemented systems to limit, when necessary, the amount of drug products supplied to certain customers and divert supplies to the areas in most critical need. They stated that they can generally respond to unanticipated requests within three or four hours. Given these practices, one participant noted that his industry finds the word “stockpile” a misnomer. “We don’t use the word,” he said. Instead, his firm thinks in terms of “inventory” and has a plan to ensure that drugs are made available to the places in the most need.

By and large, this system worked well in the days and weeks following September 11. For example, the November 1, 2001, issue of the American Journal of Health-System Pharmacy (AJHP) cites examples of how hospitals, wholesalers, and distributors, supported by ground transport companies and local police escorts, collaborated to deliver supplies to New York City and Washington, D.C. Faced with several “logistic nightmares,” AJHP reported, the organizations “rallied to get supplies to hospitals.” For example, there was a critical need for human albumin, used to stabilize patients in shock. Within hours, a supply sufficient for 25,000 patients was on its way to the attacked sites. The product was shipped on a chartered FedEx Boeing 747 freight jetliner. “Lifeguard” flight approvals from FAA during the week of September 11 made it possible to transport products and rescue supplies to areas of need. Later, when the anthrax threats emerged, Bayer Corporation, which produces Cipro (ciprofloxacin), began a “24/7” production schedule; it also had a factory in Germany ready to begin production of the drug.

The system, participants concluded, deals with crises on a routine basis and generally handles them well. As one discussant said, “Our business is to keep the day-to-day supply chain going. Fires, storms, and similar crises are routine. We have programs to survey our inventories and quickly move stuff to where it is needed. Regardless if you’re our customer or not, you’ll get it . . . . Each crisis is different. We learn from them, and we communicate. Flexibility is key.”

Emergency personnel also rose to the occasion on September 11 and thereafter. DMATs and DMRTs were deployed in New York City and Washington, D.C. One participant in the discussions gave “high grades” to CDC for the delivery of products and to the actions of support personnel in New Jersey. Health care professionals were on the scene from the beginning. Pharmacists, physicians, and other health care professionals worked side-by-side. Patients’ medical histories were taken before drugs were distributed. Team members provided counseling and followed the patients through the entire process.

**Vulnerabilities in the system**

Despite the success stories, participants agreed that the events of September 11th served as a “wake-up call.” Individual components of these systems often worked well; nonetheless, the whole was not greater than the sum of its parts. An overall coordinated plan was missing. “We don’t have a network,” said one participant, “we respond in an unorganized organized way.” Or, to quote another participant, “There are a lot of good folks doing good things. The problem is that they’re not always on the same page.”

There is a need not only to “bind the public and private sectors” more effectively but also to improve coordination within and among the agencies and organizations charged with disaster-response responsibilities. Absent an overall plan, some essential piece of the complicated drug supply chain will prove to be the weakest link. For example, a shortage
of dispensing containers hampered the otherwise well-structured drug distribution activity in New Jersey in response to anthrax exposure. The continuing problem of drug product shortages suggests that some aspects of the supply chain are fragile.

The discussions revealed that one fundamental weakness in the current system is a failure to appreciate the full context and complexity of the medication use process. As one participant stated, drug products are not "jellybean commodities." Their manufacture, distribution, and sale depend on coordinated interactions among a variety of players. Locating a sufficient supply of a product, while sometimes difficult in itself, is far from enough. There must be a system to ensure that the product is packaged and labeled and accompanied by written product information. Personnel must be available to take patients' medical histories, counsel them, and answer questions. Appropriate follow-up though measures must be established.

Another major vulnerability of the pharmaceutical supply chain is a lack of communication. This may be attributed in part to the historical lack of interaction between the public and private sectors of the U.S. health care system. This vulnerability is heightened by the current status of the nation's public health infrastructure, which has, according to many accounts, deteriorated in recent decades. Forging a strong bond between these two sectors is essential for emergency response, but it is at present, in one participant's words, an "unnatural marriage." The lack of communication and coordination continues at many levels—between individual professional disciplines, such as pharmacy and medicine, between agencies and organizations, and between cities and states. Overcoming "parochial barriers" is essential.

Also missing is a system by which health-professional volunteers can be drawn into the system when needed. Concerns for professional liability and state board regulations were seen as significant barriers to ensuring that pharmacists, physicians, and other providers can be mobilized to serve in areas of need.

Lack of pharmacist involvement is a particular vulnerability in the current system. Pharmacists have not participated in most emergency-preparedness planning processes. They have not assumed a community leadership role in this area. This is unfortunate because pharmacists have a "pragmatic and science-based knowledge" that is invaluable. Their accessibility in hospitals and the community is an additional benefit.

A final vulnerability of the pharmaceutical supply chain is a lack of education and awareness, which extends to all persons directly and indirectly involved in disaster response. Overcoming this barrier requires a multifaceted approach. The media need to be educated to ensure that the general public receives accurate information. Physicians need drug-use guidelines and an awareness of the resources available to them. Health professionals need to know how to volunteer in disaster-response and disaster-planning processes. Federal agencies need information from the frontline to tailor programs and services more effectively. The need for a unified, credible voice at the federal level—which might be provided by, for example, the United States Surgeon General—has been evident in recent weeks. The absence of such a voice leads to inconsistent messages that may cause undue public alarm and an inappropriate use of resources.

Recommendations for improvement

Participants offered many suggestions for improving the nation's capability to respond to acts of homeland terrorism and other emergencies. Central to their recommendations was the need to dramatically strengthen the country's public health system. Investments in the country's beleaguered public health system would have tremendous payoffs, not only in enhancing responses in times of a crisis but also in improving the overall health status of the U.S. population. There is enormous potential for pharmacist involvement in this effort; the current situation, said one participant, offers the opportunity to "reinvigorate the profession's public health roots."

Discussions about overcoming these perceived vulnerabilities also focused on the following points, which were identified for further consideration and analysis (the group did not attempt to reach a consensus on these matters): collaboration, education and information sharing, federal responsibilities, and legislative and regulatory activities.

Collaboration

The federal government has created and established an effective infrastructure for emergency preparedness and response. To ensure maximum efficiency and eliminate redundancy, organizations and individuals should tap into this national system rather than undertake separate efforts. For example, health-professional organizations wishing to become involved in planning and response systems should contact their local MMRS. Most of the MMRSs are still working on their plans and offer many opportunities for pharmacist participation. Only if such a group does not exist in their areas should health professionals undertake a new effort, and if they do, their plans should be based on the MMRS collaborative model focused on the overall needs of the community.

Collaboration is a "push-pull" affair. Public health departments should reach out to health professionals in the private sector, including pharmacists. These departments rarely have pharmacists on staff.

The community pharmacist should be an integral part of disaster-
response efforts. For example, patients might receive a few days' supply of a medication at an emergency distribution center; a prescription could then be filled by a community pharmacist, who would assume responsibility for additional counseling and follow-up.

Distributors and wholesalers should consider being more forthcoming in sharing information with appropriate officials about where their products are stored. General information on storage locations is already known, but by sharing specific information with the appropriate federal authorities, responding to requests in times of emergency would be simpler and would not put anyone at a competitive disadvantage.

**Education and information sharing**

Information of many kinds, such as clinical guidelines for the use of medications or other issues and lists of frequently asked questions, should be developed and disseminated. The federal government could take a lead role in this; however, professional organizations could also develop the needed material and share it with the government. These documents should be available in print and electronic formats. Of particular value would be the following:

- A diagram showing the components of the disaster-response system and illustrating how the components can be accessed;
- Recommendations for the appropriate responses to attacks by specific bioweapons. Had such a document been available before the anthrax episode, it might have saved a great deal of confusion and frustration; and
- Emergency-response guides for state and local pharmaceutical and medical organizations.

National organizations such as ASHP, the American Medical Association, and the American Hospital Association, which have strong state affiliate systems, should use these networks for information sharing.

Members of the pharmaceutical industry should take a more active role in educating the public, media, and health professionals. They can mobilize their sales forces and science liaisons to serve in educational roles.

Group purchasing organizations can facilitate communications with their constituents and provide educational programs.

Hospital drug information centers and poison control centers are natural allies and should be included in the resource and information-sharing process.

**Federal responsibilities**

The federal government should have a single designated authority—an individual with scientific credibility and the ability to connect with the public and media—to serve as a spokesperson for the health system.

FDA should take a more active role in identifying and resolving problems stemming from drug shortages. This is a matter of increasing concern with respect to the day-to-day drug supply, and it is critical in times of emergency.

OEP should provide more guidance to local communities regarding planning for, procuring, distributing, and controlling pharmaceuticals in a local cache. Information should be provided on how a local cache relates to NPS and vendor-managed inventories. The OEP effort to develop "best practices" guidelines should be expedited to the extent possible.

CDC should do more to inform local emergency-preparedness officials about NPS. Sites that receive push packages must be made aware in advance of the packages' contents, onsite services that will be needed to use them, and how to replenish them.

**Legislative and regulatory activities**

State boards of pharmacy and medicine should explore ways that make it easier for health professionals to provide crisis-response services in states other than those in which they are licensed. This is particularly important at a time when there is a shortage of pharmacists in the national workforce. A model for this already exists: for health professionals participating in federal disaster-response programs, credentialing and liability responsibilities are assumed by the U.S. government.

State legislatures will be seeking ways to increase emergency preparedness within their jurisdictions. Some states have already done this, and the provisions in state law cover diverse areas. For example, Colorado recently passed legislation that addresses quarantines. Health-professional organizations should provide information that will enable elected officials to make informed decisions as they draft and vote for new legislation.

One reason for hospitals' interest in stockpiling of pharmaceutical products is the concern for liability. This issue could be addressed in legislation.

**Next steps**

Participants agreed that the executive session had laid a solid foundation for future cooperative efforts. They expressed a desire to hold at least one additional large-group session and discussed the possibility of forming work groups around specific issues. The creation of a "listserv" (i.e., an electronic mailing list) was suggested. Group members concurred that the inclusion of persons with a variety of perspectives was essential to any deliberations and, in that vein, suggested that the group be expanded to include representatives from FEMA, appropriate agencies within the Department of Transportation, professional nursing organizations, and security agencies.
Conference participants, by affiliation

Government Offices

CAPT Charles Bruner
U.S. Coast Guard
Washington, D.C.

Tomas Daley
Chief, Pharmaceuticals Group
Directorate of Medical Material
Defense Supply Center
Philadelphia
Philadelphia, Pennsylvania

CAPT Kathleen Downs
Office of Emergency Preparedness
U.S. Department of Health and
Human Services
Rockville, Maryland

Susan E. Gorman, Pharm.D., DABAT
Senior Science Officer
National Pharmaceutical
Stockpile Program
Centers for Disease Control and
Prevention
Atlanta, Georgia

COL W. Mike Heath, M.S.
Pharmacy Consultant, U.S. Army
Office of the Army Surgeon General
Falls Church, Virginia

RADM Arthur Lawrence
Office of Public Health and Science
Acting Principal Deputy Assistant
Secretary for Health
Washington, D.C.

CAPT Thomas J. McGinnis
Deputy Associate Commissioner
Office of Policy, Planning & Legislation
Food and Drug Administration
Rockville, Maryland

COL Ardis J. Meier
Pharmacy Consultant to USAF
Surgeon General
Associate Chief, Biomedical Sciences
Corps for Pharmacy
Andrews Air Force Base,
Maryland

Jimmy R. Mitchell, M.P.H., M.S.
Director, Office of Pharmacy Affairs
Health Resources and Services
Administration
U.S. Department of Health and
Human Services
Bethesda, Maryland

John E. Ogden, M.S., FASHP
Chief Consultant for Pharmacy
Benefits Management
Department of Veterans Affairs
Washington, D.C.

CAPT Jerry Phillips
Associate Director
Medication Error Prevention
Office of Postmarketing Drug Risk
Assessment
Food and Drug Administration
Center for Drug Evaluation and
Research
Rockville, Maryland

CAPT Kathleen Downs
Office of Emergency Preparedness
U.S. Department of Health and
Human Services
Rockville, Maryland

RADM Richard S. Welling
Director, Office of the Americas &
Middle East ORIH
Rockville, Maryland

Drug Manufacturers

Dan Horn
Vice President
Distribution & Customer Service
Abbott Laboratories
Abbott Park, Illinois

Frank J. Malinoski, M.D., Ph.D.
Assistant Vice President
Global Medical Affairs
Wyeth-Ayerst Pharmaceuticals
St. Davids, Pennsylvania

W. B. Novotny
Director, Pharmaceutical Supply
Planning
Wyeth-Ayerst Laboratories
Frazer, Pennsylvania

Group Purchasing Organizations

Allen Dunehew
Vice President of Pharmacy
AmeriNet Inc.
St. Louis, Missouri

Mick Hunt, Jr., M.S., FASHP
Senior Director of Pharmacy
Novation
Irving, Texas

Weldon Johnson
Director of Contracting
Premier, Inc.
Oak Brook, Illinois

Wholesalers

Mark Hartman
Senior Vice President, Operations
and Planning
Cardinal Distribution
Dublin, Ohio

Dan Skalecki
Corporate Vice President, Health
Systems Grp.
AmeriSourceBergen
Carmel, Indiana

Ronald J. Streck
President and CEO
Healthcare Distribution
Management Assoc.
Reston, Virginia

James Trance
Vice President
Distribution Operations
McKesson Corporation
Rocky Hill, Connecticut

Community Pharmacy

Calvin J. Anthony
Executive Vice President
National Community Pharmacists
Association
Alexandria, Virginia

Bruce Roberts
Executive Vice President-Designate
National Community Pharmacists
Association
Alexandria, Virginia

Edward J. Staffa
Director
Pharmacy Practice &
Communications
National Association of Chain
Drug Stores
Alexandria, Virginia

Practitioners

Paul W. Abramowitz, Pharm.D., FASHP
Director of Pharmacy and Professor
Department of Pharmaceutical
Care
University of Iowa Hospitals and
Clinics
Iowa City, Iowa

David Chen, M.B.A.
Pharmacy Director
Shady Grove Adventist Hospital
Rockville, Maryland
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Douglas J. Scheckelhoff, M.S., FASHP
Children’s National Medical Center
Pharmacy Department
Washington, D.C.

Other Associations
Steve Bende, Ph.D.
Vice President
Science, Professional & Regulatory Affairs
The Generic Pharmaceutical Association
Washington, D.C.
Barry Dickinson, Ph.D.
Director, Science Policy
American Medical Association
Chicago, Illinois
Mitchel Rothholz
Vice President
Professional Practice
American Pharmaceutical Association
Washington, D.C.
Douglas R. Smith, Pharm.D.
Senior Director, Pharmacy and Oncology
University HealthSystem Consortium
Oak Brook, Illinois
R. Joseph Trauger
Associate Director
Congressional & Executive Branch Relations
American Hospital Association
Washington, D.C.

Other
David A. Zilz, B.S., M.S.
Consultant to ASHP
Iola, Wisconsin

American Society of Health-System Pharmacists
Henri R. Manasse, Jr., Ph.D., Sc.D.
Executive Vice President and Chief Executive Officer
American Society of Health-System Pharmacists
Bethesda, Maryland

Charles E. Myers, M.S., M.B.A.
Vice President
Professional and Scientific Affairs Office
American Society of Health-System Pharmacists
Bethesda, Maryland
Steven L. Sheaffer, Pharm.D., FASHP
President
American Society of Health-System Pharmacists
Associate Professor and Vice Chair for Experiential Learning
University of the Sciences in Philadelphia
Philadelphia, Pennsylvania
William A. Zelmer, M.P.H.
Deputy Executive Vice President
American Society of Health-System Pharmacists
Bethesda, Maryland