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For immediate release

Link to Summit report: <http://www.ismp.org/pressroom/2014-Drug-Shortages-Summit.pdf>

Health Care Groups Identify Potential Measures to Address Ongoing Drug Shortages
Report from 2014 Summit Explores Factors Causing Shortages to Persist

As shortages of lifesaving medicines, including antibiotics, chemotherapy, and cardiovascular drugs continue to plague the United States, a group of health care organizations released a report exploring measures that should be considered to address this ongoing issue. The report summarizes manufacturing, regulatory, and economic issues related to drug shortages, as well as potential solutions that were considered at a 2014 Summit attended by 22 stakeholder groups, including health care professionals and other non-profit organizations, industry, public interest, and government agencies.

The 2014 Drug Shortages Summit was organized by the American Hospital Association (AHA), the American Society of Anesthesiologists® (ASA®), the American Society of Clinical Oncology (ASCO), the American Society of Health-System Pharmacists (ASHP), the Institute for Safe Medication Practices (ISMP), and The Pew Charitable Trusts. Previous summits were held in 2010 and 2013.

Presentations during the Summit validated a number of existing efforts to address drug shortages, including a provision in the Food and Drug Administration (FDA) Safety and Innovation Act that requires manufacturers to report supply disruptions for certain medications to the agency. Although new drug shortages are on the decline, existing shortages have persisted in significant numbers. According to the Government Accountability Office, the U.S. experienced more than 450 shortages in 2012 alone.

The Summit report explores the potential manufacturing, economic, and regulatory causes of drug shortages, and considers several possible solutions that merit further exploration, including:

- Improve quality systems to better prevent production problems that can lead to shortages by encouraging companies to foster a corporate quality culture, and use of an FDA-developed set of quality metrics to support early collaboration between manufacturers and the agency on quality issues.

- Identify regulatory efficiencies, such as synchronizing regulatory reviews by different global agencies to shorten the overall time for full approvals for facility upgrades.
- Allow for commercialization of trial batches of drugs that meet quality specifications to help mitigate losses during plant or line upgrade approvals.
- Incentivize manufacturer investments in capacity and reliability by increasing contractual penalties for failing to supply a product, and also allowing price increases.
- Support the market through better guarantees of demand by committing to the purchase of specified volumes of products vulnerable to shortage, either by a group purchasing organization or through a government program.
- Establish limited and/or shared exclusivity agreements to incentivize companies to produce needed drugs where there are no active producers.
- Standardize commonly used doses and concentrations in unit-of-use packaging to reduce waste and avoid contamination.

While no single solution or “silver bullet” to end drug shortages was identified, Summit participants agreed that these potential solutions merited further exploration.

About the Co-Conveners

American Hospital Association

The AHA is a not-for-profit association of health care provider organizations and individuals that are committed to the health improvement of their communities. The AHA is the national advocate for its members, which includes nearly 5,000 hospitals, health care systems, networks, other providers of care and 43,000 individual members. Founded in 1898, the AHA provides education for health care leaders and is a source of information on health care issues and trends. For more information, visit the AHA website at www.aha.org.

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**American Society of
Anesthesiologists**

Founded in 1905, ASA is an educational, research and scientific society with more than 52,000 members organized to raise and maintain the standards of the medical practice of anesthesiology. ASA is committed to ensuring physician anesthesiologists evaluate and supervise the medical care of patients before, during and after surgery to provide the highest quality and safest care every patient deserves.

For more information on the field of anesthesiology, visit ASA online at asahq.org. To learn more about the role physician anesthesiologists play in ensuring patient safety, visit asahq.org/WhenSecondsCount. Join the social conversation today. Like ASA on [Facebook](#), follow [ASALifeline](#) on Twitter.

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American Society of Clinical Oncology

Founded in 1964, ASCO is the world's leading professional organization representing physicians who care for people with cancer. With more than 35,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds ground-breaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit www.asco.org. Patient-oriented cancer information is available at www.cancer.net.

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American Society of Health-System Pharmacists

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student

pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.safemedication.com.

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Institute for Safe Medication Practices

ISMP is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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The Pew Charitable Trusts

The Pew Charitable Trusts is driven by the power of knowledge to solve today's most challenging problems. Pew's work on drug safety helps to ensure a safe, reliable pharmaceutical manufacturing and distribution system. Learn more at www.pewtrusts.org/drugsafety.

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