



U.S. Food and Drug Administration

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Agenda

CDER Drug Shortage Workshop

A Workshop Sponsored by the Food and Drug Administration (FDA)

September 26, 2011
Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Building 31, Room 1503 B and C (Great Room)
Silver Spring, MD 20993

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Silver Spring, MD 20993**

Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop

Goal of Workshop:

This public workshop is intended to provide information for, and to gain additional insight from, professional societies, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons about the causes and impact of drug shortages, and possible strategies for preventing or mitigating drug shortages.

Objectives:

1. Update on the status of drug shortages in the US
 - examination of trends in drugs shortages over time
 - discussion of the impact of shortages on patients and the healthcare system
2. Describe FDA's role in and regulatory authority related to drug shortages
3. Hear perspectives from the healthcare sector, patient representatives, and industry on the topic of drug shortages
4. To seek perspectives on solutions that may alleviate or prevent drug shortages

LISTING OF PANEL MEMBERS AND SPEAKERS

Name	Affiliation
Douglas Throckmorton, M.D. Deputy Director CDER	Office of the Center Director, CDER Food and Drug Administration
RADM Sandy Kweder, M.D. Deputy Director OND	Office of New Drugs, CDER Food and Drug Administration
Edward Cox, M.D., M.P.H. Coordinator	CDER Drug Shortage Program Food and Drug Administration
CAPT Valerie Jensen, R.Ph. Associate Director	CDER Drug Shortage Program Food and Drug Administration
CDR Jouhayna Saliba, Pharm. D., Senior Program Management Officer	CDER Drug Shortage Program Food and Drug Administration
CDR Emily Thakur, R.Ph., Senior Program Management Officer	CDER Drug Shortage Program Food and Drug Administration
Ilisa B.G. Bernstein, Pharm.D., J.D. Director (Acting)	CDER Office of Compliance Food and Drug Administration
Norman R. Schmuff, Ph.D., Associate Director for Product Quality	Office of New Drug Quality Assessment Food and Drug Administration
CAPT Harvey Greenberg, R.Ph, Special Assistant	Office of Generic Drugs, Drug Shortage Coordinator Food and Drug Administration
Bona Benjamin, RPh, Director	American Society of Health-System Pharmacists (ASHP)
Joesph Hill, Director, Federal Legislative Affairs	American Society of Health-System Pharmacists (ASHP)
Erin R. Fox, Pharm.D., Manager	Drug Information Service University of Utah Hospitals & Clinics
Michael Cohen, RPh, President	Institute for Safe Medication Practices (ISMP)
Arnold Berry, MD	American Society of Anesthesiologists (ASA)
Jason Byrd	American Society of Anesthesiologists (ASA)
Karen Hagerty, Director Reimbursement Policy	American Society of Clinical Oncology
Jay Mirtallo, RPh, MS, BCNSP, FASHP	American Society for Parenteral and Enteral Nutrition
Lawrence A. Solberg, Jr., MD, PhD	American Society of Hematology
Debbie Malina, CRNA, MBA, DNSc	American Association of Nurse Anesthetists
Ralph Neas, President	Generic Pharmaceutical Association (GPhA)
Ron Hartmann, Pharm.D. Senior Vice President, Pharmacy	MedAssets – Representing the Health Industry Group Purchasing Association
Roslyne D. W. Schulman, Director, Policy Development	American Hospital Association (AHA)
Robert DeChristoforo, RPh, MS, FASHP, Chief	NIH Clinical Center Pharmacy
Anita T. Ducca Vice President, Regulatory Affairs	Healthcare Distribution Management Association
DeWayne Pursley, MD MPH FAAP	American Academy of Pediatrics

Frederick C. Blum, MD, FACEP	American College of Emergency Physicians
Ali McBride, Pharm.D., MS, BCPS	Hematology/Oncology Pharmacists Association
Kathy Pham, Pharm.D.	Pediatric Pharmacy Advocacy Group
Jonathan M. Kafer, Vice President Sales & Marketing	Teva Health Systems
Thomas G. Moore, Pharm.D., President	Hospira USA
Juliana M. Reed, Vice President Government Affairs	Hospira, USA
Scott Meacham, Executive Vice President & Chief Commercial Officer	APP Pharmaceuticals
Bryant Mangum, R.Ph., Vice President of Pharmacy Services	Premier, Inc.
Michael A. Mone, BSPHarm, JD VP of Quality and Regulatory	Cardinal Health
James M. Hoffman, PharmD, MS, BCPS, Medication Outcomes & Safety Officer Pharmaceutical Services	St Jude's Children's Research Hospital
Nancy Davenport-Ennis	National Patient Advocate Foundation
Diane L. Hamlin and Abagale L. Hamlin	Patient Perspective
Davria Cohen	Patient Perspective
Jay Cuetara	Patient Perspective
Barbara Bennicoff, RN	Patient Perspective
John VanEeckhout	Child Healthcare Association of America
Susan Winckler, R.Ph., Esq.	The Food and Drug Law Institute
Vincent Calabrese, Pharm.D.	Department of Veterans Affairs
Burgunda V. Sweet	University of Michigan Health System and College of Pharmacy
Leonard Lichtenfeld, MD Deputy Chief Medical Officer	American Cancer Society
Maya J. Bermingham Senior Assistant General Counsel	PhRMA
David R. Gaugh, R.Ph. Vice President and General Manager	Bedford Pharmaceuticals

Workshop Agenda: Monday, September 26, 2011	
7:30 – 8:00 AM	Registration
8:00 – 8:05 AM	Welcome Edward Cox, MD MPH
8:05 – 8:15 AM	Introductory Comments and CDER Perspective on Drug Shortages Douglas Throckmorton, MD, Deputy Director, CDER
Current Status of Drug Shortages and FDA Shortage Strategies	
8:15 – 8:25 AM	Public Health Impact of Drug Shortages RADM Sandy Kweder, MD Deputy Director, Office of New Drugs
8:25 – 8:45 AM	Drug Shortages: FDA Strategies and Role Edward Cox, Coordinator, CDER Drug Shortage Program
8:45 – 9:05 AM	Update on the Status of Drug Shortages, Causes, and Significant Trends Erin Fox, Pharm. D.
9:05 – 9:20 AM	Impact of Drug Shortages on Hospitals and Health-Systems: Results from Recent Surveys Roslyne Schulman, AHA and Burgunda V. Sweet, University of Michigan Health System and College of Pharmacy
9:20 – 9:40 AM	Break
Drug Shortages – The Patient Perspective	
9:40 – 9:45 AM	Improving Patient Care with Regulatory and Policy Initiatives Nancy Davenport-Ennis, National Patient Advocacy Foundation
9:45 – 9:50 AM	Diane L. Hamlin and Abagale L. Hamlin
9:50 – 10:00 AM	Davria Cohen
10:00 – 10:10 AM	Jay Cuetara
10:10 – 10:15 AM	Barbara Bennicoff, RN
Drug Shortages – Health Care Provider Perspective	
10:15 – 10:25 AM	Impact of Drug Shortages on Medication Errors – the ISMP Survey Mike Cohen, R.Ph., ISMP

10:25 – 11:30 AM	<p>Presentation and Panel Discussion on Perspectives from the Point of Care Mike Cohen, R.Ph., Moderator <i>Objectives: Practitioners who serve patient populations significantly affected by drug shortages describe the most significant challenges in providing care</i> (Five minute presentations for each speaker, followed by a discussion by speakers and panelists on the top challenges they face.)</p> <ul style="list-style-type: none"> • Oncology - Hematology/Oncology Pharmacists Association, American Cancer Society, American Society of Hematology, American Society of Clinical Oncology (speakers: Ali McBride, Pharm.D., Len Lichtenfeld MD., Lawrence A. Solberg, Jr. MD, Karen Hagerty) • Anesthesiology - American Society of Anesthesiologists, American Association of Nurse Anesthetists (speaker: Arnold Berry) • Pediatrics - American Academy of Pediatrics, Pediatric Pharmacy Advocacy Group (spearker: DeWayne Pursley, MD MPH) • Specialty Settings - Department of Veterans Affairs, American College of Emergency Physicians, St Jude’s Children’s Research Hospital (speakers: Vincent Calabrese, Pharm.D., Frederick Blum, MD, James M. Hoffman, PharmD, MS, BCPS)
11:30 – 12:00 PM	<p>Open Question and Comment Period (interested persons should sign up at the registration table just outside of the meeting room before 9:20 a.m. break)</p>
12:00 – 1:00 PM	Lunch
Recommendations for Solutions to Address Drug Shortages	
1:00 – 1:05 PM	<p>Legislative Update Joseph M. Hill, ASHP</p>
1:05 – 1:15 PM	<p>Recommendations from the Co-Conveners of the Stakeholder Workgroup of the Drug Shortages Summit Jason Byrd, ASA and Juliana Reed, Hospira (Workgroup Roster attached)</p>
1:15 – 2:15 PM	<p>Panel Discussion: Recommendations for Solutions from Healthcare Professional Groups (Discussion of Solution-based Panel Questions for Healthcare Professional Groups) Bona Benjamin, RPh, Moderator <i>Objective: To identify the most serious drug shortages in the healthcare community, describe the current strategies used to support members, and propose additional regulatory and non-regulatory solutions</i></p> <p>Panel members: American Hospital Association, American Society of Health-System Pharmacists, American Society of Clinical Oncology, American Society of Anesthesiologists, American Society for Parenteral and Enteral Nutrition, Institute for Safe Medication Practices, Child Healthcare Association of America</p>

2:15 – 2:30 PM	<p>Panel Discussion: Recommendations for Solutions from Supply Chain Entities (Discussion of Solution-based Panel Questions Supply Chain Panel) Susan Winckler, R.Ph., Esq., Moderator <i>Objective: To identify drug shortage issues that create supply chain problems and propose regulatory and non-regulatory solutions</i> (Five minute presentations from each speaker followed by panel discussion)</p> <ul style="list-style-type: none"> • Cardinal Health (Michael A. Mone) • Premier (Bryant Mangum) <p>Panel members: Cardinal Health, Premier, Inc., Health Industry Group Purchasing Association, Healthcare Distribution Management Association</p>
2:30 – 2:45 PM	<p>Break</p>
2:45 – 3:45 PM	<p>Panel Discussion: Recommendations for Solutions from the Pharmaceutical Industry (Discussion of Solution-based Panel Questions for Industry) Susan Winckler, R.Ph., Esq., Moderator <i>Objective: To identify significant regulatory causes of shortages and propose regulatory and non-regulatory changes needed to prevent shortages or resolve them more quickly.</i> (Five minute presentations from each speaker followed by panel discussion)</p> <ul style="list-style-type: none"> • GPhA (Ralph Neas) • Hospira (Thomas G. Moore) <p>Panel members: APP, Hospira, Teva, Bedford, GPhA, PhRMA</p>
3:45 – 4:55 PM	<p>Open question and comment period. Susan Winckler, R.Ph., Esq., Moderator (interested persons should sign up at the registration table just outside of the meeting room before 2:30 break)</p>
4:55- 5:00 PM	<p>Closing Remarks Edward Cox, M.D., M.P.H.</p>

ADJOURN – 5:00 p.m.

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov/Drugs/NewsEvents/ucm265968.htm>.

Please be advised that we are in the process of re-opening the docket to accept comments. Go to docket # FDA-2011-N-0002. Written and electronic comments will be accepted after the hearing until December 23, 2011. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

Panel Questions on Solutions for Drug Shortages

Healthcare Professional Groups Panel

1. What drug shortage information do you and your members need to make sure your patients get the care they need?
2. In addition to drug shortage information, what other resources would help you and your members manage drug shortages more effectively?
3. How does FDA assist your organization with drug shortages? What recommendations do you have to improve this assistance?
4. What actions does your organization recommend for other stakeholders, such as industry, distributors, group purchasing organizations, other government agencies, to help prevent or reduce drug shortages?

Supply Chain Entity Panel

5. What challenges do drug shortages specifically create for the supply chain?
6. What strategies have you used to ensure continuity of supply for your customers?
7. What actions does your organization recommend for other stakeholders, such as industry, the healthcare community, hospitals and health-systems, and other federal agencies, that would prevent shortages or reduce the number of shortages?
8. What do you see as FDA's role in assisting you with drug shortages?

Industry Panel

9. What are the most significant causes of shortages in the pharmaceutical industry?
10. What changes would help your company prevent or reduce drug shortages?
11. How does FDA assist your firm with drug shortages? What recommendations do you have to improve this assistance?

Drug Shortages Summit
Regulatory-Legislative Work Group
Organizational Leads: Joseph Hill, ASHP and Jason Byrd, ASA

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