

**The National Drug Shortage  
inEMS**

Brent Myers, MD, MPH  
Sabina Braithwaite, MD, MPH

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- Objectives**
- Describe what factors are contributing to the drug shortage
  - List recent advocacy efforts pertinent to the drug shortage
  - Discuss several options that may be available at a state and local level to mitigate ongoing drug shortages
  - Describe patient safety issues that result from the drug shortage

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- Who regulates what?  
How do they potentially impact EMS?**
- FDA
  - DEA
  - State Board of Pharmacy
  - State Board of EMS
  - State Public Health

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## Advocacy

- Federal focus
  - Congress: PDUFA
  - GAO: FDA and DEA studies
  - DEA: request to add to FICEMS
  - FDA
  - HHS: stakeholder meetings
- State focus
  - Oregon
  - Florida
  - Texas

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**United States Senate**  
 COMMITTEE ON THE JUDICIARY  
 WASHINGTON, DC 20510-4275

MURKIN A. GANUS, CHIEF COUNSEL AND STAFF DIRECTOR  
 WILLIAM L. BROWN, REAR CHIEF COUNSEL AND STAFF DIRECTOR

May 3, 2012

The Honorable Gene Dodaro  
 Comptroller General  
 U.S. Government Accountability Office  
 441 G Street, N.W.  
 Washington, D.C. 20548

We write to request that the Government Accountability Office (GAO) conduct a study of the extent to which Drug Enforcement Administration (DEA) policies and regulations may contribute to the growing drug shortage crisis with regard to controlled substances prescribed by physicians.

We are concerned that patients with medical needs lack access to a number of controlled substances (as defined by The Controlled Substances Act codified at 21 U.S.C. § 801 et. seq.) in short supply. Accordingly, we would like to better understand any impediments to production or distribution of such drugs and, if so, how such impediments can be ameliorated to ensure a sufficient supply of controlled substances for lawful patient care purposes. More specifically, we would like to better understand the impact of DEA quotas on patients with emergency medical and critical care conditions and traumatic injuries, and the extent to which DEA policies and regulations may impede the ability of physicians and health care providers to mitigate a shortage of a drug on any of the applicable schedules.

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4. With respect to the impact on patients: identification of patient populations at serious risk of death, disability, or medical errors due to lack of access to essential drugs; identification of patient safety risks such as substantial alterations of drug formulation and concentration; the potential for increased risk of drug administration errors, including in the transport environment; tools for mitigating drug shortages such as sharing products between agencies or among stations within agencies or the utilization of expired drugs when no other alternative is available; and the amount or prevalence of unnecessary waste and whether repackaging drugs in short supply and implementing shelf-life extension programs are viable options for mitigating shortages.

5. Whether DEA regulations and policies and the application and enforcement thereof adversely impact or exacerbate the shortage of drugs used to treat patients with emergency and critical conditions and traumatic injuries, or otherwise impede the ability of emergency physicians, and EMS and CCT physician medical directors and agencies to maximize access to a limited supply of controlled substances for their patients.

6. Whether access for patients with emergency and critical conditions and traumatic injuries to controlled substances needed for their treatment would be improved by: i) improving DEA regulatory applicability to the field EMS/CCT setting; ii) addressing potential inconsistencies in enforcement of DEA rules in the field EMS/CCT transport environment to ensure clear and consistent application nationwide; and iii) removing any impediments that GAO may identify regarding mitigation of drug shortages for patients with emergency and critical conditions and traumatic injuries.

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### Federal: FDASIA

X	1001	Final Rule	Not later than 18 months after the date of enactment, FDA shall adopt final regulations implementing provisions regarding drug shortages, including defining certain terms.	1/9/2014
X	1002	Report to Congress	FDA shall submit an annual report to Congress providing information on drug shortages, including information on the agency's efforts to prevent or mitigate shortages.	1/31/2013
X	1003	Plan	FDA shall establish a task force to develop and implement a strategic plan for enhancing the agency's efforts to prevent and mitigate drug shortages.	7/9/2013
X	1003	Report to Congress	Not later than one year after the date of enactment, FDA shall publish the drug shortage strategic plan and submit the report to Congress.	7/9/2013

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### Federal: PDUFA

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### Need for Regulatory Support

- Advocacy:
  - State level:
    - Drug classes (at most) in statute / regs
    - Expired drug use?
  - Federal level: FDA, DEA
- Purchasing consortia

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### Issues

- Economic factors
- Production capacity
- Alternate medications
- Expiration vs. "use by"
- Manufacturing vs. compounding
- Substitute medications
- Medication safety, training, etc.

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### The View from The Right

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### The Word



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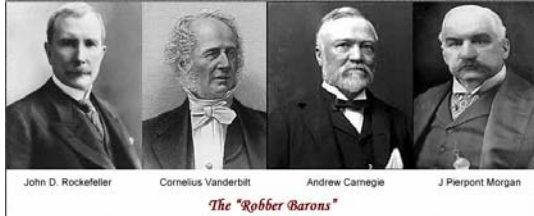
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### Prior to Pesky Regulation



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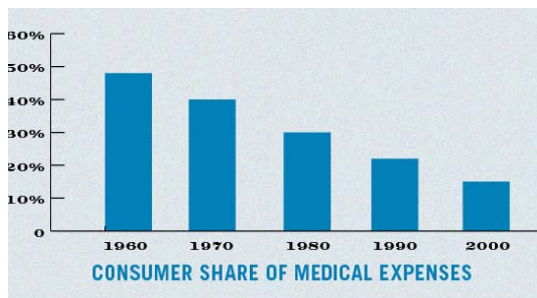
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### From BCBS of North Carolina



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### Why Are There Drug Shortages?

- Alteration of market forces
  - 2003 Medicare Modernization Act
  - Private Insurance Following Medicare Lead
  - Affordable Care Act

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### Seriously, Prior to 2003



- Medicare paid a percentage of the average wholesale price for generic drugs
- This wholesale price was relatively easy to inflate
- Profit motive was supported, albeit artificially

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### 2003 Medicare Bill



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### The Fine Print of 2003 Medicare

- The reimbursement model changed from a wholesale basis to a retail basis
- As of 2005, Medicare reimbursed 106% of the average retail price of the previous 2 quarters
- Private insurance followed
- The "fix" was out



SOURCE: Cassidy and Cobb, Wall Street Journal, November 11, 2012

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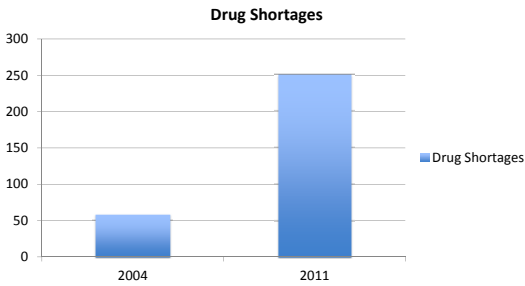
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### Generic Drug Shortage Comparison



SOURCE: Cassidy and Cobb, Wall Street Journal, November 11, 2012

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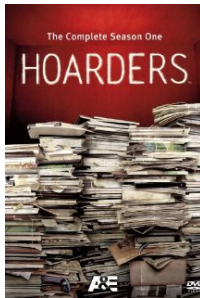
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### Confounding Factors

- 90% of generic drugs in the United States are made in one of three factories
- Fear of impending shortages has lead retailers and providers to hoard drugs



SOURCE: Cassidy and Cobb, Wall Street Journal, November 11, 2012

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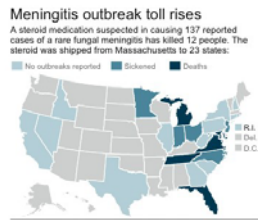
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### From The Left: Safety Regulation is Needed



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### Where Are We Now?

- Prior to 2003, profits rather artificially inflated by wholesale market
- After 2003, profits restricted by retail market
- Safety is a true concern
- Limited suppliers limit options



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### July 9, 2012



- FDA Safety and Innovation Act
- Reduces generic approval process from 30 to 10 months
- Requires notification of impending drug shortages
- Advocates for EMS major player

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### What Does This Mean for Us Now?

- Must be prepared for complete unavailability of certain drugs
- More often, patient safety is compromised by changing concentrations/packaging of drugs or changes in drugs in a certain class (e.g., midazolam substitution for lorazepam).

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### Drug Shortage Reports

Drug ID	SNYD	Drug Name	SNYD (NDC) - Unit of Measure	Date SNYD is no longer available	Forecasted 12	SNYD	SNYD	SNYD	SNYD	SNYD
00100	00100	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00101	00101	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00102	00102	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00103	00103	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00104	00104	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00105	00105	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00106	00106	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00107	00107	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00108	00108	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00109	00109	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00110	00110	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00111	00111	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00112	00112	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00113	00113	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00114	00114	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00115	00115	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00116	00116	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00117	00117	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00118	00118	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00119	00119	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00120	00120	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00121	00121	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00122	00122	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00123	00123	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00124	00124	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00125	00125	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00126	00126	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00127	00127	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00128	00128	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00129	00129	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012
00130	00130	Amoxicillin (Long Act. Chlork)	300 (300mg)	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012	12/18/2012

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**Regulatory and Legislative Recommendations from the Drug Shortages Summit Steering Group**  
 [Developed with Input from the Drug Shortage Legislative-Regulatory Work Group]

American Hospital Association  
 American Society of Anesthesiologists  
 American Society of Clinical Oncology  
 American Society of Health-System Pharmacists  
 Institute for Safe Medication Practices

1. Reallocate FDA resources to facilitate resolution of shortages
2. Require reporting of interruptions / discontinuations
3. Establish criteria for drug vulnerability to shortage and create incentives to manufacture
4. Expedite increased manufacturing quotas for shortage of controlled substances
5. Expedite approval for medically necessary unapproved drugs that are vulnerable to shortage

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### Medication Safety: Logistics

- Provider scope of practice issues?
- How to transition between meds?
- Just-in-time training for entire workforce?
- Engineered solutions?
- Hospital role?
- Expense?

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### Potential medication safety strategies

- Limit concentration changes
- Limit medication substitution
- Just-in-time training
- Flexible protocols
- Heightened awareness
- Create specific visual cues
- Error traps

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### What drugs are “essential” to EMS?

- Narcotics
- Benzodiazepines
- Resuscitation drugs
- ???

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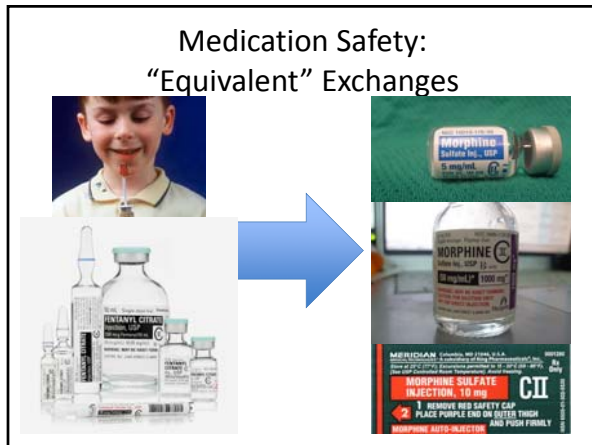
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### Medication Safety: Protocol Buffet

Consider Sedation ↓ Consider Analgesia ↓	<b>MIDAZOLAM IV / IM / IN</b> May repeat x1 in 5 minutes
	<b>LORAZEPAM IV / IM</b> May repeat x1 in 5 minutes
	<b>FENTANYL IV / IM / IN</b> May repeat x1 in 5 minutes
	<b>MORPHINE IV / IM</b> May repeat x1 in 5 minutes

**FOR MUSCULOSKELETAL OR SOFT TISSUE PAIN:**  
 Determine the best pharmacological treatment for pain from the list below:

- ◆ Nitrous Oxide
- ◆ Fentanyl IV/IO, titrated to effect over 1-2 minutes, repeat x1 after 5 minutes PRN, max single dose of 100 mcg.
- ◆ If vascular access is not readily accessible or unobtainable, Fentanyl 1.5 mcg/kg intranasal may be administered and repeated x1 after 10 minutes PRN, max single dose of 100 mcg.
- ◆ Morphine Sulfate over 1-2 minutes and repeat x1 after 5 minutes PRN (max repeat dose 2 mg)

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### NC Example of "Classes" vs "Specific Drugs"

EMS Medications	MR	EMT	EMT-I	EMT-P
Acetaminophen	O	O	B <sup>1</sup>	B
Adenosine				B
Beta-agonists (Albuterol, Levalbuterol, etc.)		B <sup>2</sup>	B	B
Amiodarone				B <sup>1</sup>
Anti-emetic preparations				B
Aspirin		B <sup>3</sup>	B	B
Atropine	O <sup>1</sup>	O <sup>1</sup>	O <sup>1</sup>	B
Beta Blockers (Metoprolol, etc.)				B <sup>4</sup>
Benzodiazepine (Diazepam, Midazolam, etc.)				B <sup>4</sup>
Calcium Channel Blockers (Diltiazem, etc)				B <sup>4</sup>
Calcium chloride/gluconate				B
Charcoal		O	O	O
Crystalloid solutions (Normal Saline, etc)			B	B
Diphenhydramine		O <sup>2</sup>	B	B
Dobutamine				S, O
Dopamine				B
Epinephrine	B <sup>5,6</sup>	B <sup>5,6</sup>	B	B
Etomidate				O

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### Medication Safety: JIT Training

- Protocol redundancy
- Highlights of differences between meds
- Availability of dosing reference
- Availability of contraindication / interactions
- Information to receiving hospitals
- Information to restocking pharmacies
- Tracking of substituted medications and targeted QI

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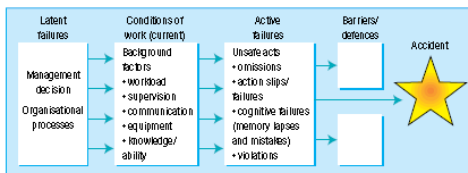
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### Address Accident Model



Vincent C, Taylor-Adams S, Stanhope N. 1998. Framework for analysing risk and safety in clinical medicine. *BMJ* 316: 1154-7

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### Controlled Substances

- Maintain tight control and awareness
- Board of Pharmacy alignment or conflict with DEA regulation

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### Drug Shortage Strategies

- Provide for therapeutic equivalents in protocols
- Make decisions on which drugs are “essential”
- Create best practices:
  - provider training
  - patient safety
  - expense

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### Take Home Points

- Drug Shortage isn’t going away
- Create best practices and strategies specific to your organization and needs that can be applied to all drugs
- Utilize error traps / decision support
- Monitor through quality measures for unanticipated sources of error or need for process change

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## Drug Shortage Resource Links

- Federal:
  - FDA: <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) <http://www.nccmerp.org/>
- ASHP (American Society of Health System Pharmacists) <http://www.ashp.org/>
  - Senate Finance testimony on drug shortages December 2011: <http://www.ashp.org/DocLibrary/Advocacy/SenateFinanceComm-on-Drug-Shortages.aspx>
- HDMA (Healthcare Distribution Management Association) <http://www.healthcaredistribution.org/>
- Legislation:
  - HR 2245: Access to Life-Preserving Medications Act of 2011. <http://www.gpo.gov/fdsys/pkg/BILLS-112hr2245h/pdf/BILLS-112hr2245h.pdf>
  - S 296: Preserving Access to Life-Saving Medications. Partner to HR 2245. <http://www.gpo.gov/fdsys/pkg/BILLS-112s296h/pdf/BILLS-112s296h.pdf>
  - HR 3839: Drug Shortage Prevention Act of 2012. <http://www.gpo.gov/fdsys/pkg/BILLS-112hr3839h/pdf/BILLS-112hr3839h.pdf>
    - ASHP letter of support: <http://www.ashp.org/DocLibrary/Advocacy/GAD/PDUFA-and-Drug-Shortages.aspx>
- Other Resources:
  - A Review of FDA's approach to Drug Shortages: <http://www.fda.gov/oc/oc/2011/04/20110420DrugShortagesReportMainWebForms/Reports/UCM277755.pdf>
  - Presidential Order 13588 (October 2011) regarding Drug Shortages: <http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages>

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## DEA's Resource Links

- [Offices with Field Registration Program Specialists](#)
  - [To Apply for New Applications for Registration through the U.S. Postal Service](#)
- [Pharmacist's Manual](#)
- [Practitioner's Manual](#)
- [Mid-Level Practitioners \(MLP\) Authorization by State](#)
- [Questions & Answers](#)
- **Reinstated and Retired Registrant List**
  - A complete listing of all active DEA registration numbers can be obtained from the U.S. Department of Commerce National Technical Information Service (NTIS) Web Site at <http://www.ntis.gov/products/dea.aspx?> For your convenience and the most accurate information of a Registrant's status, please use the [Registration Validation Tool](#). For further information, contact Richard.A.Boyd@usdoj.gov
- [Registrant Population](#)
- [State Licensing Boards](#)

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