REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-14)
National Drug Shortages--Update
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. To evaluate the findings of the 2014 Government Accountability Office (GAO) report on drug shortages and the current status of drug shortages in the United States, as well as other recent developments intended to prevent new drug shortages and resolve existing ones.

Methods. English-language reports were selected from a PubMed and Google Scholar search from 2013 to April 15, 2014, using the MeSH terms "pharmaceutical preparations," or "generics/economics," in combination with "supply/distribution," and using the text term "drug shortages." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), GAO, American Society of Health-System Pharmacists (ASHP), the Generic Pharmaceutical Association (GPhA), and the Pharmaceutical and Research Manufacturers of America (PhRMA).

Results. The number of new drug shortages has decreased significantly in the last 2 years, but the number of unresolved/existing drug shortages remains high and continues to cause many problems. The GAO report on drug shortages confirmed a number of observations made by others and summarized in previous Council reports. The most common causes of supply disruptions leading to drug shortages continue to be quality problems coupled with manufacturing delays and limited production capacity (especially in the generic sterile injectable industry), and product discontinuations. These account for more than 80% of drug shortages. Some additional recommendations to develop better long term solutions have been reported by others.

Conclusion. Easy solutions to the drug shortage problem remain elusive. Manufacturers are notifying the FDA about potential disruptions in supply or shortages earlier than in the past and new shortages are being prevented. Long term shortages, however, persist, and continue to impact clinical decision-making and patient care. The GAO report noted that it identified multiple potential underlying causes of shortages, all of which were related to the economics of the generic sterile injectable drug market. Although the GAO attempted to probe stakeholders' views on the economic drivers of drug shortages, no consensus existed, and the GAO noted its intention to further explore economic drivers for drug shortages. Only five major companies are now producing sterile injectable products, and concurrent remediation efforts are in place to upgrade facilities among them. The Generic Pharmaceutical Association's Accelerated Recovery Initiative (see CSAPH Report 8-A-13) also has not made any headway in reducing shortages of generic sterile injectable products. The AMA remains committed to supporting appropriate long term solutions to the drug shortage problem.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3–A-14

Subject: National Drug Shortages--Update

Presented by: Russell W. H. Kridel, MD, Chair

Referred to: Reference Committee E
(Jay A. Gregory, MD, Chair)

INTRODUCTION

Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages. This policy directs CSAPH to evaluate the forthcoming report on drug shortages from the Government Accountability Office (GAO) and report back on its findings. This report, entitled "Drug Shortages-Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," is now available.

Accordingly, this report evaluates the findings of the GAO report and the current status of drug shortages in the United States, as well as other recent developments intended to prevent new drug shortages and resolve existing ones.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from 2013 to April 15, 2014, using the MeSH terms "pharmaceutical preparations," or "generics/economics," in combination with "supply/distribution," and using the text term "drug shortages." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), GAO, American Society of Health-System Pharmacists (ASHP), the Generic Pharmaceutical Association (GPhA), and the Pharmaceutical and Research Manufacturers of America (PhRMA).

BACKGROUND

The Council has issued four previous reports on drug shortages.[1-4] These reports have identified sources for information on drug shortages, described trends in drug shortages and pertinent federal regulations, described the general causes and contributing factors for drug shortages, summarized various recommendations intended to help prevent or mitigate shortages, and discussed various stakeholder responses, including those of the pharmaceutical industry, Congress and the FDA. Readers are referred to those reports for further information on these topics.

Action of the AMA House of Delegates 2014 Annual Meeting: Council on Science and Public Health Report 3 Recommendations Adopted as Amended in lieu of Resolution 522 and Remainder of Report Filed.

CURRENT DRUG SHORTAGES

In recent years, the FDA has tracked and focused on shortages of "medically necessary" drugs.[a] However, the FDA recently commented that they now "post all drug shortages that the agency verifies."[5] The information supporting the drug shortage list is largely supplied by manufacturers, who are only required to report shortages or potential disruptions in supply to drugs that are "life supporting, life sustaining, or used to treat debilitating health issues." The FDA drug shortage website also now separately classifies current shortages according to therapeutic category, identifies the reason(s) for shortages based on standard terminology required by the Food and Drug Administration Safety and Innovation Act (FDASIA), and provides an estimated shortage duration.[6] The FDA considers a shortage resolved "when the total supply of the drug and any pharmaceutical equivalents is sufficient to meet demand in the market overall."[5] The FDA also maintains an internal database to "track shortages on a daily basis, document the actions taken to prevent and resolve shortages, and monitor the workload" of personnel.[5]

The drug shortage resource center maintained by ASHP in collaboration with the University of Utah Drug Information Service (UUDIS) tracks a broader array of drug and biological product shortages based largely on reports from hospital pharmacists.[7] In some cases shortages are local or regional. UUDIS "broadly defines a shortage as a supply issue that affects how pharmacies prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of supply issues." UUDIS also applies more conservative criteria than the FDA in determining when to remove a drug from the shortage list, as well as different criteria for determining if a shortage is "critical," (i.e., alternative medicines are not available, shortages affect multiple institutions). In particular, drugs may remain on the UUDIS list until all dosage forms (based on National Drug Codes[b]) have been restored. At any given time, approximately 60% of the shortages reported in the ASHP resource center may be deemed "critical."[5]

Accordingly, the number of shortages reported by the FDA is lower than the number catalogued by UUDIS/ASHP and exhibits a different dynamic over time, but may be more "clinically meaningful" according to the FDA.[8] As of April 1, 2014, the FDA identified a total of 99 drug shortages, a number that is ~25% lower than the situation in April 2013.[5] The number of new shortages for January 1, 2013 through September 30, 2013 was 38, compared with 117 new shortages during 2012. According to ASHP, and similar to the recent trend identified by the FDA, the number of new shortages in 2013 (140) was 45% lower than the number of new shortages in 2011. However the number of existing shortages remains largely unchanged. ASHP identified 230 drug shortages as of April 1, 2014, comparable to the number of existing shortages catalogued as of April 2013.[6] Therefore, although fewer new shortages are occurring, existing shortages are apparently taking longer to be resolved.

GAO REPORT ON DRUG SHORTAGES

FDASIA provided the FDA with new authorities and responsibilities and established new requirements for manufacturers to notify the agency in an effort to prevent or mitigate drug shortages. These modifications to FDASIA and potential ways that the FDA can otherwise act to address drug shortages are summarized in CSAPH Report 2-I-12.[3] The FDA has substantially

[a] A medically necessary drug product is one that is "used to treat or prevent a serious disease or medical condition for which there is no other alternative drug, available in adequate supply that is judged by medical staff to be an adequate substitute."

[b] The NDC is a unique 10-digit, 3-segment number for human drugs in the United States identifying the manufacturer, the product, and the commercial package size.

increased staff resources available for responding to drug shortages and extended this effort to district offices, while strengthening direct lines of communications among staff in the Center for Drug Evaluation and Research's (CDER) Office of Compliance, field investigators, drug shortage staff and individual manufacturers.[9]

FDASIA also mandated that the GAO examine several different aspects of drug shortages. Accordingly, the GAO released a report in February 2014 which reviewed trends in prescription drug shortages, summarized how such shortages may affect patients and providers, further examined potential causes of drug shortages and evaluated progress made by FDA in addressing this serious public health problem. Trend analyses in this report were based on data obtained from UUDIS on prescription drug shortages between January 2007 and June 2013. Information regarding impacts on patients and providers was based on answers from different stakeholders to a series of open ended questions and therefore reflects varying opinions and viewpoints.

In 2012, the number of new shortages captured by UUDIS dropped for the first time since 2006 to 195, a 24% decrease from 2011.[5] The number of new shortages captured by UUDIS continued to decrease throughout 2013, totaling 140 (personal communication, Bona Benjamin, American Society of Health-System Pharmacists). While confirming that generic sterile injectable products remain the most problematic, the GAO report provides some additional perspective. Nearly 1 in 5 drugs that were in short supply since January 2007 have been so on multiple occasions, with the majority of shortages persisting nearly 1 year. GAO also compiled an overlapping dataset of "continuing plus new shortages" that intersect on an annual basis. According to their analysis, total shortages continued to increase from 2007 peaking at 456 in 2012. The combination of ongoing and new shortages stabilized in 2013 actually decreasing somewhat to 428 based on the final total of new shortages reported. The most common therapeutic classes affected by shortages were anti-infective, anesthetic/central nervous system, and cardiovascular drugs, and those used for parenteral/enteral nutrition.

Continuing Implications of Drug Shortages

As described in previous Council reports and re-emphasized in the GAO report as ongoing concerns, drug shortages create many problems adversely affecting clinical practice, healthcare system finances, and patient outcomes. These include delays in or rationing of care, difficulties finding alternative drugs, a higher risk for medication errors, larger pharmacy staffs and drug acquisition costs, increased reliance on pharmacy compounding to meet clinical demands, and diversion of patient care resources. Some institutions may hoard or stockpile drugs that tend to be in short supply, thereby exacerbating disruptions being experienced by other practitioners or institutions. Additionally, ongoing drug shortages have prompted more direct examination of ethical issues associated with the rationing of potentially life-saving products, particularly in oncology practice.[10-12] The role and obligations of pharmacy benefit managers to address drug shortages also has been examined.[13]

Consistent with the findings of the GAO report, drug shortages continue to mandate treatment changes in oncology that may affect efficacy and toxicity and increase costs, and significantly impact parenteral and enteral nutrition practices.[14-19] Medication errors and adverse events continue to occur from drug shortages and cause problems for pharmacy and therapeutics committees in hospitals and other health care delivery organizations.[20,21] Disruption in the supply of medication used to prevent rejection of implanted tissues and organs also can significantly influence post-transplant outcomes.[22]

Causes of Drug Shortages

The GAO report confirmed a number of observations made by others and summarized in previous Council reports.[5,23] The most common causes of supply disruptions leading to drug shortages are quality problems coupled with manufacturing delays and limited production capacity (especially in the generic sterile injectable industry), and product discontinuations. These account for more than 80% of drug shortages. Many production facilities are aging and more prone to failures that may trigger FDA enforcement actions, are subject to more frequent and periodic maintenance requirements, or are targets of corporate decisions to remediate and/or upgrade manufacturing facilities. Thus, an overlap may exist between shortages caused by an initial quality issue and those that ultimately reflect a lack of capacity to produce other products on the same production line or at the same facility.[24] The GAO report noted conflicting arguments and opinions about the relative contribution of manufacture-initiated quality reports, the manufacturer's ability to adhere to current good manufacturing practices, and FDA inspections and compliance actions as root causes of supply disruptions that trigger shortages.[5,23,25,26] As previously noted, shortages sometimes are caused by a manufacturer's decision to discontinue production, the unavailability of raw materials, loss of a manufacturing site due to natural disasters, or even increased demand. Discontinuation of products (which accounted for 9% of shortages in 2011) can be driven by profitability concerns, especially when production lines are running at full capacity and new products become available to generic manufacturers because of patent expirations.[24]

While briefly discussing, the GAO report did not provide any additional clarity about economic drivers of drug shortages, other than to confirm that approximately half of the studies examined by the GAO "suggested that the immediate causes of drug shortages, such as quality problems, are driven by an underlying cause that stems from the economics of the generic sterile injectable market." Factors considered under the economic heading included the behavior of group purchasing organizations (GPO), changes in Medicare Part B reimbursement policy, the interplay of manufacturing and purchasing decisions, and whether the manufacturer's reliability or quality attributes could be considered or "rewarded" in the marketplace.[5] Although some attention has been devoted to Medicare Part B reimbursement as a cause of drug shortages, this view has not gained widespread traction[27] as the "trends in shortages of drugs affected by payment reform are similar to the pattern among drugs that should not have been affected by it."[24] Further analysis is precluded because most of the studies considered by the GAO were not specifically identified.

With respect to price competition and quality, one view postulates that the market for generic sterile injectable products does not reward quality and competition is therefore based solely on price.[24] Hospitals and clinics do not differentiate among approved generic equivalents, so manufacturers have little incentive to differentiate themselves. This lack of recognition could contribute to reactive approaches to quality management and/or reduce the incentive to invest in upgrading production facilities or create redundant manufacturing capabilities. However, the GAO noted that most generic drug manufacturers indicated that they "continue to invest in upgrading existing establishments and building new ones." Controversy also exists on whether the contracting practices of GPOs have played a significant underlying role in fostering a more fragile supply chain and causing drug shortages.[5,23,27-29]

The GAO concluded that the FDA could do a better job of "maximizing the agency's ability to use the information at its disposal to address drug shortages." Ultimately, the GAO expressed the belief that the FDA "may be missing an opportunity to identify causes of shortages, risks for shortages, and patterns in events which may be early indicators of shortages." Whether reliable data on shortages submitted by manufacturers and analyzed over time could be used for predictive

purposes or in some other proactive manner to better address drug shortages, and how that would be accomplished, is uncertain.

PROGRESS IN ADDRESSING DRUG SHORTAGES

Recent FDA Actions

As required by FDASIA, and consistent with AMA policy, the FDA developed a drug shortages task force and issued a new strategic plan for addressing drug shortages on October 31, 2013.[26] The FDA also published a proposed rule for public comment on November 4, 2013 to help implement FDASIA's expanded notification requirements[c] for manufacturers regarding potential disruptions in manufacturing or supply.[30] The proposed rule, which our AMA strongly supported, also extended the notification provision to manufacturers of biologic products.

The FDA's Strategic Plan has two overarching goals: to strengthen the agency's mitigation response and develop long term strategies for prevention of drug shortages.[26] Central to the mitigation strategy are improving communication and efficiency in responding to a notification about disruption in supply, improving database management and use, and clarifying the roles and responsibilities of manufactures and the FDA to improve remediation efforts and establish best practices to avoid or mitigate shortages. Long term strategies focused on developing a risk-based approach to identify early warning signals to prevent supply disruptions, and possible incentives to sustain and/or reward quality in the marketplace. The latter would involve other stakeholders because creating incentives for manufacturing, using manufacturing quality metrics to impact purchasing decisions, investing by industry to increase manufacturing capacity, and providing safeguards to minimize gray market activities are beyond the purview of the FDA.

Preventing Potential Drug Shortages

The GAO concluded that the FDA has continued to prevent more shortages and improved its ability to respond to shortages that occur. The GAO also provided a different perspective on the literal "meaning" of the FDA's reported success in addressing drug shortages. The FDA has publicly reported that it was able to prevent 195 potential shortages in 2011, 282 potential shortages in 2012, and, in a recent report to Congress, 140 potential shortages through September, 2013.[9] Such shortages are product and dosage form specific. If a shortage for the same product or dosage form is averted twice in one year, it is counted as two potential shortages prevented. By focusing on active pharmaceutical ingredients, the GAO concluded that the FDA had prevented 89 shortages in 2011 and 154 potential shortages in 2012.[5]

General agreement exists that the requirement in FDASIA for manufacturers to notify the FDA of a potential disruption in supply (as soon as practicable) has helped the agency to expedite solutions to prevent and/or mitigate drug shortages. A 6- to 12-fold increase in spontaneous reports from manufacturers of potential disruptions in supply has occurred since 2011.[5] See CSAPH Report 8-A-13 for further discussion on various potential expedited solutions, including exercising regulatory flexibility, that the FDA may employ.[4]

[c] FDASIA requires manufactures of drugs that are "life-supporting, life threatening, and intended for use in the prevention or treatment of a debilitating disease or condition," including those used in emergency care or surgery to notify FDA 6 months in advance (or as soon as practicable) if manufacturing is going to be interrupted or discontinued.

From January 1-September 30, 2013, FDA was notified of 202 potential shortage situations by 39 manufacturers.[9] CDER expedited the review of 188 applications (Abbreviated New Drug Applications and Supplements) to prevent or mitigate drug shortages. It also exercised regulatory flexibility and discretion in 76 other instances, affecting 68 products. While these statistics seem significant, it is not clear how many applications and supplements were approved, or over what time frame.

DRUG SHORTAGES SUMMIT

In addition to the GAO report, the findings and recommendations of a multi-stakeholder summit on drug shortages were recently released.[27] The summit was convened by the American Hospital Association, American Society of Anesthesiologists, American Society for Clinical Oncology, Institute for Safe Medication Practices, and American Society of Health-System Pharmacists and intended to evaluate potential long-term solutions to the drug shortage crisis. The AMA was an invited participant. The summit identified 13 potential solutions (see Appendix), most of which "had merit," according to the group, although "those intended to address economic factors required more study."

CONCLUSION

As result of actions taken by the President, Congress, and FDA over the last two and one-half years, manufacturers are notifying the FDA about potential disruptions in supply or shortages earlier than in the past and new shortages are being prevented, and it appears that the agency has improved both its internal communication and communication with manufacturers. Long term shortages, however, persist and continue to impact clinical decision-making and patient care.

The GAO report noted that it "identified multiple potential underlying causes of shortages, all of which were related to the economics of the generic sterile injectable drug market."[5] Although GAO attempted to probe stakeholders' views on the economics of drug shortages, including Medicare Part B reimbursement, no consensus existed. In a footnote to the report in the economic section, the GAO noted that "in subsequent work, we intend to further explore the causes of drug shortages."[5] With only five major companies now producing sterile injectable products, and concurrent remediation efforts in place to upgrade facilities among them, the Generic Pharmaceutical Association's Accelerated Recovery Initiative (see CSAPH Report 8-A-13) also has not made any headway in reducing shortages of generic sterile injectable products.[24] The AMA remains committed to supporting long term solutions to the drug shortage problem. A summary of AMA actions on this issue can be found in Appendix II.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted, and the remainder of the report be filed.

That Policy H-100.956 "National Drug Shortages" be amended by addition and deletion as follows:

1. That our AMA supports the recommendations of the 2010 Drug Shortage Summit convened by the American Society of Health System Pharmacists, American Society of Anesthesiologists, American Society of Clinical Oncology and the Institute for Safe Medication Practices and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

2. Our AMA supports requiring all manufacturers of Food and Drug Administration approved drugs and, including FDA approved drugs with recognized off-label uses, to give the agency advance notice (at least 6 months prior or otherwise as soon as practicable) of anticipated voluntary or involuntary, permanent or temporary, discontinuance of the manufacture or marketing of such a product.

3. Our AMA supports authorizing the Secretary of Health and Human Services to expedite facility inspections, and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.

4. Our AMA supports the creation of a task force to enhance the HHS Secretary's response to preventing and mitigating drug shortages and to create a strategic plan to: (a) enhance interagency coordination; (b) address drug shortage possibilities when initiating regulatory actions (including the removal of unapproved drug products from the market); (c) improve FDA's ability to track and analyze drug shortage data in an effort to develop strategies to better prevent drug shortages (~~c~~d) provide further information on expedited solutions that have worked to prevent or mitigate drug shortages; (e) communicate with stakeholders; and (~~d~~f) consider the impact of drug shortages on research and clinical trials.

5. Our AMA will advocate that the U.S. Food and Drug Administration and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

6. The Council on Science and Public Health shall continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates on progress made in addressing drug shortages.

7. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors, including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The Centers for Medicare and Medicaid Services should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences, including serving as a root cause of drug shortages. ~~The Council will monitor and evaluate the forthcoming report on drug shortages from the Government Accountability Office and report back on its findings~~.

8. Our AMA urges that procedures be put in place: (1) for the FDA to monitor the availability of Schedule II controlled substances; (2) for the FDA to identify the existence of a shortage that is caused or exacerbated by existing production quotas; and, (3) for expedited DEA review of requests to increase aggregate and individual production quotas for such substances.

9. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.

10. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.

11~~0~~. Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs. (CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in lieu of Res. 912, I-13. (Modify HOD Policy)

Fiscal Note: Less than $500

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APPENDIX

Drug Shortages Summit – Recommended Areas for Further Exploration[27]

- Accelerate and streamline Drug Enforcement Administration controlled substance quota approval procedures.
- Consider corporate tax credits and other incentives for manufacturers who maintain robust quality and facility maintenance programs.
- Consider multiple contract awards by group purchasing organizations to ensure alternate suppliers during shortages.
- Encourage collaboration between industry and healthcare stakeholders to develop better methods for demand forecasting.
- Encourage manufacturers to provide single dose medications in smaller volumes to reduce waste.
- Engage payers, including the Centers for Medicare and Medicaid Services, to develop solutions for drug shortages.
- Enhance FDA communication to providers on its mitigation plans and actions, and include more reliable information on when availability will be restored.
- Establish a process for FDA to obtain data that allows the Agency to extend expiry during critical shortages.
- Establish a list of critical drugs similar to the World Health Organization's Model List of Essential Medicines for prioritizing drug shortage resolution efforts.
- Establish traceability of medications to determine patterns of distribution.
- Evaluate the existing Biomedical Advanced Research and Development Authority (BARDA) model for applicability to managing drug shortages.
- Provide FDA with sufficient resources to conduct inspections, process paperwork, and resolve other regulatory issues that contribute to drug shortages.
- Use FDA metrics for manufacturers' quality and reliability to drive purchasing and reimbursement decisions.

APPENDIX II
Summary of AMA Actions on Drug Shortages

2001: Board of Trustees Report 7-I-01 calls for establishment of an HHS Task Force to explore causes of drug and vaccine shortages and to identify solutions.

2002: The AMA and ASHP convene a special meeting of key FDA officials and representatives of the pharmaceutical industry, drug distributors, GPOs, American Hospital Association, Institute of Medicine, and the Department of Veterans Affairs to examine drug product shortages and potential solutions. A summary is published in November 2002. In the aftermath, ASHP and the University of Utah Drug Information Service develop an electronic drug shortage resource, the precursor to the current ASHP Drug Shortage Resource Center.

2003: The AMA and ASHP met with high ranking FDA and HHS officials to propose an HHS/FDA workshop to include relevant stakeholders in order to prioritize strategies for improving the market dynamics for prescription drugs in order to reduce shortages and improve patient care.

2004: The AMA and ASHP convene a follow-up meeting to discuss next steps. Included in the discussion was draft guidance developed by the Healthcare Distribution Management Association on "Ensuring Product Availability--A Recommended Voluntary Industry Guideline."

AMA also develops policy and supports view that Congress should require all manufacturers of FDA-approved pharmaceutical products to give the FDA public notice of the anticipated voluntary or involuntary, permanent or temporary, discontinuance of manufacture or marketing of such a product at least six months in advance.

2006: The AMA develops policy and supports the view that the federal government and other key stakeholders should develop and implement strategies that will prevent and better mitigate drug shortages.

2010: Drug Shortage Summit convened by ASHP, ASA, ASCO, and ISMP. The AMA endorses a suite of 19 recommendations to address drug shortages involving regulatory and legislative factors, raw materials and manufacturing, business and market factors, and distribution.

2011-2014
CSAPH Report 2-I-11 developed for the HOD.
CSAPH Report 7-A-12 developed for the HOD.
CSAPH report 2-I-12 developed for the HOD.
CSAPH Report 8-A-13 developed for the HOD.
AMA develops dedicated drug shortage advocacy resource page.

Legislative Activities: Between October 2011 and March 2014, the AMA submitted formal comments on 12 separate occasions on issues related to preventing and mitigating drug shortages including PDUFA reauthorization, the Senate Energy and Commerce Committee, the Senate HELP Committee, and sponsors of specific legislation.

Regulatory Activities: In December 2013 the AMA submitted supportive comments on FDA's proposed rule that would require manufacturers to notify the agency of a permanent discontinuance or manufacturing interruption of a product that is likely to lead to a meaningful disruption in supply.

In March 2013, the AMA submitted recommendations to the FDA Drug Shortages Task Force on its Strategic Plan, highlighting physician concern and frustration with ongoing shortages, particularly of sterile injectable products. The AMA also indicated its support for the concept of developing a qualified manufacturing partner program; and strongly supported targeted notification of drug shortages to physician medical specialty organizations.