American Society of
Health-System Pharmacists®

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April 25, 2012

The Honorable Orrin G. Hatch
104 Hart Senate Office Building
Washington, DC 20510

Dear Senator Hatch:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments to the discussion draft to promote notification and provide incentives to reduce drug shortages. ASHP continues to work with Congress, the Food and Drug Administration, health care clinicians, and other members of the supply chain to address this problem.

As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP can offer unique and vital feedback on this important health care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. In addition, ASHP provides the only comprehensive resource for drug shortage information in the nation.

According to FDA, in 2011, the agency was able to avoid 195 drug shortages when it had advance notice from drug manufacturers of product discontinuance or an interruption in production of a product due to a quality or other manufacturing issue. We are strong supporters of the early notification requirement and believe FDA's data conclusively demonstrate that this approach is effective in helping to stem drug shortages. Furthermore, the early notification requirements are included in both the House and Senate versions of the Prescription Drug User Fee Act (PDUFA). This is further evidence that early notification is an effective tool to combat drug shortages.

Although we have extensively studied our data as well other recently issued reports for a causal relationship between reimbursement rates and drug shortages, we have found no evidence that suggests a correlation. Our data show no contemporaneous association with enactment of the Medicare Modernization Act (see Attachment A).

We appreciate the financial dilemma for oncologists, who are under-reimbursed for six months when prices increase for common standard of care cancer drugs. We have heard about the unintended consequences of lag time required to adjust reimbursement- that overall healthcare costs are increased when physicians admit patients to hospitals or that physicians prescribe alternative, more expensive therapy for their patients to lessen their financial losses. We would support research that establishes a more market-responsive reimbursement rate than the current 106% of average sales price formula. However, we do not believe this economic factor to be relevant to drug shortages and recommend addressing it in separate legislation.

Under Section 3, market stability incentives, the exemption of the 340B discounts for sterile injectable products with 4 or fewer manufacturers is extremely troublesome. Many of our members who work in safety-net hospitals and other entities that qualify for the 340B program have expressed grave concerns about financial viability if they must pay higher drug prices, while Medicaid funding is decreasing. Given that the program is minuscule compared to Medicare or Medicaid, we believe 340B is not a cause of drug shortages, and we have no data to suggest that it is. The 340B program helps sustain our nation's ability to provide care to the poor, the uninsured and other medically vulnerable patient populations. We do not believe the proposed financial incentive is sufficient to justify the number of Americans who will lose access to care they desperately need. Therefore, we oppose this exemption and respectfully ask that it be removed.

An October 2011 report by the Office of the Assistant Secretary for Planning and Evaluation within the Department of Health and Human Services examined the economic factors of drug shortages. The report largely focused on manufacturing capacity and the influence of large volume purchasers such as group purchasing organizations. The report did not identify federal health programs as a cause of drug shortages.[1]

We are also troubled by the lack of corroboration by the very entities that would theoretically benefit from this approach, the drug manufacturers themselves. We have not seen any public testimony by the manufacturer community indicating that public health programs are influencing drug shortages. One spokesperson for Teva Pharmaceuticals testified last September that lack of capacity significantly inhibits the ability of pharmaceutical firms to increase production in a timely manner when a shortage occurs.[2] If there are data to indicate that 340B discounts contribute to drug shortages, we would ask that any such data from industry or other sources be made available to the public so we have a better understanding of which market incentives are most likely to encourage firms to produce drugs in short supply.

We commend the intent behind efforts to address drug shortages through economic incentives. It is obvious that unlike brand name drugs, generic medications have no patent exclusivity and are sold for lower prices, which may appear to create a disincentive to remain or enter the market. Nonetheless, we remain cautious of unintended consequences that may result from market manipulation. The generic market remains strong and intensely competitive, while saving patients and the healthcare system 3 billion dollars weekly, according to the Generic Pharmaceutical Manufacturers Association.[3] Assuming that the proposed incentives focused on sterile injectable products produced by 4 or fewer manufacturers are favorable, what safeguards are in place to protect the market from unscrupulous activities? Currently most generic injectables are manufactured by six large firms and almost all products are produced by 4 or fewer firms. Given the market share these large producers can

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[1] Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Economic Analysis of the Causes of Drug Shortages; October, 2011.
[2] Testimony Of Jonathan M. Kafer, Vice President Sales & Marketing, Teva Health Systems, Teva Pharmaceuticals. "Examining the Increase in Drug Shortages." Before The U. S. House Representatives Committee on Energy and Commerce Subcommittee on Health; September 23, 2011.
[3] Generic Pharmaceutical Association. Facts at a Glance. http://www.gphaonline.org/about-gpha/about-generics/facts; Accessed April 24, 2012

command, smaller firms would have little incentive to enter the market. Larger firms, on the other hand, would be incentivized to maintain the “4 or fewer” monopoly, e.g., with mergers and acquisitions, in order to protect their volume business and eligibility for the theoretical incentives put forth in the draft.

We are very concerned that any attempts to give companies a market advantage may result in business decisions to manufacture certain drugs over others due to increased reimbursement. As one of the leading entities that tracks and reports drug shortage information to the American public, we have seen no evidence that suggests either reimbursements from public payers or market manipulation by drug manufacturers has caused drug shortages. While we would not rule out the influence of economic factors, we believe more study is required to fully elucidate the complexity of the global pharmaceutical industry and its economic drivers. Moreover, we are curious to know why the focus for these incentives is not toward products that are in short supply, but to all products for which there are 4 or fewer manufacturers?

We appreciate the opportunity to provide comments on the discussion draft, and we look forward to working with you to address this problem.

Sincerely,

Paul W. Abramowitz, Pharm.D., FASHP
Chief Executive Officer and Executive Vice President

Attachment A