June 4, 2008

The Honorable Stephen Buyer
United States House of Representatives
Washington, D.C. 20515

The Honorable Jim Matheson
United States House of Representatives
Washington, D.C. 20515

VIA E-MAIL AND HAND DELIVERY

Re: H.R. 5839: Safeguarding America's Pharmaceutical Act of 2008

Dear Congressman Buyer and Congressman Matheson:

The Small Business Administration's (SBA) Office of Advocacy and the SBA's Office of the National Ombudsman are writing this letter in support of H.R. 5839, Safeguarding America's Pharmaceutical Act of 2008. Based on our contacts with many pharmaceutical industry representatives we have learned that a substantial number of small pharmaceutical distributors and wholesalers also support the legislation. Those representatives have told Advocacy that the drug pedigree requirements as they currently exist will negatively impact approximately 4,000 small businesses as defined by the SBA's size standards. Also, the pedigree rulemaking, as promulgated by the United States Food and Drug Administration (FDA), may have the unintended consequence of harming the integrity of the U.S. pharmaceutical supply chain. We appreciate that you have undertaken this effort to help ensure the continued wellbeing and existence of secondary and independent distributors of pharmaceuticals.

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress.[1] The Small Business Regulatory Enforcement Fairness Act requires the SBA's Office of the National Ombudsman (Ombudsman) to receive, substantiate, and report to Congress the concerns and comments of small businesses.

[1] Advocacy is an independent office within the SBA; as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

Advocacy's and the Ombudsman's history with the FDA's drug pedigree rule

Since 1999, Advocacy has closely followed the FDA's rulemaking and policies concerning the pedigree requirements and procedures pertaining to the Prescription Drug Marketing Act of 1987, as subsequently modified by the Prescription Drug Amendments of 1992. Advocacy and the Ombudsman have historically been supportive of the FDA's overall policy objective "to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs into the United States' pharmaceutical supply chain."[2] In public comments to the FDA, Advocacy asserted that the rulemaking may have a deleterious economic effect on small pharmaceutical distributors and wholesalers.[3] While reviewing the FDA's regulation, Advocacy was primarily concerned about the possibility that changes to the pedigree rules would make it harder for small distributors to become "authorized" as defined by the rule, and would grant the pharmaceutical manufacturers the sole discretion to determine which small businesses to designate as an "authorized distributor."

During Regulatory Fairness hearings held in September 2006, and March 2008, the SBA's Office of the National Ombudsman received numerous complaints from affected small pharmaceutical distributors and wholesalers about the impact that the regulation was likely to have on their ability to continue operating in the marketplace. On October 3, 2006, the Ombudsman wrote the Senate Chairpersons of the Senate Committee of Health, Education, Labor and Pensions, the Senate Committee on Small Business and Entrepreneurship, the House Committee on Government Reform, the House Committee on Energy and Commerce, the House Committee on Small Business and the Commissioner of the FDA in an effort to inform them about the inherent problems with the pedigree regulation, and asking that they review and consider the positions espoused by affected small businesses.

Identification of the legislation's provisions supported by small pharmaceutical distributors and wholesale businesses

The industry representatives who have worked closely with Advocacy and the National Ombudsman's office on this matter support H.R. 5839. In particular, they support the provisions in Section 4 of the legislation that would require secondary distributors and wholesalers to document pedigree going as for back as the original distributor (i.e., the

[2] 71 Fed. Reg. 34250, June 14, 2006.
[3] Advocacy's February 29, 2000, comment letter to FDA Commissioner Henny regarding the pedigree regulation can be found at http://www.sba.gov/advo/laws/comments/fda00_0229.html.

large distributor that typically purchases directly from the pharmaceutical manufacturer) when those secondary distributors and wholesalers are unable to provide pedigree back to the manufacturers themselves. Also, the industry representatives indicated to Advocacy and the Ombudsman that they support Section 5 of the legislation which requires that for high-risk products (products that are most often counterfeited/adulterated) serialization/pedigree would be required starting with the manufacturer and continue for every subsequent wholesale transaction.

Finally, the industry has expressed support for the legislation as it creates a single, uniform pedigree standard nationwide. This standard is vitally important to small distributors, as it eliminates the current practice of having to navigate the numerous (and sometimes conflicting) pedigree requirements currently being imposed by more than thirty individual states. This practice is not only costly, but often impedes the ability of pharmaceutical distributors to provide urgently needed products to caregivers during times of emergency.

Conclusion

Thank you for the opportunity to share our views and the views of many of the stakeholders affected by this important legislation. We look forward to working with you on this and other issues of importance to the small business community.

Sincerely,

/s/ /s/

Thomas M. Sullivan
Chief Counsel for Advocacy

Nicholas N. Owens
National Ombudsman

cc: The Honorable John F. Kerry, Chair, Senate Small Business and Entrepreneurship Committee
The Honorable Olympia J. Snowe, Ranking Member, Senate Small Business and Entrepreneurship Committee
The Honorable Nydia M. Velazquez, Chair, House Committee on Small Business
The Honorable Steve Chabot, Ranking Member, House Committee on Small Business
The Honorable John Dingell, Chair, House Energy and Commerce Committee
The Honorable Joe Barton, Ranking Member, House Energy and Commerce Committee