

Advocacy Writes Letter Supporting H.R. 5839 Designed to Take Small Secondary and Independent Pharmaceutical Distributors Concerns into Consideration in Drug Pedigree Legislation

- On June 4, 2008, the Office of Advocacy (Advocacy) sent a letter, co-signed by the U.S. Small Business Administration's National Ombudsman, to Representatives Stephen Buyer and Jim Matheson in support of their legislation (H.R. 5839) that addresses many concerns of small secondary and independent pharmaceutical distributors as they relate to the U.S. Food and Drug Administration's (FDA) drug pedigree rule. A complete copy of Advocacy's comment letter may be accessed at www.sba.gov/advo/laws/comments/legislative.html.
- On December 1, 2006, the FDA's drug pedigree rule became final requiring drug distributors and wholesalers to provide a drug pedigree of pharmaceuticals as the drugs made their way through the United States supply system. The FDA drug pedigree rule placed prior sale documentation obligations on non-authorized distributors of pharmaceutical drugs. An authorized distributor of drugs would not have to provide the documentation if it had a pre-existing relationship with the drug manufacturer and was deemed an authorized distributor of record for the drug. Non-authorized distributors would have to provide documentation of the drug's pedigree starting from the manufacturer.
- While Advocacy was supportive of the public policy behind the rule - to prevent substandard, ineffective and counterfeit drugs from entering the drug supply chain - Advocacy suggested to the FDA that the rule was burdensome to small secondary drug distributors. Advocacy believed that the rule would place the small distributors and wholesalers at the mercy of the manufacturers who would have sole discretion to determine who was an "authorized distributor of record" as defined by the rule. Also, there was no obligation in the rule that an authorized distributor was required to provide a secondary distributor with a pedigree making it difficult for the secondary distributor to comply with the rule.
- Representatives from small pharmaceutical distributors and wholesalers approached indicated their support of H.R. 5839 which addresses many of the industries' concerns with the drug pedigree rule.

For more information, visit Advocacy's web page at www.sba.gov/advo or contact Linwood Rayford at (202) 205-6533.