



Memorandum

To: All interested parties
From: Frederick J. Balboni, Jr.
Re: Important USP Update
Date: 5 March 2009

The Consortium for the Advancement of Patient Safety (CAPS) has been diligently working to educate and promote awareness on the benefits of printing on drug packaging, specifically secondary closures, to mitigate medication errors and improve patient safety.

The current revision to USP General Chapter <1> would force pharmaceutical manufacturers to abandon certain technologies such as printing point-of-use instructions and other messages on ferrules and cap overseals that have been used to improve patient safety and to help combat the growing threat of drug counterfeiting. As a result of limiting this printing, patient safety could be compromised and supply-chain benefits as well as security may suffer.

CAPS and the USP have engaged in an effective working dialogue for the purpose of ensuring that important patient safety concerns are addressed relative to printing on ferrules and cap overseals on injectable drug products.

Executive level representatives from USP, including Roger Williams, M.D., Chief Executive Officer USP; Darrell Abernethy, M.D., Ph.D., Chief Science Officer, USP; Susan de Mars, Chief Legal Officer, USP; Matthew Heyman, Vice President External Affairs, USP; Angela Long, Vice President, Volunteer and Organizational Affairs, USP; and Andrzej Wilk, Scientific Liaison to the Nomenclature Expert Committee, USP, met with CAPS recently in Washington D.C. to discuss this issue.

After USP listened to CAPS' presentation, they expressed a strong desire to work with industry and FDA to move forward in a positive direction concerning General Chapter <1>. It is clear from our discussion that USP now has a better understanding of the issues raised by CAPS. We found the meeting to be very productive and are looking forward to working collaboratively to achieve a swift resolution in the best interests of public health. USP also understands the urgency of the situation and intends to issue a communication as soon as a resolution can be achieved.

Dr. Williams also indicated that he would reach out to FDA concerning this issue and to that end the FDA has recently accepted an invitation to meet with CAPS.

USP has indicated that this chapter is likely to be modified soon. Companies that are transitioning out of any protective measures related to the current published chapter are encouraged to monitor USP's website for notices regarding Chapter <1>.

For continuing information feel free to visit our website at: www.caps-edu.org