

## The New Face of Heparin

On October 1, 2009, the United States Pharmacopeia (USP), a non-profit organization that provides authoritative, unbiased standards for manufacturers and regulatory agencies, revised the heparin monograph as well as changed reference standards for the manufacturing of heparin.<sup>1</sup> Late 2007 and early 2008 marked the emergence of several deaths and hundreds of adverse reactions to contaminated heparin sold in the United States.<sup>2</sup> Lack of government oversight allowed the distribution of impure heparin which subsequently caused the deaths and adverse reactions.

The USP changes include a new potency assay, the chromogenic anti-Factor IIa test, to identify adulterations. A new reference standard has been created to eradicate the drift between the USP heparin unit and the WHO International Standard for heparin.<sup>1,3</sup> This conformation will result in a 10% reduction in heparin potency.<sup>1</sup> Heparin affected by these new standards will not be shipping until October 8, 2009 or later. The USP states the changes may not have any clinical significance and are unlikely to change current clinical practices.<sup>1</sup> The FDA states the changes may have significance in certain situations such as IV heparin boluses when immediate anticoagulation is needed.<sup>3</sup> It would be prudent at this point not to make any changes to heparin protocols or prescribing, since the clinical impact of the heparin changes is unknown. However, meticulous patient monitoring must be practiced to ensure patients are receiving adequate anticoagulation.

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<sup>1</sup> U.S. Pharmacopeia. USP Heparin Informaion. At: <http://www.usp.org/hottopics/heparin.html>. Accessed October 1, 2009.

<sup>2</sup> Food and Drug Administration. Important warnings and instructions for heparin sodium injection (Baxter). At: <http://www.fda.gov/drugs/drugsafety/publichealthadvisories/ucm051133.html>. Accessed October 1, 2009.

<sup>3</sup> Food and Drug Administration. Changes in heparin USP Monograph. At: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm184687.htm>. Accessed October 1, 2009.

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