American Association of Blood Banks Statement on DEHP June, 2003

Use of the plasticizer Di(2-ethylhexyl) phthalate (DEHP) in polyvinyl chloride (PVC) blood bags poses a potential dilemma. The presence of DEHP in the blood bags has been shown to have a beneficial effect on red cells during storage. However, concerns have been raised over the decades of DEHP's use in PVC that it and its metabolites may be carcinogenic or have unwanted estrogenizing effects on young male animals exposed to large amounts of the compound. While the concerns about carcinogenicity appear to have waned (and may be restricted to rodent species because of the manner in which they metabolize DEHP), the other potential detrimental effects have led the Food and Drug Administration (FDA) to encourage the use of plastics that do not contain DEHP, where possible. In particular, the FDA has cautioned about the potential effects of DEHP on young boys' reproductive systems, although the DEHP and metabolite levels seen in transfusion recipients' plasma samples are usually far below those associated with toxicity. Despite these expressed concerns, though, the FDA has not removed its approval of blood bags made of DEHP-containing plastics.

The blood banking and transfusion medicine community and manufacturers of blood bags have been following these discussions and the evolving science closely. The AABB will continue to follow the lead of the FDA in assessing the toxicologic risks of the plastics with which blood comes in contact. Should the FDA decide that DEHP is a significant health risk to transfusion recipients, the AABB and its members await the development, approval and availability of newer plastics that provide a suitable storage environment and that do not impart compounds into units that potentially create a health risk.