Position Statement
PVC in Medical Products

We remain committed to providing life-sustaining medical products and services that safely and effectively meet the needs of our health-care customers and the patients who rely on our products. As part of that commitment, we provide our customers with products made from the most appropriate materials, taking into careful consideration the unique characteristics of the solutions going into the containers, the performance characteristics required, and scientific data. To do otherwise would be irresponsible and contradictory to the primary principle of health-care practitioners, "first do no harm."

Based on more than 40 years of safe and effective clinical use, and the large body of scientific data that supports its use, Baxter believes that PVC is the material of choice in many products. PVC has a long history of use in a variety of medical products, such as contact lenses, intravenous bags, oxygen tents and catheters. These products have undergone strict regulatory review by many government and independent health agencies throughout the world, including the U.S. Food and Drug Administration. The safety of these materials has been confirmed by more than 40 years of use, with five to seven billion patient days of acute exposure and one to two billion patient days of chronic exposure without any indication of adverse effects. Environmental concerns relating to the manufacture and disposal of PVC that have arisen in recent years are being addressed with modern pollution control technologies that have reduced emissions up to 99.9 percent over the last few years.

In evaluating the appropriate material to use for a product, Baxter's research and development teams look to some basic performance criteria: clarity and transparency, strength, flexibility, sterilizability, centrifugability and barrier capability.

PVC is one of the only materials that can consistently meet all of these criteria; however it may not be optional for all products. For example, containers used for the storage of blood platelets must allow for good oxygen and carbon dioxide exchange in order to ensure the viability of the platelets. Because some PVC materials do not allow for adequate gas exchange, it shortens the storage period for platelets. As a result, non-PVC materials are often used to store platelets.

Baxter continually evaluates a variety of materials and allocates significant funding for the research and development of biomaterials. In instances where the overall performance of another material has proven superior to PVC and regulatory clearance has been obtained, Baxter has converted to the alternative. In addition to the polyolefin container used for the storage of blood platelets and certain pre-mixed drugs, Baxter also has developed containers from other materials for the storage of blood plasma and frozen blood cells.

Baxter will continue its reasoned, science-based approach toward the development and adoption of materials used in its products.

For Additional Information
FDA's Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices