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Extended Beyond-Use Dating on Drugs May Play Key Role in Dramatically Reducing Healthcare Costs

New Study Concludes Using the PhaSeal® System Helps Maintain Sterility of Drug in Vial for up to 168 Hours

COLUMBUS, OH (February 23, 2011) – A recent study published in The American Journal of Pharmacy Benefits determined that PhaSeal works to provide a mechanical barrier to the entry of contaminants into sterile solutions. ^[1]

The objective of the study was to assess the ability of the PhaSeal closed-system drug transfer device to prevent the contamination of parenteral drug products, thereby allowing extended beyond-use dating, which could significantly reduce waste and cost of these products.

Background

The USP <797> one and six-hour rules were enacted to provide additional patient protection by minimizing the impact of any microbial contamination of these products that could result in patient harm. Even though these drugs are chemically stable, if unused amounts are present after the stated USP <797> standard times, they must be discarded. This means that across the country significant amounts of high-cost drugs are being thrown away every year. In an audit of one of the oncology infusion clinics at Indiana University Health, it was estimated that more than \$1 million in viable drug product was discarded due to the USP <797> standard.

Outcome

Conducted at four distinguished cancer facilities*, this study concludes that drug solutions could be expected to remain sterile for up to 168 hours if the PhaSeal device is properly applied and all additional USP <797> standards are followed.

The study also concludes that using PhaSeal for high-cost unpreserved drugs may provide a way to avoid discarding viable drug product because of sterility concerns and help organizations worldwide reduce waste and drug costs.

About Carmel Pharma (the maker of the PhaSeal System)

Carmel Pharma AB, headquartered in Gothenburg, Sweden, is the manufacturer of the PhaSeal System for the safe handling of hazardous drugs. In the United States, PhaSeal is distributed by an U.S. affiliate office, Carmel Pharma, Inc., located in Columbus, OH. The PhaSeal System has been in use in the U.S. since 1999 and implemented in more than 2000 cancer facilities, infusion centers and private practices, including M.D. Anderson and Texas Children's in Houston, TX; City of Hope in Duarte, CA; Dana Farber Cancer Institute in Boston, MA; Vanderbilt University Medical Center in Nashville, TN; and Johns Hopkins University in Baltimore, MD, just to name a few. For more information on Carmel Pharma or the PhaSeal System, please visit www.phaseal.com or email info@carmelpharmausa.com. To request additional product details, high-resolution imagery, story ideas and expert references, or to learn more about the topic of safe handling from today's clinical thought leaders, please visit www.carmelpharmausa.com/media or contact Laura Scherer at 614-318-2635 or laura.scherer@carmelpharma.com.

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¹ McMichael D, Jefferson D, Carey E, et al. Utility of the PhaSeal closed system drug transfer device. **The American Journal of Pharmacy Benefits**. 2011; 3:9-16

*MD Anderson in Houston, TX; SwedishAmerican Hospital in Rockford, IL; Indiana University Medical Center in Indianapolis, IN; and The James Cancer Hospital at The Ohio State University in Columbus, OH.