Over 123 Million Medical Device Units Recalled in Second Quarter of 2012, Reaching an Eight-Quarter High, According to the ExpertRECALL Index

The Associated Press

More than 123 million units in the medical device category - which includes products like knee replacements, syringes, gels used in ultrasound procedures, dental implants, and products used in heart surgery - were recalled during the second quarter of 2012, according to the quarterly ExpertRECALLT Index released today.

While the number of medical device recalls governed by the U.S. Food and Drug Administration (FDA) declined 13 percent compared with the previous quarter, the number of products affected by such announcements reached an eight-quarter high, breaking 100 million units for the first time since the third quarter of 2010. Food recalls increased 19 percent when compared with the previous quarter, while the rate of recalls affecting consumer products and pharmaceuticals remained largely unchanged.

When compared with the previous quarter, the ExpertRECALL Index found that 35 percent more consumer product safety incidents were reported to the U.S. Consumer Product Safety Commission (CPSC), resulting in 154 injuries and two deaths. While recalls of all children's and infant products reached a six-quarter low during the second quarter of 2012, recalls of child nursery equipment and supplies increased by 60 percent. Recalls of toys decreased 80 percent from the first quarter to the second quarter.

"The fact that more than 120 million medical device units were affected by recalls last quarter cannot be ignored, particularly because it comes during a time when America's 50 million aging Baby Boomers are placing increasingly high demand on life-saving medical devices," said Mike Rozembajgier, vice president of recalls at Stericycle ExpertRECALL. "The growing importance of this product category means that companies need to have a comprehensive recall plan in place that can be deployed within the blink of an eye and can effectively protect their customers and brand. Manufacturers, suppliers, hospitals and retailers must also continue to stay diligent in their efforts to ensure product and consumer safety in an ever-changing environment, particularly in light of FDA's recent proposals to track certain medical devices." The ExpertRECALL Index also found that 80 percent of pharmaceutical products recalled during the second quarter of 2012 affected prescription medications.

Forty percent of food recalls were initiated due to undeclared allergens or other allergen concerns, the lead food recall cause, which continues an eight-quarter

trend. Salmonella contamination, the presence of Listeria monocytogenes and other foodborne illness concerns combined also accounted for nearly 40 percent of food recalls.

"It is critical that FDA- and CPSC-regulated industries follow the agencies' requirements and guidelines to assure that they are met, thus diminishing the likelihood of a violative product and subsequent recalls," said former FDA Senior Recall Coordinator Willie Bryant, a Stericycle consultant. "Additionally, every regulated firm needs to be prepared with a vetted Standard Operating Procedure in place for recalls so that it is ready when that unexpected recall develops." The 2012 second quarter ExpertRECALL Index is the only report that aggregates and tracks cumulative recall data from the CPSC and the FDA. Stericycle ExpertRECALL compiles the ExpertRECALL Index from data issued by the U.S. Food and Drug Administration and the Consumer Product Safety Commission. The ExpertRECALL Index report is available online at http://www.expertrecall.com/recallindex.

About Stericycle ExpertRECALLT Stericycle ExpertRECALLT is the industry leader in managing consumer product, pharmaceutical, medical device, juvenile product, and food and beverage recalls. Stericycle ExpertRECALL streamlines the entire product recall process and manages Notification & Response, Processing & Tracking, and Compliance & Reporting for a variety of companies. For more information, visit http://www.expertrecall.com.

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