


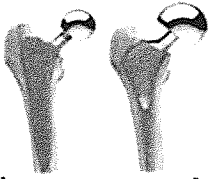













Drug or Product Name	Manufacturers	Conditions Prescribed For	Injuries Alleged from Defective Drug/Device	Date of Recall or Warning Change (if applicable)	Screening Criteria
Actos 	Takeda Pharmaceuticals North America, Inc.	Diabetes (Type 2)	Bladder Cancer	17-Sep-10 (FDA Safety Communication Issued); June 15, 2011 (FDA Issues Drug Safety Update)	Use 1 year or more; Diagnosis: Bladder Cancer (all stages).
Antidepressants - Zoloft, Prozac, Celexa 	Pfizer, Eli Lilly; and Forest Pharmaceuticals	Depression and numerous off-label uses	Primary Pulmonary Hypertension, Heart Defects	N/A	Confirmed use of product during pregnancy. Confirmed injury to infant. No other drugs or substances which could be linked to birth defect.
Alloderm Regenerative Tissue Matrix 	LifeCell	Hernia repair; breast reconstruction surgery; pelvic prolapse	Alloderm has failed prematurely resulting in unnecessary surgeries.	N/A	Cases that result in hernia recurrence due to the stretching or thinning out of the Alloderm; cases involving failed pelvic prolapse repair or breast reconstruction due to the stretching or thinning out of the

<p>DePuy ASR</p> <p>Hip Implants</p> 	<p>DePuy Orthopedics</p>	<p>Total Hip Replacement</p>	<p>Device has a high early failure rate. As a result, the device is loosening and in some cases causing metal poisoning requiring revision surgery.</p>	<p>8/24/2010</p>	<p>Any revision or non-revision case.</p>
 <p>DePuy Pinnacle Implants</p>	<p>DePuy Orthopedics</p>	<p>Total Hip Replacement</p>	<p>Device has a high early failure rate. As a result, the device is loosening and in some cases causing metal poisoning requiring revision surgery.</p>	<p>N/A</p>	<p>The original implant must have been implanted after 2005 and have been a metal on-metal model. The client must have had a revision surgery due to device failure (36 mm femoral head cases are best).</p>
<p>Fixodent and Super PoliGrip</p> 	<p>Fixodent - Procter & Gamble; Super PoliGrip - GSK</p>	<p>Over the counter product used to hold dentures in place</p>	<p>Zinc poisoning resulting in neurologic disorders</p>	<p>2/19/2010</p> <p>Super Poligrip</p>	<p>A blood test confirming high zinc and low copper in the consumer. Symptoms include weakness in the extremities and other neurologic symptoms.</p>
 <p>Fosamax</p>	<p>Merck</p>	<p>Postmenopausal osteoporosis</p>	<p>Spontaneous femur fractures</p>	<p>Label updated October 2010 to reflect femur fracture risk</p>	<p>Established use of Fosamax and client suffered a spontaneous femur fracture.</p>

<p>Gardasil Vaccine</p> 	<p>GSK</p>	<p>Prescribed to protect against diseases caused by the Human Papillomavirus (HPV)</p>	<p>Death; stroke; autoimmune diseases; Guillain-Barre syndrome (GBS) and seizures</p>	<p>N/A</p>	<p>Symptoms usually appear within 24-48 hours of vaccine. 3 year statute from date of first vaccination given. 2 years for death cases.</p>
<p>Paxil</p> 	<p>GSK</p>	<p>Depression; Anxiety</p>	<p>Babies born with birth defects</p>	<p>Dec. 8, 2005 FDA warning regarding birth defects (minor tolling applies)</p>	<p>Patient's mother took Paxil and child was born with a congenital heart defect, persistent pulmonary hypertension or other birth defects.</p>
	<p>Ortho-McNeil Janssen Pharmaceuticals</p>	<p>Migraines and numerous off-label uses</p>	<p>with cleft palate; cleft lip, or other oral malformations, hypospadias (congenital malformation of the urethra in boys), and other structural malformations in newborns.</p>	<p>FDA Warning</p>	<p>Child's mother used Topamax during first trimester and child was born with a cleft palate; cleft lip or other oral birth defect, hypospadias (a malformation of the urethra in boys), or any major congenital malformation.</p>
	<p>Johnson & Johnson, Bard,</p>			<p>FDA updated its warning for Transvaginal Mesh on</p>	

 <p>Transvaginal Mesh</p>	<p>American Medical Systems (AMS) and Boston Scientific</p>	<p>Pelvic Organ Prolapse and Stress Urinary Incontinence</p>	<p>The Mesh has failed prematurely causing the mesh to erode and/or shrink leading to infection, pain and additional surgeries.</p>	<p>13-Jul-11</p>	<p>The mesh should have been implanted after 2002. The client must have been free of complications for the first 90 days after implant. A doctor should have indicated that the clients' complications are related to the mesh and that the mesh should be removed, if possible.</p>
<p>Vaccines</p> 	<p>Various manufacturers</p>	<p>Various</p>	<p>An acute adverse reaction to a vaccine, i.e., seizures, Guillain-Barre Syndrome (GBS), death</p>	<p>N/A</p>	<p>The adverse reaction to the vaccine must occur within days/weeks of receiving the vaccination.</p>
	<p>Bayer/Berlex Laboratories</p>	<p>Oral Contraception</p>	<p>Blood clots, Pulmonary Embolism, Deep Vein Thrombosis, Heart Attack, Strokes and Gallbladder injuries</p>	<p>Label change in March 2010.</p>	<p>Blood Clots, Pulmonary Embolisms, Deep Vein Thrombosis, Heart Attack, Strokes or Gallbladder Removal while using Yaz/Yasmin/Ocella Birth Control.</p>
<p>Zimmer Durom Cup</p>	<p>Zimmer Inc.</p>	<p>Total Hip Replacement</p>	<p>Hip socket implant is failing. Patients may be required to undergo hip replacement surgery</p>	<p>24-Jul-08</p>	<p>Evidence that a Zimmer Durom Cup</p>

<p>Hip Socket Implant</p>			<p>as a result.</p>		<p>Implant has failed.</p>
					
<p>Zimmer NexGen Flex Knee Implant or MIS Tibial Tray</p> 	<p>Zimmer Inc.</p>	<p>Total Knee Replacement</p>	<p>The femoral component and/or the tibial component are loosening resulting in revision surgery</p>	<p>9/13/2010 (MIS tibial component only)</p>	<p>The original implant must have been implanted after 2005. The client must have had a revision surgery or have a revision surgery planned.</p>