Life Sciences Litigation

2017 Year-End Update

Walsworth is pleased to provide you with its year-end update regarding life sciences litigation.

Recent Updates in Life Sciences Litigation

Mesh Litigation

- J&J Philadelphia Pelvic Mesh Win Reversed

On July 26, a Pennsylvania state court judge overturned part of a jury verdict that gave Johnson & Johnson (J&J) and its subsidiary Ethicon, Inc., (Ethicon) its first win in the five pelvic mesh cases that have gone to trial in Philadelphia, holding that the jury had been inconsistent in its findings.

The judge's ruling followed a June 9 defense verdict wherein plaintiff Kimberly Adkins claimed that Ethicon's TVT-Secur pelvic mesh, which was implanted in July 2010 to treat her urinary stress incontinence, left her facing a lifetime of chronic pain. Specifically, Adkins alleged that a portion of the implant eroded in her vaginal canal, causing her injuries. The jury agreed that Ethicon had defectively designed the implant and failed to adequately warn of its risks. However, the jury did not believe that Adkins suffered injuries as a result of the defect or of Ethicon's failure to warn.

In post-trial motions, Adkins argued that her two experts and her treating physician testified that the implant caused her injuries. Adkins further argued that the jury's findings were inconsistent. The judge agreed and ordered the case to proceed to a damages hearing. The judge denied Adkins' argument related to one of the jurors.

The defense win for J&J came approximately two months after another Philadelphia jury awarded a plaintiff $20 million, including $17.5 million in punitive damages. In May, another jury awarded a plaintiff $2.1 million for similar claims. In February 2016, a Philadelphia jury also found for a plaintiff, awarding $13.5 million. In the first pelvic mesh trial against Ethicon, in December 2015, a jury added $7 million in punitive damages to a $5.5 million compensatory damages award.

- Endo Pays $775 Million to End Pelvic Mesh Lawsuits

On August 7, Endo International PLC (Endo) reported that it set aside $775 million to resolve its remaining pelvic mesh product liability claims. Endo faced a large number of lawsuits brought by plaintiffs who alleged that Endo's various vaginal mesh implants led them to suffer a wide range of health complications. Endo will start making installment payments in the fourth quarter of this year, continuing until the end of 2019.

Endo's settlement of the nearly 22,000 pelvic mesh cases means it has set aside more than $2.6 billion to resolve cases over its pelvic mesh implants.

- J&J to Pay $57 Million in Philadelphia Pelvic Mesh Trial

On September 7, in the sixth Pennsylvania trial involving Ethicon's TVT-Secur pelvic mesh, a state jury handed down a unanimous $57 million verdict, including $50 million in punitive damages. The jury found that Ethicon defectively designed the pelvic mesh implant that scarred a plaintiff's urethra and left her incontinent.

Plaintiff Ella Ebaugh had Ethicon's TVT-Secur pelvic mesh implanted in 2007 to relieve stress urinary

incontinence. She received a second implant later that year after her condition did not approve. After three years, Ebaugh informed her doctor that she was having sudden urges to urinate and significant pelvic pain. Ebaugh was made aware that the implant had eroded in her urethra and was causing her to suffer severe pain in the pelvic region as well as to experience frequent urges to urinate. Ebaugh underwent a number of operations to remove the defective implant. However, even after multiple operations, the scarring around her urethra was so severe that it left her almost completely incontinent.

Ebaugh alleged that Ethicon was negligent and the implant was defectively designed. Throughout the trial, Ethicon maintained that the implant was not the cause of Ebaugh's injuries. However, the jury unanimously agreed with Ebaugh, finding that the implant had caused internal mutilations that permanently impaired Ebaugh's urinary system.

Ethicon has indicated that it intends to appeal the verdict.

- U.S. Supreme Court Upholds $3.27 Million Pelvic Mesh Verdict

On October 3, the U.S. Supreme Court refused to hear Ethicon's request to overturn a Fourth Circuit decision that upheld a $3.27 million jury verdict in a bellwether trial.

In September 2014, plaintiff Jo Huskey brought suit against Ethicon, alleging that its TVT-O pelvic mesh implant was defectively designed and Ethicon failed to warn of its potential risks. Huskey claimed that the polypropylene mesh in her TVT-O implant eroded, causing her severe, ongoing pain, as the mesh could not be entirely removed through surgery. The jury found in favor of Huskey on all counts, including negligence, strict liability, design defect, and failure to warn. The verdict was upheld by the U.S. District Court in August 2015, and in January of this year, the Fourth Circuit also upheld the verdict, finding that Huskey showed sufficient evidence that the implant caused her injuries.

Ethicon filed a petition for writ of certiori, arguing that the court did not allow Ethicon to introduce the U.S. Food and Drug Administration's (FDA) 510(k) medical device clearance process into evidence during trial. The U.S. Supreme Court declined to review the Fourth Circuit's decision.

- J&J Gets Win in Texas Pelvic Mesh Suit

On November 13, a Texas federal jury cleared J&J and Ethicon of claims brought by a plaintiff who alleged that her injuries, which were allegedly caused by a defective pelvic mesh implant, played a huge role in her divorce.

Plaintiff Cheryl Lankston began suffering from stress urinary incontinence and pain during sexual intercourse in 1996. Lankston claimed that her urinary problems lessened until 2011, at which time she was employed at a job that provided infrequent bathroom breaks. Thereafter, Lankston sought treatment again and was implanted with Ethicon's TVT-S pelvic mesh. Eight weeks later, however, she and her husband both began experiencing pain during sexual intercourse. Lankston argued that the implant was defective in design. Specifically, Lankston argued that the implant should have been designed with a material other than Prolene polypropylene and that Ethicon knew that replacing the heavyweight mesh with a more lightweight mesh such as a product called Ultrapro would have minimized the side effects associated with the implant.

The jury ultimately found for Ethicon, determining that Lankston failed to show there was a design defect in the TVT-S pelvic mesh that was implanted in her. The jury also determined that Lankston failed to provide adequate evidence that Ultrapro was a feasible option.

- Boston Scientific Obtains Dismissal of 370 Pelvic Mesh Lawsuits

On December 14, a West Virginia federal judge dismissed approximately 370 lawsuits pending in multidistrict litigation against Boston Scientific relating to its pelvic mesh implants. The dismissals were issued after the parties filed joint motions for dismissal and are part of a confidential settlement reached between the plaintiffs and Boston Scientific over a year ago.

Boston Scientific has seen a variety of outcomes relating to the pelvic mesh lawsuits filed against it over the past year. In October, the Eleventh Circuit Court of Appeals upheld a $27 million verdict against Boston Scientific in a lawsuit brought in Florida federal court relating to its Pinnacle pelvic mesh implant. In May, however, the Fourth Circuit Court of Appeals upheld a North Carolina federal court's dismissal of claims brought against Boston Scientific relating to its Uphold pelvic mesh implants. Thousands of lawsuits against Boston Scientific remain pending in state and federal courts nationwide.

- New Jersey State Jury Hits J&J With $15 Million Pelvic Mesh Verdict

Also on December 14, J&J and Ethicon were hit with a $15 million verdict by a New Jersey state jury regarding claims that Ethicon's pelvic mesh implants caused a plaintiff's injuries. The verdict included $10 million in punitive damages and $5 million in compensatory damages to plaintiffs Elizabeth and Tad Hrymoc.

In 2008, plaintiff Elizabeth Hrymoc had Ethicon's Prolift pelvic mesh implanted to treat a pelvic prolapse and Ethicon's TVT-O pelvic mesh implanted to treat her stress urinary incontinence. Hrymoc, who was 62 when she had the pelvic mesh implanted, claimed she suffered chronic pain after the procedure, including vaginal pain and pain when having intercourse.

The Hrymocs' lawsuit alleged the Ethicon implants contained a design defect and that Ethicon failed to warn of known risks. In its verdict, the jury found that the warnings for both implants were inadequate but determined that only the Prolift implant caused Hrymoc's injuries.

The Hrymocs' lawsuit is just the second pelvic mesh case against Ethicon to go to trial in New Jersey, where Ethicon is headquartered. In March 2016, a New Jersey appeals court upheld a jury's $11.1 million award to the plaintiffs in the first pelvic mesh implant trial, and the New Jersey Supreme Court declined to review that decision.

Da Vinci Surgical System Litigation

- Georgia District Court Dismisses Suit Against Intuitive

On August 7, the Eleventh Circuit Court of Appeals found that a Georgia District Court was correct to dismiss a lawsuit brought by a potential class of heart surgery patients, holding that the plaintiffs could not prove they suffered an injury simply because Intuitive Surgical, Inc.'s (Intuitive) da Vinci surgical robot left metal fragments in their brains.

Plaintiffs Gabriel Fernando Nassar Cure and Dr. Alam M. Kozarsky, Georgia residents, brought suit against Intuitive, claiming that Intuitive designed, manufactured, marketed, and sold defective medical instruments. Shortly after undergoing mitral valve surgery during which the da Vinci surgical robot was used, the plaintiffs discovered that they had metallic debris in their brains. The plaintiffs alleged that the metal fragments were discharged from the robot, got into their bloodstreams, and became lodged in their brains.

The Court of Appeals upheld the District Court's ruling to dismiss the plaintiffs' lawsuit, finding that the plaintiffs failed to appropriately allege an injury. Specifically, the court held that the plaintiffs failed to plead any allegations regarding symptoms and/or

injuries caused by metal in their brains, including that symptoms could lead to future medical costs or lost work.

Hip Implant Litigation

- J&J to Pay $247 Million in Texas Hip Implant Case

On November 16, a federal jury in Texas ordered J&J and its subsidiary DePuy Orthopedics, Inc., (DePuy) to pay a combined $246 million, which included $90 million in punitive damages against J&J and $78 million in punitive damages against DePuy, in a trial over DePuy's line of Pinnacle metal-on-metal hip implants.

The plaintiffs, six New York residents, alleged that the Pinnacle hip implant caused them to experience tissue death, bone erosion, permanent muscle loss, intense pain, and loss of hip movement, among other injuries. The plaintiffs claimed DePuy falsely promoted the implant, most commonly used to treat joint failure caused by osteoarthritis, by saying it lasted longer than similar implants that include ceramic or plastic materials. The jury sided with the plaintiffs, finding J&J and DePuy liable for design defect, negligent misrepresentation, fraudulent concealment, intentional misrepresentation, failure to provide adequate warnings, manufacturing defect, and deceptive business practices.

J&J and DePuy currently face nearly 9,000 Pinnacle lawsuits now pending in the U.S. District Court for the Northern District of Texas. J&J and DePuy were found liable in another Texas trial in December 2016, during which a jury awarded more than $1 billion in punitive damages, a verdict that was later reduced to $573 million. Another trial ended last year in a $500 million verdict for the plaintiffs, though that award was also reduced, to $150 million.

Risperdal Litigation

- Mississippi Supreme Court Reverses $2 Million Risperdal Verdict Against J&J

On October 19, the Mississippi Supreme Court reversed a $2 million judgment of a lower court against J&J and its subsidiary Janssen Pharmaceuticals (Janssen) over a movement disorder allegedly caused by the antipsychotic medication Risperdal.

In 1998, a psychiatrist prescribed Risperdal for plaintiff Louise Taylor to treat her severe depression and psychosis. From 1998 to 2001, Taylor's psychiatrist continued to prescribe Risperdal, increasing Taylor's dosage of the medication multiple times. In February 2001, Taylor developed tardive dyskinesia, a syndrome of involuntary movements in patients treated with antipsychotic drugs. In 2002, Taylor filed a lawsuit, claiming that Risperdal caused her to develop the condition. The jury, in a 9-3 decision, found that Taylor was harmed by Risperdal due to (1) Janssen's failure to provide adequate warning and (2) Janssen's negligent marketing/misrepresentation. The jury awarded Taylor a total of $1.95 million in damages.

On review, the Mississippi Supreme Court determined that, as a matter of law, the Risperdal in question contained an adequate warning. Specifically, the label provided clear warnings to physicians that tardive dyskinesia is a potential side effect of Risperdal. Accordingly, the court reversed the jury's verdict.

- Pennsylvania Court Reverses Risperdal Defense Verdict

On November 14, a unanimous three-judge panel reversed Janssen's only defense verdict in the Philadelphia Risperdal mass tort litigation, finding that the trial court erred in allowing a physician's assistant, Michelle Baker, to provide expert testimony at trial.

Plaintiff W.C., a young male, filed a lawsuit against Janssen, alleging that its antipsychotic drug Risperdal caused his gynecomastia, a condition where males grow excess breast tissue. During the trial, a physician's assistant who assisted in W.C.'s treatment, Baker, testified that rapid weight gain, not Risperdal, caused W.C.'s enlarged breasts, because he had stopped taking Risperdal some years before. Thus, Baker opined, the level of hormones associated with breast growth and believed to be affected by Risperdal would have returned to normal.

The appellate court determined that the trial court erred in permitting Baker, a lay witness, to offer expert testimony at trial. Baker's opinion was "offered without the proper vetting and safeguards surrounding expert testimony." The appellate court noted that Baker's testimony strongly affected the trial, as it was the only testimony provided in support of causation by a witness who had personally treated W.C.

More than 5,500 cases remain pending in Philadelphia against Janssen over its alleged failure to warn about the link between Risperdal and gynecomastia. More than five Risperdal cases have come before juries in Philadelphia, and, although two cases were dismissed midtrial, the verdict against *W.C.* is the only defense verdict to date.

Depakote Litigation

- Abbott to Pay $15 Million in Depakote Trial

On June 9, a federal jury in Illinois awarded $15 million to a 10-year-old boy whose mother blamed his birth defects on her use of Abbott Laboratories, Inc.'s (Abbott) bipolar disorder drug Depakote while she was pregnant.

Stevie Gonzalez's mother, Christina Raquel, claimed that the doctors who prescribed Depakote to treat her bipolar disorder were unaware that the risk of her having a child born with spina bifida was greater than 10 percent because of the drug's active ingredient, valproic acid. The label provided to the doctors who prescribed the medication to Raquel inaccurately showed the risk of spina bifida was only 1 to 2 percent. Gonzalez's attorneys argued that Abbott failed to update its label to include the high risk of spina bifida.

The jury agreed, finding Abbott liable for $15 million to cover Gonzalez's future medical expenses as well as loss of future earnings. The jury, however, declined to award punitive damages against Abbott in a separate proceeding that immediately followed the verdict.

Abbott faces hundreds of lawsuits in which it stands accused of concealing Depakote's links to birth defects.

- $38 Million Verdict Against Abbot Confirmed by Missouri Supreme Court

On September 14, the Missouri Supreme Court affirmed a $38 million verdict, including $23 million in punitive damages, against Abbott.

The plaintiff, 12-year-old Maddison Schmidt, alleged she was born with spina bifida and is paralyzed and confined to a wheelchair due to her mother's use of Depakote in 2002 while she was pregnant with Schmidt. Similar to other suits brought by various plaintiffs, Schmidt's suit alleged that the 2002 Depakote label did not adequately warn that a significant percentage of babies exposed to Depakote while in the womb could develop spina bifida or other medical problems.

In May 2015, a St. Louis jury awarded $15 million in compensatory damages and $23 million in punitive damages to Schmidt after finding that Abbott had failed to warn her mother about the risk of birth defects with the use of Depakote. The Supreme Court of Missouri upheld the jury's award, finding that there was evidence Abbott knew the birth defect risks surpassed what it listed on the warning

labels.

- Abbott Escapes Autism Claim in Depakote Suit

On November 15, an Illinois federal judge granted Abbott's motion for partial summary judgment, barring a plaintiff from alleging his in utero exposure to Depakote caused him to develop autism, citing the grounds that the claims were unsupported by expert testimony.

Plaintiff Beatrice Sifuentes, a caretaker, argued that in utero use of Depakote caused child J.F.'s spina bifida, craniofacial dysmorphia, clubfoot, scoliosis, and developmental delay, among other things. The judge found that Sifuentes failed to provide expert testimony in opposition to Abbott's motion for partial judgment to prove proximate causation. "[A]n autism-related claim necessarily fails in the absence of any other expert evidence supporting . . . [the] causation theory."

The judge acknowledged that in light of this ruling, Sifuentes may have issues attempting to block Abbott from arguing that J.F.'s autism was actually responsible for some of the issues blamed on Depakote. The judge, however, declined to make a ruling regarding this issue and noted she would make a ruling at a later time.

Xarelto/Eliquis Litigation

- Bayer and Janssen Win in Second Xarelto Trial

On June 13, a Louisiana federal jury cleared Bayer Healthcare Pharmaceuticals, Inc., (Bayer) and Janssen of liability in the second bellwether trial in multidistrict litigation over unstoppable bleeding allegedly caused by the blood thinner Xarelto. The drug manufacturers received their first win in a Xarelto trial in May.

Widower Joseph Orr claimed the drug manufacturers were responsible for the acute brain hemorrhage that killed his wife, Shayrnn Orr, who was 67 at the time of her death, because they failed to warn doctors of Xarelto's dangers. Before she died, Orr was in a coma for 10 days. The drug manufacturers argued that Orr had several underlying conditions not related to her use of Xarelto that ultimately contributed to her death and that Xarelto was not to blame.

The jury found that the drug manufacturers did not fail to provide Orr's doctors with adequate instructions for the safe use of Xarelto.

- Bayer and Janssen Win in Third Xarelto Trial

On August 18, a Mississippi federal jury gave Bayer and Janssen their third win in a bellwether trial over claims that the drug manufacturers failed to provide adequate warnings of the possibility of dangerous internal bleeding associated with the blood thinner Xarelto.

Plaintiff Dora Mingo had hip replacement surgery and developed deep vein thrombosis (DVT) thereafter. To treat her DVT, Mingo was prescribed Xarelto. Shortly after taking Xarelto, Mingo alleges she suffered from gastrointestinal bleeding and anemia. Mingo claimed that the drug manufacturers knew of the risks of internal bleeding in patients taking Xarelto yet failed to provide adequate warnings to doctors and patients regarding the risks associated with the medication. The jury found that although Xarelto led to Mingo's gastrointestinal bleeding, the drug manufacturers did not fail to provide Mingo's doctors with adequate instructions for its use.

Immediately following the jury's verdict, Mingo moved for a new trial. In her motion, Mingo argued that as her trial was closing, a new study conducted and co-authored by "leading Bayer scientists" was released and directly contradicted the drug manufacturers' contention at trial that the anticoagulant effect of Xarelto cannot be monitored with standard laboratory testing. On December 14, a Louisiana federal judge denied Mingo's motion, specifically rejecting that the new study could have

changed the jury's mind. The ruling stated, "[t]he article in question does not contain new information. This new article is simply a restatement of Defendants' scientists' prior positions."

- Pennsylvania Judge Finds Xarelto Claims Are Not Preempted

On November 2, a Philadelphia judge refused to grant Bayer and Janssen's motion for partial summary judgment, finding that the plaintiffs' failure-to-warn claims in a mass tort program over the blood thinner Xarelto were not preempted by federal law.

In their motion, the drug manufacturers argued that there was "clear evidence" that the FDA would not have upheld a proposal to include different warnings about the risks of bleeding in various groups. The plaintiffs argued, however, that this was an inappropriate issue to be resolved with a dispositive motion and the issue needed to be left for the jury to decide.

The judge issued a one-page ruling, rejecting the drug manufacturer's argument that the plaintiffs' claims were preempted. The ruling affects all cases in the mass tort programs, in which approximately 1,500 cases are pending.

- New York Judges Dismisses 24 Complaints in Eliquis Multidistrict Litigation

On November 29, a New York federal judge dismissed 24 new complaints filed in the multidistrict litigation over claims that Pfizer, Inc., (Pfizer) and Bristol-Myers Squibb Co. (BMS) failed to warn of the risks associated with its blood thinner Eliquis, holding that the claims were preempted by federal law.

The judge dismissed the claims based on the decision in *Utts v. BMS & Pfizer,* in which the court held that federal law banned the two companies from changing their labels. In July, the court dismissed another claim brought by a Tennessee woman against Pfizer and BMS, finding that the label on Eliquis was adequate. Since this decision, the court has dismissed numerous complaints.

- Pennsylvania Jury Returns $28 Million Verdict Against Bayer and Janssen

On December 5, a Philadelphia jury handed Bayer and Janssen their first loss associated with the blood thinner Xarelto.

Plaintiff Lynn Hartman was prescribed Xarelto to prevent strokes as a result of atrial fibrillation, an irregular heartbeat. She took the drug for approximately one year before she was hospitalized with severe gastrointestinal bleeding, which she blamed on Xarelto.

Hartman claimed that the drug manufacturers failed to include information on the label that the rate of bleeding events observed in a clinical trial was significantly higher in the U.S. than in patients elsewhere worldwide (8.1 percent in the U.S. versus 3.6 percent elsewhere). The jury agreed, finding that the drug manufacturers provided inadequate warnings about the risks associated with the use of Xarelto.

The trial was the first of roughly 1,400 Xarelto cases pending in the Philadelphia court. There are, however, various other suits pending throughout the nation, including nearly 18,500 cases in multidistrict litigation at the U.S. District Court for the Eastern District of Louisiana.

Testosterone Replacement Drugs

- AbbVie to Pay $150 Million in Punitive Damages for False AndroGel Ads

On July 24, an Illinois federal jury found that AbbVie, Inc., (AbbVie) must pay $150 million in punitive damages to an Oregon plaintiff who accused the drug manufacturer of hiding the heart attack risks associated with its testosterone replacement drug,

AndroGel.

Jesse Mitchell, 54, used AndroGel for approximately four years, beginning in 2008. In 2012, Mitchell allegedly suffered a near-fatal heart attack due to his use of the medication. He claimed that the drug manufacturer understated the risks of testosterone replacement and failed to ensure the drug was safe, at the same time marketing the drug to men whose dips in testosterone were associated with age and/or obesity.

The jury concluded that Mitchell's heart attack was not caused by AbbVie's negligence; however, the jury did award punitive damages, finding that the drug manufacturer had misrepresented the danger posed to patients who used AndroGel.

- AbbVie Wins First AndroGel Suit in Illinois State Court

On August 31, a jury rejected a plaintiff's claim that AbbVie failed to warn him and his doctors of the risks associated with his use of AndroGel.

James Couch, a citizen of Oklahoma, had been suffering from a wide variety of symptoms that he attributed to low levels of testosterone. After he saw various advertisements for the testosterone replacement drug AndroGel, Couch requested a prescription. After multiple uses of AndroGel, Couch alleged he suffered a heart attack.

The heart attack ultimately led to Couch needing surgery to implant a defibrillator in his chest. AbbVie claimed that Couch's use of AndroGel was minimal, arguing that Couch filled his prescription only twice between when he received it and his heart attack. AbbVie further argued that Couch had stopped using AndroGel at least two months prior to his heart attack. The jury ultimately sided with AbbVie, finding AbbVie was not liable for Couch's injuries.

Couch's lawsuit is one of about 150 in Cook County, Illinois, state court involving testosterone side effects.

- AbbVie to Pay More Than $140 Million to AndroGel User

On October 5, an Illinois federal jury awarded a Tennessee plaintiff more than $140 million because he suffered a heart attack following his use of AndroGel.

Jeffrey Konrad, 56, suffered a heart attack in 2010 after three months of taking AndroGel. Konrad argued that AbbVie had evidence that linked testosterone to cardiovascular events. Rather than doing the proper testing, AbbVie chose to promote sales. During the trial, AbbVie argued that there were several other factors that could have caused Konrad's heart attack. Among these factors, AbbVie argued that Konrad was obese, had high blood pressure, and had a family history of heart attacks.

The jury disagreed with Konrad's claims that the use of AndroGel caused his heart attack; however, it did find in favor of Konrad on his claims of negligence, intentional misrepresentation, and misrepresentation by concealment, finding that AbbVie had failed to appropriately test AndroGel for cardiovascular risks and misrepresented that it was safe. The jury awarded Konrad $140,000 in compensatory damages as well as an additional $100,000 for pain and suffering. The jury also awarded $140 million in punitive damages.

- Auxilium Gets Win in First Testim Bellwether Trial

On November 16, an Illinois federal jury found in favor of defendant Auxilium Pharmaceuticals, LLC, (Auxilium) in the first multidistrict bellwether trial involving Testim, a testosterone replacement therapy drug. The jury rejected plaintiff Steve Holtsclaw's claim that the use of Testim caused his injuries.

After suffering from fatigue and learning that his

testosterone levels were low, Holtsclaw was prescribed Testim. In 2015, approximately seven months after he began using Testim, Holtsclaw suffered a heart attack at the age of 59. Testim's label listed various conditions it could be used for; however, the label did not include use for drop in testosterone due to age. Holtsclaw's attorneys pointed to various studies that showed giving testosterone to men increased their chances of having a heart attack. Holtsclaw alleged claims for strict liability, negligence, intentional misrepresentation, and misrepresentation by concealment against Auxilium. Based on the evidence presented, however, the jury found that Testim did not cause Holtsclaw's heart attack.

Holtsclaw's lawsuit is one of more than 6,000 brought against Auxilium over similar claims.

Talc Powder Litigation

- J&J Gets Reversal of $72 Million Verdict in Missouri Talc Cancer Case

On October 17, J&J won a reversal of a $72 million verdict in favor of the family of a woman who allegedly died from ovarian cancer after using J&J's talc-based products.

The family of deceased plaintiff Jacqueline Fox, who died at the age of 62, alleged that Fox had been using Johnson's Baby Powder and Shower to Shower for feminine hygiene for more than 35 years. The Missouri federal jury found J&J liable for negligence, conspiracy, and fraud. The verdict included $10 million in actual damages and $62 million in punitive damages.

The Missouri Court of Appeals based its reversal of the verdict on a recent U.S. Supreme Court decision in *Bristol-Myers Squibb vs. Superior Court of California,* which stated that state courts could not hear claims by nonresidents who were not injured in that particular state and where the defendant company was not based in that state. Based on this recent holding, the Court of Appeals found that Alabama resident Fox's case should not have been tried in Missouri.

Fox's estate recently asked the Missouri Court of Appeals to reconsider its decision to reverse the verdict. The estate argued that it did not contest the court's interpretation of the ruling in *Bristol-Myers Squibb*; however, "fundamental fairness and due process" required the case to be remanded to the trial court to allow Fox to present new evidence to support jurisdiction under the new standard.

- Judge Tosses $417 Million Talc Cancer Verdict in California

On October 21, a Los Angeles Superior Court judge reversed a $417 million verdict against J&J in a lawsuit filed by a California woman who alleged she developed ovarian cancer after using J&J's talc-based products for feminine hygiene.

In August, a jury issued a $417 million verdict, including $70 million in compensatory damages and $347 million in punitive damages, against J&J, finding that the company failed to warn 63-year-old plaintiff Eva Echeverria about the risks of using its talcum products. Echeverria was diagnosed with ovarian cancer in 2007. Echeverria died before the verdict was decided.

California Superior Court Judge Maren Nelson reversed the verdict, finding that Echeverria had relied on speculative expert testimony that failed to connect J&J's actions to those of its subsidiary, which manufactured and marketed the product. Under California law, the parent company, which is legally an entity separate from its subsidiary, cannot be held liable for a failure to warn if it did not manufacture and/or market the product. The judge also found that there was insufficient evidence that either J&J or its subsidiary acted with malice.

- J&J Gets Defense Verdict in California Mesothelioma Case

On November 16, a Los Angeles jury sided with J&J and Imerys Talc America, Inc., (Imerys) in the first trial over whether their baby powder caused a plaintiff's mesothelioma, an asbestos-related cancer.

Plaintiff Tina Herford alleged that she developed mesothelioma after using J&J talcum products, which she claimed contained asbestos. Hertford alleged she used Johnson's Baby Powder in the 1950s, Shower to Shower for decades up to the 1980s, and then the Johnson's Baby Powder again on her daughters starting in the 1980s and lasting until the early 1990s. Herford's attorneys argued that Herford breathed in the talc product after every use and after every diaper change for decades. The jury sided with J&J, finding that J&J was not negligent, the talc products were not defective, and J&J did not fail to warn of its potential risks.

J&J faces lawsuits by over 5,000 plaintiffs asserting talc-related claims nationally, largely based on claims that it failed to warn women about the risk of developing ovarian cancer from the products.

Herbal and Dietary Supplement Litigation

- GNC's Motion to Dismiss Consumers' Suit Over Glutamine Labels Denied

On July 19, a Florida federal judge denied General Nutrition Center's (GNC) motion to dismiss a putative class action lawsuit brought by consumers alleging that the company used misleading labels on its glutamine supplements that claimed the products had specific effects when scientific studies suggested otherwise.

In its motion, GNC argued that the studies the plaintiffs relied upon did not directly apply in the case because the plaintiffs failed to specifically test GNC's glutamine supplements, their specific dosages, and methods of ingestion. GNC also argued that since the lead plaintiff purchased only one of the many glutamine supplements, a class action lawsuit relating to all of GNC's glutamine supplements could not be maintained. The judge rejected this claim, finding that the products were all essentially the same because they all contained the same active ingredient.

- Settlement in Place for Herbal Supplement Cases

The plaintiffs involved in the multidistrict litigation involving various herbal supplements sold at Walgreens, Wal-Mart, and Target have agreed to a settlement for an undisclosed amount to end their claims. The settlement will resolve 56 cases that consumers brought against the three retailers and herbal supplement manufacturer NBTY, Inc., (NBTY) over misleading labels on the supplements made by NBTY and sold in the retailers' stores.

In filing their lawsuits, the plaintiffs primarily relied on a study done by the office of the New York attorney general, Eric Schneiderman, who conducted tests on the various herbal supplements purchased from the retailers and found that the majority of these supplements did not contain the amount of herbs advertised on the label. The study showed the products contained various fillers, including rice, beans, pine, citrus, and wheat, none of which were listed on the labels.

The parties have not disclosed any details of the settlement.

Trends in Life Sciences

- FDA Finalizes Guidance on Use of Real-World Evidence in Regulatory Decision-Making

On August 31, the FDA released final guidance on medical device companies' use of real-world data (RWD) and real-world evidence (RWE) in gaining FDA approval for their medical devices. The FDA's purpose of issuing this guidance was to explain the

"characteristics and sources of RWD and characteristics of RWE that may be sufficient for use in making various regulatory decisions."

The FDA defines RWE as evidence derived from the aggregation and analysis of RWD elements sourced outside traditional clinical trials. These include but are not limited to large sample trials, pragmatic clinical trials, prospective observational or registry studies, retrospective database studies, case reports, administrative and health care claims, electronic health records, data obtained as part of a public health investigation or routine public health surveillance, and registries (e.g., device, procedural, or disease), and also from electronic systems used in health care delivery that contain data in medical devices.

The FDA says that RWD and RWE could constitute valid scientific evidence if they meet standards of relevance and reliability. Relevance can be assessed either prior to a regulatory submission, such as via the presubmission process, or during the regulatory review process. Reliability will be determined based on how the data is collected (data accrual); whether the data collected is complete, accurate, and adequate for answering the question at hand (data adequacy); and whether the people and processes in place during data collection and analysis provide adequate assurance that bias is minimized and data quality and integrity are sufficient (data assurance).

- FDA Expands Guidance on Drug Prices

On October 2, the FDA released two new draft guidance documents that are intended to lessen the obstacles to various generic drugs entering the market and ultimately to reduce drug prices. The draft guidance documents focus on complex generics, which include generics that have complicated ingredients or require use of unique delivery devices and are hard to manufacture.

The first draft guidance, *ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin*, focuses on peptide drug products. Specifically, the draft guidance provides advice to prospective applicants to determine when an abbreviated new drug application (ANDA) can be submitted for five different types of peptide products. The FDA's hope is that compared to the longer and more traditional new drug application process, ANDAs will allow more generic products to enter the market.

The second draft guidance, *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA*, discusses opportunities for prospective ANDA applicants for complex drug products to have meetings with the FDA. The draft guidance provides details for a wide variety of meetings that may be requested. These include product development meetings, presubmission meetings, and mid-review-cycle meetings.

President Donald Trump emphasized the importance of reducing drug prices during his presidential campaign. The FDA commissioner, Dr. Scott Gottlieb, has also been very open in his discussions regarding drug prices.

- FDA Finalizes Guidance on When to Submit a New 510(k)

On October 25, the FDA released two final guidance documents. The first, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, applies broadly to medical device changes, and the second, *Deciding When to Submit a 510(k) for a Software Change to an Existing Device*, focuses on software-specific changes and complements the broader guidance document.

As medical device technology continues to change, the FDA issued these guidance documents to provide recommendations to assist manufacturers in determining when a proposed change in a legally marketed medical device would require the manufacturer to submit a premarket 510(k) notification to the FDA. The guidance documents

include a clarification of key terms, explanations of how to use the risk assessment to evaluate whether a change requires a new 510(k), harmonization of flowcharts with the text of the guidance, examples of device changes that would or would not require a new 510(k), and recommendations for documenting decisions about whether to submit a new 510(k) for a device change.

- FDA Finalizes Guidance on de Novo Classification Process and Draft Guidance Regarding de Novo Submission Acceptance Review

On October 30, the FDA issued guidance documents outlining the process for submitting and reviewing de novo classification requests.

In 1997, the Food and Drug Administration Modernization Act (FDAMA) added the de novo classification process to establish an alternative pathway to classify new devices that had automatically been placed into Class III after receiving a not substantially equivalent (NSE) determination in response to their premarket 510(k) submissions. Manufacturers that receive a NSE may consider filing a de novo submission, which allows for a Class I or Class II classification for medical devices that provide a reasonable assurance of safety and effectiveness.

According to the FDA, there are two options for de novo classification:

1. A manufacturer that receives a NSE determination in response to a 510(k) submission may submit a de novo request for the FDA to make a risk-based evaluation for classification of the device into Class I or II.

2. A manufacturer that determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a de novo request for the FDA to make a risk-based classification of the device into Class I or II without first submitting a 510(k) and receiving an NSE determination.

The guidance documents are meant to provide updated recommendations for interacting with the FDA.

- FDA Finalizes Guidance for Sharing Patient-Specific Information From Medical Devices

On October 30, the FDA released final guidance outlining its policy on medical device manufacturers sharing with patients patient-specific information from devices when the patients request it.

In response to the more active roles patients are playing in their health care and the increased rate at which patients are asking device manufacturers for information that has been recorded, processed, or stored on medical devices, the FDA provided clarification of a device manufacturer's responsibility with respect to such requests. The guidance clarifies that a device manufacturer *may* provide patient-specific information to patients who request it, but the manufacturer is not obligated to do so under the Food, Drug, and Cosmetic Act (FDCA). The FDA further specified that a device manufacturer's responsibility to provide patient-specific information under the act is distinct and separate from its obligation to provide patients with protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA), and the HIPAA Privacy Rule.

For the purpose of this guidance, FDA defines "patient-specific information" as "information [that is] unique to an individual patient or unique to that patient's treatment or diagnosis that has been recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device."

- Drug Manufacturers and Distributors Face Large Volume of Lawsuits Over Opioid Epidemic

Companies that manufacture and distribute addictive painkillers are facing a large number of lawsuits for the alleged role their products have played in various communities across the country. Opioids are prescription narcotics possessing properties similar to those of opium and heroin.

State attorneys general, local governments, and other public entities nationwide have filed lawsuits in both state and federal courts. Claims against distributors allege violations of the federal Controlled Substances Act by failing to alert the U.S. Drug Enforcement Administration (DEA) of suspicious opioid purchases (e.g., unusual size, frequency, and patterns of purchases). Claims against manufacturers allege that the companies exaggerated the benefits of the drugs and knew the drugs were overly prescribed yet failed to warn doctors of their addictive nature and the need to strictly limit the dose. The lawsuits further allege that manufacturers and distributors put profits over patients by pushing sales rather than regulating the market.

Many have compared the rise in opioid litigation to the legal tactics that were pioneered by the state of Mississippi in a case against Big Tobacco, which settled for a record $26 billion in 1998.

- Jurisdictional Issues

This year, the U.S. Supreme Court issued two opinions clarifying the requirement for establishing personal jurisdiction over out-of-state defendants, particularly where the forum in which the suit is brought had no relationship to the events in question. In determining whether the court has personal jurisdiction over a claim, courts have recognized two types of jurisdiction: (1) general jurisdiction and (2) specific jurisdiction.

- General Personal Jurisdiction

BNSF Railway Co. v. Tyrrell

In May 2017, the U.S. Supreme Court decided *BNSF Railway Co. v. Tyrrell* (BNSF) (2017) 137 S.Ct. 1549, finding that a court may assert general jurisdiction over a foreign (sister-state or foreign country) corporation only when the corporation is "at home" in the forum state.

BNSF involved cases brought in Montana state courts under the Federal Employers Liability Act (FELA), which permits railway workers injured on the job to sue their employer. The plaintiffs who brought the claims did not reside in Montana, nor were they injured in Montana. BNSF, however, did substantial business in Montana, with more than 2,000 miles of track and 2,000 employees.

The Montana Supreme Court found that state law permitted general jurisdiction based upon the defendant's level of activity in Montana. However, because BNSF was neither incorporated in Montana nor had its principal place of business in the state, the U.S. Supreme Court reversed, holding that activity-based general jurisdiction wasn't indicated because BNSF had similar levels of activities in many states.

- Specific Personal Jurisdiction

Bristol-Myers Squibb Co. v. Superior Ct. of Calif.

In June 2017, the U.S. Supreme Court decided *Bristol-Myers Squibb Co. v. Superior Court of California* (2017) 137 S.Ct. 1773, finding that California courts lacked jurisdiction to hear nonresidents' claims in a class action alleging they were injured by Plavix, a blood thinner manufactured/sold by BMS.

The case was filed in California state court by a group of over 600 plaintiffs, only 86 of whom were California residents. The plaintiffs who resided outside California did not claim to have purchased Plavix from any California source and did not claim

that they were injured by Plavix in California.

In a 8-1 decision, the U.S. Supreme Court held that California courts did not have specific personal jurisdiction over the nonresidents' claims, as they were not prescribed Plavix in California, did not purchase the drug in California, and were not injured by the drug in California. The opinion noted that it was not sufficient, or even relevant, that BMS conducted research in California on matters unrelated to Plavix, as a connection between the forum and the specific claims at issue was still missing.

> Application of Cases

Since these rulings, various courts have dismissed cases for lack of personal jurisdiction.

In June, a Missouri judge granted a motion to dismiss in a case involving 94 plaintiffs, 86 of whom were not Missouri residents, finding that although defendant Boehringer Ingelheim Pharmaceutics, Inc., (BIPI) marketed and sold their drug in Missouri, the nonresident plaintiffs did not ingest the drug in the forum, nor do they claim to have suffered resulting injuries in the forum.

In September, another Missouri court granted a motion to dismiss filed by J&J, which involved 83 plaintiffs, only two of whom were Missouri residents. J&J removed the case to federal court and moved to dismiss the non-Missouri plaintiffs on the grounds that the Missouri court had no basis for asserting personal jurisdiction over the defendants in Missouri.

As discussed above, in October, J&J won an appeal that reversed a $72 million jury verdict in a Missouri federal talc cancer case on the grounds that the court lacked personal jurisdiction to hear the case.

In November, however, a Missouri court upheld a $110 million jury verdict in a talc cancer case, finding that the plaintiff met the jurisdictional standards because the defendant used a Missouri-based company to manufacture, label, and package the products at issue.

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About Walsworth

Walsworth was founded in 1989 with a commitment to establish a law firm focused on working collaboratively with clients to meet their unique objectives. The firm has since grown to more than 75 attorneys with offices in Orange, Los Angeles, and San Francisco and is known for excellence in litigation and transactional matters. We are equally distinct in our long-standing commitment to diversity, which is recognized through our certification as a Women's Business Enterprise (WBE) by the Women's Business Enterprise National Council and the California Public Utilities Commission, and we are proud to be the largest certified WBE law firm in the United States. Walsworth is also a National Association of Minority and Women Owned Law Firms (NAMWOLF) member, the largest in California and the third-largest nationwide. For more information, visit www.wfbm.com.