Life Sciences Litigation

2018 Year-End Update

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

Recent Updates in Life Sciences Litigation

Pelvic Mesh Litigation

- New Trial Ordered in Pennsylvania Pelvic Mesh Case

On November 8, a Pennsylvania state judge ordered a new trial in a case in which a woman alleged she was injured by a pelvic mesh implant produced by Johnson & Johnson (J&J) and its subsidiary Ethicon, Inc. (Ethicon). In her lawsuit, plaintiff Kimberly Adkins claimed that Ethicon's TVT-Secur pelvic mesh, which she had implanted in July 2010 to treat urinary stress incontinence, left her facing a lifetime of chronic pain. Adkins alleged that a portion of the device eroded in her vaginal canal, causing her injuries.

In 2017, the jury ruled that the TVT-Secur device was defective in design and that Ethicon did not properly warn of the risks of using the device. However, the same jury also determined that neither the warnings nor the design defect caused Adkins' injuries.

In post-trial motions, Adkins argued that both her expert and her treating physician testified that the pelvic mesh caused her injuries. Thus, Adkins further argued the jury's findings were inconsistent with the evidence. In July, the judge agreed with Adkins and overturned that part of the jury's verdict. In his latest ruling, the judge said that a new trial "should not be limited to the issues of compensatory and punitive damages" alone, but also involve "the re-litigation on the issue of the appellants' liability for design defect."

No date has been set for the new trial.

- Mistrial Announced in Pennsylvania Pelvic Mesh Case

On September 24, a Pennsylvania state court trial relating to a J&J and Ethicon pelvic mesh implant ended with a hung jury.

Plaintiff Susan McFarland, 67, was implanted with Ethicon's Tension Free Vaginal Tape-Obturator (TVT-O) pelvic mesh on April 3, 2008. After the implantation, McFarland began to experience vaginal pain and bleeding, urinary tract infections, and dyspareunia. McFarland underwent a revision surgery on September 29, 2009. Despite the revision surgery, McFarland alleged she continued to experience severe complications due to the device.

After four days of deliberation, the trial concluded with the jury declaring a deadlock. Although the jury agreed that the device had been negligently designed, the jury could not agree on whether the design defect caused McFarland's injuries.

It is currently unclear when McFarland's case will be retried.

- Boston Scientific Gets Third Win in Massachusetts Pelvic Mesh Trial

On June 15, Boston Scientific got its third win in Massachusetts state court in a products liability case brought over two of its pelvic mesh implants.

Plaintiff Ana Martinez, who resides in Nevada, sued Boston Scientific in 2012, alleging that its Pinnacle Pelvic Floor Repair Kit and Obtryx Sling System-

Halo caused her injuries. Martinez was implanted with the two Boston Scientific pelvic mesh implants in December 2010—Pinnacle to treat her pelvic organ prolapse and Obtryx for her stress urinary incontinence. Martinez alleged that Boston Scientific failed to warn her treating physician about the long-term side effects of the devices. In response, Boston Scientific produced evidence of its warnings relating to the pelvic mesh.

After a 16-day trial, the jury found that the Pinnacle and Obtryx devices were not defectively designed and that Boston Scientific did not fail to warn of the devices' risks.

- Bard Ordered to Pay $68 Million Following First New Jersey Pelvic Mesh Trial

On April 12, a New Jersey state jury awarded $35 million as punitive damages to a plaintiff a day after the jury had awarded $33 million as compensatory damages to plaintiff and her husband. The jury found that C.R. Bard, Inc.'s (Bard) Avaulta Solo Support System and Align TO Trans-Obturator Pelvic Support System were defectively designed and that the defect was the cause of plaintiff's injury.

Plaintiff Mary McGinnis was implanted with both devices in 2009 to treat bladder prolapse and stress urinary incontinence. McGinnis claimed that she subsequently developed problems and that two doctors found that the polypropylene mesh used in the devices cut into her vagina. McGinnis underwent multiple revision surgeries to cut away the exposed mesh.

At trial, Bard argued that both pelvic mesh devices were safe and effective as designed and were adequately and properly tested. Bard further argued that polypropylene is a "surgical medical necessity," and that the devices' warnings and instructions were adequate.

Nonetheless, the jury found that the devices both contained inadequate warnings and that the inadequate warnings were a proximate cause of McGinnis' injuries.

- Judge Cuts Back $35 Million Verdict Against J&J

On March 9, J&J and Ethicon were hit with a $35 million verdict by an Indiana federal jury regarding claims that Ethicon's pelvic mesh implant was negligently designed and that Ethicon failed to warn of its potential risks. The verdict included $10 million as compensatory damages and $25 million as punitive damages to plaintiffs Barbara and Anton Kaiser. On August 8, the judge reduced the verdict to $15 million, stating the punitive damages award was "excessive and unreasonable." The judge, however, denied Ethicon's motion for judgment as a matter of law, finding there was sufficient evidence for a reasonable jury to find in favor of the Kaisers.

In 2009, Barbara Kaiser had Ethicon's Prolift pelvic mesh implanted to treat her pelvic organ prolapse. Two years later, she learned from a doctor that her complaints of low pelvic pain could be tied to the device. Kaiser claimed she suffered groin pain and bladder spasms, as well as painful sexual intercourse.

In her lawsuit, Kaiser accused Ethicon of concealing serious problems that may be caused by the pelvic mesh implant.

The jury found that Ethicon was negligent in the design of the pelvic mesh implant and that Ethicon deliberately failed to warn of its risks.

- $15 Million Verdict Against J&J Stands

On March 5, a New Jersey state judge refused to disturb a $15 million verdict against J&J and Ethicon in a lawsuit brought by a plaintiff alleging that a faulty pelvic mesh implant caused her to suffer severe and chronic pain.

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

The jury found that the warnings for both devices were inadequate, but determined that only the Prolift implant caused Hrymoc's injuries. The jury awarded $5 million as compensatory damages and $10 million as punitive damages.

Following the trial, Ethicon filed a motion for judgment notwithstanding the verdict. Within the motion, Ethicon argued Hrymoc failed to establish a practical, effective, and reasonably safe alternative to the device. The judge disagreed, finding that Hrymoc adequately established there were feasible and safer alternative designs.

- Fourth Circuit Upholds $18.5 Million Pelvic Mesh Verdict

On February 7, the Fourth Circuit Court of Appeals rejected Boston Scientific's appeal of an $18.5 million verdict awarded to four plaintiffs in a trial over injuries allegedly caused by its Obtryx Transobturator Mid-Urethral Sling System. Boston Scientific was ordered to pay plaintiffs a total of $14.5 million as compensatory damages and $4 million as punitive damages.

Boston Scientific challenged the verdict on multiple grounds, arguing that the court's consolidation of plaintiffs' cases allowed evidence that otherwise would have been inadmissible in some of the cases, which confused the jury. It also argued that the court wrongly excluded evidence of the device's approval by the U.S. Food and Drug Administration (FDA) while admitting what Boston Scientific called hearsay warnings about the materials used. Boston Scientific further argued that plaintiffs failed to establish specific design defects and that the jury received erroneous instructions on punitive damages.

The three-judge panel disagreed with Boston Scientific, finding that all four plaintiffs had set forth sufficient evidence to prove their case.

Testosterone Replacement Drugs

- AbbVie Wins Fifth Bellwether Trial in Testosterone MDL

On June 14, an Illinois federal jury rejected a plaintiff's claims that AbbVie's testosterone replacement drug, Androgel, caused his deep vein thrombosis. Plaintiffs Robert and Sherrie Rowley, Utah residents, filed suit in 2015 against AbbVie, claiming Robert Rowley's use of Androgel had caused him to develop deep vein thrombosis. Rowley was prescribed Androgel after he visited his doctor and complained about fatigue. Knowing Rowley had a testicle removed years prior, his doctor checked Rowley's testosterone levels and found them to be low.

During trial, AbbVie argued that the FDA has repeatedly said there is no connection between blood clots and testosterone replacement therapy. The jury ultimately sided with AbbVie, finding AbbVie was not liable for Rowley's injuries.

Rowley's trial over claims of strict liability, negligence, negligent misrepresentation, and fraud was the first in the multidistrict litigation (MDL) to test whether Androgel could cause deep vein thrombosis.

- AbbVie Gets Win in Fourth Illinois Androgel Bellwether Trial

On May 15, an Illinois federal jury returned a defense verdict in favor of AbbVie in the fourth Androgel multidistrict litigation bellwether trial. Plaintiff Arthur Myers claimed that he suffered a pulmonary embolism in February 2008 after ingesting Androgel. Myers claimed that AbbVie misleadingly marked the drug as a safe and effective treatment for age-related low testosterone. He also claimed that AbbVie failed to adequately warn that Androgel could cause deep vein injuries. The jury ultimately found that Androgel did not cause Myers' injuries.

- AbbVie Ordered to Pay $3.2 Million in Androgel Trial

On March 26, the jury ended a trial that spanned nearly three weeks against AbbVie, finding for plaintiff on his claims of negligence on the grounds that AbbVie failed to adequately warn of the risks of

taking its testosterone replacement drug, Androgel.

Plaintiff Jesse Mitchell, 54, said he was prescribed Androgel when he complained to his doctor about depression and fatigue after a test revealed his testosterone levels were low. Mitchell used Androgel on and off for years until he suffered a heart attack. In his lawsuit, Mitchell alleged AbbVie did not have FDA approval to promote Androgel for men who were not diagnosed with a specific condition causing their low testosterone levels. AbbVie argued that it relied on the FDA guidance to market and label the drug.

The jury awarded Mitchell $200,000 as compensatory damages and $3 million as punitive damages. The majority of the compensatory damages—$150,000—were for economic injuries, with $50,000 awarded for noneconomic injuries such as pain and suffering.

The $3.2 million jury verdict was the result of the second trial in the case of Mitchell, who last July was awarded $150 million in a jury verdict that was later vacated by the court.

- Endo, Auxillium, and GSK Reach Settlement in Testosterone MDL

On February 23, Endo International PLC (Endo), Auxillium Pharmaceuticals LLC (Auxillium), and GlaxoSmithKline LLC (GSK) reached a global settlement in a testosterone multidistrict litigation. Within their lawsuits, plaintiffs alleged the drug manufacturers failed to warn of risks of heart attacks and other heart-related conditions while taking Androgel. Plaintiffs further alleged that the manufacturers were aware that the drugs could increase the risk of cardiovascular events but declined to test for such risks.

The settlement resolved more than 1,300 suits filed against the drug manufacturers. The settlement does not cover any cases targeting AbbVie.

- AbbVie Wins Androgel Trial in Testosterone MDL

On January 23, an Illinois federal jury cleared AbbVie of claims brought by a plaintiff who alleged he suffered a pulmonary embolism as a result of his use of Androgel. Plaintiff Robert Nolte of Arizona claimed he suffered a pulmonary embolism two months after he began using Androgel to treat a drop in testosterone levels, an off-label use. Complications from the embolism and the subsequent treatment he received caused blood to pool in his brain.

At trial, Nolte argued that AbbVie fraudulently misrepresented the drug's risks and misled patients by marketing Androgel on television for off-label use. AbbVie, in turn, argued that its marketing of Androgel adhered strictly to uses approved by the FDA and that it was in full compliance with all applicable standards.

The jury rejected Nolte's claims and found in favor of AbbVie.

- Settlement Reached in Philadelphia Testosterone Case

On January 2, Auxillium reached a settlement in a case where a plaintiff alleged Auxillium's testosterone replacement therapy, Testim, caused him to suffer a stroke. Plaintiff Robert Hoehl was prescribed Testim to treat fatigue and erectile dysfunction related to low testosterone levels. About nine months after he began taking Testim, Hoehl suffered a stroke.

In his lawsuit, Hoehl alleged Testim was unreasonably dangerous and had inadequate warnings. He further alleged that Auxillium did not adequately warn that use of Testim increased the risk of cardiovascular events including heart attacks, strokes, blood clots, and death.

The terms of the settlement were not disclosed.

Pradaxa Litigation

- Boehringer Gets Third Win in Connecticut Pradaxa Bellwether Case

On October 5, a Connecticut state jury cleared Boehringer Ingelheim Pharmaceuticals Inc. (Boehringer) of liability in a lawsuit alleging its blood thinner, Pradaxa, caused a man to suffer severe bleeding. Plaintiff William Bedsole was prescribed Pradaxa to thin his blood and prevent blood clots due to Bedsole's atrial fibrillation. In July 2011, Bedsole suffered internal bleeding, which he alleges was caused by Pradaxa, and was hospitalized for three days. Bedsole sued Boehringer, alleging that Boehringer failed to warn of Pradaxa's potential risks.

After a three-week trial, the jury found that Bedsole failed to provide evidence to support his claims for negligence and strict products liability.

- Boehringer Gets Second Win in Connecticut Pradaxa Bellwether Trial

On May 7, another Connecticut state jury cleared Boehringer of claims brought by a plaintiff who alleged that the blood thinner Pradaxa landed her in the hospital. Plaintiff Mary Lou Gallam claimed that taking Pradaxa caused her to be hospitalized for two days in 2014 due to gastrointestinal bleeding—she had been taking the drug for two and a half years. Gallam alleged that neither she nor her doctors were adequately warned about the drug's risks and that it was defectively designed.

The jury found for Gallam on her claim that the company negligently failed to test or investigate the drug, but rejected her claims that it caused her injuries and Boehringer failed to warn of its risks. The jury also rejected Gallam's claim that Pradaxa was defectively designed.

- Boehringer Gets First Win in Connecticut Pradaxa Bellwether Case

On March 23, a Connecticut jury found in favor of Boehringer in a state action over alleged bleeding risks of its blood thinner, Pradaxa. Plaintiff Geralynn Boone (G. Boone) filed a wrongful death lawsuit against Boehringer alleging that the defective design of Pradaxa led to the death of her mother, Mary Boone (M. Boone). M. Boone was prescribed 150 milligrams of Pradaxa twice a day in 2010 to treat her atrial fibrillation, an irregular heartbeat that increases the risk of stroke. In 2014, M. Boone was hospitalized for an upper gastrointestinal bleed. G. Boone claimed her mother's uncontrollable gastric bleeding was caused by her taking Pradaxa.

The jury found that Boehringer failed to adequately warn of the dangers of Pradaxa, but found that M. Boone's death was not caused by the drug.

Approximately three years ago, Boehringer agreed to pay roughly $650 million to settle claims in multidistrict litigation over allegations that Pradaxa caused serious injuries including severe bleeding. The settlement resolved roughly 4,000 state and federal cases in the U.S.

Abilify Litigation

- Three Bellwether Cases Settle Just Before Trial in Abilify MDL

On April 30, Bristol-Myers Squibb (BMS) and Otsuka Pharmaceuticals (Otsuka) reached settlement agreements in three cases that were scheduled for bellwether trials in Florida. The lawsuits claimed that Abilify, although approved by the FDA to treat schizophrenia, bipolar disorders, and major depressive disorders, caused consumers to display compulsive behaviors, including gambling, shopping, sexual activity, and eating.

According to the court's order, the parties reached settlements through mediation with a settlement master. The order stated that BMS and Otsuka must pay settlement proceeds and plaintiffs must enter full releases within 30 days under their agreement terms. The parties then must file dismissal stipulations within 10 days of plaintiffs executing their releases. The court did not disclose any further settlement details.

The three cases were chosen for bellwether trials

from more than 800 in the multidistrict litigation.

- Summary Judgment Denied in Abilify MDL

On March 16, a Florida federal judge denied BMS and Otsuka's motion for summary judgment in a multidistrict litigation over alleged side effects of the antipsychotic drug Abilify. BMS and Otsuka moved for summary judgment, challenging plaintiffs' expert testimony under the federal rules of evidence and the *Daubert* standard. The court, however, found that most of plaintiffs' evidence was sufficient. Specifically, the court ruled that plaintiffs' evidence to support causation was reliable and that there was a genuine dispute of material fact over whether Abilify could cause compulsive behavior.

Xarelto Litigation

- Janssen and Bayer Get Defense Verdict in Pennsylvania Xarelto Trial

On April 27, a Pennsylvania state jury returned a verdict in favor of Janssen Pharmaceuticals Inc. (Janssen) and Bayer AG (Bayer) in the state's second complex litigation Xarelto trial.

Plaintiff Daniel Russel suffered a massive gastrointestinal bleed after using Xarelto for a week following emergency treatment for a blocked coronary artery and an irregular heartbeat. Russel was prescribed a mix of Plavix and aspirin to prevent blood clots near the stent and Xarelto to prevent stroke-inducing blood clots. Russel claimed Xarelto caused him to suffer massive internal bleeding and other serious medical complications.

In his lawsuit, Russell alleged that Janssen and Bayer were liable for claims that the Xarelto label did not adequately instruct treating physicians of the risks of bleeding associated with Xarelto. He brought claims of negligence, strict products liability—manufacturing defect, design defect, and failure to warn—breach of express and implied warranty, negligent misrepresentation, fraud, violation of Pennsylvania and New Jersey state consumer protection laws, and loss of consortium.

- $28 Million Verdict Reversed in Xarelto Case

On January 9, a Pennsylvania state court judge reversed a nearly $28 million jury award to an Indiana couple who accused Janssen and Bayer of failing to warn of risks associated with their drug Xarelto.

Plaintiff Lynn Hartman was prescribed Xarelto to prevent strokes as a result of atrial fibrillation. Hartman alleged she took Xarelto for approximately one year before she was hospitalized with severe gastrointestinal bleeding. Hartman and her husband sued Janssen and Bayer, alleging that Xarelto was unreasonably dangerous and that Janssen and Bayer failed to warn about a serious risk of uncontrollable and irreversible bleeding in emergencies. After a three-week trial, a jury awarded the couple $1.8 million as compensatory damages and $26 million as punitive damages.

Subsequently, the court granted Janssen and Bayer's motion to reverse the verdict, arguing that a physician for Hartman testified that additional warnings would not have changed her decision to prescribe the drug.

Hip Implant Litigation

- Stryker Reaches Settlement in Hip Replacement Cases

On November 2, Howmedica Osteonics Corp., the manufacturer of hip replacement components used in Stryker's LFIT V40 Anatomic CoCr Femoral Heads, reached a confidential settlement agreement in two cases filed by plaintiffs who claimed to have suffered pain, difficulty walking, and tissue damage from corrosion of the components used in their hip replacements. The confidential settlement agreement includes a multidistrict litigation case in Massachusetts federal court and a multicounty litigation in New Jersey state court.

Approximately 125 cases relating to the device were centralized in Massachusetts federal court. In October 2017, the court scheduled the first bellwether trial to begin in September 2019.

- Judge Enters $245 Million Verdict in Defective Hip Implant Case

On August 29, a Texas federal judge finalized a $245 million verdict against J&J's subsidiary DePuy Orthopaedics (DePuy) in a bellwether case over its allegedly defective Pinnacle line of metal-on-metal hip implants. Plaintiffs Ramon Alicea, Uriel Barzel, Karen Kirschner, Hazel Miura, Eugene Stevens Jr. (E. Stevens), and Michael Stevens (M. Stevens) alleged they were forced to have their implants removed after suffering from bone erosion, tissue death and poisoning from metal debris, and other injuries.

In November 2017, a unanimous jury concluded after a two-month trial that the metal-on-metal hip implants had design and manufacturing defects and that J&J and DePuy knew about the flaws but failed to warn physicians.

The $245 million verdict included approximately $48.6 million for Kirchner, $43.7 million for Miura, $39.8 million for Alicea, $39.4 million for Barzel, $37.8 million for M. Stevens, and $36.8 million for E. Stevens. This is the third consecutive nine-figure verdict in the multidistrict litigation.

- J&J Gets New Trial After $502 Million Verdict

The Fifth Circuit Court of Appeals vacated a $502 million verdict against J&J and DePuy over defective hip implant claims, ruling the trial judge committed "serious evidentiary errors" and allowed numerous "misrepresentations" made by plaintiff's attorney to go before the jury.

During the trial, plaintiff's attorney repeatedly told the jurors that two orthopedic surgeons testifying as experts were voluntarily providing their testimony due to their concerns for plaintiffs. After the trial, J&J learned that plaintiff's attorney had given a $10,000 donation to a charity chosen by one of the orthopedic surgeons before trial and paid an additional $35,000 as a "thank you" after the trial. The other orthopedic surgeon was paid $30,000 after the trial.

In post-trial motions, J&J argued that plaintiff's attorney had given the jury a "false aura of objectivity" by misrepresenting that they were unpaid. The court found that information regarding payment may have "opened up potentially promising impeachment tactics on cross-examination, which it patently did," and ordered a retrial.

- $4.5 Million Verdict Upheld in Hip Defect Claim

On March 6, a California appeals court reversed a trial court's order for a new trial on damages in a Wright Medical Technology Inc. (Wright) Profemur R metal-on-metal hip implant case, reinstating the $4.5 million jury verdict.

Plaintiff Alan Warner had the Profemur R hip prosthesis implanted in 2006 when he suffered an injury after he slipped and fell at home. After several failed revision surgeries, Warner's surgeon implanted Wright's Profemur R. In 2010, the stem fractured, requiring Warner to undergo an additional surgery. In his lawsuit, Warner alleged he has since experienced a dislocated hip, had revision surgery, and developed a serious infection that required emergency surgery. He had a fifth hip replacement in 2013. Wright argued that Warner's femur failed to provide adequate support for the implant, causing the stem to suffer unexpected stress. The jury disagreed.

Risperdal Litigation

- J&J Reaches Settlement in Risperdal Case Days Before Trial

On October 19, just days before trial, J&J reached a confidential settlement in a case brought by a Mississippi family who alleged their son developed breasts after taking the antipsychotic drug Risperdal.

Plaintiff was a young boy who was tentatively diagnosed with bipolar disorder in 2004; thereafter, he was prescribed Risperdal. The boy's parents alleged that he gained weight and developed breasts, a condition called gynecomastia, as a result of the increase in hormones.

Prior to 2006, Risperdal warning labels indicated that gynecomastia was a rare side effect suffered by adults. Plaintiff claimed that J&J was aware that gynecomastia was much more common in adolescent boys, but failed to warn of the risk.

- U.S. Supreme Court Denies Review of Janssen Liability in Risperdal Case

Earlier this year, a California appellate panel reversed a $5.6 million jury verdict against Janssen, finding the mother of a man who died after participating in a clinical trial for Risperdal could not hold Janssen liable for a physician's malpractice. On October 1, the U.S. Supreme Court denied review of the appellate court's ruling.

Plaintiff Marion Liu, mother of Leo Liu, was handed the verdict in October 2015 after alleging her then-25-year-old son, a schizophrenic, had enrolled in a human drug trial for Risperdal with Janssen. Despite knowing that Liu had a preexisting heart condition, the physicians administered a small test dose of the drug. Liu's son died after being transferred to a hospital from the study facilities. An autopsy revealed Liu's son died from dilated cardiomyopathy, a heart injury, which is a "readily treatable" condition that can be complicated by the use of Risperdal.

- Judge Overturns $1 Million Risperdal Verdict Against Janssen

On September 21, a New York federal court judge granted Janssen's motion for judgment as a matter of law, finding plaintiff Shaquil Byrd's claims were preempted because Janssen could not have updated its Risperdal label to warn of the risk of gynecomastia. The court also found that plaintiff's attorney's comments relating to his own childhood bullying were biased.

Byrd was prescribed Risperdal in 2002 at the age of 8. After continuously taking the drug for three to five years, Byrd developed female breast tissue, which required surgical removal. Byrd and Janssen went to trial in September 2017, where the jury found that Janssen negligently designed and failed to warn of the associated risks. The jury awarded $500,000 for past pain and suffering and an additional $500,000 for future pain and suffering.

- Summary Judgment Granted In Massachusetts Risperdal Case

On September 5, judgment was entered in favor of J&J and Janssen after the companies prevailed on a motion for summary judgment in a case alleging Risperdal caused a teen boy to gain excessive weight.

The U.S. District Court judge granted summary judgment on the grounds that plaintiff Emmanuel Jackson failed to proffer any expert testimony to support his claims that Risperdal caused his weight gain. Within their motion, J&J and Janssen pointed to the numerous prescription medications that Jackson was taking that could have attributed to the side effects he claimed. These included Depakote, Cogentin, Tialin, Trilafon, and Adderall. One of Jackson's doctors testified that Jackson's weight gain could have resulted from his discontinuing the use of Adderall.

"At this critical juncture, with defendants' motion for summary judgment pending and a trial date looming, it would be inequitable to allow Jackson to continue to press these claims without sufficient evidentiary support," the court stated in its order.

Talc Litigation

- J&J Gets Win in New Jersey Talc Case

On October 11, a New Jersey state jury unanimously sided with J&J in finding that a woman's alleged exposure to asbestos in baby powder did not contribute to her mesothelioma. Plaintiffs Rosalind

Henry and her husband claimed that asbestos fibers in J&J's talc products caused Henry's mesothelioma, a rare cancer associated with asbestos exposure. After less than a day of deliberation, the jury rejected Henry's claims.

J&J is currently facing more than 10,000 lawsuits across the U.S. over its talcum powder products.

- Delaware Talc Cases Dismissed for Lack of Personal Jurisdiction

On September 11, a Delaware state judge overseeing more than 200 lawsuits filed against J&J alleging that its talcum powder products caused ovarian cancer dismissed all claims filed by out-of-state plaintiffs, finding that the court lacked jurisdiction to hear the cases after the U.S. Supreme Court's ruling in *Bristol-Myers Squibb v. Superior Court of California*. In a 31-page opinion, the court stated that plaintiffs who did not reside in Delaware failed to establish a direct link between J&J's official actions in Delaware and the specific allegations underlying claims in the lawsuits. The court found that while J&J may have sold and marketed its talc in Delaware, the out-of-state plaintiffs were presumably subject to the marketing and advertising in their own states, not in Delaware. Thus, the court had personal jurisdiction over only those suits filed by Delaware residents, as J&J does not have its principal place of business in Delaware nor is it incorporated in Delaware.

The court also denied plaintiffs' request to engage in jurisdictional discovery.

- $4.69 Billion Talc Verdict Against J&J Affirmed

On August 22, a Missouri state judge affirmed a $4.69 billion verdict against J&J in a case involving 22 women and their families who alleged J&J's talcum powder products, including its baby powder, contained asbestos and caused them to develop ovarian cancer. In a unanimous decision, the jury found J&J liable for strict products liability and negligence, finding that J&J's talcum powder products caused cancer in all 22 plaintiffs. The jury awarded the women $550 million as compensatory damages and $4.14 billion as punitive damages.

- $117 Million Talc Verdicts Against J&J Stand

On June 29, a New Jersey state judge denied motions brought by J&J and Imerys Talc America Inc. (Imerys) to set aside a $117 million verdict ($37 million as compensatory damages and $80 million as punitive damages) awarded to plaintiffs Stephen Lanzo III and his wife in April.

Lanzo alleged he developed mesothelioma after inhaling dust that was generated through his regular use of J&J talcum powder products since his birth in 1972. During the trial, plaintiffs introduced internal documents which showed that J&J and Imerys were aware that the products contained asbestos as early as the 1960s.

The court found that the evidence in the case did "not shock the judicial conscience," such that the punitive damages award needed to be reconsidered.

Other Litigation

- Settlement Reached After $384 Million Award in Dialysis Suit

On November 2, DaVita HealthCare Partners (DaVita) informed the court it reached a settlement with the families of three patients who died from cardiac arrest after receiving treatment by DaVita with solutions that were allegedly known to be dangerous. The settlement comes after a Colorado federal jury ordered DaVita to pay $384 million, which included $375 million as punitive damages, to the families of three patients.

Irma Menchaca, Gary Saldana, and Deborah Hardin were all treated with the solutions GranuFlo and NaturaLyte, which were recalled by the FDA for purported contribution to cardiac arrests. Although some of the patients died prior to the recall, their family members believed that DaVita knew of the risks associated with the use of the solutions.

The solutions, which were manufactured by

Fresenius Medical Care North America, were subject to an FDA Class I recall in March 2012 over risk of heart attack, cardiac arrhythmias, hypotension, stroke, and death.

- Bard Gets Win in Third IVC Bellwether Trial

On October 5, an Arizona federal jury awarded Bard a win in the third bellwether trial alleging Bard's clot-stopping vein filter broke, sending metal pieces to plaintiff's heart. Plaintiff Lisa Hyde of Wisconsin had a history of deep vein thrombosis and pulmonary emboli. In 2011, she received a Bard IVC filter implant, which is meant to catch blood clots before they enter the heart and lungs. In 2014, she learned that the filter had tilted, with one strut lodged into the right ventricle of Hyde's heart. The fractured strut punctured her vein and migrated into her abdominal cavity and a heart chamber. After one day of deliberation, the jury found that Bard was not liable for a design defect or for negligence.

The first bellwether trial resulted in a $3.6 million verdict in March and is currently on appeal in the Ninth Circuit Court of Appeals. The second bellwether trial resulted in a defense verdict in June. Bard was granted summary judgment in another bellwether case on statute of limitations grounds. Over 4,000 cases are still pending in the multidistrict litigation.

- New Jersey Supreme Court Dismisses More Than 500 Accutane Cases

On October 3, the New Jersey Supreme Court ended more than 500 cases against F. Hoffman-LaRoche Inc. (LaRoche) that were based on LaRoche's purported failure to warn of possible gastrointestinal side effects from its acne drug Accutane, finding that plaintiffs' claims were barred by the New Jersey Product Liability Act.

The court found that the more than 500 consumers from over 40 states could not overcome the state's presumption that because the Accutane warnings were approved by the FDA the warnings on drug labels are adequate. This is because, under the Product Liability Act, the FDA-approved warnings on drug labels are presumed to be adequate.

- Judge Cuts $70 Million Surgical Stapler Verdict Against J&J

On June 13, a California appeals court reduced a $70 million punitive damages award to $19.6 million in a case alleging J&J and Ethicon's defective surgical stapler, in conjunction with a doctor's negligence, caused a woman's anus to be stapled shut during a hemorrhoid surgery.

Plaintiff Florence Kuhlmann alleged that during surgery in January 2012 the defective stapler misfired, sealing the patient's anal canal shut and leading to 21 days of emergency hospitalization and a massive infection, as well as resulting abdominal surgeries, including a full laparotomy and colostomy. In addition to the punitive damages award, Kuhlmann was awarded $9.8 million as compensatory damages.

The court found that the $70 million was a "constitutionally excessive award" and cut the punitive damages down to $19.6 million, or two times the compensatory damages.

- $450 Million Punitive Damages Award Reduced in Surgical Gowns Verdict

On May 30, a California federal court found that the $450 million punitive damages award against Kimberly-Clark Corp. (Kimberly-Clark) and its spinoff Halyard Health Inc. (Halyard) was too high, cutting the award by over $400 million to just over $20 million.

Bahamas Surgery Center (Bahamas) filed a class action lawsuit in October 2014 accusing Kimberly-Clark and Halyard of falsely representing that their MicroCool surgical gowns provided the highest level of liquid barrier protection. Although no physical harm had been reported, Bahamas argued that the misrepresentation of the gowns' permeability put caretakers at substantial risk when they believed their apparel would protect them against pathogens, such as Ebola. Last year, a California federal jury

awarded Bahamas $454 million against Kimberly-Clark and Halyard for misrepresenting the impermeability of their MicroCool surgical gowns. The jury award consisted of $450 million as punitive damages, exceeding the $4 million compensatory damages by more than a hundredfold.

Although the U.S. District Court judge agreed that Kimberly-Clark and Halyard should be held responsible for misleading buyers, including Bahamas, the judge found the punitive damages unconstitutionally high.

- $1.2 Million Awarded Against Cook Medical

On May 24, after a three-week trial, a Texas state jury ordered Cook Medical, Inc. (Cook Medical), to pay $1.2 million to a plaintiff who suffered injuries following implantation of a Celect IVC filter.

Plaintiff Jeff Pavlock, a 35-year-old Houston firefighter, had the IVC filter implanted in 2015 to prevent blood clots from reaching his heart and lungs. Pavlock claimed that the filter tilted within his vein and perforated his aorta and duodenum, which necessitated further surgeries.

The jury found that Cook Medical failed to adequately warn physicians about the risks associated with the Celect device. However, the jury also found that the IVC filter did not contain a design defect and, thus, Cook Medical was not negligent in designing the device that allegedly caused Pavlock's injuries. The jury awarded Pavlock a total of $1,240,500 as compensatory damages.

Cook Medical was successful in the first two cases over its IVC filters, getting a defense verdict in one and prevailing on a motion for summary judgment in the other.

- Judgment Reversed in Avandia Claims Against GSK

On April 16, a California appeals court reversed the ruling on GSK's motion for summary judgment in a lawsuit that claimed GSK failed to properly warn non-English speakers about the risks of its antidiabetic drug Avandia. Four plaintiffs claimed that GSK failed to warn of the cardiovascular risks associated with Avandia, which they each consumed between 2002 and 2007. All four plaintiffs were diagnosed with cardiovascular injuries.

The trial court granted GSK's motion for summary judgment on the grounds that the available information properly informed plaintiffs of the potential risks. In their appeal, plaintiffs argued the trial court did not consider that they spoke only Armenian and had no access to English-language media.

A three-judge panel found that there was a triable issue of fact over whether the four Armenian-speaking plaintiffs had information that revealed Avandia was the cause of their heart problems and reversed the ruling. The case was remanded to the trial court.

- Eleventh Circuit Reverses Dismissal of Defibrillator Vest Lawsuit

On February 8, the Eleventh Circuit reversed a dismissal of a defibrillator vest case, finding that plaintiffs' claims were not preempted by federal law.

On November 1, 2013, plaintiff Debra Godelia was diagnosed with a heart condition and underwent cardiac catheterization. Thereafter, her doctor prescribed a LifeVest, a wearable cardio defibrillator manufactured by Zoll Services, LLC (Zoll), that is designed to detect abnormal heart rhythms and deliver a corrective shock to the heart. After receiving confirmation from a physician that she was using the LifeVest appropriately, Godelia experienced a "defibrillation event" and lost consciousness. The LifeVest detected a problem and sounded an audible alarm but did not deliver a resuscitative shock. Godelia died on November 20, 2013. Godelia's husband and son sued Zoll, alleging that the LifeVest contained a manufacturing defect that led to Godelia's death.

In September 2014, the FDA sent Zoll a warning letter, finding that its medical device was adulterated as the LifeVest administered "inappropriate shocks."

In January 2017, the lower court dismissed plaintiffs' claims against Zoll, finding that the claims were preempted by federal law as they relied on a defect with the LifeVest that contradicted the FDA's prior approval of the LifeVest as safe. On appeal, the Eleventh Circuit disagreed, finding that the 2014 letter provided by the FDA that told Zoll it was in violation of federal regulations could establish a claim.

- Hernia Patch Claims Barred by Physician's Knowledge of Risks

On February 8, the Eleventh Circuit affirmed a lower court's dismissal of a lawsuit alleging a hernia patch manufactured by Davol Inc. (Davol) and Bard was defective, finding the physician's knowledge of the risks associated with the patch barred any failure-to-warn claim.

In its two-page opinion, the appellate court stated that "[i]f the physician had independent knowledge of the risk that caused the plaintiff's injuries—substantially the same knowledge an adequate warning should have communicated—then the plaintiff cannot prevail on a failure-to-warn claim."

- Proposed Actos Class Action Dismissed

On January 29, a California federal judge dismissed a proposed class action accusing Takeda Pharmaceuticals America Inc. (Takeda) and Eli Lilly and Co. (Eli Lilly) of concealing health risks associated with the diabetes treatment Actos, holding that the patients previously released their claims as part of a settlement in multidistrict litigation. "When plaintiffs settled and released their claims against defendants before the putative class was certified, their claims became moot, thereby depriving the court of subject matter jurisdiction."

Named plaintiffs initially brought the proposed class action in 2012. In their complaint, plaintiffs alleged Takeda and Eli Lilly failed to disclose that Actos, a Type 2 diabetes treatment, increased the risk of bladder cancer, congestive heart failure, and other adverse cardiovascular effects. Named plaintiffs ultimately developed bladder cancer as a result of the treatment. The case was ultimately transferred to multidistrict litigation where plaintiffs participated in a global settlement in 2014, ending all personal injury claims related to Actos.

Named plaintiffs conceded that they could no longer pursue their claims, but argued that they should be able to amend their complaint to substitute new named plaintiffs. The court held that plaintiffs cannot do so because the class had not yet been certified.

- Eleventh Circuit Affirms Amgen Win in Enbrel Case

On January 22, the Eleventh Circuit affirmed a lower court's decision to grant Amgen, Inc. (Amgen), Pfizer, Inc. (Pfizer), and Wyeth, Inc.'s (Wyeth) motion for summary judgment in a case alleging that their drug Enbrel caused a woman to suffer severe infections.

Plaintiff Rebecca Small was prescribed Enbrel for treatment of rheumatoid arthritis. She continued using it until she developed an infection. When she appeared to be infection-free, she began using the drug again and almost immediately suffered life-threatening complications, such as a perforated bowel from an infection she said was caused by the drug. Small and her husband filed a lawsuit, claiming that Enbrel caused her infection. The complaint alleged causes of action for strict products liability (failure to warn), breach of express warranty, negligence, and loss of consortium.

The U.S. District Court for the Middle District of Florida granted summary judgment on the failure-to-warn claims, finding the claims were precluded by the learned intermediary defense. This defense provides that a drug manufacturer's duty to warn is

directed at the prescribing physician, not the patient. If the warning to the physician is adequate, the manufacturer has fulfilled its duty. The three-judge panel held that Small's rheumatologist qualified as a learned intermediary, finding that the physician intentionally treated Small with Enbrel despite her knowledge of risks associated with the drug.

Trends in Life Sciences

- FDA Looks to Update 510(k) Process for Medical Devices

On November 26, the FDA stated it intends to update the 510(k) clearance process for medical devices to ensure it stays on pace with the rapid development of health technology. Since device manufacturers going through the 510(k) process typically depend on comparisons to devices that are already on the market to show that a new device is just as safe and effective as the older product, the FDA would like manufacturers to rely on devices that are no more than 10 years old.

Commissioner Scott Gottlieb stated that the FDA plans to finalize guidance in early 2019 to establish an alternative 510(k) clearance process to allow manufacturers of well-established and well-understood types of medical devices to use objective safety and performance criteria to show that they are substantially equivalent to products already on the market.

- California's First Internet of Things Law and Medical Device Cybersecurity

In September, California Governor Jerry Brown signed the first-ever state legislation aimed at covering "smart" devices: Senate Bill 327 (SB327). Beginning on January 1, 2020, manufacturers of connected devices are required to equip such devices with "reasonable security features" designed to protect a connected device and any information it holds from "unauthorized access, destruction, use, modification, or disclosure." The bill also requires that if such a device has a "means for authentication outside a local area network," that will be considered a reasonable security feature if either the preprogrammed password is unique to each device made or the device requires a user to create a new "means of authentication" before initial access is granted.

The bill likely applies primarily to manufacturers of consumer-facing connected devices, although the language of the bill is quite broad. Notably, various exemptions apply, including those for:

(1) unaffiliated third-party software or applications that a user adds to a connected device; (2) providers of means of purchasing or downloading software or applications, such as the provider of an electronic store or marketplace; (3) connected devices already subject to federal law or regulation promulgated by a federal agency; and (4) entities or persons subject to the Health Insurance Portability and Accountability Act (HIPAA) or the California Confidentiality of Medical Information Act with respect to activity regulated by those laws.

The above exemptions likely exclude large numbers of existing connected devices, such as those regulated by the FDA or the Office for Civil Rights (the agency with HIPAA enforcement responsibility). However, some otherwise-regulated connected devices that fall under an exemption may be subject to the requirements of this bill if the devices are sold to and used by household consumers. For example, while a manufacturer of a HIPAA-regulated connected medical device appears to fall under an exemption to the extent that federal law applies, the manufacturer may nonetheless remain subject to the new bill for that device where the manufacturer engages in direct-to-consumer sales.

- FDA Releases Final Guidance on Medical Product Communications and Labeling

Earlier this year, the FDA issued two final guidances on medical product communications, including communications by medical device manufacturers about unapproved uses of approved/cleared medical

products entitled "Medical Product Communications That Are With the FDA-Required Labeling—Questions and Answers" (CWL Guidance) and "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers" (Payor Guidance). In both documents, the FDA acknowledges that there is a variety of information not contained in product labeling that is nevertheless valuable to payers, patients, and prescribers.

The CWL Guidance outlines three factors that must be satisfied to be considered consistent with FDA-required labeling:

1. The conditions for use expressed in the communication must be consistent with labeling with respect to the (a) indication, (b) patient population, (c) limitations and directions for handling/use, and (d) dosing or use regimen/administration;

2. The representations/suggestions in the communication should not increase the potential for harm to health relative to information provided in the labeling; and

3. The directions for use in the labeling should enable the product to be safely and effectively used under the conditions represented or suggested in the communication.

The Payor Guidance addresses how manufacturers may communicate information to payors. The Food, Drug, and Cosmetic Act states that manufacturers may communicate "health care economic information" to a "payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis" so long as the information "relates to" an approved indication and "is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information" and the approved labeling. This information may include an anticipated timeline for approval/clearance, pricing information, patient utilization projections, patient services and programs, and clinical and preclinical data.

- FDA Issues Draft Guidance on Expanding 510(k) Program

Earlier this year, the FDA also released a draft guidance titled "The Special 510(k) Program." The intent of the guidance is to describe an optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed medical device, along with rigorous design control procedures that produce highly reliable results that can form, in addition to other 510(k) content requirements, the basis for a finding of substantial equivalence.

The draft guidance looks to evaluate whether design and labeling changes can be reviewed under a Special 510(k) by focusing on whether the method(s) to evaluate the change(s) are well-established and whether the results can be sufficiently reviewed in a summary or risk analysis format.

- President Signs Bill Addressing Opioid Crisis Into Law

President Donald Trump signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (H.R. 6) into law. H.R. 6 is a bipartisan bill that will help in efforts to fight the opioid crisis by advancing treatment and recovery initiatives, improving prevention, and increasing efforts to fight deadly illicit synthetic drugs. Key provisions in the bill include changes to the Medicaid program to expand addiction treatment options and reauthorizations of federal health and public safety programs, among many others.

On June 22, the House passed H.R. 6 by a vote of 396 to 14. On September 17, the Senate passed an amended version of H.R. 6 by a vote of 99 to 1. On September 28, the House passed a final bipartisan, bicameral agreement on H.R. 6 by a vote of 393 to

8. On October 3, the Senate passed the final version of H.R. 6 by a vote of 98 to 1. The final bill was signed into law by President Trump on October 24.

- Government Must Identify Specific Prescriptions at Issue in Opioid MDL

On October 16, U.S. District Judge Dan Aaron Polster, an Ohio federal judge overseeing the multidistrict litigation over the opioid crisis, ruled that local governments suing drug manufacturers must identify the specific prescriptions that were allegedly influenced by the dishonest marketing.

If the prescriptions are not identified, the government must agree that: (1) at the time of trial, the government cannot assert that these specific prescriptions "were unauthorized, medically unnecessary, ineffective or harmful" or that "the filling of any specific prescriptions caused or led to harm for which plaintiffs seek to recover"; and (2) the government must rely "solely on a theory of aggregate proof." This means that the government must prove its case by describing the purported schedule in general terms, rather than focusing on particular prescriptions, patients, and physicians.

Claims against drug manufacturers allege that the companies exaggerated the benefits of the drugs and knew the drugs were overprescribed, yet failed to warn doctors of their addictive nature and the need to strictly limit the doses. The lawsuits further allege that manufacturers and distributors put profits over patients by pushing sales rather than regulating the market.

- FDA Releases Draft ANDA Submission Guidance

On January 3, the FDA issued a draft guidance entitled "Good ANDA Submission Practices—Guidance for Industry" as part of its Drug Competition Action Plan. In the guidance, the FDA highlights common deficiencies previously found in abbreviated new drug applications (ANDAs) that may delay approval, and provides recommendations for avoiding delays and minimizing review times.

The draft guidance specifically addresses deficiencies frequently arising in four areas of ANDA submissions: (i) patents and exclusivities, (ii) labeling, (iii) product quality, and (iv) bioequivalence.

Contacts

Lisa M. Rice, Partner
(714) 634-2522 | lrice@wfbm.com

Laurie E. Sherwood, Partner
(415) 781-7072 | lsherwood@wfbm.com

Katie A. Stricklin, Partner
(714) 634-2522 | kstricklin@wfbm.com

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.