Life Sciences Litigation

2020 Year in Review

Walsworth is pleased to provide you with its year in review update regarding life sciences litigation.

Updates in Litigation – Drugs

Pradaxa Litigation

- **Boehringer Settles Nearly 3,000 Pradaxa Lawsuits Across the Country**

According to a brief filed by Boehringer Ingelheim Pharmaceuticals Inc. ("Boehringer") on November 10, Boehringer, the manufacturer of the blood thinner Pradaxa, informed a Connecticut state appellate court that it had tentatively reached a settlement of nearly 3,000 lawsuits across the country over the bleeding risks associated with the drug. Boehringer asked the Connecticut Supreme Court to implement a stay in two cases brought by plaintiffs Eugene Roberto ("Roberto") and Charles F. Adkins ("Adkins") pending the outcome of the settlement.

Within one of the two cases Boehringer sought to have stayed, Roberto alleged he experienced gastrointestinal bleeding as a result of Pradaxa. Roberto's case was the fourth to go to trial of the Pradaxa bellwether cases. A jury found in favor of Roberto, and the trial judge denied in part and granted in part Boehringer's request to set aside the verdict, prompting Boehringer's appeal. Similarly, Adkins also alleged he suffered a bleeding injury as a result of his use of Pradaxa. Unlike Roberto, Boehringer was granted summary judgment as to Adkins' claims on the grounds that they were preempted by federal law, to which Adkins appealed.

The total amount of Boehringer's tentative settlement was not disclosed.

- **Georgia Federal Judge Grants Summary Judgment in Favor of Boehringer in Pradaxa Lawsuit**

On September 30, a Georgia federal judge granted summary judgment in favor of Boehringer in a wrongful death lawsuit in which a woman claimed Boehringer failed to warn about the bleeding risks associated with the drug Pradaxa.

Plaintiff Kimberly Lyons, on behalf of the estate of Cora Underwood, claimed Underwood, 75, was prescribed Pradaxa in 2016 and was later admitted to the hospital with cardiac tamponade, in which fluid around the heart reaches a pressure that interferes with its function. Underwood later passed away as a result. Lyons claimed Underwood passed as a result of the high concentration of Pradaxa found in her blood. She further alleged Boehringer failed to warn of the increased risk associated with age, other medications, and the use of Pradaxa. She further claimed Boehringer failed to recommend plasma monitoring to avoid such events. She brought claims for design defect and failure to warn.

U.S. District Court Judge William M. Ray II found that the claims were preempted by federal law, as evidence proffered by Boehringer showed that the data submitted by Lyons was known to the U.S. Food and Drug Administration ("FDA") when it approved Pradaxa for marketing in the U.S. Judge Ray further found that the remainder of the evidence was inconclusive. He also rejected the claim for design defect.

- **Boehringer Wins in Connecticut Pradaxa Labeling Case**

On August 26, a Connecticut state court found that Boehringer was not liable for claims brought by a deceased woman's family over the risks of bleeding

related to the use of Pradaxa, finding the claims were preempted by federal law.

The Estate of Myrna Kearns alleged Kearns, 72, was prescribed Pradaxa for irregular heart rhythm while she also had a history of gastroesophageal reflux disease ("GERD"). She was later hospitalized for gastrointestinal bleeding and died one month later. Her estate filed suit against Boehringer, alleging her consumption of Pradaxa was a factor in her death and the company failed to adequately warn doctors of the risk of bleeding in patients with GERD.

During the course of litigation, Boehringer produced evidence showing that prior to Pradaxa's approval in 2010, it submitted reports to the FDA showing that gastritis-like symptoms, including GERD, were associated with an increased risk of major gastrointestinal bleeding, and thus the claims were preempted by federal law. Judge Carl Schuman ruled in favor of Boehringer, finding that Kearns' claims were preempted by federal law.

- **Connecticut Supreme Court Upholds Pradaxa Win**

On May 4, the Connecticut Supreme Court upheld a jury verdict in favor of Boehringer in a bellwether trial over the 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. She also argued Boehringer defectively designed Pradaxa by failing to concurrently seek the approval of a so-called reversal agent used to treat patients when bleeding cannot be controlled. Boehringer launched such a drug, Praxbind, in 2015. In 2018, a state 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. The lower court also found that Boone's design defect claims were preempted by federal law. The Connecticut Supreme Court rejected G. Boone's arguments that a trial judge wrongly concluded federal law preempted some of her claims and barred her from presenting evidence about records the company lost or destroyed.

Risperdal Litigation

- **California Court of Appeal Reinstates Risperdal Labeling Claims**

On May 11, a California state appellate court reinstated claims brought by against Johnson and Johnson ("J&J") and its subsidiary Janssen Pharmaceuticals Inc. ("Janssen"), finding that the trial court erred in granting summary judgment in a consolidated action involving Risperdal, an antipsychotic drug.

Thousands of plaintiffs, whose claims were consolidated into a single trial court, sued J&J and Janssen alleging that male children with autism who were given Risperdal to address destructive behavior disorders developed elevated levels of the hormone prolactin, which causes boys to develop breast tissue, a condition known as gynecomastia. J&J and Janssen filed a motion for summary judgment on federal preemption grounds, which was granted. The California Court of Appeal reversed the summary judgment decision, finding that J&J and Janssen failed to disclose relevant data which showed there was a "statistically significant association" between Risperdal and elevated blood prolactin levels to the FDA at the time of approval. This information, had it been shared with the FDA, showed that there was a much greater risk of developing the side effect than was reported on the label.

This decision may impact over 300 lawsuits filed by individuals who took Risperdal as children prior to a 2006 label change that did warn of gynecomastia.

► Philadelphia Judge Reduces $8 Billion Risperdal Award

On January 17, a Philadelphia state judge reduced a jury's $8 billion punitive damages award against J&J and Janssen to $6.8 million in a case over side effects related to Risperdal.

Plaintiff Nicholas Murray was prescribed Risperdal at age 9 for symptoms related to autism spectrum disorder. Murray claimed that taking Risperdal as a child caused him to grow breast tissue, an incurable condition known as gynecomastia. In 2015, a jury awarded Murray $1.75 million in compensatory damages, finding that the drug's warnings provided at the time failed to adequately warn doctors of the risks of abnormal breast growth in adolescent boys. The award was later reduced to $680,000. At that time, an order in the Risperdal mass tort program barred a jury's award of punitive damages. An appellate court later ruled that a jury could award such damages and the jury ordered J&J and Janssen to pay $8 billion in punitive damages.

The judge sided with J&J and Janssen on their motion to reduce the jury award, finding that the $8 billion damages award was disproportionate to the $680,000 in compensatory damages. The one-page order reducing the verdict was not accompanied by an opinion.

Other Drug Litigation

► Boehringer Gets Win in Lawsuit Over Under-Filled Inhalers

On September 23, a Connecticut federal judge granted Boehringer's motion to dismiss a class action lawsuit in which consumers complained that the company falsely marketed a lung disease inhaler by stating that it had twice the number of doses than it actually did.

Plaintiffs Carl Ignacuinos of Florida and Pamela Davis of Indiana, who were seeking to represent a national class and an alternative Florida class, were both prescribed Combivent Respimat, an inhaler used to treat chronic obstructive pulmonary disease, in 2016. After using dozens of the inhalers, Ignacuinos and Davis alleged that the inhalers carried only 60 of the 120 doses that were advertised. Ignacuinos and Davis both claimed they had taken independent notes to show the number of doses they were getting from the inhalers.

In making its ruling, the judge held that the consumers lacked scientific evidence, finding that "self-reporting and other negative online reviews" are not grounded in scientific research. The judge further held that the consumers' manufacturing defect claims are preempted by federal law.

► Bayer Will Pay $1.6 Billion to Settle Claims Over Essure Contraceptive

On August 20, Bayer AG ("Bayer") agreed to pay $1.6 billion to settle lawsuits brought by thousands of women who alleged they developed debilitating long-term health problems by their use of the Essure birth control implant. The lawsuits originally stemmed from a Facebook campaign started in 2011 by Angie Firmalino of Tannersville, New York. On the Facebook page, women who had received the implant and were experiencing health issues could share stories and become policy activists.

The settlement will end approximately 90 percent of the nearly 39,000 cases filed against Bayer in federal court and litigation consolidated in California.

► Otsuka Wins in California Abilify Lawsuit

On May 18, a California federal judge granted Otsuka America Pharmaceutical Inc.'s ("Otsuka") motion for summary judgment in a lawsuit in which a woman claimed Otsuka failed to warn her of the long-term health risks of taking low doses of the antipsychotic drug Abilify for depression.

Plaintiff Ina Ann Rodman was prescribed Abilify between 2010 and 2015 to treat her depression. In 2016, she was diagnosed with tardive dyskinesia ("TD"). TD is a serious and irreversible neurological condition that is characterized by repetitive involuntary purposeless movements and is known to be caused by antipsychotic drugs. Within her lawsuit, Rodman claimed that Otsuka failed to warn of the risks associated with Abilify. Otsuka moved for summary judgment and argued that there was no evidence that the Abilify label misstated the TD incidence rate and that Rodman's doctor was aware of the risks and warned her. The judge agreed and granted Otsuka's motion. In fact, in his 19-page order, U.S. District Judge William H. Orrick stated that Rodman failed to proffer any evidence to show that Abilify's label was inadequate or that an additional warning would have changed her physician's mind about prescribing the medication to her.

Rodman's is one of the hundreds of cases filed against Otsuka for side effects experienced as a result of Abilify.

► Pfizer Dismissed in New York Lipitor Litigation

On April 7, a New York federal granted Pfizer Inc.'s ("Pfizer") motion for judgment on the pleadings and dismissed 24 plaintiffs' cases in which they alleged the drugmaker's cholesterol drug – Lipitor – caused their type 2 diabetes.

Plaintiff Barbara Gayle and 23 other plaintiffs each alleged that Pfizer failed to adequately warn about the link between Lipitor and diabetes. The plaintiffs claimed that in 2012, Lipitor underwent a label change which included adding a warning that the drug could increase glucose levels and hemoglobin A1c, which binds to glucose. Although these risks were related to diabetes, the plaintiffs alleged that it did not specifically warn of type 2 diabetes. In making its ruling, the court found the plaintiffs' claims were either preempted by federal law or time-barred by the applicable statute of limitations. The judge also denied the plaintiffs' request for additional time, finding there was no amount of discovery that could save the plaintiffs' claims.

► Allergan Wins in Teen Suicide Lawsuit

On February 12, the Ninth Circuit Court of Appeals affirmed the dismissal of Allergan Inc. ("Allergan") in a case in which the parents of a teenage boy alleged the company hid the fact that side effects from its antidepressant Lexapro could lead to suicide.

Plaintiffs Stephanie Patton and Kendrick Knighten allege their daughter, Kennadi Knighten, was prescribed Lexapro in 2015. Shortly after she began taking Lexapro, she died by suicide. The lower court held that the drug had adequate warning labels, as it clearly warned of the heightened risk of suicide in adolescents. The Ninth Circuit agreed, finding that Allergan in fact warned of the risk, and that the lower court was correct in finding in favor of Allergan.

► Sanofi Win Affirmed in Louisiana Taxotere MDL

On January 24, a Louisiana federal judge refused to reverse a claim brought in multidistrict litigation ("MDL") in which two women alleged Sanofi-Aventis U.S. LLC ("Sanofi") failed to inform them that its chemotherapy drug Taxotere could cause permanent hair loss, a condition known as alopecia.

Plaintiffs Deborah Johnson ("Johnson") and Tanya Francis ("Francis") alleged they both experienced permanent alopecia after they were administered Taxotere. Both Johnson and Francis testified that their chemotherapy treatments ended over a decade ago and that they noticed changes in their hair the same year, or shortly thereafter. The judge found both Johnson's and Francis' claims were time-barred under Louisiana's one-year "prescriptive period" in product liability actions. Johnson and Francis both moved for reconsideration of the court's ruling, which was denied.

Many drug companies, including Sanofi, are currently facing over 10,000 cases in the MDL involving Taxotere.

Updates in Litigation – Devices

Pelvic Mesh Litigation

► **Bard Pays $60 Million to End Pelvic Mesh Marketing Claims**

On September 24, C.R. Bard Inc. ("Bard") agreed to pay $60 million to end claims brought by the attorneys general of 48 states and Washington, D.C., in which they alleged Bard deceptively marketed its transvaginal surgical mesh devices to patients. The investigation was led by California and Washington state attorneys general. California's complaint stated Bard failed to disclose that complications from its pelvic mesh devices could be permanent even after surgical intervention. The state also alleged that Bard misrepresented that these risks occurred as the result of doctor error or surgical technique.

► **West Virginia AG Reaches $3.9 Million Settlement With J&J Over Pelvic Mesh Claims**

On May 4, a $3.9 million settlement was reached between West Virginia Attorney General Patrick Morrisey and J&J over claims that the company deceptively marketed its pelvic mesh products by misrepresenting their safety history.

In October 2019, J&J agreed to pay $117 million in settlement to end litigation brought by 41 states' attorneys general alleging the companies deceptively marketed pelvic mesh devices by misrepresenting the safety and effectiveness of the devices and failing to disclose the associated risks. Mr. Morrisey stated West Virginia received "significantly" more funds by bringing its own lawsuit.

► **Retrial Ordered in Pennsylvania Pelvic Mesh Case**

On April 15, a Pennsylvania state appellate court upheld a trial court's decision to void a jury's finding that J&J's TVT-Secur device, while defective, had not caused injuries suffered by a woman.

Plaintiff Kimberly Adkins ("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.

On appeal, J&J argued that the mesh erosion Adkins suffered was not the result of a defect but was a known side effect of the implant. The appeals court found that the evidence failed to show that the device did not cause Adkins' injuries. A new trial date has not been set.

► **New Jersey Appellate Court Affirms J&J Win in Pelvic Mesh Lawsuit**

On March 6, a New Jersey state appellate court affirmed a trial court's decision in favor of Ethicon in an action involving its Prolene mesh device.

Plaintiff Deborah Kline ("Kline") claimed she was implanted with the mesh device in 2007 to repair a hernia. Thereafter, Kline began experiencing significant medical complications. Within her lawsuit, Kline claimed that Ethicon defectively designed, manufactured, and labeled the mesh; however, Kline failed to present competent evidence to show that Ethicon manufactured the mesh, and the trial court granted summary judgment in favor of Ethicon.

On appeal, Kline argued that her medical experts had opined that the mesh that had been removed from Kline's body was Ethicon's Prolene device. The appellate court, however, affirmed the decision, finding that Kline failed to show that Ethicon actually manufactured the mesh device, finding the experts' opinions unreliable, as there was no way to tell that the device that was removed from Kline's body was indeed the Prolene device.

► **California State Judge Awards $344 Million in Pelvic Mesh Bench Trial**

On January 30, San Diego Superior Court Judge Eddie Sturgeon issued an 88-page statement of decision following a two-month bench trial, finding that J&J and its subsidiary Ethicon Inc. ("Ethicon") violated California's false advertising and unfair competition laws.

Within the lawsuit, California Attorney General Xavier Becerra claimed that J&J and Ethicon falsely marketed their pelvic mesh products, the Tension-Free Vaginal Tape or TVT and Prolift, in California and that their marketing was likely to deceive reasonable doctors and lay consumers. The state had sought nearly $800 million in civil penalties during the bench trial. Within his statement of decision, Judge Sturgeon noted that J&J kept sending out "deceptively incomplete" instructions for use with the devices in that they failed to warn of the devices' most serious risks including severe, long-term complications such as shrinking of the tissue surrounding the mesh, chronic pain, and pain during sex.

► **Ethicon Gets Win in Florida Pelvic Mesh Trial**

On January 21, a Florida federal jury found that Ethicon's pelvic mesh, the Artisyn Mesh, did not cause a women's constant pain.

Plaintiff Charlotte Salinero ("Salinero") underwent implantation of Ethicon's Artisyn Mesh to treat her pelvic organ prolapse in December 2012. On April 24, 2017, Salinero had a lengthy removal surgery, which included eroded pieces that had traveled to the bladder, colon, and vagina. Salinero alleged the removal was necessary because she was experiencing fistulas, fecal incontinence, and severe pain. After short deliberations, the jury found that Salinero failed to show that the Artisyn Mesh was defectively designed.

► **$20 Million Verdict Against J&J and Ethicon Stands**

On January 14, the Seventh Circuit Court of Appeals upheld a $20 million verdict against J&J and Ethicon in an action involving the Prolift pelvic mesh device.

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 implant. 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 and awarded a $35 million verdict. This included $10 million in compensatory damages and $25 million in punitive damages. The trial judge reduced the award by $15 million, stating the punitive damages award was "excessive and unreasonable," which was ultimately upheld by the Seventh Circuit.

► **Kentucky Federal Judge Grants Summary Adjudication in Pelvic Mesh Suit**

On January 9, a Kentucky federal judge granted summary adjudication in an action involving Ethicon's Prolift pelvic mesh device on grounds that many of the claims were time-barred.

Plaintiff Jenesta Cutter ("Cutter") received Ethicon's device in 2006 to treat her pelvic organ prolapse. Soon thereafter, she began experiencing pelvic pain, soreness, burning, constipation, and urine leakage. Her doctor determined these symptoms were caused by the mesh becoming loose. Cutter underwent two corrective surgeries and a third surgery to remove the mesh. She brought suit in 2012 claiming negligence, defects, and misrepresentation on the part of Ethicon. Ethicon moved to dismiss and for summary judgment on all counts.

The judge dismissed Cutter's personal injury and product liability claims, finding they were time-barred by the one-year statute of limitations. He also dismissed Cutter's failure to warn, breach of implied warranty, breach of express warranty, and

misrepresentation claims because Cutter did not receive any information about Prolift directly from Ethicon, but relied entirely upon her doctor's advice. The only causes of action which now remain are claims for violations of consumer protection laws and unjust enrichment.

Other Device Litigation

► Biomet to Pay $21 Million in Hip Implant Case

On November 24, a Missouri federal jury awarded $21 million to plaintiffs who alleged Zimmer Biomet Inc.'s ("Biomet") hip implants were defective and caused injuries to a woman who had her hips replaced.

Plaintiff Mary Bayes ("Bayes") claimed she had both of her hips replaced in 2008 with Biomet's M2a Magnum. Bayes claims she thereafter began experiencing severe pain. The pain led to numerous additional hip surgeries in 2011. Within her lawsuit, Bayes argued that Biomet should have known the M2a Magnum was defective because its design was based on an already defective hip product, the M2a Taper. The Missouri jury awarded Bayes $20 million and $1 million to her husband, plus post-judgment interests and costs of action. An appeal is expected.

Thousands of people filed lawsuits against the manufacturer, and Biomet agreed to settle a large number of cases in 2014. However, hundreds of lawsuits remain pending against the company.

► Allergan Gets Win in Illinois Defective Breast Implants Lawsuit

On October 9, an Illinois state judge dismissed Allergan from a lawsuit accusing the company of manufacturing breast implants without giving consumers timely warnings about the potential issues that could result from the implantation.

Plaintiff Christine Dietz ("Dietz") filed a lawsuit against both Allergan and her plastic surgeon, Dr. Michael Epstein. Within the lawsuit, Dietz claimed Allergan failed to warn the doctor and her about the risks associated with its breast implants. Dietz further alleged that Allergan failed to timely report adverse events associated with the implants, including that they could cause cancer, while continuing to sell them.

The judge found that Dietz' claims for negligence and products liability were preempted by federal law because they challenged the manufacturing processes and procedures implemented by the FDA. However, the judge refused to dismiss actions against Dr. Epstein, finding there was ample evidence, including various blog posts made by Dr. Epstein, which showed he had knowledge that breast implants could cause cancer.

► Ninth Circuit Affirms $3.6 Million Award Against Bard

On August 14, the Ninth Circuit Court of Appeals upheld a $3.6 million verdict against Bard in the first bellwether trial over claims its clot-stopping vein filter could break and send metal shards toward patients' hearts. In affirming the decision, the court found the claims were not preempted by federal law.

Plaintiff Sherr-Una Booker ("Booker"), 37, was implanted with a Bard G2 blood filter in 2007 to prevent blood clots. Booker claimed the filter broke apart and spread metal fragments to her heart which required open-heart surgery to remove. Trial in the action went forward in Phoenix, Arizona.

The jury award against Bard included $1.6 million in compensatory damages and $2 million in punitive damages. As part of the punitive damages claim, the jury found that Bard was not negligent in the design of the filter that was implanted in Booker, but that Bard company officials consciously disregarded public safety by putting profits ahead of safety.

At this time, there are approximately 3,700 pending lawsuits for injuries purportedly caused by Bard's

filter, which are all being handled by a U.S. district court judge in Phoenix, Arizona.

► Ninth Circuit Affirms Dismissal of J&J in Breast Implant Case

On May 18, the Ninth Circuit Court of Appeals affirmed a lower court's decision to dismiss claims brought by a woman against J&J and its subsidiary Mentor Worldwide LLC ("Mentor") in which she alleged Mentor's breast implants caused her numerous health problems that left her bedridden.

Plaintiff Sara Ebrahimi ("Ebrahimi") alleged the chemicals used in Mentor's MemoryGel silicone breast implants caused her to suffer severe pain, weakness, and fatigue. In her lawsuit, Ebrahimi claimed Mentor and J&J were aware that the device was defective, yet continued to allow the implants to be surgically placed into Ebrahimi. She further alleged that Mentor and J&J failed to warn the FDA of the risks associated with the implants in that they failed to conduct appropriate studies.

In 2018, a federal district court judge dismissed Ebrahimi's claims, finding the claims were preempted by federal law, and the Ninth Circuit affirmed.

Updates in Litigation – Talc

► Missouri Appeals Court Reduces $4.7 Billion Talc Verdict Against J&J

On June 23, a federal Missouri appellate court reduced a $4.7 billion talc verdict against J&J but refused to overturn it completely, finding that the evidence at trial showed J&J's conduct regarding its Shower to Shower Shimmer Effects "was outrageous."
The lawsuit in question was brought by 22 women who alleged that J&J's talcum powder contained asbestos and caused them to develop ovarian cancer. Documents admitted into evidence revealed that J&J has known for decades about the risk of asbestos contamination in its talc, yet failed to disclose the information. In a unanimous decision, the jury found J&J liable for strict liability and negligence as to all of the plaintiffs' injuries. The jury awarded $550 million in compensatory damages and an additional $4.14 billion in punitive damages.

The appeals court reduced this award by $2.6 billion, finding that J&J's subsidiary's conduct could not be imputed to J&J. The appellate court, however, found that the punitive damages awards were appropriately awarded based on the evidence provided at trial.

► J&J to Pay $9 Million in Florida Talc Lawsuit

On February 27, a Miami state jury awarded $9 million to a plaintiff who alleged she developed mesothelioma from her use of J&J's Baby Powder.

Plaintiff Blanca Moure-Cabrera ("Moure-Cabrera") claimed she was exposed to asbestos while using J&J's Baby Powder, which caused her to develop mesothelioma. At trial, Moure-Cabrera argued that J&J knew for decades that the talc it used in its products could become contaminated with cancer-causing asbestos, and that the company was negligent by selling a defective product.

The jury found that J&J had been negligent and sold a defective product, and awarded Moure-Cabrera $9 million, which included $3 million for past medical expenses and an additional $6 million for future pain and suffering.

► J&J Reaches Settlement in New York Talc Lawsuit

On February 25, J&J reached a settlement following opening statements in a trial in which a 62-year-old New York woman alleged she was diagnosed with mesothelioma as a result of her use of J&J's Baby Powder.

Plaintiff Laura Shanahan ("Shanahan") alleged she was diagnosed with mesothelioma in July 2018 as a result of her daily use of J&J's Baby Powder starting as a young child. Shanahan's lawsuit was the second time this year that J&J cut a midtrial deal with a plaintiff. The settlement amount was not disclosed.

► J&J to Pay $186.5 Million in New Jersey Talc Lawsuit

On February 6, a New Jersey state jury ordered J&J to pay $186.5 million in punitive damages to four plaintiffs who were previously awarded $37.3 million in compensatory damages in a consolidated trial where they alleged they each developed mesothelioma from using J&J's Baby Powder.

Plaintiffs Douglas Barden, David Etheridge, D'Angela McNeill-George, and Will Ronning argued that exposure to asbestos in J&J's talcum powder as babies was a substantial cause of their mesothelioma. At trial, J&J argued that its talcum powder was not contaminated with asbestos and not the cause of the plaintiffs' mesothelioma. After the court struck J&J's entire closing argument, the jury disagreed and issued separate awards to each plaintiff: $7.25 million to Barden, $9.45 million to Etheridge, $14.7 million to McNeill-George, and $5.9 million to Ronning in September 2019.

A separate trial went forward on punitive damages. After two hours of deliberation, the jury issued a separate verdict totaling $186.5 million for each of the four plaintiffs, awarding $36.6 million to Barden, $47.25 million to Etheridge, $73.5 million to McNeill-George, and $29.5 million to Ronning. J&J moved to set aside the punitive damages award following trial, a motion which was ultimately denied.

► J&J Win in California Talc Lawsuit Upheld

On January 29, a California state court rejected a woman's request for a new trial in a case in which she claimed she developed mesothelioma as a result of her use of J&J's Baby Powder.

Plaintiff Carolyn Weirick ("Weirick") alleged she was diagnosed with mesothelioma as a result of her use of J&J's Baby Powder "for decades." Weirick claimed there was a defective presence of asbestos in J&J's product, of which the company was aware. In October 2019, a jury rejected Weirick's argument and found that J&J's Baby Powder did not contain a defect, did not fail to perform as safely as expected, and did not have any risks that were known or knowable in light of the scientific data available at the time of manufacture or sale. Weirick requested a new trial, citing the FDA's recent finding of asbestos in J&J's talcum powder. The judge found that this new evidence did not outweigh the evidence presented at the October 2019 trial.

► California Court of Appeal Affirms Dismissal of J&J Talc Lawsuit

On January 23, a California state appellate court affirmed the dismissal of a lawsuit in which a woman claimed asbestos in J&J's talc-based powder caused her mesothelioma.

Plaintiff Ann Gibbons ("Gibbons") claimed she used J&J's Shower to Shower daily from 1980 to 2000 and used J&J's Baby Powder from 1983 to 1985 while changing her son's diaper. She was diagnosed with malignant mesothelioma in July 2016.

J&J moved for summary judgment and argued that the talcum powder from its source mines did not contain asbestos, shifting the burden of proof to Gibbons to produce evidence of threshold exposure to J&J's products. The trial court granted summary judgment and found Gibbons failed to demonstrate the existence of a triable issue of fact as to the presence of asbestos in the J&J products Gibbons alleged she used. Gibbons also failed to proffer expert testimony to counter J&J's expert's opinion.

The California Court of Appeal agreed, finding the trial court did not err in finding that J&J's talcum powder was not a substantial cause of Gibbons' mesothelioma.

► J&J Reaches Midtrial Settlement in California Talc Case

On January 6, J&J agreed to pay an unknown amount to end a trial involving its talcum powder.

Plaintiff Linda O'Hagan ("O'Hagan") alleged she was diagnosed with mesothelioma in August 2018 as a result of her use of J&J's Baby Powder. O'Hagan claimed she was given an estimated year and a half to live and had since undergone multiple rounds of

immunotherapy and chemotherapy to no avail. The trial began December 2, 2019, but took a lengthy holiday break through December 20, 2019, during which time the settlement was reached. The California state jury heard opening statements about the FDA's announcement that a blind test of J&J talc found chrysotile asbestos in one sample, and was expected to be one of the first that would be able to directly weigh this information in deliberation.

Updates in Litigation – Opioids

► Purdue Pleads Guilty in New Jersey Opioid Case

On November 24, Purdue Pharma LP's ("Purdue") top officers entered guilty pleas on behalf of the pharmaceutical company to a three-count felony indictment highlighting Purdue's long conspiracy to defeat federal opioid control programs.

Purdue CEO and Chairman Robert S. Miller admitted the company knowingly and intentionally conspired with others to aid or facilitate health care providers in dispensing prescription drugs without legitimate medical purpose. As part of the guilty plea, Purdue reached a civil settlement with the U.S. Department of Justice to pay $3.54 billion in criminal fees and an additional $2 billion criminal forfeiture – the largest ever against a pharmaceutical company – including up to $3.54 billion in criminal fees and an additional $2 billion criminal forfeiture.

The U.S. Department of Health and Human Services has estimated that over two-thirds of the 760,000 drug overdose deaths since 1999 were tied to opioids.

► Three Distributors Agree to Pay $21 Billion to End Opioid MDL

On November 3, McKesson Corp. ("McKesson"), Cardinal Health Inc. ("Cardinal"), and AmerisourceBergen Drug Corp. ("AmerisourceBergen") agreed to pay a combined $21 billion to end MDL over allegations that the manufacturers contributed to the opioid crisis with reckless sales of painkillers and by downplaying their drugs' addiction risks. The companies have denied allegations that their marketing and distribution practices are to blame for instigating the opioid epidemic.

The MDL contains approximately 3,000 cases filed mostly by cities and counties that are seeking money for health care and law enforcement costs related to opioid abuse.

► J&J Tentatively Agrees to Pay $5 Billion to Settle Nearly 3,000 Opioid Lawsuits

On October 13, J&J reached a tentative agreement to settle approximately 3,000 cases brought by states, local governments, and Native American tribes over the company's involvement in the opioid epidemic. The tentative deal is $1 billion larger than a global resolution that was offered by J&J last year, which was rejected. In its announcement, J&J stated that the tentative agreement was "an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties, and tribal governments."

Last year, J&J was ordered to pay $465 million following a seven-week bench trial in Oklahoma. The verdict is currently on appeal. Other major opioid settlements include a $10 billion deal with Purdue for its OxyContin and a $1.6 billion deal with Mallinckrodt PLC. Both companies have filed for bankruptcy.

► Sixth Circuit Refuses to Certify Negotiating Class in Opioid MDL

On September 24, the Sixth Circuit Court of Appeals reversed an Ohio federal judge's certification of a "negotiation class" in a nationwide prescription opioid MDL, concluding the federal rules do not permit certification of a class for negotiation purposes, as opposed to litigation or settlement.

The Ohio opioid MDL consists of over 1,300 lawsuits filed by cities and counties alleging that manufacturers and distributors of opioids misled medical professionals into prescribing various drugs,

which resulted in significantly increased public health and safety costs. Throughout litigation, the court repeatedly encouraged the parties to settle. To that end, 51 cities and counties moved to certify a "negotiation" class. Several pharmaceutical distributors opposed the motion, as did numerous state attorneys general and various putative class members. The district court, however, certified the class finding no defendant was required to negotiate and non-class members could proceed as they wished in terms of litigation and settlement.

On appeal, the Sixth Circuit reversed. In making its ruling, the 2-1 panel stated that the court must find that questions of law or fact among the class members exceed individual questions. However, federal law does not allow for class certification solely for purposes of settlement.

► Endo Agrees to Pay $8.75 Million to End Oklahoma Opioid Litigation

On January 10, Endo Pharmaceuticals Inc. ("Endo"), the manufacturer of Opana ER, a narcotic painkiller, agreed to pay $8.75 million to end a lawsuit brought by the Oklahoma attorney general over its role in the state's opioid epidemic. Pursuant to the terms of the settlement, Endo will not employ or contract any sales representatives to market opioids in Oklahoma. Endo will also not be allowed to pay for any marketing efforts to promote its opioids in the state.

Oklahoma's lawsuit also targeted Purdue and Teva Pharmaceuticals ("Teva"), which settled for $270 million and $85 million, respectively.

Trends in Life Science

Coronavirus (COVID-19) Updates, Trials, and Trends

► The PREP Act and COVID-19

On March 17, the secretary of the Department of Health and Human Services ("HHS") published a declaration under the 2005 Public Readiness and Emergency Preparedness Act ("PREP Act") to provide liability immunity for activities related to medical countermeasures being taken against the ongoing COVID-19 pandemic. The declaration provides liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, testing, development, distribution, administration, and/or use of COVID-19 medical countermeasures (covered countermeasures).

Under the PREP Act and the HHS secretary's declaration, immunity from liability is limited and does not apply to liability for death or serious physical injury caused by willful misconduct. In addition:

- Immunity is not available for foreign claims where the U.S. has no jurisdiction or where U.S. law does not apply.
- The grant of immunity does not protect organizations from claims that are unrelated to covered countermeasures.
- Covered products must be "administered" to treat the coronavirus and used to treat the "population" of coronavirus patients. (There is no geographical limit on this, which means that covered products can be used to treat patients outside the U.S.)

HHS provided detailed information on covered countermeasures. These include:

- Any antiviral, other drug, biologic, diagnostic, other device, respiratory protective device, or vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV-2, or the transmission of a virus mutating from it, as well as any device used for the administration of any such product, and all components and constituent materials of any such product; and
- Respiratory protective devices that may not be medical devices, provided they are approved by the National Institute for Occupational Safety and Health ("NIOSH") and subject to the FDA's Emergency Use Approval Pathway ("EUA").

At this time, there are very few reported cases interpreting the PREP Act. COVID-19 class action lawsuits have already begun to enter the court system, such as a putative class action complaint filed against Vi-Jon Inc., the makers of alcohol-based hand sanitizer Germ-X, for Vi-Jon's "false and misleading promotion of its products' purported medicinal and virus preventive benefits."

In addition, federal courts in New Jersey and Kansas issued the first two orders addressing PREP Act immunity in the context of the COVID-19 declaration. In each case, the defendants operated residential health care facilities (nursing homes and/or rehabilitation centers), while the plaintiffs represented residents who allegedly had died at those facilities from COVID-19-related complications.

In the New Jersey case, the district court acknowledged that "claims related to the administration of designing, manufacturing, and distributing covered countermeasures to individuals [are] preempted." The court also noted that the purpose of the declaration "is to embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID 'countermeasures') with the assurance that they will not face liability for having done so."

In the Kansas case, the court found that the PREP Act creates immunity for all claims of loss causally connected to the administration or use of covered countermeasures, which are certain drugs, biological products, and devices. The court also recognized that the immunity provisions apply to a wide range of circumstances and situations, including (1) injuries "arising out of, relating to, or resulting from" the administration of covered countermeasures (rather than those directly "caused" by the use), (2) "activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients," (3) "management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures," (4) situations in which the injured party was not the one who "received the countermeasure," and (5) situations involving a variety of countermeasures including biological products, devices, and respiratory protective devices.

For pharmaceutical and medical device companies (and related entities), these cases present relatively good news. Although it is early and all the relevant statements are dicta, both courts seem to interpret the PREP Act broadly to provide expansive liability protection for situations in which injuries (or damages) occur as a result of the use (or even misuse) of drugs and medical devices intended to treat, prevent, or otherwise assist in the care of patients with COVID-19.

The CBD Industry

► House Bill Would Allow FDA to Regulate CBD as Supplement

This year, a bipartisan group of representatives introduced a bill that would provide the FDA with authority to regulate cannabidiol ("CBD") as a dietary supplement. The bill, known as H.R. 5587, would allow hemp-derived CBD and substances containing CBD to be marketed as dietary supplements. It would also allow CBD and CBD substances in food. Representatives are asking that the Federal Food, Drug, and Cosmetics Act ("FDCA") be amended to incorporate regulation of hemp-derived CBD and hemp-derived CBD-containing substances. The bill remains pending.

Jurisdictional Litigation

► Pending U.S. Supreme Court Cases

The U.S. Supreme Court recently heard oral argument on two consolidated cases that may impact the jurisdictional arguments out-of-state defendants can make. The cases are *Ford Motor Co. v. Montana Eighth Judicial Dist Ct.* ("*Montana*") and *Ford Motor Co. v. Bandemer* ("*Bandemer*"). Both cases look to answer the same question – whether a state court can exercise personal jurisdiction over a nonresident defendant when none of the defendant's contacts within that state caused the plaintiff's injuries. In particular, these cases hone in on the U.S. Supreme

Court's ruling in *Burger King Corp.* in which the Court found that a state court can only exercise specific jurisdiction over a nonresident defendant when the plaintiff's claims "arise out of or relate to" the defendant's forum contacts, as well as the U.S. Supreme Court's ruling in *Bristol Myers Squibb*, which held that there must be a "connection between the forum and the specific claims at issue."

The facts in these cases, however, make applying those rules a bit difficult. In *Montana*, an action was brought on behalf of a Montana resident, who was driving a Ford Explorer on a Montana freeway when the tread on one of her tires separated. She lost control of the vehicle and died as a result of the vehicle rolling into a ditch. Her estate sued Ford in Montana state court, alleging causes of action for design defect, failure to warn, and negligence. Ford moved to dismiss the claims for lack of personal jurisdiction. Within its motion, Ford argued it was headquartered in Michigan and incorporated in Delaware. The vehicle in question was assembled in Kentucky and first sold to a dealership in Washington state. The dealership then sold it to an Oregon resident, who later sold it to someone who took it to Montana. Ford's motion to dismiss was denied by the district court, on the grounds that Ford did have a "connection between the forum and the specific claims at issue." The Montana Supreme Court affirmed, further finding that Ford had advertised and sold parts within the state of Montana and had availed itself of the privilege of doing business in the state, such that it was subject to specific jurisdiction.

Similarly, in *Bandemer*, the Minnesota Supreme Court decided that Ford could be sued in Minnesota state court over an accident that occurred in 2015 in which the plaintiff was allegedly injured after the 1994 Crown Victoria in which he was riding slammed into the back of a snowplow. The plaintiff claimed that the Crown Victoria's airbag failed to deploy. Ford didn't deny it made the vehicle but rather argued that it was manufactured in Ontario, sold in North Dakota, and only wound up in Minnesota after 17 years and several transactions on the used-car market. The Minnesota Supreme Court upheld the trial court's decision to exercise personal jurisdiction over Ford. The U.S. Supreme Court heard oral argument on the consolidated cases on October 7. Although the court has not yet released an opinion, a positive outcome of these cases would certainly strengthen an out-of-state defendant's position in future motions to dismiss based on lack of personal jurisdiction in federal court and motions to quash for lack of personal jurisdiction in California state court.

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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. Since then, the firm has grown to over 55 attorneys, with offices in Orange, Los Angeles, San Francisco and Seattle, and is known for excellence in litigation and transactional matters. We are equally distinct in our longstanding commitment to diversity, which is recognized through our certification as a Women's Business Enterprise (WBE) by the Women's Business Enterprise National Council (WBENC) and by the California Public Utilities Commission. We are proud to have the largest California attorney presence of certified WBE law firms in the United States. Walsworth is also a National Association of Minority and Women Owned Law Firms (NAMWOLF) member, the largest in California. For more information, visit www.wfbm.com.