
# Life Sciences Litigation

## 2021 Year in Review

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

### Updates in Litigation – Drugs

► Out-of-State Claims Dismissed in Valsartan MDL

On January 12, a New Jersey federal judge found that out-of-state consumers in a multidistrict litigation ("MDL") who alleged contamination of the blood pressure drug Valsartan did not have standing to bring claims under the laws of states in which they do not reside.

In his order, U.S. District Judge Robert B. Kugler noted the named plaintiffs represent only 21 states but have asserted claims under the laws of all 50 states. Because the plaintiffs brought claims in states where they neither lived nor were injured, Judge Kugler dismissed their claims for lack of standing. Judge Kugler rejected the plaintiffs' argument that non-resident plaintiffs may bring out-of-state claims so long as the class representatives have standing.

The MDL arose out of a 2018 investigation by the U.S. Food and Drug Administration ("FDA") of impurities found in Valsartan. After a number of voluntary recalls, consumers filed proposed class actions alleging personal injuries as well as financial losses, claiming the drugs they received were not therapeutically equivalent to Valsartan's reference-listed drug, Diovan.

► Bristol Myers and Sanofi to Pay $834 Million in Hawaii Plavix Case

On February 15, a Hawaii state judge ordered Bristol-Myers Squibb Co. ("Bristol Myers") and Sanofi SA ("Sanofi") to pay $834 million to the state for failing to properly warn non-white users of the health risks of its blood thinner Plavix.

Within the lawsuit, Hawaii Attorney General Clare Connors claimed the companies violated state consumer protection laws by marketing Plavix without disclosing that the drug could have a diminished or no effect on some people, particularly those of East Asian and Pacific Island ancestry. Judge Dean Ochiana, who presided over the four-week, non-jury trial conducted entirely over Zoom due to the COVID-19 pandemic, found that the companies were aware when they began marketing Plavix in 1998 that it had a diminished or no effect on 30% of the population due to poor drug metabolism, including some with genetic predisposition who could be identified with genetic testing.

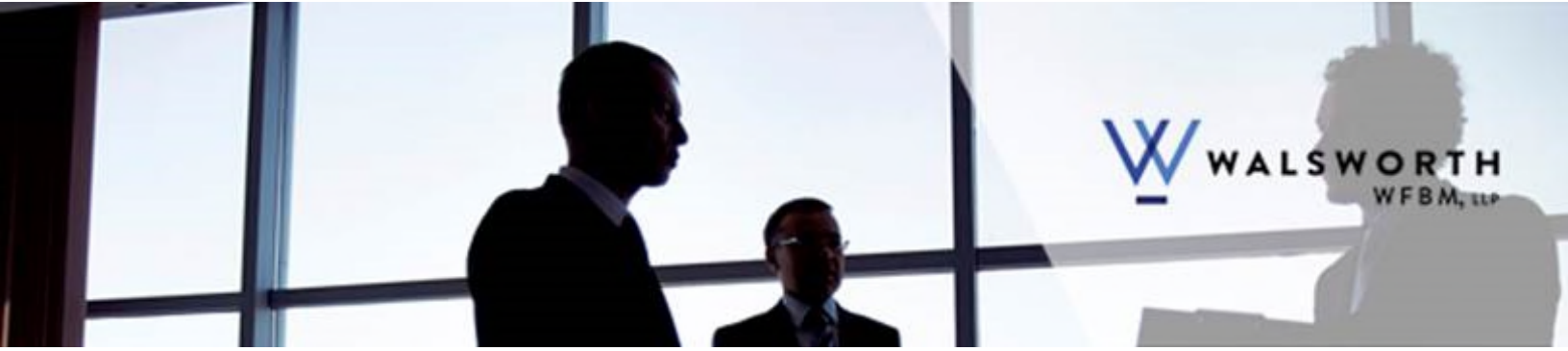
Plavix, which is manufactured by Bristol Myers and Sanofi, is prescribed to prevent strokes and heart attacks and received FDA clearance in 1997. The blood thinner needs to get activated by the body's own enzymes, which can vary genetically. In 2010, the FDA added a black box warning to Plavix's label warning about the metabolic issues, and it pushed prescribers to use genetic testing to determine patients' enzymatic function.

Bristol Myers and Sanofi face a similar lawsuit over Plavix by the State of New Mexico.

► AstraZeneca Dismissed in Farxiga Case

On April 5, a Delaware state judge dismissed AstraZeneca PLC ("AstraZeneca") in a case in which plaintiffs alleged the company's diabetes drug – Farxiga – caused the development of gangrene, requiring emergency surgery.

Plaintiffs Jeffrey Pope ("J. Pope") and Cynthia Pope alleged J. Pope was prescribed Farxiga in 2016 to treat his Type 2 diabetes as well as to aid in weight loss. In




June 2018, J. Pope was diagnosed with Fournier's gangrene, an acute necrotic infection of the scrotum. J. Pope was hospitalized for 10 days and had to undergo emergency surgery. Plaintiffs argued that Farxiga was defectively designed and because J. Pope was prescribed Farxiga for an off-label use, i.e., managing his weight loss, it thus fell under the federal preemption exemption.

Judge Sheldon K. Rennie disagreed and found that plaintiffs' claims were preempted by federal law. In making his ruling, Judge Rennie noted that because J. Pope was prescribed Farxiga for its FDA-approved use – treating Type 2 diabetes – he could not show that the off-label use, as opposed to the FDA-approved use, caused his injuries. As to the design defect claim, Judge Rennie noted that AstraZeneca could not have changed the design of the drug after the FDA's approval.

- Fifth Circuit Affirms Sanofi Win in Taxotere Case

On April 5, the Fifth Circuit Court of Appeals affirmed a lower court's decision to grant summary judgment in favor of Sanofi in an action in which a woman alleged Sanofi failed to inform her that its chemotherapy drug Taxotere could cause permanent hair loss, a condition known as alopecia, rather than temporary hair loss.

Plaintiff June Phillips ("Phillips") alleged Sanofi failed to warn her that she could experience permanent alopecia as a result of the use of Taxotere. Phillips' claims were dismissed last May following testimony from her oncologist, Dr. Scott Sonnier, who said he was aware that permanent hair loss was a risk when prescribing Taxotere to treat her breast cancer; however, it was the best available medication because of Phillips' age and cardiac condition. While Phillips argued she would have refused to take the medication if she had known about the risk of permanent hair loss, this was contradicted by her testimony during which she admitted that before receiving chemotherapy, she accepted its risks, including hair loss.

- GSK Dismissed in More Than 420 Lawsuits in Zofran MDL

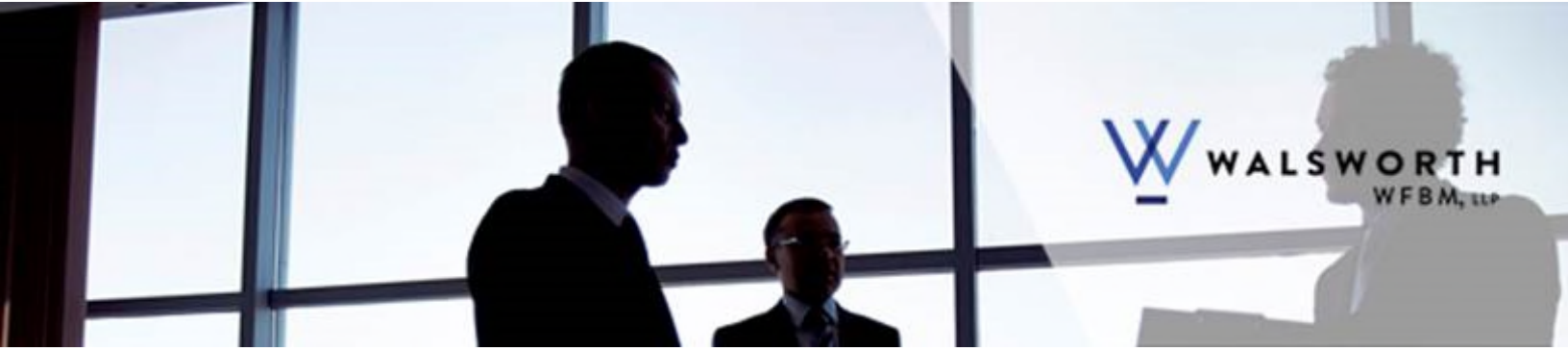
On June 1, a Massachusetts federal judge granted GlaxoSmithKline's ("GSK") motion for summary judgment in an MDL in which plaintiffs alleged GSK's anti-nausea medication – Zofran – caused birth defects finding that. This decision comes after a previous denial of GSK's motion for summary judgment. GSK's motion for summary judgment was previously denied by U.S. District Judge F. Dennis Saylor IV in 2019 on the grounds that preemption could be decided by jury. This recent decision, however, was premised on the U.S. Supreme Court's ruling in *Merck v. Albrecht*, which found that judges, not juries, should be the ones to determine which issues are promulgated by the FDA.

Within his 68-page opinion, Judge Saylor wrote that the FDA repeatedly rejected adding a warning label for pregnant women, despite knowing that Zofran was prescribed to pregnant women for years. Judge Saylor found there was "no question that the FDA is now fully informed of all relevant information concerning the safety of the drug. [The FDA] has made the determination that a label change is not warranted."

GSK will not have to face more than 420 lawsuits in the MDL in light of this ruling. The MDL was previously formed after the MDL panel found that 12 lawsuits, some of which are proposed class actions, warranted consolidation, as they all involved common allegations about GSK's Zofran and its generic equivalent.

- Pharmacies and Retailers Dismissed From Zantac MDL

On July 1, a Florida federal judge dismissed Albertsons Cos. Inc., Walgreen, CYC Pharmacy Inc., Costco Wholesale Corp., the Kroger Co., Amazon.com, and others in an MDL over the heartburn medication – Zantac – in which plaintiffs claimed the companies' negligence played a part in a carcinogen forming in the drug.




► Actavis Gets Win in Illinois Androderm Trial

On August 17, an Illinois federal jury found that Actavis Inc.'s ("Actavis") testosterone replacement drug – Androderm – did not cause a man's heart attack.

Plaintiff Brad Martin ("Martin") claimed his use of Androderm patches between October 2012 and May 2013 caused him to suffer a heart attack in May 2013. One (1) week prior to the trial concluding, Actavis asked U.S. District Judge Matthew Kennelly to end the trial because Martin had failed to establish that his use of Androderm caused his heart attack. Judge Kennelly denied the motion and allowed the jury to hear closing arguments and to deliberate.

After a nine (9) day trial and roughly one (1) hour of deliberation, the jury found in favor of Actavis.

► Florida Judge Gives Eisai and Arena a Partial Win in Belviq Diet Drug Action

On December 14, a Florida federal judge dismissed a woman's claim for fraudulent misrepresentation but allowed her claims for design defect in an action against Eisai Inc. ("Eisai") and Arena Pharmaceuticals, Inc. ("Arena") in which the woman alleged the companies' recalled diet drug – Belviq – caused her breast cancer.

Plaintiff Colleen Scala ("Scala") was diagnosed with breast cancer in May 2017. She alleged an active ingredient, lorcaserin, in Belviq was linked to increased instances of tumors. Within her complaint, Scala pointed to preclinical trial two-year studies conducted by the companies that identified lorcaserin as a possible carcinogen, as there were observed increases in mammary tumors among male and female rats that were exposed. Belviq was removed from the market in February 2020.

Arena won approval for the drug in 2012, and Eisai acquired it in 2016. It was the first time the FDA had approved a weight-loss drug since 1999.

## Updates in Litigation – Devices

### Hip Implant Litigation

► Federal Judge Affirms $21 Million Award Against Biomet

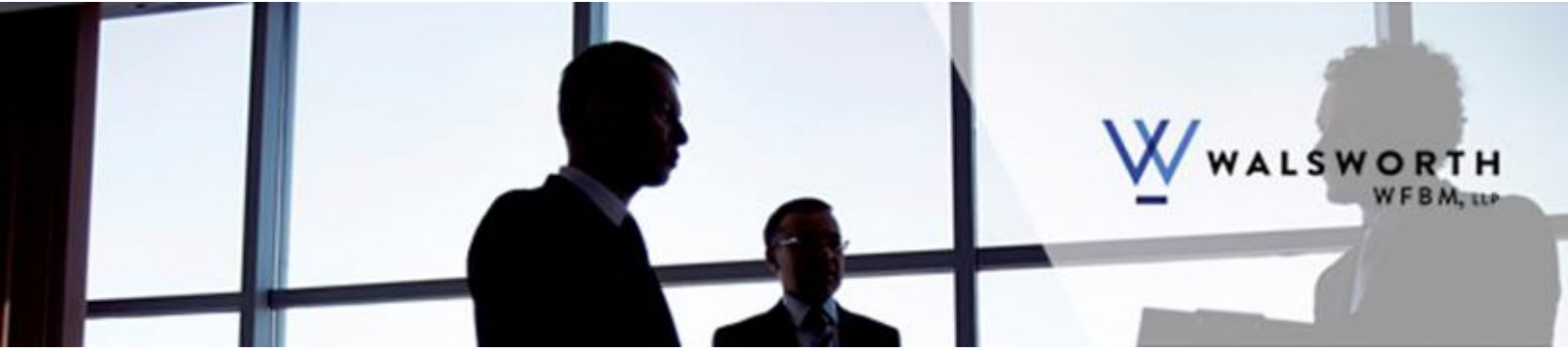
On August 3, a Missouri federal judge denied multiple post-trial motions brought by Biomet Inc. ("Biomet") in an effort to reverse a $21 million jury verdict in favor of a woman who alleged Biomet's hip implants were defective and caused her injuries.

Plaintiff Mary Bayes ("Bayes") 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. On November 24, 2020, a Missouri jury awarded $20 million to Bayes and $1 million to her husband, plus post-judgment interest and costs of action.

Following the verdict, Biomet filed various motions, including requests for a new trial, judgment as a matter of law, and alteration of the verdict. Within the motions, Biomet argued the award was excessive, especially in relation to a recent $3.5 million verdict against the company. The judge denied these arguments and found Bayes was entitled to higher damages because she endured much greater pain and had to undergo multiple surgeries following her first hip replacement.

► New York Federal Judge Grants Summary Judgment in Favor of Zimmer in Hip Implant MDL

On August 9, a New York federal judge granted summary judgment in favor of Zimmer Inc. ("Zimmer") in the first bellwether trial in MDL in which a woman claimed Zimmer's hip prosthetics were defective and caused her injuries.




Plaintiff Tamma Nutting ("Nutting") had total hip replacement surgery in 2011, when her surgeon used two of Zimmer's products, a cobalt-chrome VerSys Femoral Head and a Taper Kinectiv Stem and Neck. In 2017, Nutting began experiencing pain in the area, and a series of tests showed her cobalt levels were elevated. Nutting's physician replaced the Zimmer products and found inflammation, dead tissue, and signs of corrosion on the femoral head device. Nutting claimed the Zimmer products were defective in design and labeling. To support her claim, Nutting proffered expert opinions from a biomedical engineer, Mari Truman, who opined that a "mismatch" in the connection between the femoral head and the Kinectiv neck caused Nutting's injuries because it allowed movement, which resulted in corrosion. Zimmer moved to have Truman's testimony excluded on the grounds that it lacked support. U.S. District Judge Paul A. Crotty agreed and found that Truman's conclusions had "too large of a gap." Judge Crotty noted that any pair of medical devices will have some mismatch, and Truman failed to identify what degree of mismatch would create corrosion.

In his opinion, Judge Crotty found Nutting could not establish a design defect claim without an expert. He also found that Nutting's failure-to-warn claims failed because Nutting's physician testified he read the company's warnings and instructions and relied on his own experience in implanting the device and that Zimmer's duty to warn ran to her physician, not to Nutting.

- DePuy Gets Win in Hip Implant Lawsuit

On September 17, a New York federal judge granted summary judgment in favor of DePuy Orthopedics Inc. ("DePuy") in an action in which a woman alleged she suffered injuries following a hip implant.

Plaintiff Jodie Rouviere ("Rouviere") had hip replacement surgery in 2012, during which time her doctor implanted a device that combined components made by two (2) companies, DePuy and Howmedica Osteonics, Corp. ("Howmedica"). Rouviere claimed the parts conflicted with one another and caused pieces to improperly move. To support her claims, Rouviere retained three (3) experts – the first expert "mysteriously" withdrew, and the second expert was disqualified because he had previously been used as an expert by DePuy in another action involving its hip implant parts, which led to the retention of the third expert. However, because the second expert was disqualified while DePuy's summary judgment motion was pending, the judge allowed only the third expert to provide expert testimony on the same subjects the second expert had discussed, and the second expert testified about only alleged defects in Howmedica's product, not in DePuy's. The judge also found that Rouviere's warning defect claims failed because Rouviere failed to show her doctor would have acted differently had the warnings been changed.

Howmedica is now the only remaining defendant in this lawsuit.

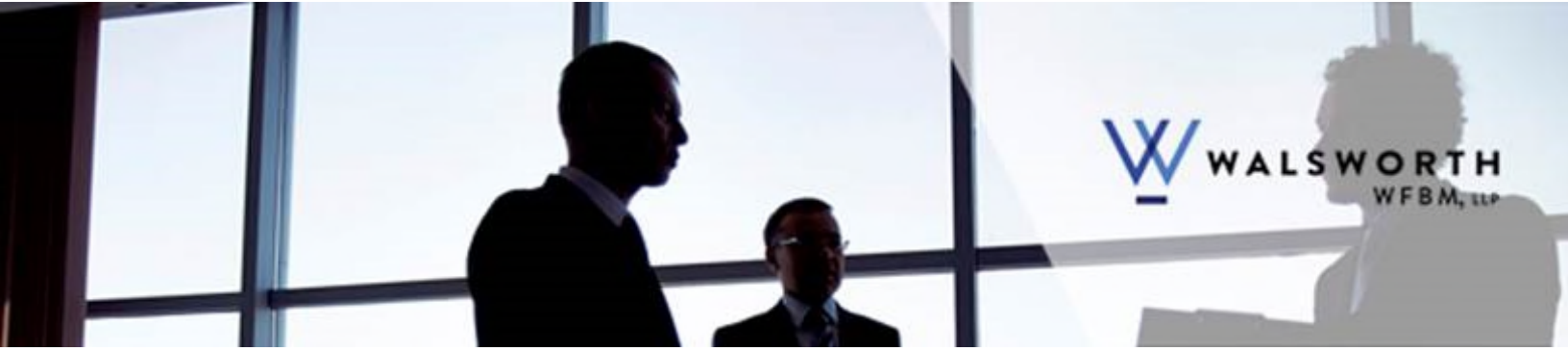
## Pelvic Mesh Litigation

- New Jersey Appeals Court Overturns 2 Verdicts Totaling $83 Million in Pelvic Mesh Lawsuit

On March 2, a New Jersey appeals court overturned two (2) verdicts totaling $83 million in separate pelvic mesh lawsuits against Johnson & Johnson ("J&J") subsidiary, Ethicon Inc. ("Ethicon") and C.R. Bard, Inc. ("Bard").

In the Ethicon lawsuit, a jury awarded plaintiffs Elizabeth and Tadeusz Hrymoc $5 million in compensatory damages and $10 million in punitive damages after finding Ethicon's pelvic mesh device was defective in design and labeling under New Jersey product liability laws. In the Bard lawsuit, a jury awarded plaintiffs Mary and Thomas Walsh McGinnis $33 million in compensatory damages and $35 million in punitive damages after finding Bard's pelvic mesh device was defective in design and labeling under North Carolina product liability laws.

The appeals court overturned both verdicts, holding that the trial judges erred in disallowing evidence that each company's mesh product received FDA 510(k)




clearance, as it precluded the companies from sharing relevant and important information about the devices. The three-judge panel concluded that the "disallowance of such proof had the patent capacity to deprive defendants of a fair trial, most poignantly with respect to the state-of-mind and venal conduct issues that underlie the punitive damages awards."

The jury decisions were vacated, and the cases were remanded for new trials.

- Boston Scientific Will Pay $188 Million to Settle Surgical Mesh Claims

On March 23, Boston Scientific Corporation ("Boston Scientific") agreed to pay $188 million to settle lawsuits brought by 47 states and the District of Columbia, which alleged the company deceptively marketed its transvaginal surgical mesh devices to women by failing to disclose the full range of potentially serious and irreversible complications caused by surgical mesh, including chronic pain, voiding dysfunction, and new onset of incontinence. As part of the terms of the settlement, Boston Scientific is also required to complete a number of marketing, training, and clinical trial reforms.

Since 2018, Boston Scientific has faced more than 48,000 lawsuits related to its surgical mesh. The FDA ordered the company to pull the products from the market after it determined Boston Scientific had not demonstrated the safety and efficacy of the devices.

- Sixth Circuit Reinstates Ethicon Pelvic Mesh Claims

On August 5, the Sixth Circuit Court of Appeals reinstated claims brought against Ethicon, finding the trial court erred in granting summary judgment in an action involving Ethicon's Prolift pelvic mesh device.

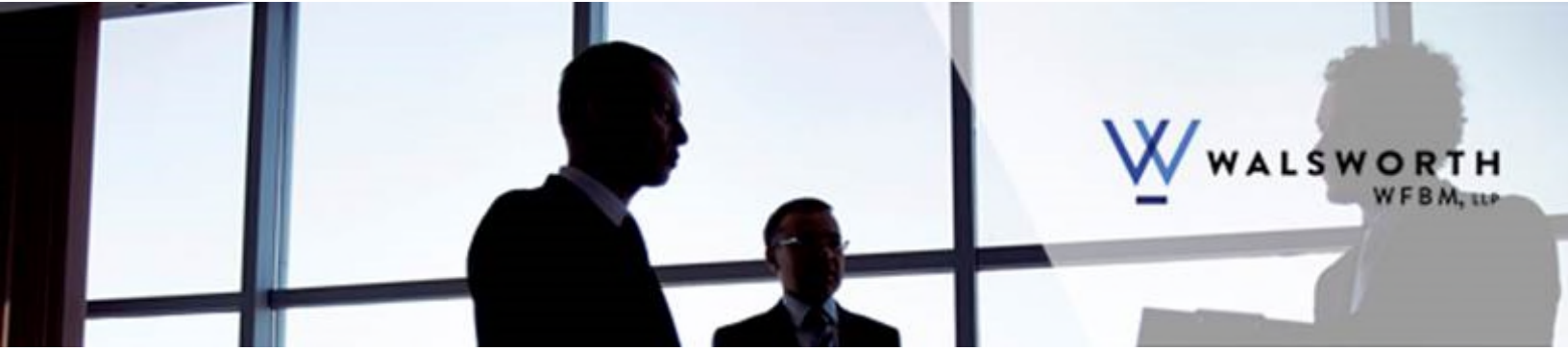
Plaintiff Jenesta Cutter ("Cutter") received Ethicon's device in 2006 to treat her pelvic organ prolapse. Soon thereafter, she began experiencing pelvic pain, soreness, burning, constipation, and urine leakage. Her doctor determined these symptoms were caused by the mesh becoming loose. Cutter underwent two corrective surgeries and a third surgery to remove the mesh. She brought her lawsuit in May 2012 claiming negligence, defects, and misrepresentation on the part of Ethicon. Ethicon moved to dismiss and for summary judgment on all counts. In January 2020, the district judge dismissed Cutter's 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 on her doctor's advice.

On appeal, Cutter argued the earliest she discovered her injuries was in June 2011, and thus her claims were not time-barred. The three-judge panel agreed and noted that the discovery rule is tolled when the cause of the injury is not immediately apparent. The panel found Cutter exercised due diligence by repeatedly visiting physicians after she began to experience pain after the mesh was implanted; however, her physicians told her the mesh was not the problem, and it was not until June 2011 that Cutter believed the mesh caused her injuries. The district court's ruling on the failure-to-warn claims was upheld.

- Florida Federal Judge Denies Ethicon's Summary Judgment Motion in Pelvic Mesh Lawsuit

On October 1, a Florida federal judge denied Ethicon's summary judgment motion in a lawsuit involving its pelvic mesh product, the Gynecare Prolift Pelvic Floor Repair System and Gynecare TVT Obturator System.

Plaintiff Adhelheir Pirlein ("Pirlein") had Ethicon's Gynecare Prolift Pelvic Floor Repair System and Gynecare TVT Obturator System surgically implanted in March 2008 to fix her pelvic organ prolapse and stress urinary incontinence issues. After the surgery, Pirlein complained to her doctor about vaginal bleeding and stress urinary incontinence. Pirlein's doctor found the mesh had become exposed, and in




August 2008, she underwent corrective surgery. Pirlein filed her lawsuit in August 2012.

In its motion, Ethicon argued that Pirlein's claims were barred by Florida's four-year statute of limitations because Pirlein was put on notice that something was wrong soon after her March 2008 surgery. U.S. District Judge Aileen M. Cannon disagreed. In her opinion, Judge Cannon stated that Pirlein's symptoms were not sufficiently distinct from what is normally expected following surgery and she had no reason to believe at first that the mesh was defective.

## Inferior Vena Cava ("IVC") Filter Litigation

► Bard to Pay $3 Million in Vein Filter Lawsuit

On June 18, a Wisconsin federal jury awarded $3 million to a woman who alleged a vein filter made by Bard broke and a part became embedded in her heart.

Plaintiff Natalie Johnson ("Johnson"), 60, was implanted with Bard's Meridian IVC Filter in 2013 in anticipation of a surgery involving her lower extremities. The IVC filter was placed to prevent a pulmonary embolism. In 2018, a CT scan revealed the IVC filter had fractured into pieces. One of the pieces traveled to her heart, and another piece became embedded in her vein. Due to these serious complications, she required multiple surgeries to remove the filter as well as the broken pieces.

Following a nine (9) day trial and three (3) days of deliberation, the unanimous jury awarded Johnson $3.3 million.

► Bard Gets a Win and a Loss on the Same Day in 2 Separate IVC Filter Lawsuits

On July 21, a Michigan federal judge granted summary judgment in favor of Bard in a lawsuit in which a woman claimed she was injured after Bard's Eclipse IVC Filter broke inside her. The same day, a Texas federal jury awarded a woman $386,250 in compensatory damages in an action involving Bard's Recovery IVC Filter.

In the Michigan case, resident plaintiff Mary Lou McMan ("McMan") was treated with Bard's Eclipse IVC Filter in August 2010 because of lower extremity deep vein thrombosis and an upcoming gastric bypass surgery. An October 2012 x-ray showed the filter was missing a leg and that the filter leg was in the left side of McMan's pelvis. McMan initiated her action against Bard in December 2016. U.S. District Court Sean F. Cox found McMan's claims were barred by Michigan's three-year statute of limitations.

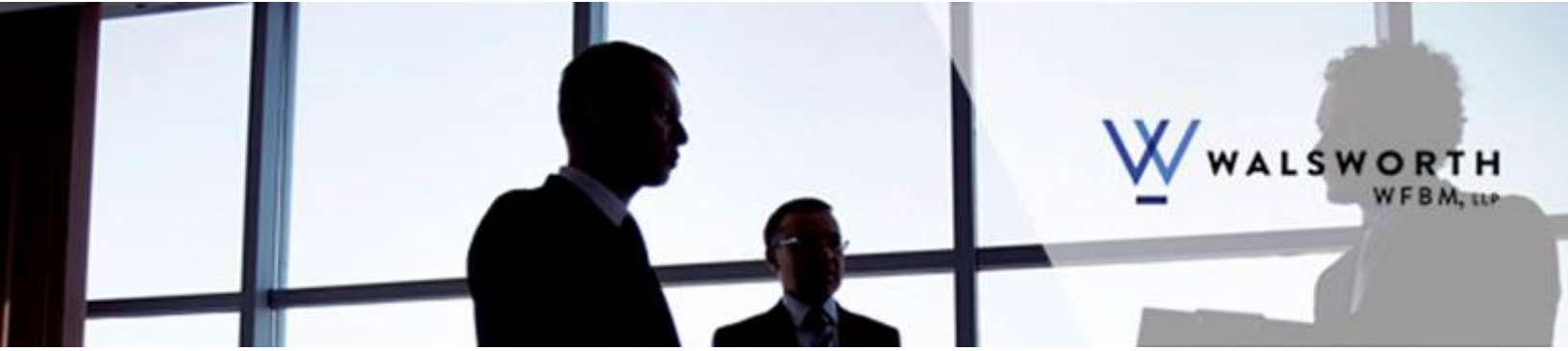
In the Texas case, resident plaintiff Debra Branch was treated with Bard's Recovery IVC filter. The filter fractured after it was implanted and caused Branch serious medical complications. The jury awarded Branch $110,625 for past and future pain and mental anguish, $164,375 for past and future disfigurement, and $111,250 for past and future physical impairment and found Bard was negligent in the design of the filter; however, the jury found there was no defect in the warnings.

► Cook Gets Win in Indiana Vein Filter Lawsuit

On August 12, an Indiana federal judge granted Cook Medical LLC's ("Cook") motion for judgment on the pleadings in an MDL in which a Michigan man claimed he suffered injuries after a faulty IVC filter manufactured by Cook was implanted.

Plaintiff Diondrae Boone ("Boone") was implanted with a Cook Gunther Tulip Vena Cava Filter in 2015. Two months later, his physician attempted to remove the filter but was unsuccessful. Boone filed his complaint in May 2019, nearly four (4) years after the attempted removal. U.S. District Judge Richard L. Young found Boone's claims were barred by Michigan's three-year statute of limitations.

Lawsuits against Cook were filed in federal court in 11 states. In these actions, plaintiffs alleged Cook failed to warn patients of the known dangers and risks associated with the vein filters, produced "unreasonably dangerous" filters with a design defect,




was negligent in its duty of care to patients, and breached warranties with respect to the filters.

► C.R. Bard Gets Win in California IVC Lawsuit

On August 24, a California federal jury found in favor of Bard in an action in which a California man alleged its G2x IVC was negligently designed because the device broke following implantation and could not be surgically removed.

Plaintiff Francis Laloli ("Laloli") was implanted with the Bard G2x filter in 2009 after being admitted to a California hospital for lower extremity deep vein thrombosis. Laloli claimed the filter broke and fragments migrated into his lungs and heart, where they could not be retrieved.

After a three (3) week trial and less than two (2) hours of deliberation, the jury found Bard did not negligently design the G2x filter.

## Other Device Litigation

► Sorin Gets Win in Heart Valve Death Lawsuit

On February 12, a Massachusetts federal judge granted summary judgment in favor of Sorin Group USA Inc.'s subsidiary, LivaNova PLLC ("Sorin"), in a lawsuit in which the parents of a teenager alleged Sorin failed to disclose a defect in its heart valve, leading to the teenager's death.

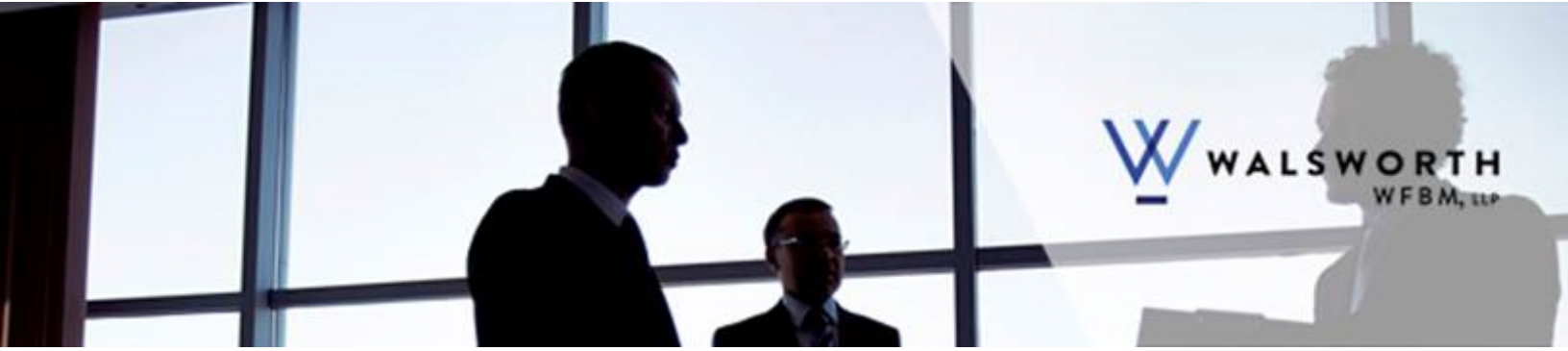
Plaintiffs William Plourde ("W. Plourde") and Freda Merill ("Merill") claimed physicians at Boston Children's Hospital ("BCH") surgically implanted the Sorin Mitroflow Bovine Pericardial Bioprosthetic Aortic Heart Valve in Allison Plourde ("A. Plourde") in June 2012. Approximately 1.5 years later, BCH conducted an autopsy of a 13-year-old girl who had received the same kind of implant. The autopsy revealed the valves of the implant were heavily calcified. The BCH doctors then called young patients, including A. Plourde, informed them of their findings, and requested additional screening of the patients. The day after, A. Plourde underwent heart surgery, during which time the doctors discovered the device had deteriorated. A. Plourde died following the procedure. W. Plourde and Merill alleged Sorin knew about these issues and failed to inform the FDA.

Sorin stated it informed the FDA of these issues six (6) months before A. Plourde's death and argued the claims were preempted by federal law. Sorin further noted the risk of calcification was known to Plourde's physician at the time of implant. Any additional information would not have influenced his decision to use the device. The court agreed and found judgment in favor of Sorin.

► Tennessee Federal Judge Grants Summary Judgment in Zoll Defibrillator Defect Lawsuit

On December 3, a Tennessee federal judge granted summary judgment in favor of Zoll Medical Corp. ("Zoll") in a wrongful death lawsuit in which a woman claimed the company's refurbished defibrillator vest – the LifeVest – failed to save her husband's life.

Plaintiff Doris Smith's ("Smith") husband, Alex Smith ("Decedent"), was provided a refurbished LifeVest to treat his arrhythmia. The LifeVest is used to detect irregular rhythms of the heartbeat. Upon detection, the device sets off an auditory alarm and delivers electric shocks to get the heartbeat back to a regular rhythm. In March 2019, Decedent died when the LifeVest failed to perform. Smith claimed an inspection of the LifeVest showed the battery was not connected properly and Zoll had performed an incomplete refurbishment to get the device back on the market quickly. In its motion, Zoll argued Smith had failed to proffer any expert opinion to support her claims. Despite the court providing Smith with additional time to provide the necessary evidence, Smith failed to do so, and the court granted judgment in favor of Zoll.




## Updates in Litigation – Talc

- New Jersey Appellate Court Overturns $117 Million Talc Verdict Against J&J and Imerys

On April 28, a New Jersey state appeals court overturned a $117 million verdict against J&J and Imerys Talc America ("Imerys") in a lawsuit in which plaintiffs claimed J&J's talcum powder products contained asbestos and caused a man's mesothelioma.

Plaintiffs Stephen Lanzo III ("Lanzo") and his wife alleged Lanzo developed mesothelioma after inhaling dust that was generated through his regular use of J&J talcum powder products after his birth in 1972. The three-judge appellate panel ordered a new trial and concluded that although Lanzo's expert testified there has been "published literature showing that non-asbestiform amphiboles cause mesothelioma, and that there have been studies of groups exposed to non-asbestiform minerals that show elevated rates of mesothelioma," she did not "identify any other specific literature or studies supporting those claims during her testimony."

- J&J Gets Win in Illinois Talc Trial

On July 30, an Illinois state court jury found that J&J was not liable for a woman's death from ovarian cancer, which her family claimed was caused by the woman's decades long use of J&J's talc-based powders.

Plaintiff Colleen Cadagin alleged her aunt, Elizabeth Driscoll ("Driscoll"), 69, used J&J's baby powder throughout her adolescent and adult lives on several areas of her body, including her perineal area for feminine hygiene purposes. Driscoll was diagnosed with stage four ovarian cancer in February 2015 and died in September 2016.

After a three (3) week trial, the jury ruled in favor of J&J and found that it did not cause Driscoll's fatal ovarian cancer.

- J&J Ordered to Pay $26.5 Million in California Talc Mesothelioma Trial

On August 23, a California state jury awarded $26.5 million to a plaintiff who alleged she developed mesothelioma from her use of J&J's talcum powder.

Plaintiff Christina Prudencio ("Prudencio"), 35, used J&J's talcum powder from birth until age 16, when she stopped using it. However, her exposure continued, as the product was used on her two (2) younger siblings. On her 34th birthday, Prudencio underwent surgery to try to get rid of her cancer. She was confined to bed rest for five (5) days following the surgery and also hemorrhaged.

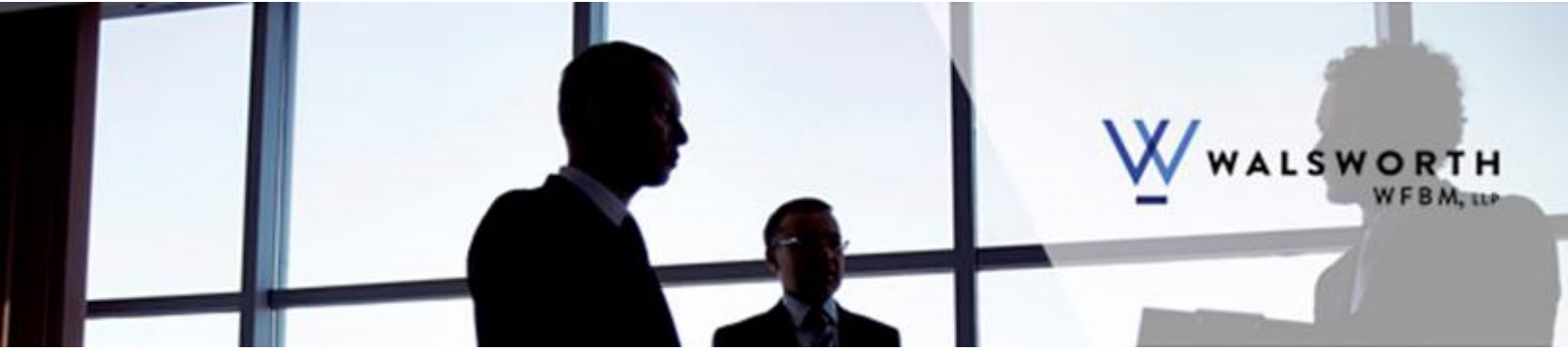
The jury sided with Prudencio and found J&J's baby powder caused Prudencio's cancer. The jury awarded $15 million for future noneconomic damages, including pain and suffering; $5 million for past noneconomic damages; $4.1 million for lost past and future income; $1.57 million for lost household services; and $800,000 for past medical costs.

- J&J Gets Win in Multi-Plaintiff Missouri Talc Trial

On September 28, a Missouri state jury rejected claims brought by three women who alleged J&J's talcum powder caused their ovarian cancer.

Plaintiff Susan Vogeler (Vogeler") was diagnosed with ovarian cancer in 2009 at the age of 51 and endured a dozen rounds of chemotherapy. She is currently in remission. Victoria Giese ("Giese") was diagnosed with ovarian cancer in 2013 at age 44 and has had two recurrences since. She is in treatment for the second one. Deborah Marino ("Marino"), who died of ovarian cancer in 2015, was diagnosed in 2009 at age 45. All three women required surgery to remove their uterus, fallopian tubes, and ovaries.

Following a two-week trial, the 12-panel jury returned a unanimous verdict in favor of J&J, finding that all three women suffered from different cancers – Giese had a low-grade serous cancer, Vogeler had a clear-cell cancer, and Marino had a high-grade serous




cancer. J&J argued it was unlikely that J&J's baby powder could have caused all three types of cancers. The jury agreed.

## Updates in Litigation – Opioids

- McKinsey Settles Opioid Marketing Lawsuits With All 50 States

On February 3, consulting firm McKinsey & Co. ("McKinsey") agreed to pay $573 million to settle lawsuits brought by 47 states related to its role in the opioid epidemic and to advice it gave to Purdue Pharma ("Purdue") regarding OxyContin. The settlement comes after documents showing McKinsey worked with Purdue to increase sales of OxyContin. McKinsey's work included advising Purdue to focus on selling lucrative high-dose pills. The firm also told Purdue that it could "band together" with other opioid manufacturers to head off "strict treatment" by the FDA.
On March 22, McKinsey agreed to pay $45 million to settle claims brought by the Nevada Attorney General related to its contribution to the opioid epidemic. The settlement was reached after Nevada opted out of the $573 million settlement with 47 other states. Nevada Attorney General Aaron Ford stated that Nevada has been hit hard by the opioid crisis, leading to the death of thousands of the state's residents, which is why it worked to achieve its own settlement.

Washington also entered into a separate opioid settlement, in the amount of $13.5 million, as did West Virginia, in the amount of $10 million.

McKinsey has now reached settlements with attorneys general of all 50 states as well as five U.S. territories and the District of Columbia. The settlement funds will be used to pay for opioid addiction treatment, prevention, and recovery programs.

- Indivior to Pay $300 Million to End Suboxone Lawsuits

On April 27, Indivior PLC ("Indivior") agreed to pay $300 million to all 50 states to settle allegations it falsely and aggressively marketed the opioid-based drug – Suboxone.

Indivior was accused of falsely promoting Suboxone Sublingual Film as safer and less addictive than other similar products. Indivior's former parent company, Reckitt Benckiser Group PLC, had already paid $700 million to resolve similar allegations in a 2019 settlement. Under the settlement, Indivior will pay $204 million to Medicaid and nearly $91 million to the states plus the District of Columbia and Puerto Rico for their Medicaid recovery. The payments resolve various civil fraud allegations that affected Medicaid and other federal health care programs, according to the settlement.

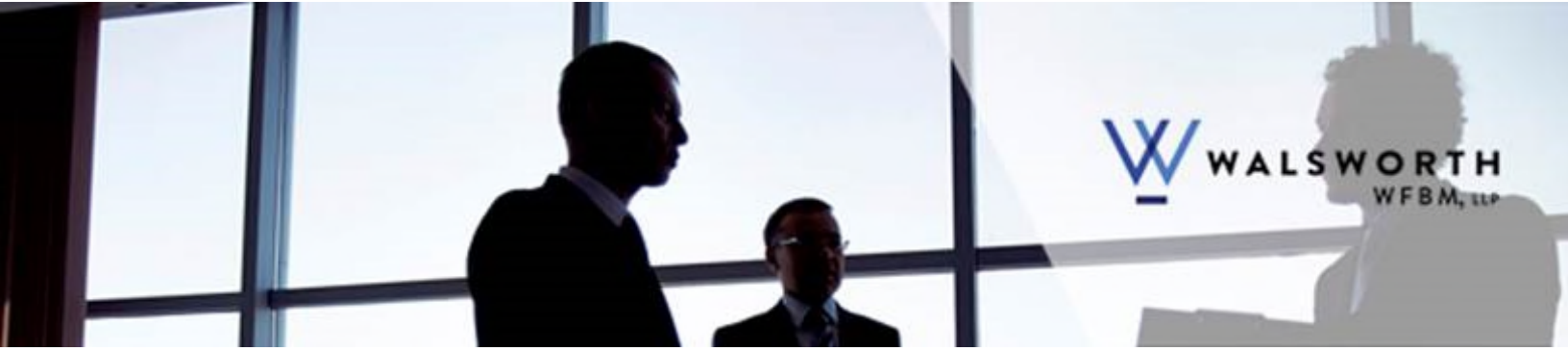
- Cardinal Health, AmerisourceBergen, and McKesson to Pay $1.1 Billion to Settle New York Opioid Lawsuit

On July 20, Cardinal Health Inc. ("Cardinal Health"), AmerisourceBergen Corp. ("AmerisourceBergen"), and McKesson Corp. ("McKesson") agreed to pay $1.1 billion to end their involvement in a lawsuit brought by the New York attorney general. The settlement will total $1.17 billion, $1 billion of which will go toward opioid addiction treatment and prevention programs. The remainder will assist with attorney fees.

The settlement will require all three (3) companies to share sales data with a clearinghouse to ensure opioid purchasers are properly using pills for legitimate medical needs.

- Purdue Reaches $4.5 Billion Opioid Deal With 15 States

On July 8, fifteen (15) states announced they would join the $4.5 billion opioid settlement in exchange for a release of millions of documents and an additional




$50 million contribution from the company's owners – the Sacklers. Over two years ago, the Sacklers proposed a $3 billion settlement in response to increasing litigation. Both the company and the family members had resisted releasing the full documents, including thousands of work emails and communications with lawyers, dating back 20 years. Purdue and the Sacklers will now release some 33 million pages of documents.

- Attorneys General Announce $26 Billion Global Opioid Deal

On July 21, several attorneys general announced a $26 billion global settlement with J&J, Cardinal Health, AmerisourceBergen, and McKesson. This settlement ends the majority of suits against the drug maker and the distributors. Of the settlement amount, $5 billion will come from J&J over the next nine years, and $21 billion will come from the distributors over the next 18 years. Up to $23.5 billion of the total settlement will go toward efforts to ease the opioid epidemic. Under the terms of the settlement, J&J will stop its opioid sales, and the drug distributors will share data about opioid shipments with an independent monitor.

The states attorneys general from the following states joined the global settlement: New York, California, Colorado, Connecticut, Delaware, Florida, Georgia, Louisiana, Massachusetts, North Carolina, Ohio, Pennsylvania, Tennessee, New Jersey, and Texas.

- Endo Agrees to Pay $50 Million in New York Opioid Lawsuit

On September 9, Endo Pharmaceuticals ("Endo") agreed to pay $50 million to end a New York opioid trial against it following allegations that the company and its lawyers, Arnold & Porter, concealed evidence of Endo's improper marketing of its painkillers. The settlement will not impact the state's pending motion to have Arnold & Porter held in contempt for its role in Endo's alleged failure to fulfill discovery obligations; however, it did render the state's motion to have Endo deemed liable by default for alleged discovery violations moot.

- Ohio Accepts $808 Million Settlement With 3 Opioid Distributors

On September 16, Cardinal Health, AmerisourceBergen, and McKesson agreed to pay $808 million to end an opioid lawsuit brought by the Ohio attorney general. As part of the settlement, the distributors also agreed to pay $42.4 million in legal fees and to implement reforms to end the opioid crisis in Ohio.

More than 23,700 Ohioans died of opioid overdose from 2010 through 2019. The settlement will require that the three (3) distributors undergo a series of reforms and also "establish a centralized independent clearinghouse to provide all three distributors and state regulators with aggregated data and analytics about where drugs are going and how often, eliminating blind spots in the current systems used by distributors."

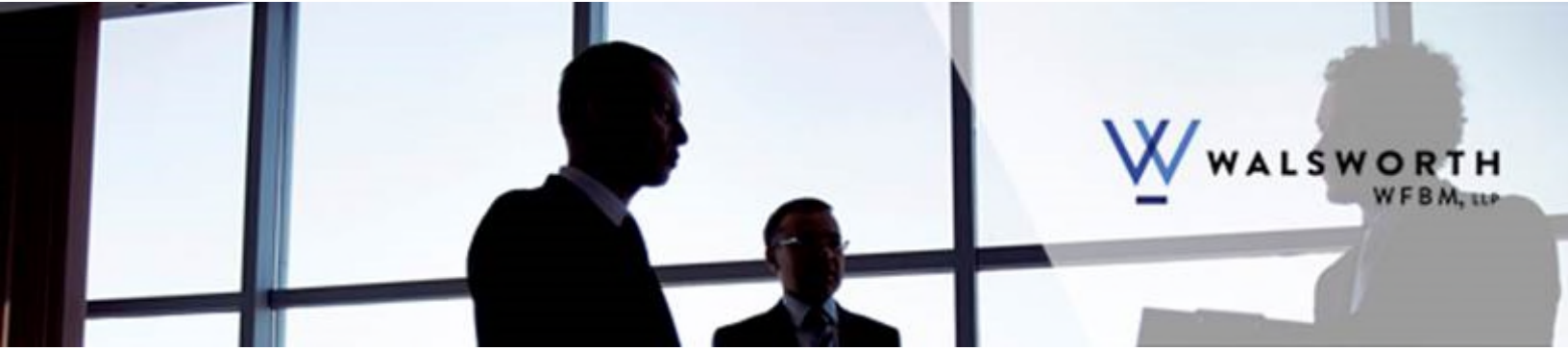
- Cherokee Nation Reaches $75 Million Settlement With 3 Opioid Distributors

On September 28, the Cherokee Nation announced it reached a $75 million settlement with Cardinal Health, AmerisourceBergen, and McKesson over claims that the companies contributed to the opioid epidemic. Cherokee Nation Attorney General Sara Hill said the settlement will go toward helping reduce and prevent opioid addiction within the reservation.

The settlement came three (3) weeks after U.S. Magistrate Judge Stephen P. Shreder paused the Cherokee Nation's bellwether trial to allow the parties to discuss a possible global settlement of claims.

- Endo to Pay $7.5 Million in Louisiana Opioid Lawsuit

On September 28, Endo reached a settlement in principle in the amount of $7.5 million with the Louisiana attorney general to end all opioid claims brought by the state and other Louisiana governmental entities. The settlement will be subject




to the full participation of Louisiana's political subdivisions. The settlement will not include an admission of wrongdoing, fault, or liability of any kind by Endo.

- Oklahoma Supreme Court Reverses $465 Million Opioid Verdict Against J&J

On November 9, the Oklahoma Supreme Court overturned a $465 million opioid verdict against J&J, finding that the lower court incorrectly interpreted the state's public nuisance law.

In a 5-1 decision, the court found that District Judge Thad Balkman incorrectly found that J&J and its subsidiary, Janssen Pharmaceuticals ("Janssen"), violated the state's public nuisance statutes. In the 28-page decision, the court noted that "J&J had no control of its products through the multiple levels of distribution, including after it sold the opioids to distributors and wholesalers, which were then disbursed to pharmacies, hospitals, and physicians' offices, and then prescribed by doctors to patients."

Public nuisance claims are at the heart of some 3,000 lawsuits brought by state and local governments against drug manufacturers and distributors and pharmacies. However, it is not clear whether the legal theory is in trouble in light of the thousands of pending cases.

- Allergan to Pay $200 Million in New York Opioid Lawsuit

On December 8, Allergan PLC ("Allergan") announced it reached a settlement of up to $200 million, putting a New York opioid trial brought by state and county governments against the company. Allergan was one of three remaining defendants in a trial that has lasted more than six (6) months over claims that the drug manufacturers helped fuel the opioid crisis.

- J&J, Endo, Teva, and Allergan Get Win in California Opioid Lawsuit

On December 14, a California state judge issued a final ruling and rejected allegations that J&J, Endo, Teva Pharmaceuticals ("Teva") and Allergan created a "public nuisance" in the form of the opioid crisis. In a 42-page tentative ruling, which was issued on November 1 following a month long trial and ultimately made final, Orange County Superior Court Judge Peter J. Wilson wrote that the City of Oakland and Counties of Orange, Los Angeles, and Santa Clara "failed to prove an actionable public nuisance for which defendants ... are legally liable" and further stated there was "no evidence to show that the rise in prescriptions was not the result of the medically appropriate provision of pain medications to patients in need."

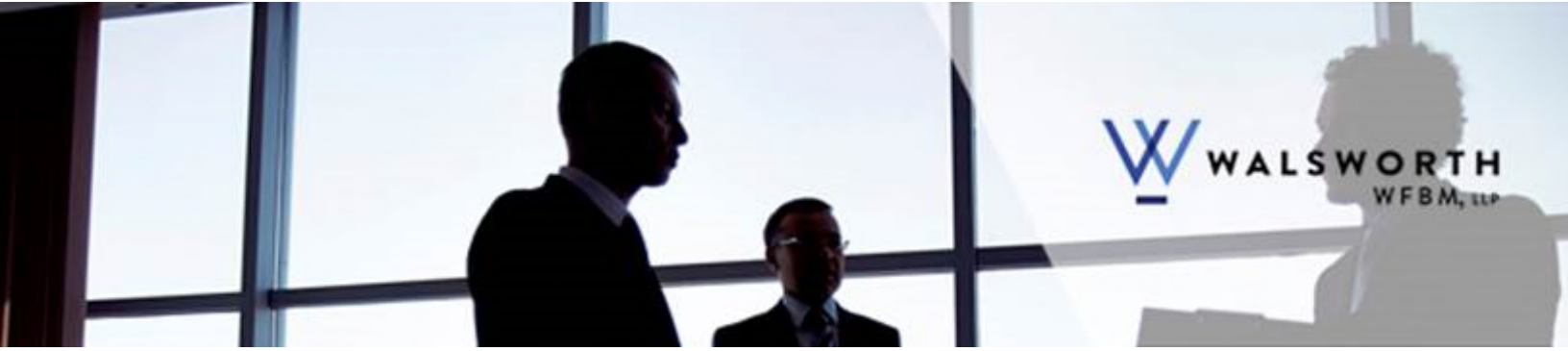
## Trends in Life Science

### Coronavirus (COVID-19) Updates

- COVID-19 Vaccines, Emergency Use Authorizations, and FDA Approval

Three (3) manufacturers previously received Emergency Use Authorizations ("EUA") for their COVID-19 vaccines. On December 11, 2020, the FDA issued an EUA for the use of the Pfizer-BioNTech COVID-19 vaccine; on December 18, 2020, the FDA issued an EUA for the use of the Moderna COVID-19 vaccine; and on February 27, 2021, the FDA issued an EUA for the use of the J&J COVID-19 vaccine. The EUA allowed use of the vaccines without full FDA approval.

On August 23, Pfizer became the first manufacturer to receive full FDA approval for its COVID-19 vaccine. Two days later, Moderna applied for full FDA approval for its COVID-19 vaccine. By September 2, Pfizer began the submission process for a booster dose for individuals age 16 and older. On September 23, the FDA authorized Pfizer's booster shot for older adults, people with high exposure risk, and those at risk for severe COVID-19. On October 22, the FDA




authorized boosters for all three (3) COVID-19 vaccines for specific groups. Unlike Pfizer and J&J's vaccines, the Moderna booster shot was a lower dose compared to the original vaccine series. The J&J vaccine was also authorized for boosters for any adult who is at least two (2) months out from the initial J&J vaccine series. The FDA also authorized mix-and-match booster doses. On November 3, the FDA authorized Pfizer's COVID-19 vaccine for children ages 5 to 11. On November 22, Pfizer and Moderna received authorization for booster shots for all adults. On December 17, Pfizer requested full approval for its COVID-19 vaccine for people age 12 and older.

Since then, multiple variants of the virus, including the Delta variant and the Omicron variant, have swept across the world. At this time, Omicron is the dominant strain of COVID-19 in the United States. For the week ending December 18, Omicron accounted for 73.2% of cases, while Delta accounted for 26.6%. The week prior, Omicron was estimated at just 12.6%, and in the first week of December, Omicron accounted for about 1% of new cases. With the Delta and Omicron variants spreading across the nation, health experts have urged Americans to get COVID-19 boosters to protect themselves and others.

► Biden Administration Vaccine Mandates

On September 9, the Biden Administration issued an executive order requiring all federal employees be vaccinated. Federal employees and contractors will need to have their final vaccination dose – either their second dose of Pfizer or Moderna, or a single dose of J&J – by January 4, 2022.

On November 4, the Biden Administration announced details of two (2) additional policies to fight COVID-19. First, the Department of Labor's Occupational Safety and Health Administration ("OSHA") announced employers with 100 or more employees must ensure each of their workers is fully vaccinated or tests for COVID-19 on at least a weekly basis. The OSHA rule also requires employers to provide paid time for employees to get vaccinated, and to ensure all unvaccinated workers wear a face mask in the workplace. This rule covers 84 million employees.

Second, the Centers for Medicare & Medicaid Services ("CMS") at the Department of Health and Human Services announced details of its requirement that health care workers at facilities participating in Medicare and Medicaid be fully vaccinated. The rule applies to more than 17 million workers at approximately 76,000 health care facilities, including hospitals and long-term care facilities.

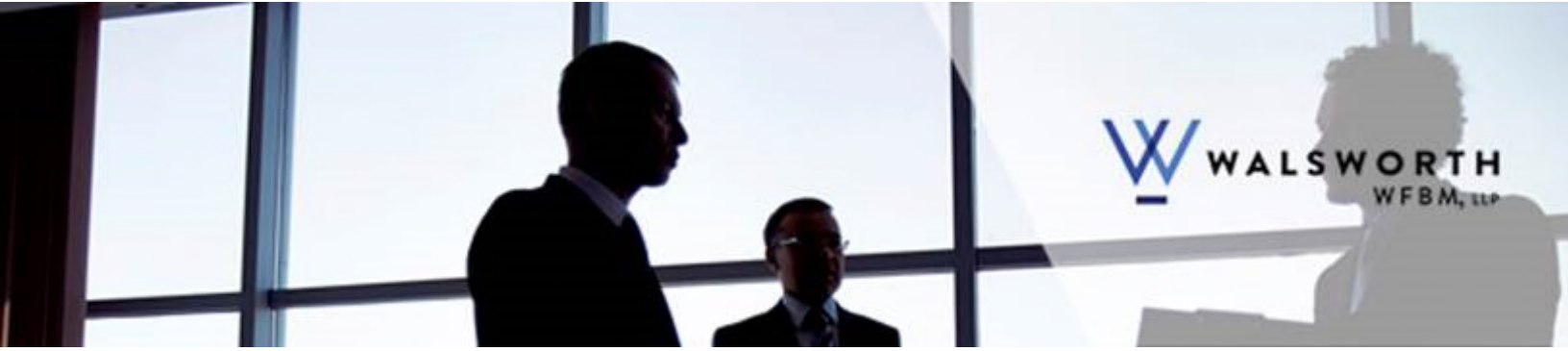
Since these requirements were announced, more than half the states and many coalitions of business and religious groups are asking the U.S. Supreme Court to take emergency action and block the Biden Administration's nationwide vaccine-or-testing mandate for large businesses. The Biden Administration is also up against lower-court decisions that have blocked vaccine mandates for health care workers in facilities that receive Medicare and Medicaid funds.

The Court has asked for additional briefing on these cases by December 30, which suggests a ruling will likely be made early next year.

► FDA Issues EUA for Pfizer's COVID-19 Treatment

On December 22, the FDA issued an EUA for Pfizer's PAXLOVID (PF-07321332; ritonavir), an oral tablet for the treatment of mild to moderate COVID-19 in patients at increased risk of hospitalization or death. PAXLOVID is the first oral antiviral of its kind, a 3CL protease inhibitor specifically designed to combat SARS-CoV-2.

PAXLOVID was specifically designed to be administered orally so that it can be prescribed at the first sign of infection or at first awareness of an exposure – potentially helping patients avoid severe illness (which can lead to hospitalization and death), experience a decreased symptomatic period, or avoid disease development following contact. PF-07321332 blocks the activity of the SARS-CoV-2-3CL protease,




an enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir helps slow the metabolism, or breakdown, of PF-07321332 in order for it to remain active in the body for longer periods of time at higher concentrations to help combat the virus.

PF-07321332 inhibits viral replication at a stage known as proteolysis, which occurs before viral RNA replication. In preclinical studies, PF-07321332 did not demonstrate evidence of mutagenic DNA interactions.

Pfizer relied on data from EPIC-HR, a randomized, double-blind, placebo-controlled clinical trial, which studied Paxlovid for the treatment of non-hospitalized symptomatic adults with a laboratory-confirmed diagnosis of SARS-CoV-2 infection. The patients studied had a pre-specified risk factor for progression to severe disease or were 60 years and older regardless of pre-specified chronic medical conditions and had not received a COVID-19 vaccine or been previously infected with COVID-19. The main outcome measured in the trial was the proportion of people who were hospitalized due to COVID-19 or died due to any cause during 28 days of follow-up. Compared to the placebo, Paxlovid significantly reduced the rate of people with COVID-19 related hospitalization or death by 88% among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. In this study, 1,039 patients had received Paxlovid, and 1,046 patients had received a placebo; among these patients, 0.8% who received Paxlovid were hospitalized or died during 28 days of follow-up compared to 6% of the patients who received a placebo.

The FDA's evaluation of the safety and effectiveness of Paxlovid for the treatment of COVID-19 is ongoing.

- Televangelist Jim Bakker to Pay $156,000 in COVID-19 Cure Claim

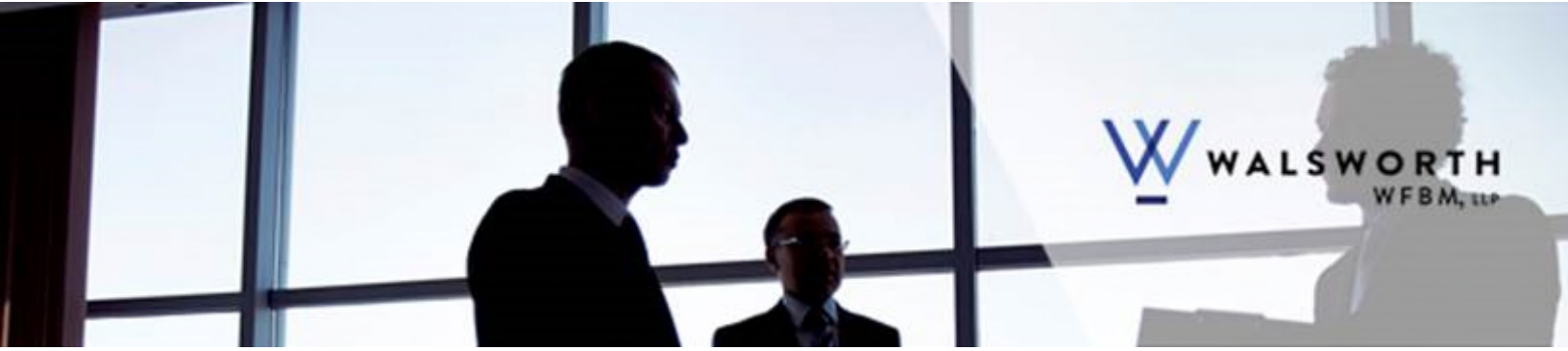
On June 23, Missouri Attorney General Eric Schmitt announced that televangelist Jim Bakker ("Bakker") and his company Morningside Church Productions Inc. ("Morningside") will pay as much as $156,000 in restitution to resolve claims that he marketed "Silver Solution" as a cure for the virus that causes COVID-19. The state filed suit against Bakker and Morningside in March 2020, after seeing a clip from his show advertising the product as being able to cure the coronavirus. Bakker offered Silver Solution in exchange for contributions of $80 to $125 to Morningside. Bakker was one of several entities that received warnings from the FDA to stop pushing unapproved drugs as COVID-19 cures.

Under the agreement, Bakker is barred from advertising or selling Silver Solution to diagnose, prevent, treat, or cure any disease or illness, and will pay up to $115,766 to Missouri residents who made contributions to his church in exchange for the solution. The judgment also calls for $50,000 in civil penalties and $10,000 for the attorney general's costs, both of which will be suspended if Bakker and Morningside abide by the other terms of the agreement.

## The CBD Industry

- New House Bill Allows FDA to Regulate CBD as Supplement

On February 4, Congress introduced House Resolution 841 (HR 841), also called the "Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2021," which provides the FDA with authority to regulate cannabidiol ("CBD") as a dietary supplement. Under this bill, hemp-derived CBD and hemp extract manufacturers would be required to comply with the existing comprehensive regulatory framework for dietary supplements. This would help ensure that hemp products are deemed safe, prepared using good manufacturing practices ("GMP"), and properly labeled. This would protect




consumers and address the FDA's concerns about the development and distribution of safe products. The bill's passage would also help stabilize the hemp market and possibly open a promising economic opportunity for hemp growers.

## Jurisdictional Litigation

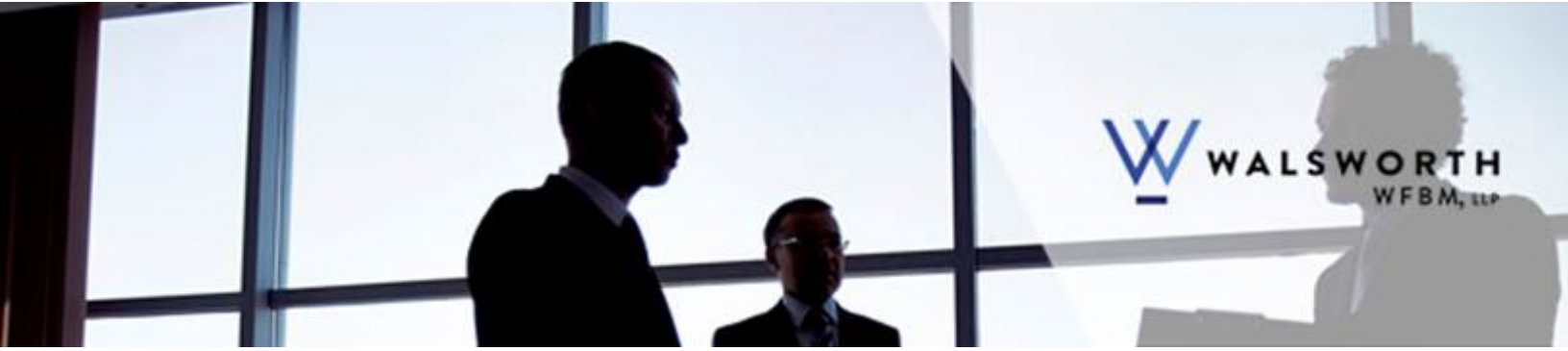
### ► U.S. Supreme Court Cases

This year, the U.S. Supreme Court made its ruling in two consolidated cases which impact the jurisdictional arguments out-of-state defendants may make. The cases are *Ford Motor Co. v. Montana Eighth Judicial Dist. Ct.* ("*Montana*") and *Ford Motor Co. v. Bandemer* ("*Bandemer*").

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 did not 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.

In March, five months after hearing oral argument on the cases, the U.S. Supreme Court unanimously found Ford Motor can be sued in Montana and Minnesota over accidents involving used cars that were initially sold out-of-state with allegedly defective tires or airbags. In the decision, the justices said there were sufficient connections between the plaintiffs' claims and Ford's business activities in the states for it to be sued there. Those activities include Ford's extensive marketing, selling, repairing, and maintaining Ford vehicles in Minnesota and Montana.

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## About Walsworth

Walsworth was founded over 30 years ago based on a sincere commitment to work with our clients to use our experience, resources, and diverse backgrounds to best serve their needs. Since 1989, the firm has grown to over 55 attorneys and we still strive to provide our clients with the individualized attention they need. Our goal is to be our client's first choice for legal representation. Our attorneys have extensive experience in a variety of litigation and transactional matters to meet our clients' objectives. Our work includes advice and counseling in complex business and litigation matters, handling litigation in state and federal courts, and briefing and arguing appeals in courts, including the California Supreme Court and the Ninth Circuit Federal Court of Appeals. From our offices in Orange County, Los Angeles, and San Francisco, we handle and try matters in several states and internationally, including, serving as national trial counsel. Walsworth is a certified Women's Business Enterprise (WBE) by the Women's Business Enterprise National Council (WBENC) and by the California Public Utilities Commission. Walsworth is the largest California member of the National Association of Minority and Women-Owned Law Firms (NAMWOLF).

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