Life Sciences Litigation

2019 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

- Judgment Entered in Favor of Boehringer in Pradaxa Failure to Warn Case

On February 1, 2019, a California state judge granted summary judgment in favor of Boehringer Ingelheim Pharmaceuticals ("Boehringer") in a case set for trial in a consolidated action brought by various plaintiffs who alleged that the company failed to provide adequate warnings for its blood thinner Pradaxa.

Plaintiff Krishna Narain began taking Pradaxa in June 2011. Five months later, she was admitted to a hospital for gastrointestinal bleeding. Narain's lawsuit alleged that Boehringer failed to warn that Pradaxa could cause her injury. During the course of the litigation, Narain's physician was deposed and testified that additional warnings would not have changed his decision to prescribe Narain the drug. The trial court, Judge Mary Wiss, found the physician's testimony was sufficient evidence "to demonstrate that defendant's alleged failure to warn did not proximately cause plaintiff's injury."

The day before the ruling on Narain's case, Judge Wiss dismissed 141 cases within the consolidated proceeding brought by out-of-state plaintiffs, finding that those plaintiffs could not establish personal jurisdiction in California against Boehringer, an out-of-state defendant, as the conduct giving rise to the plaintiffs' claims did not occur within the state. Following the U.S. Supreme Court's ruling on *Bristol-Myers Squibb Co. v. Superior Court of California*, Judge Wiss stated, "All of the conduct giving rise to the non-California plaintiffs' claims occurred outside California."

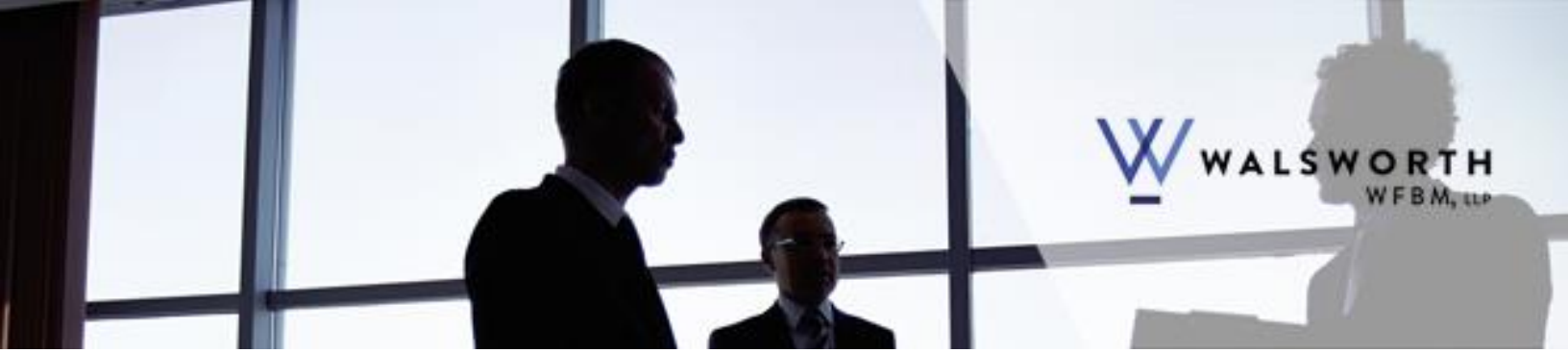
- Jury Award of $542,000 in Pradaxa Bellwether Trial Upheld

On May 20, a Connecticut state jury awarded a plaintiff $542,000 in a consolidated action filed against Boehringer over its blood thinner Pradaxa. The verdict gave Boehringer its first loss in several bellwether trials. Pradaxa is commonly used to reduce the risks of blood clots in patients with atrial fibrillation not caused by a heart valve problem.

Plaintiff Eugene Roberto, who had a significant history of gastrointestinal reflux, was prescribed Pradaxa in August 2011. Roberto was already taking a blood thinner to prevent blood clots that could be caused by his atrial fibrillation when he switched to Pradaxa. In January 2014, he suffered a life-threatening gastrointestinal bleed which resulted in a 10-day hospital stay. Roberto filed an action against Boehringer in September 2016, accusing the company of failing to include warnings on its U.S. label regarding the potential for increased bleeding in patients with gastrointestinal reflux, a warning which is included on Pradaxa's European label. Roberto also claimed that Boehringer should have warned doctors to monitor the level of Pradaxa in their patients' blood.

After a two-week trial and three days of deliberation, the jury awarded Roberto $42,464 in economic damages and $500,000 in noneconomic damages. The jury also found that punitive damages should be awarded against Boehringer. In accordance with Connecticut law, the amount of punitive damages, which is determined by the trial court judge, could be up to $1.095 million, or double what the jury awarded in compensatory damages.

On September 12, Connecticut Superior Court Judge Carl Schuman denied Boehringer's motion for judgment or a new trial, upholding the $542,464 verdict in favor of Roberto. In a 65-page ruling, Judge



Schuman wrote, "[t]he matter is a close call but, because the court must construe the evidence in a light most favorable to the plaintiff, the court concludes that there was sufficient evidence of causation …." Within the ruling, however, Judge Schuman also said that federal law preempts Roberto's allegations that Boehringer should have warned doctors to monitor Pradaxa levels. The following day, Judge Schuman awarded only $1 million in punitive damages. Boehringer has indicated it will appeal the verdict.

Judge Schuman is currently presiding over nearly 2,800 cases involving Boehringer's alleged failure to warn of the side effects associated with Pradaxa. While Roberto's verdict was upheld because of his claim that Boehringer should have included an additional warning for patients with reflux, the majority of the lawsuits in the consolidated proceeding allege only the blood monitoring claim. Commentators agree that Judge Schuman's ruling may lead to those lawsuits being dismissed on summary judgment.

- Pradaxa Failure to Warn Claims Are Preempted by Federal Law

On November 8, a California state judge granted summary judgment in favor of Boehringer, finding that federal law preempted claims that the company should have more adequately warned physicians of bleeding risks associated with its blood thinner Pradaxa.

Plaintiff Rosemary Lawson was diagnosed with atrial fibrillation in January 2010 and began treating her condition with Pradaxa a year later. In 2016, she experienced bleeding in her brain, which she claimed was caused by elevated levels of Pradaxa in her blood. In her lawsuit, Lawson alleged that Pradaxa's labeling was inadequate and did not warn physicians of bleeding risks, particularly among patients with renal impairment, like Lawson. In its motion for summary judgment, Boehringer argued on the basis of federal preemption that in 2016 there was no new evidence that would have warranted changing the label. Boehringer also argued that Lawson could not prove that Pradaxa caused her injury.

California Superior Court Judge Teri Jackson granted Boehringer's motion "for the same reasoning" set forth in Judge Schuman's September 12 ruling in the Connecticut proceeding. Specifically, Lawson did not provide any persuasive evidence showing that Boehringer had discovered any new information about Pradaxa that would have permitted it to unilaterally add language about blood monitoring to the label previously approved by the U.S. Food and Drug Administration ("FDA").

In a separate ruling, Judge Jackson also noted that Lawson did not show that any additional warnings would have changed her physician's decision to prescribe Pradaxa. Therefore, Judge Jackson ruled that the evidence is sufficient to show that the "alleged failure to warn did not proximately cause plaintiff's injury."

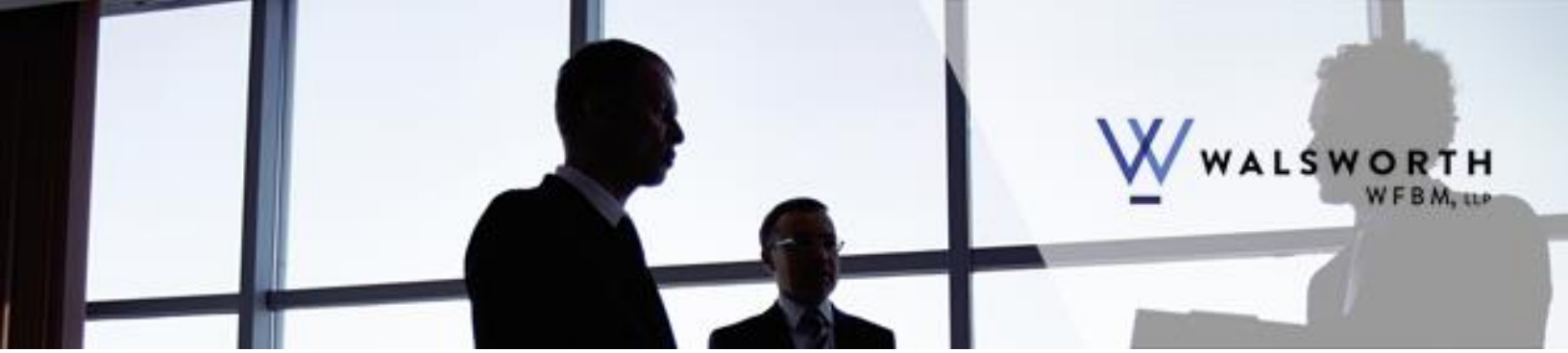
Risperdal Litigation

- Janssen Win in Risperdal Case Overturned by Appeals Court

On July 16, the Pennsylvania Superior Court reinstated a Risperdal case that was dismissed after 11 days of trial in December 2016. In a 35-page ruling, the appellate court reversed a decision in which Johnson & Johnson ("J&J") subsidiary Janssen Pharmaceuticals, Inc. ("Janssen"), was granted a motion for nonsuit in a lawsuit brought by plaintiff Tommy Moroni of Texas.

Moroni began using Risperdal at age 7. He was originally prescribed the drug to treat symptoms of ADHD, obsessive-compulsive disorder, anxiety, depression and suicidal ideation. Moroni initiated his lawsuit in 2013 and his case came to trial in December 2016. After 11 days, the trial court, Judge Sean Kennedy, issued a bench ruling dismissing Moroni's case due to his belief that, under Texas law, Moroni's expert witness provided insufficient testimony in arguing that Risperdal caused Moroni's gynecomastia, the growth of breast tissue in males.

The appellate court, however, disagreed with Judge Kennedy's rationale on causation evidence indicating that the issue was procedural rather than substantive and thus should have been considered under Pennsylvania law, not Texas law. Janssen has stated



that it is reviewing its options going forward.

- $2.5 Million Verdict Against Janssen Upheld

On August 2, the Pennsylvania Supreme Court refused to review a jury's $2.5 million verdict against Janssen and in favor of a boy who alleged the antipsychotic drug Risperdal caused him to grow breasts.

Plaintiff Austin Pledger, now 20, began taking Risperdal at the age of 7 to treat symptoms of autism, an off-label use of the drug. At the age of 8, Pledger began growing breasts. At the time of Pledger's use, the drug was indicated for use only by adult patients; however, the FDA later approved it for use in children. Along with the approval, Janssen changed its label to show that abnormal breast growth, a condition known as gynecomastia, had been seen in 2.3% of children who used Risperdal.

At trial in 2015, Pledger argued that Janssen failed to adequately warn physicians of the heightened risk of hormone spikes in adolescent boys. The jury ultimately found in favor of Pledger and awarded him $2.5 million in compensatory damages. Pledger's case is expected to be back at trial to determine if punitive damages claims are appropriate.

- Jury Orders J&J and Janssen to Pay $8 Billion in Philadelphia Risperdal Case

On October 8, a Philadelphia jury ordered J&J and Janssen to pay $8 billion in punitive damages to a man who was previously awarded $680,000 for his claims that the companies failed to warn that young men using the antipsychotic drug Risperdal could grow breasts. The jury's verdict came in the first case in which a Pennsylvania state jury had been able to consider awarding punitive damages in one of the thousands of Risperdal cases pending in the state's mass tort program.

Plaintiff Nicholas Murray, now 26, 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 breasts, 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 adolescents. 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.

Commentators agree that the extremely large punitive damages award is likely to be reduced on the grounds that it violates due process.

- $70 Million Verdict Against J&J and Janssen Upheld

On November 26, the Pennsylvania Superior Court upheld a $70 million verdict against J&J and Janssen in a lawsuit alleging the antipsychotic drug Risperdal caused a boy to grow breasts. In addition to upholding the verdict in favor of Tennessee resident, plaintiff Andrew Yount, the appellate court sent the case back to the trial court on the issue of punitive damages.

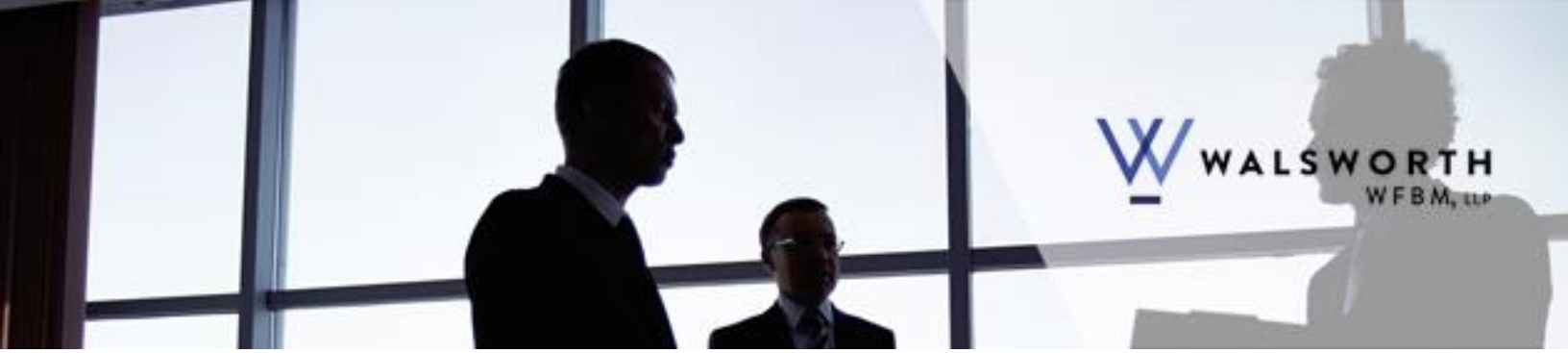
The case stems back to a 2013 lawsuit brought by Yount and his mother. Yount had taken Risperdal since he was a toddler and alleged his breast growth left him with a "severe and permanent disfigurement" that made him a target for bullies. The appellate court said it found no reversible error in the original verdict.

J&J and Janssen continue to face over 13,000 Risperdal cases in the Pennsylvania mass tort program.

Other Drug Litigation

- BMS and Otsuka Reach Confidential Settlement Ending Abilify MDL

On February 15, Bristol-Myers Squibb Co. ("BMS") and Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), reached a confidential global settlement with 600 plaintiffs in multi-district litigation ("MDL") over side effects of the antipsychotic drug Abilify, prescribed for the treatment of bipolar disorder, depression and schizophrenia. Plaintiffs claim that Abilify caused them to engage in uncontrollable, compulsive behaviors, most notably gambling.



If 90% of the plaintiffs agree to the settlement, it will end the litigation that has been pending for nearly three years. In late 2016, an MDL was established in the U.S. District Court for the Northern District of Florida. The settlement applies to all cases pending in the MDL as of January 28, 2019, and includes cases being heard in California and New Jersey, as well as in other state and federal courts.

Since the approval of the global settlement, between September and October, U.S. District Court Judge M. Casey Rodgers has dismissed a total of 168 cases as a sanction for those plaintiffs who failed to comply with court directives. Specifically, Judge Rodgers set several deadlines and ordered all plaintiffs participating in the settlement to timely submit completed claim forms, valid supporting documentation, a fully executed release and either a proposed order for dismissal or a fully executed stipulation. Judge Rodgers dismissed the claims of all plaintiffs who failed to follow her instructions by either failing to submit supporting documentation for their claims or submitting documentation that failed to establish that they used name brand Abilify, noting that many plaintiffs had a "clear pattern" of failing to abide by her orders.

- Janssen and Bayer Pay $775 Million to End Xarelto MDL

On March 25, Janssen and Bayer Corporation ("Bayer") agreed to pay $775 million to end approximately 25,000 lawsuits alleging the companies failed to warn that the blood thinner Xarelto could cause internal bleeding. The settlement ends the MDL consolidated in Louisiana, as well as numerous state court claims. Janssen and Bayer will split the $775 million settlement equally; however, the companies will have the option to withdraw from the settlement if certain participation rates are not met.

The Xarelto litigation against Janssen and Bayer began over five years ago. To date, six cases have gone to trial and the companies have prevailed in all of them. The most recent win was in August 2018, wherein plaintiff Kevin Cooney claimed he suffered gastrointestinal bleeding after taking Xarelto as a precaution against his venous thromboembolism. Cooney unsuccessfully claimed that the companies should have recommended lower dosages for certain patients to prevent the risk of internal bleeding.

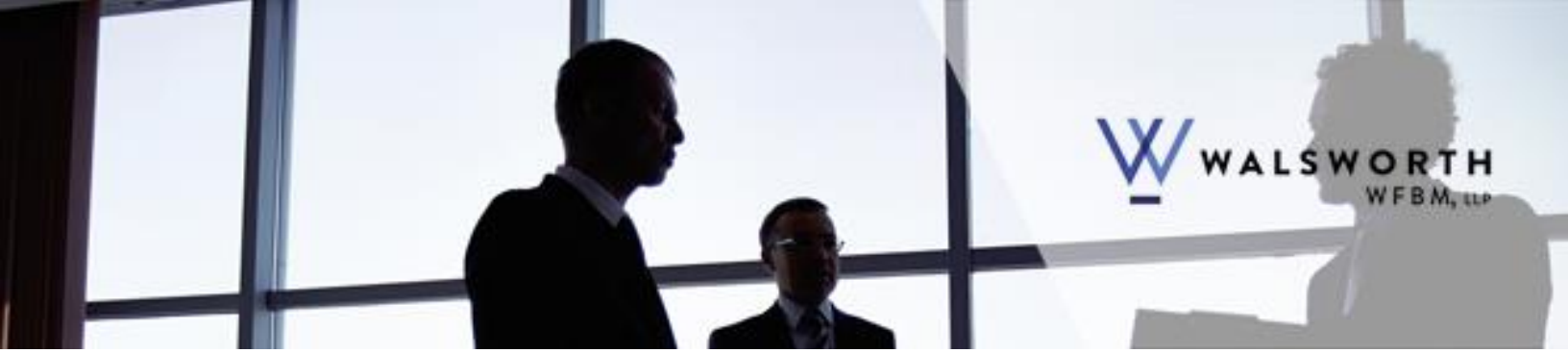
- Second Circuit Upholds Dismissal of Claims in Eliquis MDL

On March 26, the U.S. Court of Appeals for the Second Circuit upheld the dismissal of 15 cases against BMS and Pfizer, Inc. ("Pfizer"), on grounds that the plaintiffs' claims that the companies failed to warn of the risks associated with the blood thinner Eliquis were preempted by federal law. Within their lawsuits, plaintiffs claimed that Eliquis' label failed to provide warnings about the risk of internal bleeding. In light of this risk, plaintiffs claimed that the dosages needed to be patient-specific to minimize risks of internal bleeding, and that patients should be monitored after taking the drug. The Second Circuit refused to overturn the U.S. District Court's ruling, finding that because plaintiffs had failed to show that the FDA would have approved a label change, their claims were preempted by federal law.

In an earlier ruling, U.S. District Court Judge Denise Cote dismissed 68 cases on the grounds that the plaintiffs' claims were barred because federal law preempted BMS and Pfizer from making changes to their labels. An additional 45 lawsuits were filed in Delaware and were removed to federal court by BMS and Pfizer. Plaintiffs sought to remand the claims back to U.S. District Court for the Northern District of Florida, but Judge Cote denied the motion and dismissed the claims on preemption grounds. Fifteen plaintiffs appealed, arguing that their cases should not have been removed because they were residents of Delaware and the companies were Delaware corporations. As to those 15 plaintiffs, the Second Circuit also determined that the removal was proper.

- U.S. Supreme Court Rules Judges, Not Juries, Decide Whether Federal Preemption Bars State-Law Tort Claims

On May 20, in the 9-0 decision, the U.S. Supreme Court vacated a decision by the Third Circuit that had revived 500 claims brought by plaintiffs who took Merck & Co.'s ("Merck") brand-name drug



Fosamax and suffered atypical femoral fractures between 1999 and 2010. Each of the plaintiffs in the underlying action brought state-law tort claims alleging that Merck failed to add an adequate warning of the risk of atypical femoral fractures to Fosamax's FDA-approved drug label. Despite the defense verdict in an initial bellwether trial, the district court issued an opinion finding that the bellwether plaintiff's failure-to-warn claim was preempted by federal law, which the district court later extended to all plaintiffs.

In deciding that federal law preempted the plaintiffs' failure-to-warn claims, the district court observed that, under the Supreme Court's decision in *Wyeth v. Levine*, the issue "was whether clear evidence existed that the FDA would not have approved a stronger warning to the Fosamax label, thereby warranting preemption[.]" The district court found that, under this standard, the FDA would not have approved a stronger warning and dismissed the plaintiffs' claims.

The Third Circuit, however, interpreted the term "clear evidence" as denoting a standard of proof, which goes to "how difficult it will be for [a] manufacturer to convince the factfinder that the FDA would have rejected a proposed label change." The Third Circuit then held that "the question of whether the FDA would have rejected a proposed label change is a question of fact that must be answered by a jury."

The Supreme Court adopted a different view, instead finding that preemption is for a judge to decide, not a jury. In reaching its decision, the Supreme Court explained that treating preemption "as a legal question for judges makes sense given the fact that judges are normally familiar with principles of administrative law" and that having judges decide the issue "should produce greater uniformity among courts."

The Supreme Court also held that "clear evidence" is evidence that shows that the manufacturer fully informed the FDA of the justifications for the warnings required by state law and that the FDA, in turn, informed the manufacturer that it would not approve a change to the drug's label to include that warning. The Supreme Court explained, that is a high bar as the "possibility of impossibility [is] not enough."

The Supreme Court sent the action back to the Third Circuit to determine if plaintiffs' claims are preempted. In November, the Third Circuit sent the action back to the district court with an order to determine whether plaintiffs' state-law tort claims are preempted under the standards set forth in the Supreme Court's opinion.

- Sanofi Gets Win in First Bellwether Trial in Taxotere MDL

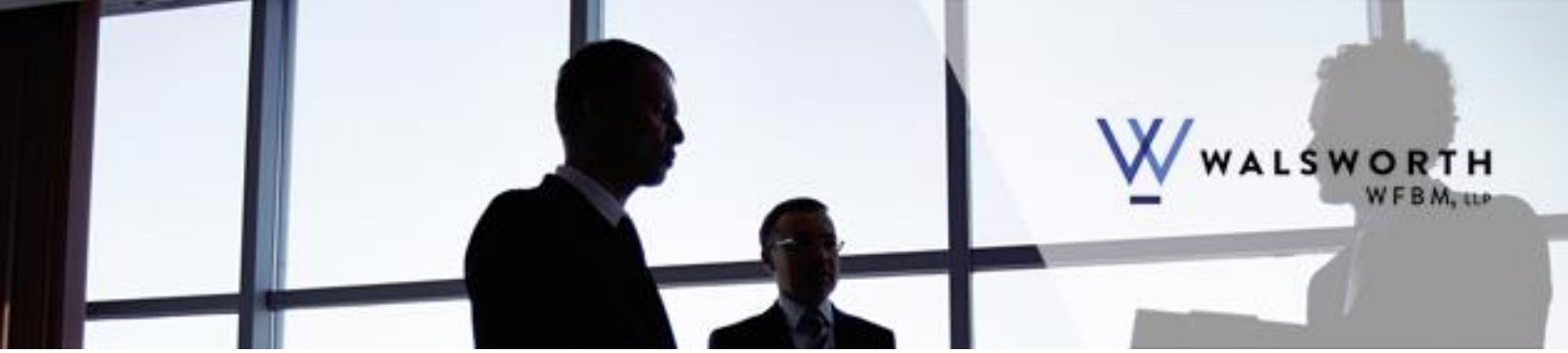
On September 27, a Louisiana federal jury found that Sanofi-Aventis U.S. LLC's ("Sanofi") breast cancer chemotherapy drug Taxotere did not cause a woman to develop permanent hair loss. This was the first in thousands of cases in the MDL over the drug to go to trial.

Plaintiff Barbara Earnest was diagnosed with breast cancer in 2011. She underwent chemotherapy that included Taxotere. As a result of her treatment, Earnest lost her hair. Unlike most chemotherapy patients, however, Earnest claimed that her hair did not grow back, and that the drug caused alopecia. After two weeks of trial and a few hours of deliberation, the jury found that Earnest's permanent chemotherapy-induced alopecia was not caused by Taxotere.

Multiple drug companies are facing more than 10,000 cases in the MDL alleging that Taxotere and its generic form, docetaxel, cause permanent hair loss.

- Kentucky AG Reaches $17 Million Settlement With Bayer Over Birth Control Drugs

On October 23, a $17 million settlement was reached between Kentucky Attorney General Andy Beshear and Bayer over claims that the company misled women about risks associated with its birth control drugs, Yasmin and Yaz. The settlement resolved a 2013 lawsuit that alleged Bayer failed to provide accurate marketing information to women. Specifically, the lawsuit alleged that Bayer did not disclose the scientific evidence that indicated the drugs put users at a higher risk for blood clots than



similar contraceptives.

Updates in Litigation – Devices

Pelvic Mesh Litigation

- Jury Awards $41 Million in Philadelphia Pelvic Mesh Case

On January 31, a Pennsylvania state jury awarded $41 million to a plaintiff who alleged injury following the implantation of a Prolift pelvic mesh device made by J&J subsidiary Ethicon, Inc. ("Ethicon"). Plaintiff Suzanne Emmett, who filed suit in July 2013, claimed she experienced severe complications after receiving the pelvic mesh device six years earlier to treat her urinary stress incontinence. Jurors sided with Emmett, finding that Ethicon failed to provide warnings that the device could erode through soft tissue in the pelvis and cause permanent injury.

The jury awarded Emmett $15 million in compensatory damages and $25 million in punitive damages. The jury also awarded Emmett's husband $1 million for loss of consortium.

- $13.5 Million Verdict Against Ethicon Stands

On April 11, the Pennsylvania Superior Court upheld a $13.5 million verdict against Ethicon in an action involving its TVT-O pelvic mesh device, finding that Ethicon failed to adequately warn plaintiff Sharon Carlino of the associated risks. Carlino had the device implanted in 2005 to treat her stress urinary incontinence. Thereafter, Carlino began feeling something sharp in her vagina. She went to her doctor and was advised that part of the device had eroded. Carlino underwent two revision surgeries to have the eroded material removed. As a result, Carlino alleged constant pain and the inability to engage in sexual relations.

Carlino's case was the second pelvic mesh trial in Pennsylvania state court. The jury awarded Carlino $3.5 million in compensatory damages and $10 million in punitive damages. The jury also awarded $250,000 for loss of consortium to Carlino's husband. On appeal, Ethicon raised several issues in an effort to overturn the verdict, including contending that certain evidence and testimony should have been allowed at trial and that Carlino's case should have been barred by the statute of limitations, but the appellate court rejected all of Ethicon's arguments.

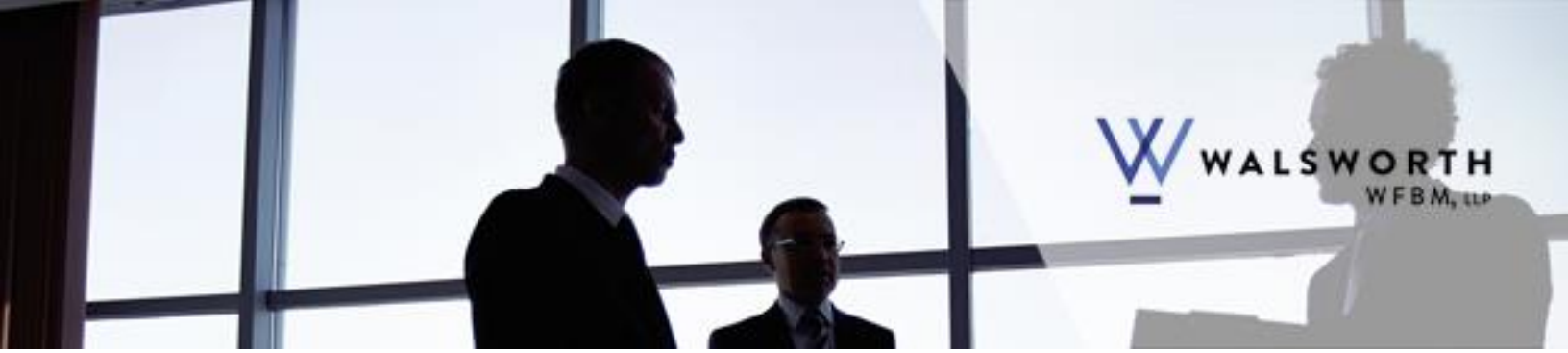
- Ethicon Gets Win in Philadelphia Pelvic Mesh Trial

On April 17, a Pennsylvania state jury returned a verdict in favor of Ethicon, finding that Ethicon's TVT-Secur pelvic mesh device did not cause a Philadelphia plaintiff's injuries.

Plaintiff Malgorzata Krolikowski received Ethicon's device in 2008 to treat a mild case of urinary stress incontinence. After implantation, Krolikowski allegedly began experiencing pain and urine leakage during sex, which made it all but impossible for her to pursue a romantic relationship. Ethicon argued that simply because the device did not stop Krolikowski's urinary incontinence did not mean it was defective. The jury found that, although Ethicon had negligently designed, marketed and distributed the pelvic mesh device, it was not the cause of Krolikowski's alleged injury.

- Jury Orders Ethicon to Pay $120 Million in Philadelphia Pelvic Mesh Case

On April 24, Ethicon was ordered by a Pennsylvania state jury to pay $120 million to a plaintiff allegedly injured by the company's TVT-O pelvic mesh device. Plaintiff Susan McFarland was implanted with the device in 2008 to treat urinary incontinence. McFarland claimed that the device eroded into the soft tissue in her pelvis and punctured her vagina. McFarland was required to undergo a revision surgery to remove broken pieces of the device and was ultimately left with chronic pain.



McFarland's case originally went to trial in September 2018, but the jury was deadlocked on whether the device caused her injury. The retrial began in March, but was continued for a month after an expert witness suffered a heart attack. The jury awarded McFarland $20 million in compensatory damages and $100 million in punitive damages.

The verdict came just one week after the FDA ordered manufacturers of all pelvic mesh devices to immediately stop selling and distributing their products due to a lack of "reasonable assurance" that they were safe or effective. J&J and Ethicon had already halted sales of their pelvic mesh devices.

► Jury Awards $80 Million in Pelvic Mesh Case

On May 17, a Pennsylvania state jury awarded $80 million to a plaintiff who claimed that Ethicon's Prolift pelvic mesh device caused her to suffer chronic pain. Plaintiff Patricia Mesigian had Ethicon's device implanted in 2008 to treat pelvic organ prolapse. During a follow-up visit, Mesigian informed her doctor that she was experiencing vaginal bleeding. The doctor recommended she undergo a revision surgery, at which time it was discovered that a portion of the mesh had eroded into her vagina. Mesigian underwent three more surgeries to address the mesh erosion. In two of these treatments, Mesigian was chemically burned while doctors were attempting to remove scar tissue that had built up around the mesh. The jury awarded Mesigian $80 million, which included $50 million in punitive damages.

► Jury Awards $500,000 in Pelvic Mesh Case

On June 28, another Pennsylvania state jury awarded $500,000 in compensatory damages to a plaintiff who claimed Ethicon's Prolift pelvic mesh device caused her to suffer significant injury. Plaintiff Linda Dunfee had the device implanted in 2007 to treat pelvic organ prolapse. Two years later, Dunfee's physician discovered the device had eroded into the wall of her vagina. Although the initial erosion healed on its own, three years later, in 2015, Dunfee had to undergo an additional procedure after the mesh had again cut into her vagina.

The jury awarded Dunfee $500,000 in damages after finding that design defects in the device caused her injuries. The jury, however, rejected Dunfee's arguments that Ethicon's conduct warranted an award of punitive damages.

► $2.4 Million Pelvic Mesh Verdict Upheld Against Ethicon

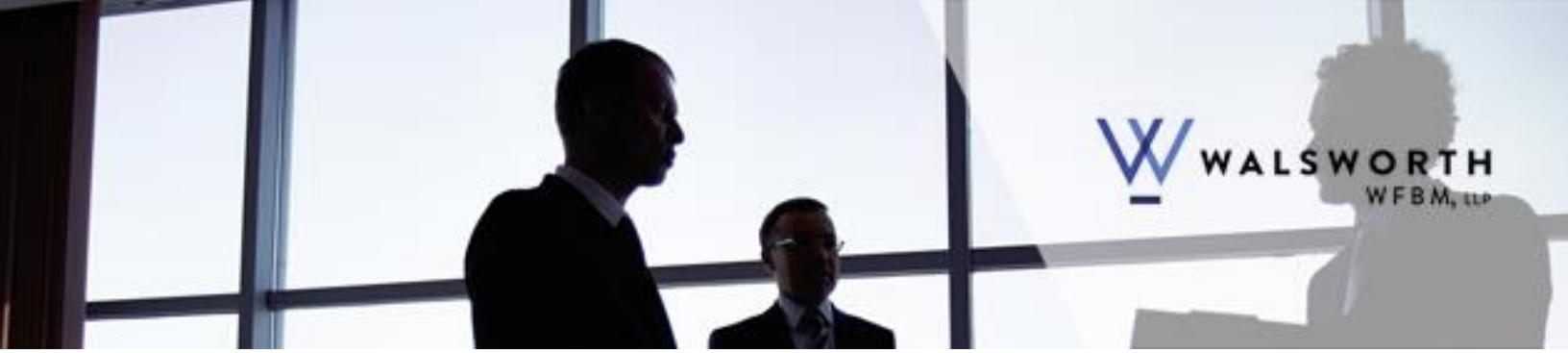
On August 21, the Pennsylvania Supreme Court declined to hear Ethicon's appeal of a $2.4 million jury verdict that came in a trial over its Prolift pelvic mesh device. Plaintiff Sharon Beltz was treated with the device in 2006 after allegedly suffering from pelvic organ prolapse and stress urinary incontinence following four pregnancies. Within her lawsuit, Beltz alleged that the device eroded and caused her to experience pain, scarring, organ perforation, painful sexual relations and damage to her pelvic floor. A Pennsylvania state jury awarded Beltz $2.2 million in compensatory damages in 2017.

Ethicon filed post-trial motions 17 days after the verdict, which was seven days past the deadline for such motions under Pennsylvania law. The trial court denied Ethicon's motions and Ethicon appealed. The Pennsylvania Superior Court affirmed the trial court's decision before the Pennsylvania Supreme Court denied allocatur in a one-page order.

► Florida Federal Court Dismisses J&J From Pelvic Mesh Case Aimed at Ethicon

On September 20, a Florida federal court dismissed J&J from a lawsuit in which a plaintiff alleged that Ethicon's Artisyn pelvic mesh device caused her injury. U.S. District Court Judge Ursula Ungaro ruled that plaintiffs Charlotte Salinero and her husband failed to provide evidence to support their claims against J&J as Salinero's injuries were "downstream" of the device's original designer.

Judge Ungaro stated in her ruling that the Salineros made "no effort to explain any legal grounds for liability [against J&J], and if the evidence they submitted was their best factual basis for liability, it was far from good enough." Judge Ungaro also ruled that there was no evidence to support "piercing the corporate veil" because J&J submitted evidence that it was truly separate from Ethicon. The Salineros'



lawsuit will, however, continue against Ethicon.

- Pennsylvania Appeals Court Reduced $20 Million Award Against Ethicon to $15 Million

Also on September 20, the Pennsylvania Superior Court reduced a $20 million verdict in a case involving Ethicon's TVT-Secur pelvic mesh device to $15 million, rejecting Ethicon's argument that the award should be stricken in its entirety. Plaintiff Margaret Engleman received Ethicon's device to ease symptoms of stress urinary incontinence. Within two months of Engleman receiving the device, her doctor discovered that the mesh had eroded. The erosion caused Engleman chronic pain, and eventually forced her to undergo three separate surgeries to remove the material.

In 2017, a Philadelphia jury awarded Engleman $20 million, including $2.5 million in compensatory damages and $17.5 million in punitive damages. The appellate court found that a reduction in the punitive damages award was warranted, because under New Jersey law, punitive damages are capped at five times the compensatory damages, reducing the $17.5 million punitive damages award to $15 million.

- J&J and Ethicon Reach $117 Million Multistate Settlement Over Pelvic Mesh Devices

On October 17, J&J and Ethicon 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. Among other things, the settlement will require J&J and Ethicon to disclose a list of risks related to the use of the pelvic mesh devices, including loss of sexual function, mesh erosion and the possible need for revision surgery. The companies must also ensure that training provided to physicians covers those risks.

Prior to the multistate settlement, on April 22, just hours before trial was scheduled to begin, J&J and Ethicon agreed to pay the state of Washington $9.9 million to end a similar lawsuit. The Washington Attorney General claimed that J&J and Ethicon violated Washington's Consumer Protection Act by failing to inform patients and their doctors about the risks associated with the pelvic mesh devices, including urinary dysfunction, loss of sexual function, constipation and severe pain.

Hip Implant Litigation

- J&J and DePuy Settle Hip Implant Claims for $120 Million

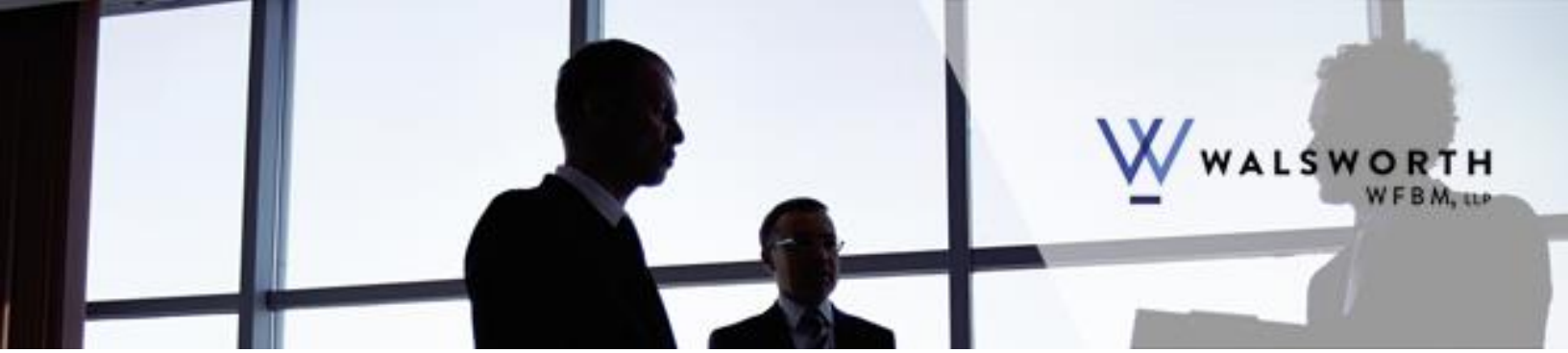
On January 22, J&J and its subsidiary, DePuy Orthopaedics ("DePuy"), agreed to pay $120 million to end multistate litigation which alleged that the companies misled patients about the longevity and efficacy of metal-on-metal hip implants. Within the litigation, attorneys general from various states claimed that DePuy engaged in unfair and deceptive practices in the promotion of two of its hip implants, the ASR XL and Pinnacle Ultamet. In light of these false claims, patients frequently had to undergo revision surgery well before DePuy's advertised time frame of five years. Forty-five states and Washington, D.C., were part of the settlement; only Mississippi, West Virginia, Oregon and Wyoming remain.

In 2010, DePuy recalled more than 90,000 of its ASR XL implants. The Pinnacle Ultamet was ultimately discontinued in 2013 when the FDA strengthened its artificial hip regulations. J&J and DePuy currently face more than 10,000 lawsuits in courts throughout the U.S. over the Pinnacle Ultamet device.

- Zimmer Gets Win in Florida Hip Implant Trial

On July 12, a Florida state jury cleared Zimmer, Inc. ("Zimmer"), of liability in a case in which the plaintiff alleged that Zimmer sold defective hip implants and failed to warn physicians of the potential risk of metal corrosion.

Plaintiff Diane Noto alleged that Zimmer's Kinective dual modular hip implant led to increased levels of metal in her body, which required surgery to remove. Noto claimed that Zimmer failed to warn her physician about the potential risks, including metal wear debris, corrosion and other byproduct releases that cause adverse tissue reactions, cell injury and swelling. After less than one hour of deliberation, the jury found that Zimmer's hip implant was neither defective nor the cause of



Noto's injury.

- Zimmer Ordered to Pay $7.7 Million in California Hip Implant Case

On July 26, a California state jury awarded $7.68 million in damages to a plaintiff who claimed he was injured by Zimmer's metal-on-metal hip implant. Plaintiff Gary Kline alleged that he suffered severe osteoarthritis in his right hip. After trying various forms of conservative treatment, Kline's doctor recommended that he undergo a total hip replacement using Zimmer's Durom Cup hip implant. After his 2007 surgery, Kline allegedly developed progressively worsening pain and ultimately underwent a second surgery to replace the entire hip implant.

At trial, Zimmer argued that the implant did not cause Kline's injury and that Kline had significant pain well before the Durom Cup was implanted, after the Durom Cup was implanted and after the Durom Cup was removed. The jury awarded Kline $4 million in future noneconomic loss, $3.6 million in past noneconomic loss and more than $80,000 in medical expenses.

The $7.68 million award was the result of a second trial in the case of Kline, who in July 2015 was awarded $9.2 million. That award was overturned on appeal.

IVC Filter Litigation

- Cook Ordered to Pay $3 Million in Indiana IVC Filter Bellwether Trial

On February 4, an Indiana federal jury awarded $3 million in compensatory damages to a Georgia plaintiff who suffered medical complications when a Cook Medical, Inc. ("Cook"), inferior vena cava ("IVC") filter deteriorated inside her. In 2009, plaintiff Tonya Brand was implanted with Cook's Celect Premium Vena Cava Filter in preparation for a spinal-fusion surgery. In May 2011, she began experiencing pain in her right thigh, and then a month later she saw something protruding from her skin. She pulled it out and found it was part of the filter. Brand then underwent a full body scan, which showed the filter had broken and a piece of it had migrated near her spine. Brand had surgery in October 2015 to remove the filter, but pieces which cannot be safely removed remain lodged in her body.

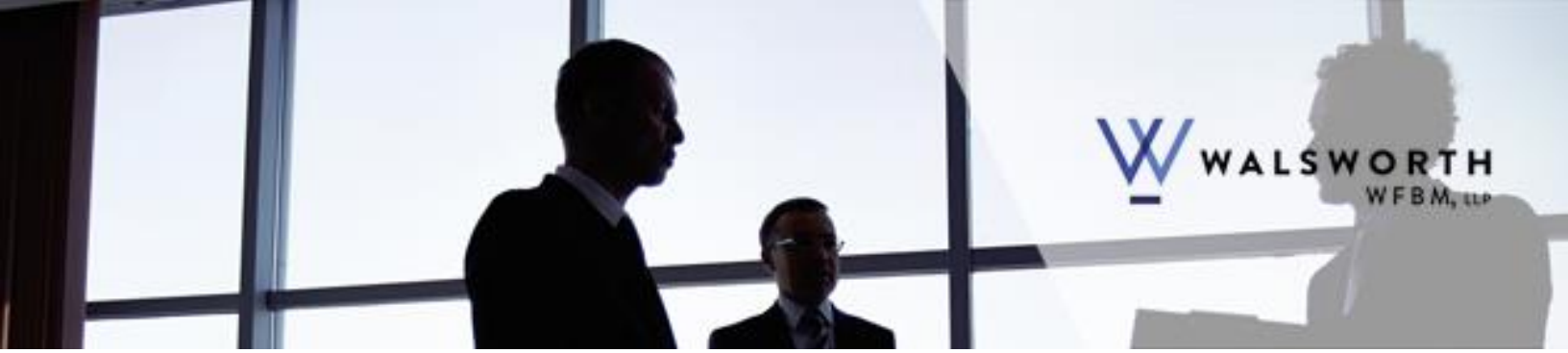
Brand's lawsuit alleged causes of action for strict liability and negligent failure to warn, strict liability and negligent design defect, negligent manufacturing, negligence per se, breach of warranty, and loss of consortium. All causes of action, except design defect, had previously been dismissed on summary judgment. Nonetheless, the jury ruled that the design of the IVC filter was defective and that the defective design was the proximate cause of Brand's injury.

More than 7,000 cases against Cook are currently pending in the MDL in the U.S. District Court for the Southern District of Indiana. Cook has appealed the verdict.

- Jury Awards $34 Million in Philadelphia's First IVC Filter Trial

On October 26, a Pennsylvania state jury awarded $34 million to a Georgia plaintiff who was allegedly injured as a result of a defective IVC filter manufactured by Rex Medical LP ("Rex"). Plaintiff Tracy Reed-Brown had Rex's Option IVC filter implanted in 2016 to prevent pulmonary embolisms. Reed-Brown alleged that the filter later perforated the wall of her vein, causing severe pain. Her physicians struggled for three hours to dislodge the filter, but it remains inside her body. At trial, Rex attempted to blame Reed-Brown's physicians, arguing that the doctors failed to properly implant the filter.

Following more than two weeks of testimony, the jury found in favor of Reed-Brown and awarded her $34 million. The verdict included $1 million in future medical expenses, $2.3 million in future pain and suffering and $30.3 in punitive damages. Reed-Brown's case is the first IVC filter case to come before a Philadelphia jury. More than 760 such cases are pending in Pennsylvania's mass tort program.



Updates in Life Sciences Litigation – Talc

- Pennsylvania Court Grants Colgate's Motion for Summary Judgment in Talc Case

On February 7, a Pennsylvania state court dismissed a lawsuit brought on behalf of a plaintiff against Colgate-Palmolive Co. ("Colgate") after the court excluded the opinions of three experts who claimed Colgate's Cashmere Bouquet talcum powder contained breathable asbestos fibers. Plaintiff Sally Brandt claimed that her mother and older sister used Cashmere Bouquet on a daily basis after bathing and that she herself used the product in the mid-1950s through 1970. Brandt was diagnosed with mesothelioma in November 2015 and initiated litigation against Colgate the following month. Brandt died in February 2018, leaving her husband to carry on the litigation on her behalf.

Brandt's case began to face difficulty in September 2017 when the court ruled that a pair of expert witnesses retained on behalf of Brandt had relied on unsound methods in a scientific paper in which they determined that Cashmere Bouquet contained asbestos fibers. Despite Brandt's arguments that there was sufficient evidence to show that the Cashmere Bouquet contained asbestos, the court granted Colgate's motion for summary judgment, dismissing her case.

- J&J Gets Win in New Jersey Talc Case

On March 27, a New Jersey state jury sided with J&J, finding that a plaintiff's alleged exposure to asbestos in baby powder did not cause his mesothelioma. Plaintiff Ricardo Rimondi, a native of Peru, claimed he was exposed to asbestos from J&J's Baby Powder, which caused his mesothelioma. Following a trial that lasted one month and less than an hour of deliberations, the jury rejected Rimondi's claim, finding that Rimondi's mesothelioma came as a result of his once living near a factory in Lima, Peru, that dealt with asbestos-laden cement and not from J&J's Baby Powder.

- J&J Reaches Settlement in Three Mesothelioma Talc Cases

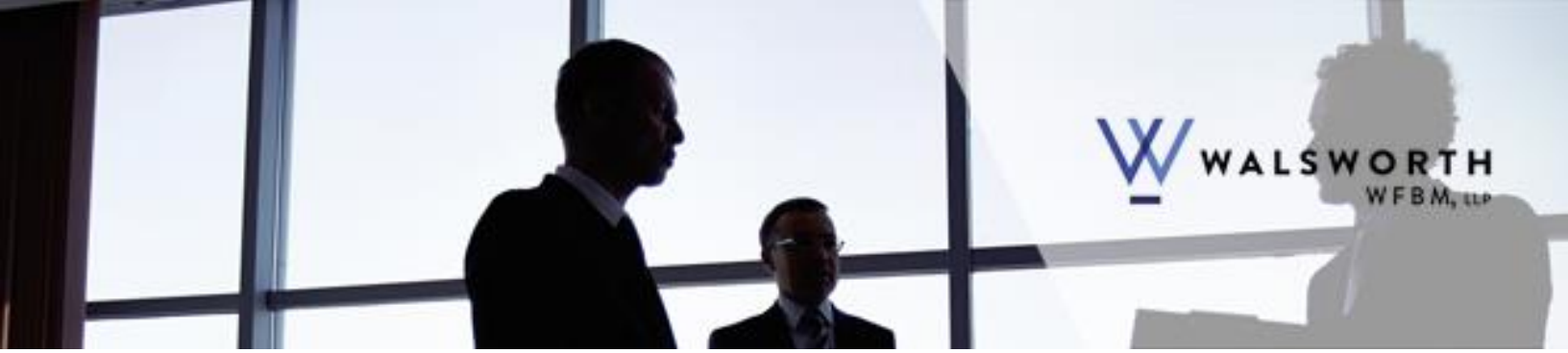
Also on March 27, J&J reached a settlement with three plaintiffs who alleged they were diagnosed with mesothelioma as a result of using J&J's talcum powder products. Two of the settlements occurred in the midst of trials. Plaintiff Sharon Pipes received J&J's settlement offer as an Oklahoma state jury began deliberations following a two-and-a-half week trial. During trial, Pipes was seeking $13.1 million in damages and $580,000 for past and future medical expenses, although the financial terms of her settlement with J&J were not disclosed.

J&J also settled with California plaintiff Gail Koretoff, who was diagnosed with mesothelioma in 2016. Koretoff blamed her diagnosis on more than three decades' use of J&J's Baby Powder. J&J reached a settlement with Koretoff two days into trial.

Finally, J&J reached a settlement with New York plaintiff Jenny Shulman. Shulman was diagnosed with mesothelioma in 2016 after she underwent surgery for endometrial cancer. Shulman claimed her condition was caused by exposure to J&J's Baby Powder, which she had used for feminine hygiene for many years. Shulman's case was set for trial in April.

- California Jury Finds J&J's Talcum Powder Did Not Contain Asbestos

On April 5, a California state jury rejected a plaintiff's claims that J&J's Baby Powder caused his mesothelioma. Plaintiff Robert Blinkinsop claimed he developed mesothelioma from his personal use of J&J's Baby Powder between 1977 and 1994 and then use on his children from 1992 to 1996. Blinkinsop claimed that the asbestos particles in the baby powder caused his mesothelioma. The jury, however, found that J&J's Baby Powder does not contain asbestos and thus was not the cause of Blinkinsop's mesothelioma.



► J&J Gets Win in South Carolina Talc Case

On May 21, a South Carolina state jury rejected claims that asbestos in J&J's Baby Powder caused a plaintiff to develop mesothelioma. Plaintiff Beth-Anne Johnson claimed that her inhalation of asbestos fibers present in J&J's Baby Powder dating back to the 1960s caused her to develop mesothelioma. J&J successfully argued that the form of mesothelioma Johnson had was naturally occurring and could not have been caused by J&J's product. In making this argument, J&J relied on medical tests which showed there was no asbestos present in Johnson's lungs. The jury sided with J&J.

► $29.5 Million Talc Verdict Against J&J Stands

On May 24, a California state court denied J&J's request for a new trial after a jury ordered J&J and its former talc supplier Cyprus Mines Corp. ("Cyprus") to pay $29.5 million to a plaintiff who was diagnosed with mesothelioma after using J&J's Baby Powder. Plaintiff Teresa E. Leavitt claimed that her mother used J&J's Baby Powder when she was a baby in the 1960s, and Leavitt continued using it on her hair and face in the decades that followed. Leavitt was diagnosed with mesothelioma in 2017.

Within her lawsuit, Leavitt claimed that manufacturers, marketers and suppliers failed to warn users that talcum powders, including J&J's Baby Powder, posed serious health risks. Leavitt claimed that J&J was aware that the talc it used contained asbestos, yet it failed to alert federal regulators or warn consumers. The $29.5 million award included $291,000 for past medical expenses, $1 million for future medical expenses, $1.2 million for loss of earnings, $7 million for past pain and suffering, and $15 million for future pain and suffering. The jury also awarded $5 million to her husband, Dan McElroy, for loss of consortium.

► Jury Awards $325 Million in New York Talc Case

On May 31, a New York state jury awarded a total of $325 million to a plaintiff who claimed J&J's Baby Powder caused her mesothelioma. Plaintiff Donna Olson and her husband initiated their lawsuit in October 2017, alleging that J&J's Baby Powder caused Olson to develop mesothelioma. At trial, Olson presented evidence that J&J knew as early as the 1960s and 1970s that its baby powder contained asbestos. Instead of warning consumers or switching from talc to cornstarch, however, J&J changed its tests to a method that did not detect asbestos. The jury concluded that Olson's regular use of the baby powder over many years caused her mesothelioma.

The jury awarded Olson and her husband $25 million in compensatory damages and $300 million in punitive damages. J&J has indicated it will appeal the verdict.

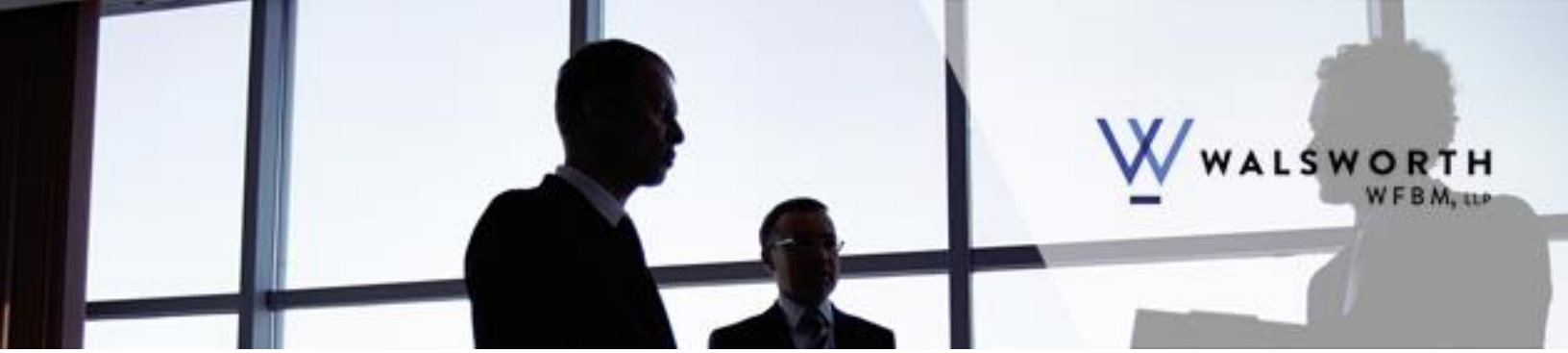
► J&J and Colgate Get Win in Kentucky Talc Case

On August 2, a Kentucky state jury found in favor of J&J and Colgate over claims that the companies' talcum powder products caused a plaintiff's mesothelioma. Plaintiff Donna Hayes claimed she developed mesothelioma by inhaling asbestos allegedly present in J&J's Baby Powder and Colgate's Cashmere Bouquet for decades. After a three-week trial and only one hour of deliberations, the jury found that Hayes' mesothelioma was the result of exposure to asbestos from various garages where her husband worked over the course of many years as a mechanic, and not from her use of J&J and Colgate products.

► Wisconsin Appeals Court Upholds Colgate Win in Talc Action

On August 27, a Wisconsin appeals court affirmed a trial court's ruling in favor of Colgate's motion for summary judgment, finding there was no evidence to show that a woman's use of Colgate's talcum powder product caused her mesothelioma. Plaintiff Dale Chapp alleged that his wife, Ruth Chapp, was exposed to asbestos through her daily use of Colgate's Cashmere Bouquet talcum powder. On appeal, Chapp argued that the trial court erred in granting Colgate's motion for summary judgment because, based on the evidence, it could be inferred that his wife used some Cashmere Bouquet that was contaminated with asbestos.

The appellate court disagreed with Chapp, finding that his evidence was insufficient to infer a



connection between his wife's mesothelioma and Cashmere Bouquet, as a factfinder would have to pile "one possibility on top of another possibility." The appellate court further found that any finding regarding Colgate's liability would be based on speculation.

- New Jersey Appeals Court Upholds P&G Mesothelioma Trial Win

On August 29, a New Jersey appeals court upheld a defense verdict in favor of Procter & Gamble Co.'s ("P&G") predecessor, Shulton Inc. ("Shulton"), over claims that asbestos in its talcum powder products caused a woman's mesothelioma. Plaintiff David Fishbain, the husband of decedent Linda Fishbain, claimed that his wife contracted mesothelioma by using asbestos-containing talcum powder products manufactured by Shulton. At trial, Fishbain sought to introduce evidence that samples of Shulton products purchased on eBay tested positive for asbestos, which the court refused to admit into evidence.

On appeal, Fishbain argued that the trial court erred in refusing to admit the samples into evidence. The appellate court disagreed with Fishbain, finding that the trial court did not abuse its discretion in excluding from evidence vintage talcum powder purchased on eBay as there was "a lack of any evidence concerning the chain of custody of the samples."

- J&J Ordered to Pay $37.3 Million in New Jersey Talc Case

On September 11, a New Jersey state jury awarded a total of $37.3 million in compensatory damages to four plaintiffs in a consolidated trial who allegedly 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 products were 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. A separate trial will go forward on punitive damages.

- $12 Million Verdict Against J&J Stands

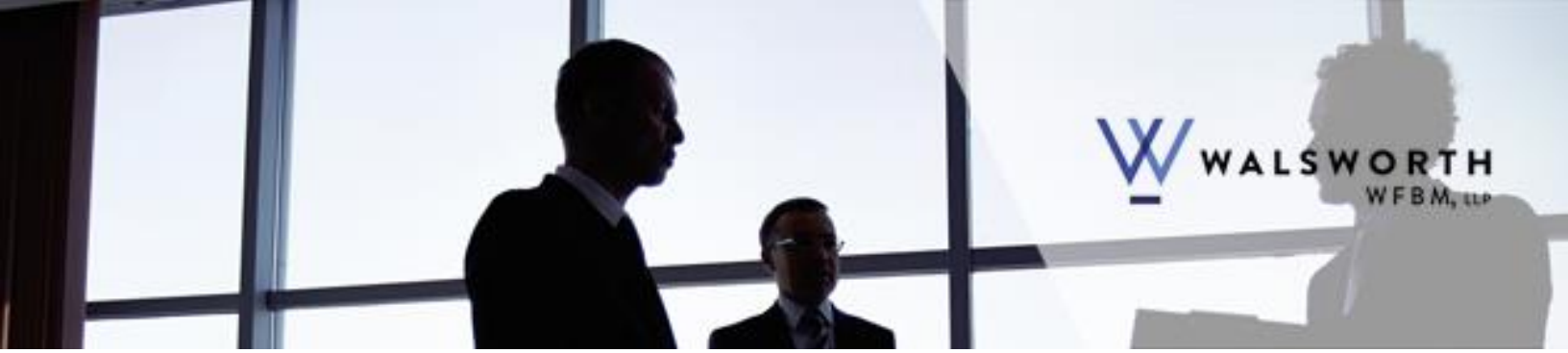
On September 25, a California state court refused to disturb a $12 million jury award against J&J and Colgate in a lawsuit brought by a plaintiff who alleged that her use of the companies' talcum powder products caused her mesothelioma. Plaintiff Patricia Schmitz alleged she developed mesothelioma after using both J&J's Baby Powder and Colgate's Cashmere Bouquet for 40 years. During trial, Schmitz argued that the products tested positive for asbestos and there were no warnings about the risks of such exposure on the bottles.

In June, Schmitz was awarded a total of $2 million in economic damages and $10 million in noneconomic damages. Schmitz died in July, shortly after a California jury found in her favor 11-1. The judge denied J&J and Colgate's request to vacate the judgment and found that state law supported the jury's finding that the companies were jointly liable for Schmitz's mesothelioma.

- J&J Ordered to Pay $40 Million in California Talc Case

On September 27, following a four-week trial, a California state jury ordered J&J to pay $40.3 million to a plaintiff who alleged she developed mesothelioma from her use of J&J's Baby Powder. Plaintiff Nancy Cabibi claimed that she was exposed to respirable asbestos fibers after using J&J's Baby Powder and Shower to Shower, which caused her to develop mesothelioma. According to court papers, Cabibi's body tissue showed the presence of tremolite and anthophylite asbestos, both of which are known contaminants of J&J's talcum powder products.

After six days of deliberations, the jury found that J&J sold talc containing asbestos and that Cabibi's condition could be attributed to her use of J&J's products, but also found that J&J did not negligently design and sell its talc or act with malice or fraud.



Cabibi was awarded $1.2 million in economic damages, $6.5 million in past noneconomic damages and $12.6 million in future noneconomic damages; $20 million was awarded to Cabibi's husband for loss of consortium. No punitive damages were awarded.

- Mistrial in Georgia Talc Powder Case

On October 8, a Georgia state court trial over J&J's Baby Powder ended with a hung jury. Plaintiff Diane Brower initiated her lawsuit in 2016, alleging that J&J's Baby Powder caused her ovarian cancer. Brower allegedly began using the product in 1963 after seeing it advertised in a teen magazine when she was 12, and continued to use the product twice daily for more than two decades. Brower died shortly after her complaint was filed and the case went to trial with Brower's minor granddaughter as the plaintiff, represented by her legal guardian.

Following a three-week trial and three days of deliberations, the Atlanta jury informed Judge Jane Morrison of the Fulton County State Court that they could not reach a decision as to the issue of proximate cause and further information would likely not be fruitful. Judge Morrison declared a hung jury and a mistrial.

- California Jury Clears J&J in Talc Mesothelioma Trial

On October 9, a California state jury rejected a plaintiff's claims that her exposure to asbestos in J&J's Baby Powder caused her mesothelioma. Plaintiff Carolyn 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. The 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's case originally resulted in a hung jury in 2018.

- J&J Gets Win in California Asbestos-in-Talc Trial

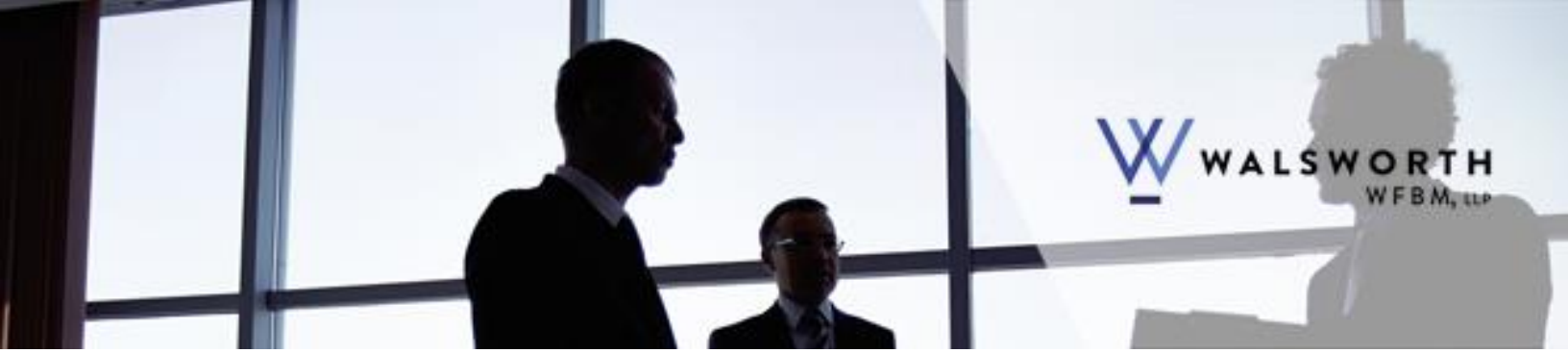
On October 11, a California state jury rejected a plaintiff's claims that asbestos in J&J's baby powder caused his mesothelioma. Plaintiff George Crudge alleged, among other things, that J&J's Baby Powder, which he used for more than three decades, contributed to his condition. The case went to trial with J&J as the only defendant. At trial, J&J argued that Crudge's mesothelioma was caused by his exposure to asbestos during his travel aboard military ships specifically designed to transport asbestos and during his various construction jobs. Following a three-week trial and one day of deliberations, the jury agreed with J&J and found in its favor.

- Missouri Appeals Court Reverses $110 Million Verdict Against J&J

On October 15, the Missouri Court of Appeals reversed a $110 million verdict against J&J, finding that the Virginia plaintiff did not have jurisdiction to bring her case in Missouri under the U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb v. Superior Court of California*.

Plaintiff Lois Slemp alleged she developed ovarian cancer in 2012 after using J&J's Baby Powder and Shower to Shower products on her genitals on a daily basis for nearly 40 years. Following a 17-day trial, a Missouri state jury found in favor of Slemp on all her claims, including conspiracy, breach of implied warranty, and negligence against J&J and its talc supplier, Imerys Talc America Inc. ("Imerys").

Following the trial, J&J and Imerys filed post-trial motions arguing, among other things, that the court did not have jurisdiction over the out-of-state companies. J&J and Imerys made the argument earlier in the litigation, but the trial court rejected the argument, finding that jurisdiction was proper because J&J used a Missouri-based company to "manufacture, mislabel, and package" the products at issue.



- J&J Gets Win in California Talc Case

On December 16, J&J convinced a California state jury that it was not to blame for a plaintiff's mesothelioma. Plaintiff Pui "Amy" Fong, a mother of two who moved to the U.S. from Hong Kong in 1983, claimed she had been exposed to asbestos in J&J's Baby Powder from her birth in 1971. At trial, J&J argued that Fong's expert lacked credibility, successfully striking portions of his testimony.

Following a month-long trial and a day-and-a-half of deliberations, the jury returned a verdict in favor of J&J, finding that its baby powder was not defective, did not pose a substantial danger to its users and was not to blame for Fong's mesothelioma.

Updates in Life Sciences Litigation – Opioids

- Purdue and Teva Agree to End Oklahoma Opioid Litigation

On March 26, Purdue Pharma LP ("Purdue"), the manufacturer of OxyContin, agreed to pay $270 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, Purdue will donate $20 million worth of addiction treatment medication. It will also provide $102.5 million to fund a new addiction treatment and research center at Oklahoma State University. An additional $60 million will cover litigation fees and costs. The remainder of the settlement will be used to provide funding to Oklahoma State University's center for addiction.

On May 26, Teva Pharmaceuticals Industries Ltd. ("Teva") agreed to an $85 million settlement with Oklahoma. Oklahoma Attorney General Mike Hunter has indicated that the funds from Teva's settlement will go towards combating the opioid epidemic in the state.

- McKesson Agrees to Pay $37 Million to End West Virginia Opioid Litigation

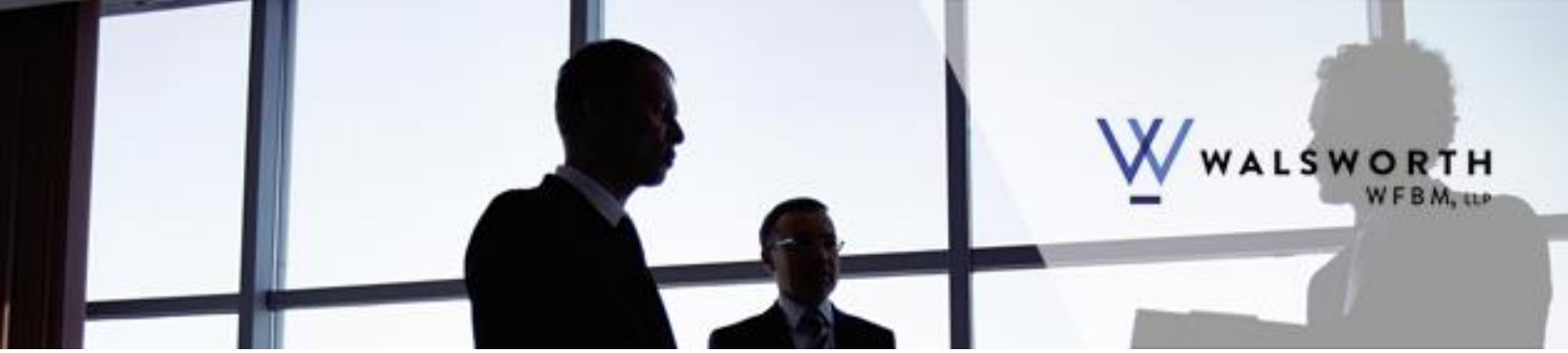
On May 2, pharmaceutical distributor McKesson Corp. ("McKesson") agreed to pay $37 million to end a lawsuit brought by the West Virginia Attorney General over allegations that McKesson oversupplied the state with opioids. Pursuant to the settlement, McKesson will pay $15.5 million this year, and will pay an additional annual payment of $4.5 million for the next five years. The settlement does not include lawsuits filed against McKesson by counties or cities in West Virginia.

- Court Dismisses North Dakota Attorney General's Case Against Purdue in Opioid Litigation

On May 10, a North Dakota state court dismissed a lawsuit filed against Purdue by the state's attorney general, alleging that Purdue contributed to the opioid epidemic by misrepresenting the risks of OxyContin. Burleigh County District Court Judge James Hill's decision was the first granting the dismissal of a state's lawsuit over the opioid epidemic.

Within the litigation, Purdue filed a motion to dismiss, which was later converted into a motion for summary judgment by Judge Hill. Judge Hill ruled that the state's claims were preempted by federal law because the FDA "was aware of issues asserted by the state, studied all relevant available information, and instructed that no labeling or warning change was yet warranted." Therefore, North Dakota could not maintain its claim that Purdue's marketing was fraudulent under state law. Judge Hill also found that the North Dakota Attorney General failed to show that Purdue's actions led directly to North Dakota's opioid epidemic.

Within his 27-page order, Judge Hill stated, "[t]he reality is that Purdue has no control over its product after it is sold to distributors, then to pharmacies, and then prescribed to consumers, *i.e.* enters the market . . . Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give." Judge Hill's dismissal of North Dakota's lawsuit was affirmed by an appellate court in June.



- Insys Agreed to Pay $225 Million to End Federal Opioid Investigation

On June 5, Insys Therapeutics, Inc. ("Insys"), agreed to pay $225 million to end criminal and civil investigations into allegations that it bribed doctors to prescribe its opioid Subsys, a powerful but highly addictive opioid spray. As part of the settlement, Insys admitted to bribing doctors to prescribe its product.

In May, a federal jury in Boston found five top Insys executives, including billionaire founder John Kapoor, guilty of racketeering conspiracy for these same practices. As part of the criminal resolution, Insys will enter into a deferred prosecution agreement and plead guilty to five counts of mail fraud. Insys will pay $2 million in fines, and forfeit an additional $28 million. As part of the civil resolution, the company will pay $195 million to settle claims that it violated the False Claims Act.

- Manufacturers and Distributors Agree to Settle Ohio Opioid Litigation

On August 20, Endo International PLC ("Endo") agreed to pay $10 million to settle claims made by two Ohio counties in exchange for a dismissal from the Ohio opioid MDL. The first bellwether case was scheduled for trial in October. Similarly, on August 30, Allergan PLC ("Allergan") agreed to pay $5 million to the counties. As part of the settlement, Allergan agreed to pay $1.9 million to Summit County and $3.1 million to Cuyahoga County.

On September 6, Mallinckrodt PLC ("Mallinckrodt") followed suit and agreed to pay $24 million and donate up to $6 million in addiction and overdose treatment drugs to exculpate itself from the litigation. Then on October 1, J&J settled for $20.4 million, which includes $10 million to Summit and Cuyahoga counties, reimbursement of $5 million in the counties' legal fees and costs, and $5.4 million to non-profit organizations that run opioid-related programs within the counties.

On October 21, just prior to the start of trial, Teva, Cardinal Health, Inc. ("Cardinal"), McKesson Corp. ("McKesson"), and AmerisourceBergen Drug Corp. ("AmerisourceBergen") also reached settlements with the counties. Distributors Cardinal, McKesson, and AmerisourceBergen agreed to collectively pay $215 million, while Teva agreed to pay $20 million and donate an additional $25 million in addiction and overdose treatment drugs.

All companies have denied allegations that their marketing and distribution practices are to blame for instigating the opioid epidemic in Ohio.

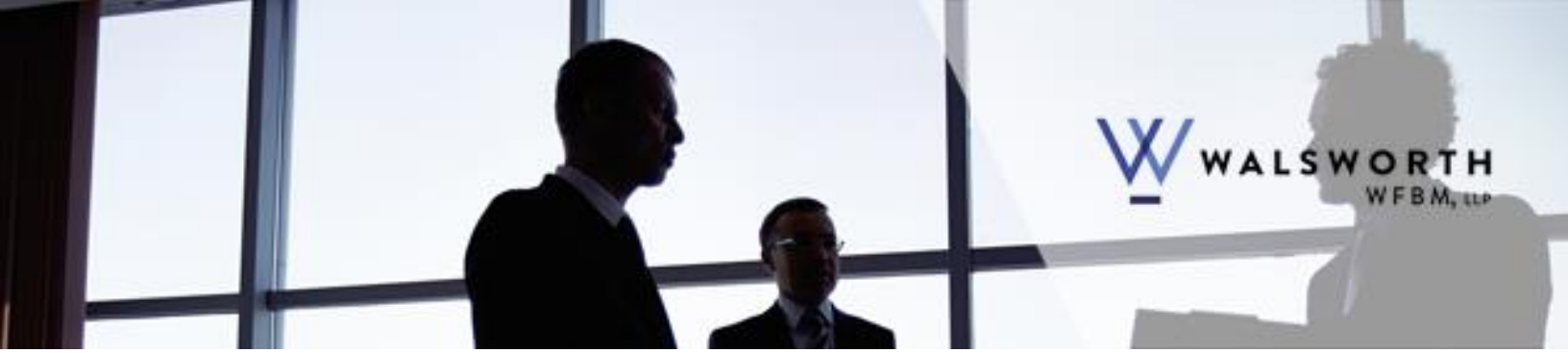
- Purdue Agrees to Settle Nearly 2,000 Opioid Lawsuits and Files for Bankruptcy

On September 11, Purdue reached a tentative agreement to settle approximately 2,000 lawsuits brought by states, Native American tribes and local governments over the company's involvement in the opioid epidemic. As part of the settlement, Purdue is expected to file for a structured bankruptcy and pay as much as $12 million over time, with $3 million coming from Purdue's owners, the Sackler family. Purdue also agreed to donate drugs to assist in the treatment of opioid addition and overdose. The agreement does not cover lawsuits brought by select states' attorneys general, including those of Massachusetts and Connecticut. In addition, although Arizona initially agreed to participate in the settlement, it has since withdrawn due to Purdue's purported attempts to undermine the deal.

Despite other pharmaceutical companies reaching settlements in opioid litigation, Purdue's deal will be the first global settlement resolving nearly all cases filed against it.

- Oklahoma Judge Cuts $572 Million Verdict Against J&J to $465 Million

On November 15, an Oklahoma state court cut a $572 million verdict against J&J to $465 million after finding an "astonishing arithmetic error." In August, following a seven-week bench trial, Cleveland County District Court Judge Thad Balkman ordered J&J to pay $572 million for its involvement in the state's opioid epidemic. During a November hearing, however, Judge Balkman noted that he had erred in the section of the original judgment which allocated funding for treatment and evaluation of babies whose



mothers used narcotic painkillers while pregnant. Judge Balkman stated that he had originally allocated $107,683,000 for neonatal abstinence syndrome but later found that this number inadvertently contained an additional three zeros; the intended number was $107,683.

The state of Oklahoma originally sought $17 billion in damages against J&J's for an abatement program to be spread over 20 years. Judge Balkman's August verdict was the first holding a pharmaceutical company accountable for the opioid epidemic. Judge Balkman ruled that J&J created a "public nuisance" and acted improperly with its "misleading marketing and promotion of opioids." In September, J&J filed an appeal, arguing that the state's public nuisance law had been wrongly applied and that the verdict should be overturned.

On December 17, following Judge Balkman's verdict reduction, the Oklahoma Attorney General filed an appeal seeking authority to come back and ask for more money later.

Trends in Life Sciences

- New 510(k) Guidance Shifts Away From Predicate Devices

On January 22, the FDA announced its final guidance establishing the framework for the new "Safety and Performance Based Pathway" that device manufacturers can use to show their new products are substantially equivalent to ones already on the market. The biggest change to the 510(k) program is that instead of testing a new device in comparison with what is already on the market (a predicate device), new technology seeking clearance can be measured against a set of "objective, transparent and well validated safety and performance metrics." The FDA said, "The benefit of this approach is that the pathway will benchmark modern technology against modern standards while, at the same time, offering a potentially more efficient way to demonstrate that a new device is substantially equivalent to devices already on the market, and thereby ensure patients have timely access to beneficial products." The FDA also believes this new approach may drive greater market competition to develop safer devices. "By using this pathway, manufacturers would have demonstrated that their products meet objective safety and performance criteria that are based on modern technological principles."

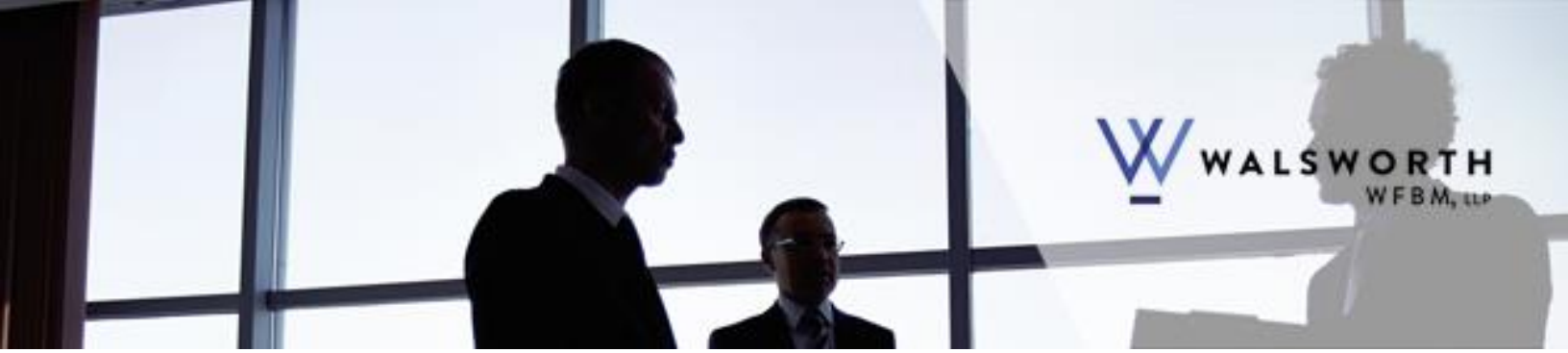
This change has been a key issue for the FDA for some time. Last November the FDA released a statement announcing that it was considering potential updates to the 510(k) clearance pathway for devices, and in the time since it has offered a number of amendment proposals for the process. The FDA stated: "To be clear, we don't believe devices that rely on old predicates are unsafe, or that older devices need to be removed from the market. However, we believe that encouraging product developers to use more modern predicates would give patients and their doctors a choice among older and newer versions of a type of device, promote greater competition to adopt modern features that improve safety and performance, and help make sure that newer devices reflect more modern technology and standards that can improve patient care and outcomes. It would help the overall product environment continue to evolve in the direction toward more modern performance standards."

The FDA allowed public comment on a number of issues surrounding the new guidance for 90 days.

- FDA Issues Final Labeling Guidance

Also on January 22, the FDA issued its final guidance, "Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Pathway." This guidance is intended to assist applicants in developing the "indications and usage" statements in the prescribing information for products approved under the accelerated approval regulatory pathway.

The accelerated approval program allows the FDA to approve drugs to treat serious conditions following a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity, taking into account the severity, rarity or prevalence of the condition and the availability or lack of



alternative treatments. The guidance provides information regarding how accelerated approval is represented in the "indications and usage" statements, and also provides recommendations for labeling products and offers recommendations on language to best convey the various circumstances related to accelerated approval.

- FDA Issues Two Draft Guidances to Improve REMS Programs

On January 24, the FDA released two draft guidance documents focused on improving the FDA's ability to ensure that the risk mitigation programs in place for drugs and biologics as a condition of their approval are working properly. The draft guidances are expected to provide a framework for companies to develop a Risk Evaluation and Mitigation Strategy ("REMS") Assessment Plan at the same time the REMS program is being developed.

REMS is a safety program designed to help reduce the occurrence or severity of particular serious adverse events for certain medications with serious safety concerns. It is used to help ensure the benefits of a medication outweigh its risks. At this time, the FDA has designated 75 medications for which a REMS is necessary.

REMS Assessment: Planning and Reporting Draft Guidance for Industry

The first guidance explains how to develop a REMS Assessment Plan by considering how the program goals, objectives and design may impact the selection of metrics and data sources that could be used to assess whether the REMS is meeting its risk mitigation goals. It further recommends incorporating both process indicators (i.e., the number of patients or physicians who are enrolled or certified in the REMS) and outcome measures in the REMS Assessment Plan.

Survey Methodologies to Assess REMS Goals That Relate to Knowledge

The second guidance provides recommendations on how to conduct REMS assessment surveys to evaluate patient or physician knowledge of REMS-related information, such as the serious risks and safe use of a medication. The draft guidance also discusses general principles and recommendations related to conducting REMS assessment knowledge surveys, including study design, survey data collection and processing, and data analysis.

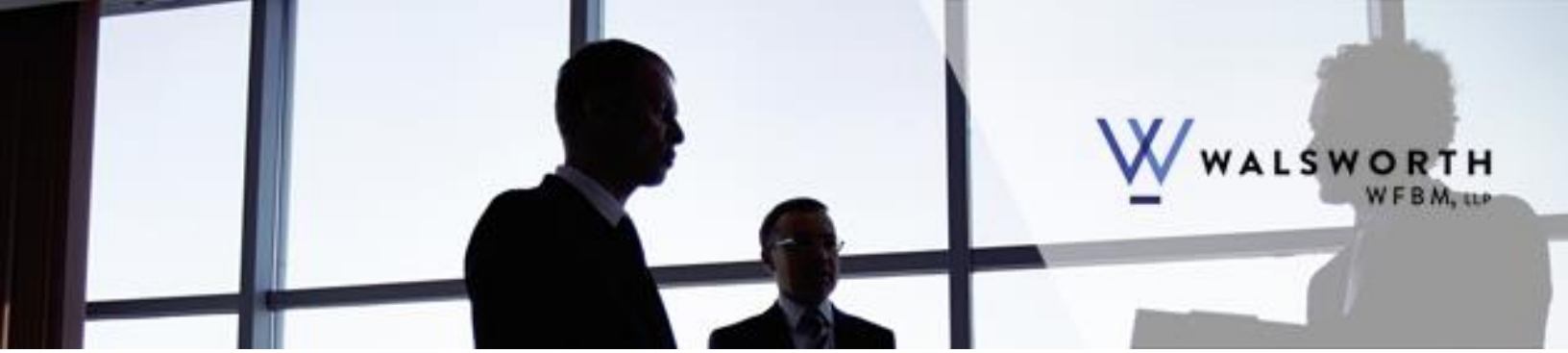
- FDA Issues Draft Guidances on Medical Device Inspections

The FDA has released two draft guidance documents aimed at improving transparency with medical device manufacturers regarding inspections. On February 19, the FDA issued draft guidance titled "Nonbinding Feedback After Certain FDA Inspections of Device Establishments," and on March 29, the FDA issued draft guidance titled "Review and Update of Device Establishment Inspection Processes and Standards."

Nonbinding Feedback After Certain FDA Inspections of Device Establishments

Under the FDA's Reauthorization Act of 2017 ("FDARA") section 702, the FDA must provide nonbinding feedback after an FDA inspection of a device manufacturer if the "owner, operator, or agent in charge of such establishments" requests feedback within 15 business days after issuance of a Form 483. Form 483 is issued to management at the conclusion of an inspection when an investigator has observed any conditions that, in his or her judgment, may constitute violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and related acts, and the request relates to actions proposed by the FDA to be taken that (1) involve a public health priority, (2) implicate systemic or major concerns or (3) involve emerging safety issues that, if left unresolved, are likely to result in the release of devices that are likely to cause death or serious injury.

This guidance provides clarification regarding the feedback request process. It also explains that a request should clearly state the observations for which the nonbinding feedback is requested, and should include a detailed description of the actions proposed in response to the observations, as well as a detailed explanation as to why the requestor believes that the observation in Form 483 meets at least one of the three statutory eligibility criteria explained above.



If the criteria is met, the FDA will provide nonbinding feedback within 45 days.

Review and Update of Device Establishment Inspection Processes and Standards

Under the FDARA, the FDA is required to review and update, as needed, the processes and standards applicable to inspections (other than for-cause) of domestic and foreign device manufacturers in place as of August 18, 2017. This draft guidance suggests that an investigator notify the owner, operator or agent in charge of a medical device establishment by telephone prior to a surveillance or preapproval inspection at least five calendar days in advance of the inspection. During this call, the investigator should describe the "type and nature" of the inspection, including whether the inspection is "abbreviated," "comprehensive" or "preapproval." The guidance states that approximately three to six business days for surveillance or preapproval inspection are reasonable.

► FDA Issues Final Guidance on Interchangeable Biosimilars

On May 10, the FDA finalized its guidance regarding how biosimilars can achieve an interchangeable status, which means they may be substituted for the reference biologic without a prescriber intervening. The guidance provides clarity on the pathway for interchangeability, including:

- Data and information needed to support a demonstration of interchangeability;
- Considerations for the design and analysis of a switching study or studies to support a demonstration of interchangeability;
- Considerations regarding the comparator product in a switching study or studies; and
- Abbreviated considerations for developing presentations, container closure systems and delivery device constituent parts for proposed interchangeable products.

The FDA stated that the guidance will help, for example, individuals with diabetes gain access to biosimilar or interchangeable insulin. This could be significant for patients with diabetes because there are no currently approved insulin products that can be substituted at the pharmacy level.

► The FDA and CBD

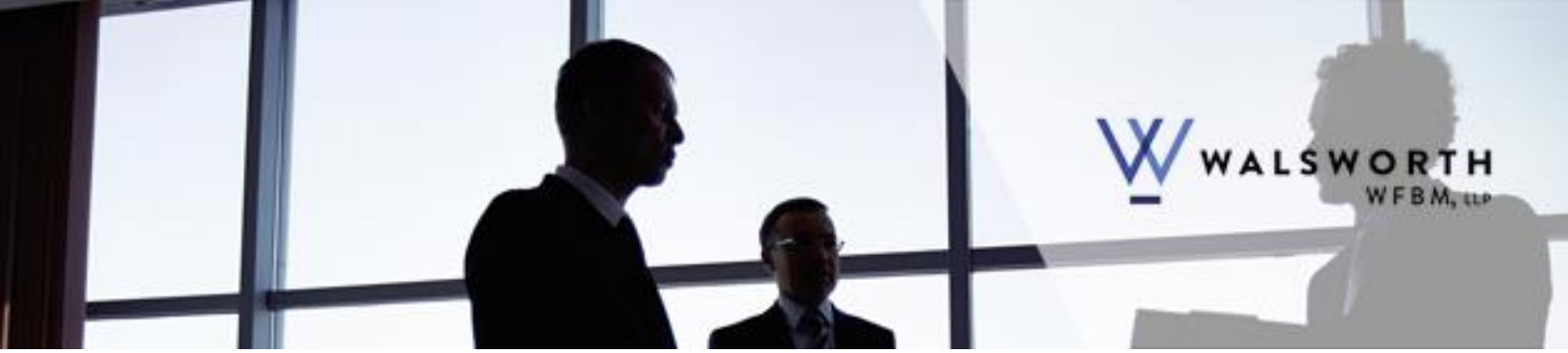
On May 31, the FDA listened to more than a hundred advocates argue for and against cannabidiol ("CBD") in food. Since the passage of the Agriculture Improvement Act of 2018, or the Farm Bill, which removed hemp and CBD compounds derived from hemp from the Controlled Substances Act definition of marijuana and legalized the cultivation of hemp for certain purposes, the FDA has repeatedly informed manufacturers that it remains unlawful under the FDCA to market conventional foods or dietary supplements containing CBD.

In support of this position, the FDA issued warning letters to several companies marketing CBD products purportedly using "egregious and unfounded claims that are aimed at vulnerable populations." Notably, the warning letters were issued jointly with the Federal Trade Commission, which is authorized to protect consumers from unfair trade practices, including false or misleading advertising claims. The letters objected to claims that CBD products can prevent, diagnose, cure or treat serious and complex medical conditions, such as cancer, Alzeheimer's, substance use disorder, amyotrophic lateral sclerosis, and anxiety and depression.

While the FDA is trying to figure out ways to regulate CBD, various state departments have cracked down on the sale of CBD and CBD foods by introducing bills that would allow CBD in food. This suggests that the FDA is currently leaving it up to states to regulate CBD products and is saving its resources for more serious offenses, such as claims that CBD can treat cancer.

► FDA Releases Four Final Guidances on 510(k) Medical Device Approval Programs

On September 13, the FDA issued four final guidance documents related to 510(k) medical device approval programs. The guidance documents relate to the Special 510(k) and Abbreviated 510(k)



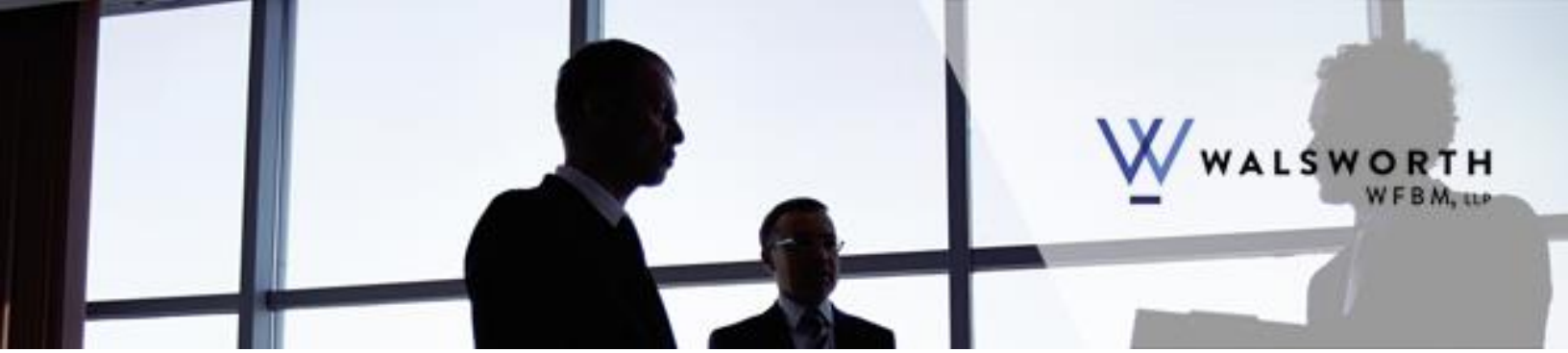
Programs, as well as to the Format for Traditional and Abbreviated 510(k)s and the Refuse to Accept Policy for 510(k)s. These final guidance documents come as part of the FDA's effort to modernize the 510(k) clearance pathway. The final guidances are as follows:

- Special 510(k) Program: This guidance identifies an optional pathway for well-defined device modifications for a legally marketed device, where design control procedures produce reliable results that can form the basis of substantial equivalence. The guidance also clarifies the types of changes appropriate for Special 510(k) review, including certain design, labeling and indications for use changes.
- Abbreviated 510(k) Program: This guidance identifies an optional approach that device manufacturers can use to demonstrate substantial equivalence of predicate devices. FDA review through the Abbreviated pathway involves the use of guidance documents, special controls and/or voluntary consensus standards. The FDA notes that it believes "that its review of Abbreviated 510(k)s may be more efficient than that of Traditional 510(k) submissions," and that "by allowing FDA staff to rely on a manufacturer's summary report on the use of an FDA guidance document(s), special control(s), and/or voluntary consensus standard(s), FDA's review resources can be used in an efficient manner."
- Format for Traditional and Abbreviated 510(k)s: This guidance describes a general framework of how to format a Traditional or Abbreviated 510(k) submission, but does not provide recommendations for any specific device types, or other types of premarket submissions. The guidance goes through each of the 20 sections in Traditional or Abbreviated 510(k) submissions, and provides recommendations for the format and content of each section.
- Refuse to Accept Policy for 510(k)s: This guidance explains the procedures and criteria the FDA intends to use to assess whether a 510(k) submission "meets a minimum threshold of acceptability and should be accepted for substantive review." The FDA will review the submission against specific acceptance criteria and inform the submitter within 15 calendar days after submission if the submission is administratively complete, or if it is not, will identify the missing elements. The guidance contains detailed checklists to assist reviewers in determining the acceptability of the submission.

▶ Senate Confirms Stephen M. Hahn as New FDA Commissioner

On December 12, the Senate confirmed Stephen M. Hahn to take over leadership of the FDA from acting Commissioner Ned Sharpless. In a 72-18 vote, the Senate confirmed Hahn, a radiation oncologist from the University of Texas' MD Anderson Cancer Center, to replace Sharpless, who began leading the FDA after former Commissioner Scott Gottlieb stepped down in April.

Commentators agree that Hahn will likely tackle a number of key issues the FDA has been addressing lately, including an outbreak of lung injuries linked to vaping and, as discussed above, CBD products.



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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 50 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.