



THE
JERE BEASLEY REPORT JANUARY 2017

Beasley Allen

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Attorneys at law



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I. CAPITOL OBSERVATIONS

HEADING INTO THE NEW YEAR

All of us at Beasley Allen were blessed to have had a very good year in 2016. We helped lots of folks who very badly needed our help. In addition to helping our clients, we also were able to once again play a major role in bringing about some badly needed changes in the way some companies in corporate America operate.

Those changes would never have happened without an open, accessible and independent court system and without trial lawyers being willing and able to represent victims in that system. Numerous cases were handled by lawyers in our firm where the results were directly responsible for bringing about needed changes in how several corporations dealt with safety issues.

We have handled several cases where companies were aware of safety defects—hid them from the government and from the public—and put innocent folks at risk of serious injury or death. Several of the companies tried their best to cover up their wrongdoing, but were caught during pretrial discovery in cases handled by our lawyers.

Making a difference in the lives of our clients is what makes having the privilege of being a trial lawyer, and helping folks who need help, worth every bit of the time, effort and financial resources we put into each case. I can think of nothing else that I would rather be doing at this juncture in my life. I thank God for the opportunities given to me to help folks who badly need help in their lives.

Our lawyers and support staff have worked extremely hard this year and we are blessed to have good folks in our firm who do things not only in the right way, but also for the right reason. I thank God every day for the lawyers and support staff in our firm and for what they do for others. They have been a blessing to thousands of folks over the years and that makes what we all do worthwhile.

The New Year will present lots of opportunities and challenges for all of us at Beasley Allen. I really look forward to 2017. God has blessed me with the ability to help others and has also given me the desire to do so.

II. MORE AUTOMOBILE NEWS OF NOTE

The Volkswagen Update

There have been a number of significant developments since our last issue involving the Volkswagen litigation. Things in that arena have been on a very fast track and I will mention several of these developments below. You will see that U.S. District Judge Charles Breyer, the federal judge who has the U.S. Litigation, has done a tremendous job of moving this litigation toward resolution. This was a monumental undertaking and it worked out for all concerned as well as could have been expected.

VOLKSWAGEN REACHES \$1 BILLION SETTLEMENT IN DIESEL SCANDAL SUIT

Volkswagen (VW) has reached a tentative settlement worth at least \$1 billion over 80,000 3.0 liter cars that were implicated in the company's emissions scandal. U.S. District Judge Charles Breyer said last month that he was "extremely pleased to report the parties have reached an agreement about what to do about 80,000 3.0 liter cars on the road and the associated environmental consequences of these vehicles." Judge Breyer said the announcement—which was originally scheduled for Nov. 30 but was delayed several times—was the result of "nearly round the clock" negotiations. At the end of the hearing on Dec. 20, he told the parties to continue working out the details of the settlement.

Volkswagen has divided the class into two generations of cars, determined by engine. "Generation One" includes 20,000 Touaregs and the Audi Q7. Owners of those older cars will have the option to decide whether to have VW buy back their cars or have the cars modified to be more fuel efficient. Lessees will be able to opt out of their leases.

VW says it can fix the remaining 60,000 cars in the "Generation Two" category to make them "fully emissions compliant." Pending government approval, the automaker will implement this fix on all these cars, but if the settlement isn't approved, car owners will have the option to sell their cars back to VW and lessees will be able to opt out of their leases. The Environmental Protection Agency (EPA) and the Department of Justice (DOJ) have estimated the settlement to be worth \$1

billion, assuming the Generation Two fix works. That amount also includes \$225 million that will be allocated to an environmental mitigation trust created by an October settlement for 2.0 liter cars. VW will also pay the California Air Resources Board (CARB) \$25 million to support the development of zero-emissions vehicles in the state.

Assistant Attorney General John C. Cruden said at a December press conference that Volkswagen had committed "an egregious breach of duty," but added that the agreement with 3.0-liter vehicle drivers meant every car with an emissions cheat device would be off the road or fixed. Attorney General Cruden said in a statement:

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The settlement marks another significant step in holding Volkswagen accountable for cheating Americans out of the promise of cleaner air by selling vehicles equipped with defeat devices.

The \$1 billion figure does not include the “substantial compensation” to which Judge Breyer said the class would be entitled. The exact dollar amounts for those payments to consumers haven’t been made public. The Plaintiffs’ Steering Committee (PSC) updated Judge Breyer on its negotiations with Volkswagen during a telephone conference on Dec. 22.

In a statement, Elizabeth Cabraser, the committee’s court-appointed lead counsel, confirmed that she had reached “an agreement-in-principle” with Volkswagen, but Judge Breyer’s confidentiality order is still in place. As we previously reported, the court has already finalized a \$14.7 billion settlement in October allowing 475,000 owners of affected Volkswagen and Audi 2-liter diesel vehicles to sell their cars back to the company or get them fixed. That settlement included payments of \$5,100 to \$10,000 to most consumers who bought their cars before last September in addition to the buybacks. It also agreed to invest \$2 billion in projects that support the increased use of zero emission vehicles, as well as \$2.7 billion to mitigate the effects of the emissions from cars equipped with the so-called defeat devices.

Dee Miles from our firm serves on the steering committee in this litigation. Elizabeth Cabraser and the other lawyers on the committee have done a tremendous job in this matter. The case is *In re: Volkswagen “Clean Diesel” Marketing, Sales Practices and Products Liability Litigation* in the U.S. District Court for the Northern District of California.

Source: Law360.com

VOLKSWAGEN AUDI SETTLES CANADIAN CONSUMER DIESEL CLAIMS FOR \$2.1 BILLION

Volkswagen Canada has reached a \$2.1 billion settlement to resolve class claims with about 105,000 vehicle owners in the diesel emissions scandal in what Canadian regulators are calling one of the largest consumer settlements in history. The proposed settlement will provide certain VW and Audi vehicle owners and lessees with cash payments as well as buybacks, trade-ins, potential modifications and early lease termination. The settlement is subject to approval by two courts to resolve actions filed by owners of vehicles with 2.0-

liter turbocharged direct-injection diesel engines.

As a result of the settlement, Canada’s Competition Bureau said that it reached a consent agreement with Volkswagen Group Canada and Audi Canada for an additional monetary penalty of \$15 million. The Bureau found that consumers were misled by the promotion of clean diesel engines. Commissioner of Competition John Pecman in a statement:

Consumers expect and deserve truth in advertising, particularly when it relates to such a significant investment. We are pleased that Canadians will now begin to receive compensation and that Volkswagen Canada and Audi Canada will address the impact this matter has had on the marketplace. The Bureau works to ensure that Canadians can trust advertising claims made by businesses and can be confident in their purchasing decisions.

Approval hearings are expected to be held in March 2017, according to Canadian regulators. Volkswagen has faced multiple investigations and legal actions since the U.S. Environmental Protection Agency (EPA) and the California Air Resources Board (CARB) in September 2015 accused the company of deliberately installing devices in the computers of its many diesel vehicles that would allow them to cheat testing labs. The U.S. government hit VW and its subsidiaries with a Clean Air Act suit in January. U.S. District Judge Charles Breyer granted final approval to a \$14.7 billion settlement for 2.0-liter vehicles in October, though that sum may rise as VW negotiates an agreement for its 3.0-liter cars.

The company faced two class actions in Canada from consumers seeking damages over the emissions scandal, one in Ontario Superior Court of Justice and the other in Superior Court of Quebec.

Volkswagen said terms of the settlement were reached by Volkswagen and class counsel in consultation with the Commissioner of Competition. Each eligible class member will qualify for a restitution payment based on the year and make of their vehicle, as well as whether they owned or leased their vehicle. Payments for eligible owners range from \$5,100 to \$8,000, according to VW, while lessees can receive between \$1,275 and \$4,000, based on the model, make and year of their vehicle.

To see if their vehicle is covered under the settlement Canadian consumers can enter their car’s VIN number on a website created to advise the terms and inform

class members. Affected vehicles include 2-liter diesel engine models of the 2009-2015 VW Jetta, 2009 VW Jetta Wagon, 2010-2013 and 2015 VW Golf, 2010-2014 VW Golf Sportwagon, 2013-2015 VW Golf Wagon, 2012-2015 VW Passat, 2010-2013 and 2015 Audi A3, and 2013-2015 VW Beetles.

The settlement class is represented by Harvey T. Strosberg of Sutts Strosberg; Charles M. Wright of Siskinds; and Daniel Belleau of Belleau Lapointe. The settlement agreement is filed under *Commissioner of Competition v. Volkswagen Group Canada Inc. and Audi Canada Inc.* in the Competition Tribunal.

Source: Law360.com

ANOTHER STATE SUES VOLKSWAGEN OVER EMISSIONS SCANDAL

Minnesota has become the latest state to sue Volkswagen AG over its diesel emissions scandal. A complaint was filed in Minnesota state court on Dec. 8 accusing the German automaker of violating state environmental laws by selling diesel vehicles equipped with software designed to cheat emissions tests. The state’s attorney general and the Minnesota Pollution Control Agency stated that between 2008 and 2015, Volkswagen and subsidiaries Audi AG and Porsche AG, along with their American counterparts, sold more than 11,500 defective vehicles, which emitted as much as 35 times the legal limit of nitrogen oxides. Minnesota said the automaker and its subsidiaries implemented this plan through the use of the “defeat devices,” which masked the amount of pollution the vehicles emitted while undergoing federal emissions testing.

Minnesota said the use of these devices allowed the automakers’ excess emissions to go unnoticed and gave them the opportunity to market the vehicles as “clean” and “environmentally friendly,” when they were not. The complaint alleges:

Until September 2015, each defendant fraudulently concealed and failed to disclose to the state of Minnesota and the public that it had installed illegal defeat devices in the subject vehicles sold in the United States, including in Minnesota. The conduct of Volkswagen AG, VW of America, Audi, Porsche and Porsche NA alleged in this complaint was knowing and willful.

The Minnesota present lawsuit is separate from the partial settlement agreement reached with Volkswagen in June related

to consumer protection claims. That settlement only resolved claims for false advertising and consumer fraud related to owners of TDI “clean” diesel vehicles with 2.0 liter engines. Minnesota said that it did not reach a settlement for consumers with 3.0-liter diesel engine vehicles. The automaker has not approved a suitable fix to ensure that the pollution control systems will be effective in real world driving situations.

Minnesota’s settlement was part of Volkswagen’s \$14.7 billion settlement with 2.0-liter diesel owners and the U.S. government, which provided relief to consumers as well as environmental remediation and investment in zero emissions vehicle technology by the automaker.

According to Minnesota’s complaint, Volkswagen and the others sold the vehicles through the automaker’s 10 franchise dealerships throughout the state. The state said Volkswagen created several iterations of the defeat device, which the automakers used in model year 2009 to 2016 vehicles, including diesel versions of the the VW Golf, VW Jetta, Audi A3 and Porsche Cayenne. Minnesota alleged that while Volkswagen admitted to using the defeat devices in September 2015, the automaker sought to mislead the public about the use of the software for months after a March 2014 study suggested that the vehicles emitted more nitrogen oxide than originally thought.

The state contended that Volkswagen, Audi and Porsche all acted in concert to implement the illegal defeat device scheme, as the companies all share engineering research and development concepts. Minnesota said that at minimum, the automakers provided each other with substantial assistance in implementing the defeat device software.

Minnesota is seeking relief for its claims under the state’s Motor Vehicle Air Pollution Control Systems Act and the Pollution Control Agency’s Air Pollution Control Systems Restrictions Rule. Minnesota adds to the growing number of states suing Volkswagen for state environmental law violations. Most of the cases have been moved to the multidistrict litigation (MDL). Many of the states, including New York, Pennsylvania, New Hampshire and Alabama, have asked to send their suits back to their respective state courts based on standstill agreements they signed with Volkswagen.

Minnesota is represented by Attorney General Lori Swanson Deputy Attorney General J W. Canady and Assistant Attorneys General Jason Pleggenkuhle and Katherine F. Key. The case is *State of Min-*

nesota v. Volkswagen Aktiengesellschaft, in Hennepin County District Court.

Source: Law360.com

More Automobile Litigation News

CARMAX REACHES SETTLEMENT OVER INSPECTIONS AND RECALLS

CarMax has reached a settlement with the Federal Trade Commission (FTC) over claims it didn’t reveal recall information on its cars. CarMax settled a federal complaint over the used car dealer’s failure to disclose safety recall information on some of its vehicles. The Federal Trade Commission announced the settlement with Virginia-based CarMax and two other major used auto retailers last month. The FTC said the dealers touted how rigorously they inspected their used cars, yet they failed to adequately disclose that some of the vehicles were subject to unrepaired safety recalls.

CarMax advertised a “125-plus point inspection” for its cars with “12 hours of renewing—sandwiched between two meticulous inspections.” The fact that some of the cars being sold were subject to safety recalls—and those repairs had not been done—was not adequately explained to buyers. The FTC said:

These recalls included defects that could cause serious injury, including the GM key ignition switch defect, as well as the Takata airbag defect.

Similar complaints were made against the Georgia-based Asbury Automotive Group, which also does business as Coggin Automotive Group and Crown Automotive Group, and New York-based West-Herr Automotive Group. The settlement prohibits the auto dealers from claiming their used vehicles are safe or have been repaired or inspected unless they are free of open recalls. The companies are in the process of notifying customers by mail of an open recalls for vehicle purchased as far back as July 1, 2013.

Source: AL.com

PORSCHE REACHES SETTLEMENT IN WINDSHIELD GLARE LITIGATION

Porsche Cars North America Inc. has agreed to settle several class actions that accuse the company of selling vehicles with windshield glare that poses a safety hazard to drivers. Documents filed in New Jersey federal court say the company will pay between \$50 and \$175 to tens of thou-

sands of drivers who leased or bought a vehicle with a brightly colored dashboard that could cause a noticeable glare on the windshield when it reflects sunlight.

The settlement, which still requires court approval, could benefit more than 74,000 people who leased or bought a Porsche if they can submit proof that they bought sunglasses or made other out-of-pocket expenses to cut down on the glare. Current lessees and owners can receive \$75 or \$175, depending on the age of their vehicle, and former owners and lessees can get up to \$50.

The lawsuit covers Porsche cars from 2007 through 2016 with dashboards in Luxor Beige, Sand Beige, Cognac, Platinum Grey and Natural Brown. The plaintiffs claim that Porsche may have known as early as 2009 that those colors can reflect off the windshield, blinding drivers, but chose to do nothing about the supposed defect even as complaints piled up with auto regulators, dealers and online forums.

The case was settled in its early stages. There had been no class certified and no ruling by the court on a pending motion for dismissal. The parties began mediation early this year and worked out the details by August. The proposed settlement also calls for a pending case in California to be consolidated with the New Jersey case. The settlement also calls for Porsche to notify prospective buyers online and in sales brochures about the reflection issue. The notice language encourages potential customers to test drive the car under different conditions and consider using sunglasses.

The Plaintiffs are represented by Jordan L. Lurie and Tarek H. Zohdy of Capstone Law; Robert L. Starr of the Law Office of Robert L. Starr; Stephen M. Harris of the Law Offices of Stephen M. Harris; and Joseph Santoli of the Law Offices of Joseph R. Santoli. The case is *Chan v. Porsche Cars North America Inc.*, in U.S. District Court for the District of New Jersey.

Source: Law360.com

FEDERAL JUDGE DISMISSES “DEFEAT DEVICE” EMISSIONS CLAIM FOR LACK OF STANDING

A New Jersey federal judge has ruled that the Plaintiffs lacked basic standing in their emissions suit against Mercedes-Benz USA LLC. The suit centers on a “defeat device” that Mercedes used in its vehicles to cheat emissions tests, deceptively and fraudulently inducing customers to buy Mercedes vehicles. However, the judge ruled that the Plaintiffs lacked standing

because their complaint did “not contain sufficient facts to allege that Plaintiffs’ injuries were fairly traceable to any of the Defendant’s representations.”

The proposed class action claims that Mercedes installed a “defeat device” in its BlueTEC system that allowed its vehicles to pass emissions inspections. Plaintiffs allege that the BlueTEC system, which “cleans” the vehicle’s emissions by converting mono-nitrogen oxides into the relatively harmless components nitrogen and oxygen, only works when temperatures are above 50 degrees Fahrenheit. European governments and some independent companies have found that when the vehicle is operated in sub-50 degree temperatures, the BlueTEC system engines can produce up to 65 times amount of pollutants allowed by the U.S.

The judge based the dismissal on Article III standing, essentially holding that, while Plaintiffs alleged multiple specific advertisements throughout the complaint, which touted the emissions safety and compliance of BlueTEC systems Mercedes, Plaintiffs had not alleged that any of these advertisements were actually relied upon and induced a purchase of any vehicle. However, lead Plaintiff Ulyana Lynevykh, an Illinois resident, claimed that she bought her Mercedes SUV based on Mercedes’ statements that the BlueTEC engines were cleaner, more powerful, and more efficient than competing gas engines.

The suit was dismissed without prejudice, and Plaintiffs will have another chance to properly invoke standing. Lynevykh is represented by James Cecchi and Lindsey Taylor of Carella Byrne Cecchi Olstein Brody & Agnello; Steve Berman and Sean Matt of Hagens Berman Sobol Shapirp; David Freydn and Timothy Scott of the Law Offices of David Freydn and Jeffrey Goldenberg of Goldenberg Schneider. The case is *Ulyana Lynevykh v. Mercedes-Benz USA LLC* in the U.S. District Court for the District of New Jersey.

Source: Law360

III. DRUG MANUFACTURERS FRAUD LITIGATION

20 STATE ATTORNEYS GENERAL FILE DRUG PRICE FIXING SUIT

On Dec. 14, 2016, 20 state attorneys general filed suit against several Defendants in federal district court in Connecticut. The attorneys general have alleged that pharmaceutical manufacturers Aurobindo Pharma USA, Inc.; Citron Pharma, LLC; Heritage Pharmaceuticals, Inc.; Mayne Pharma (USA), Inc.; and Teva Pharmaceuticals USA, Inc., entered into illegal conspiracies to fix the market and artificially inflate the prices for two common generic drugs, doxycycline hyclate and glyburide.

Governmental investigations by the Department of Justice (DOJ) and state attorneys general have revealed that top executives for these six drug companies and their sales representatives unlawfully increased the prices of these drugs, and potentially a large number of other generic drugs, in addition to entering into agreements to divide the drug market among themselves.

For example, it is alleged that Mylan Pharmaceuticals, Inc. allocated the market by agreeing to abandon at least one major wholesaler and one large pharmacy chain to allow another manufacturer, Heritage Pharmaceuticals, to gain a foothold in the doxycycline hyclate market, which is a delayed release antibiotic. The attorneys general have also alleged that when pharmaceutical manufacturer Mayne Pharma (USA), Inc. entered the market in 2014 for doxycycline, Mayne contacted Heritage and Mylan to negotiate details regarding how prices would be set and customers would be allocated. The complaint further alleges that Heritage reached out to its contacts at each competitor company and attempted to reach agreements on price increases for glyburide, an older drug used to treat diabetes.

Governmental investigators believe that these drug manufacturers seek out rivals in an attempt to reach agreements on how to maintain market share and avoid competing on price for many drugs. Price fixing and market allocation are illegal and violate antitrust laws. Top executives of these pharmaceutical companies, knowing that their conduct was illegal, allegedly coordinated their unlawful price increases through secret, informal indus-

try gatherings and personal calls and text messages.

The attorneys general lawsuit is *State of Connecticut et al. v. Aurobindo Pharma, et al.*, 3:16-cv-2056 and the Plaintiff states include: Connecticut, Delaware, Florida, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, North Dakota, Ohio, Pennsylvania, Virginia and Washington. While these states have already found evidence of broad, well-coordinated schemes against these six pharmaceutical manufacturers, their attorneys general have made clear that the investigation is continuing and includes more drugs and more pharmaceutical manufacturers.

More than 80 percent of all prescriptions dispensed in the United States are for generic drugs, which have been credited with saving consumers and taxpayers billions of dollars by introducing competing products into the market. Companies that conspire to fix prices for generic drugs in order to increase their profits must answer for the harm caused to the federal government, states and consumers.

Beasley Allen lawyers have handled a number of cases involving fraud, deceit and anticompetitive conduct within the pharmaceutical industry. If any of our readers are aware of these type of anti-competitive acts, contact Ali Hawthorne, a lawyer in our firm’s Consumer Fraud & Commercial Litigation Section, at 800-898-2034 or by email at Alison.Hawthorne@beasleyallen.com.

Sources: Law360.com and *New York Times*

EX-INSYS THERAPEUTICS EXECUTIVES CHARGED IN PAINKILLER KICKBACK SCHEME

Six former executives of pharmaceutical company Insys Therapeutics Inc. have been arrested and charged in a Massachusetts federal court. They are accused of conspiring to bribe doctors to prescribe the company’s highly potent fentanyl-based pain medication. The six former executives of the Arizona-based Insys include its former chief executive Michael Babich, who resigned from the company in November 2015; its former national sales director Richard Simon; former vice president of sales Alec Burlakoff; former regional sales directors Sunshine Lee and Joseph Rowan; and Michael Gurry, the former vice president of managed markets.

The Defendants are accused of conspiring to bribe pain clinic-based practitioners nationwide to prescribe the medication known as Subsys - which is a powerful narcotic used to treat intense pain in

cancer patients – to individuals, including those not diagnosed with cancer, according to the U.S. Department of Justice (DOJ).

Babich is charged with conspiracy to commit racketeering, conspiracy to commit wire and mail fraud and conspiracy to violate the Anti-Kickback Law. Burlakoff, Simon, Lee and Rowan are charged with Racketeer Influenced and Corrupt Organizations (RICO) Act conspiracy, mail fraud conspiracy and conspiracy to violate the Anti-Kickback Law. Gurry is charged with RICO conspiracy and wire fraud conspiracy. Carmen Ortiz, the U.S. Attorney for the District of Massachusetts, said in a statement:

Patient safety is paramount and prescriptions for these highly addictive drugs, especially fentanyl, which is among the most potent and addictive opioids, should be prescribed without the influence of corporate money. I hope that today's charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.

According to Justice Department officials, the former executives also conspired to defraud health insurance providers reluctant to approve payment for the drug when prescribed to non-cancer patients by setting up a “reimbursement unit” that obtained prior authorization directly from insurers. The 60-page indictment against the six Defendants alleges that the bribes and kickbacks were mostly disguised as fees the company paid the doctors for marketing events, such as social gatherings at expensive restaurants designated as “speaker program” events.

Insys has been at the center of investigations by the U.S. Department of Health and Human Services and more than 10 state attorneys general over its fentanyl-based painkiller. Several Insys employees have since pled guilty or have been charged by the Justice Department for certain sales techniques, including the kickback scheme disguised as the doctor speaker program.

Former Insys employees who have also been charged in connection with the scheme include Jonathan Roper, a former district manager from New York, and Fernando Serrando, a former sales representative. They were charged in June with one count of conspiracy each to violate the anti-kickback scheme.

In August, Illinois attorney general Lisa Madigan filed suit against Insys, accusing the company of deceptively marketing a

spray version of fentanyl to doctors for off-label uses when the drug is intended to be used for cancer patients. The complaint alleged that Insys aggressively targeted doctors who prescribe opioid drugs instead of oncologists treating the cancer patients Subsys is intended for, marketing the medicine for off-label uses like back and neck pain in order to boost profits, even though it is a known gateway drug for heroin.

Subsys was approved by the U.S. Food and Drug Administration (FDA) in January 2012 for pain management in cancer patients who are already receiving, and thus are tolerant to, opioids for their underlying persistent pain. The drug is highly addictive and significantly more powerful than morphine, offering a rapid onset because it is administered under the tongue.

The arrests reflect the highest-level arrests within Insys' ranks in connection with the alleged kickback conspiracy. Last November, Babich stepped down from the company in the wake of allegations of the fraudulent drug marketing scheme. Justice Department officials allege that the scheme occurred from about June 2012 to around December 2015.

According to the indictment, the six former executives deliberately targeted practitioners at pain clinics and saw an increase in the number of fentanyl spray prescriptions after these alleged bribes took place. Following establishment of the reimbursement unit, the prior authorization rate for prescriptions rose from about 33 percent to 46 percent during the first week of a pilot program and up to 85 percent after the first year it was created, according to the indictment.

The U.S. government is represented by Assistant U.S. Attorneys K. Nathaniel Yeager and Susan M. Poswistilo. The case is *United States of America v. Michael L. Babich et al.*, in U.S. District Court for the District of Massachusetts.

Source: Law360.com

BRISTOL-MYERS SQUIBB TO PAY \$19.5 MILLION OVER ABILIFY MARKETING

Bristol-Myers Squibb (BMS) will pay \$19.5 million to 42 states and Washington, D.C., to settle claims that the company improperly marketed the antipsychotic drug Abilify. The states, including New York, Texas and California, claimed that BMS improperly promoted Abilify for use by children and certain elderly patients and also misrepresented the findings of scientific studies done on the drug, which led to a misrepresentation of the risks

Abilify posed to patients, including weight gain. BMS has not marketed the drug since 2013.

The agreement prohibits the drugmaker from promoting Abilify for off-label use, making false or misleading claims about it, paying health care providers for merely attending a promotional event for the drug, using medical education grants to promote the drug and rewarding health care providers with grants based on prescribing habits, among other restrictions. New York Attorney General Eric T. Schneiderman said in a statement:

Drug companies should not market their drug for off-label uses or make claims that are not supported by scientific evidence. Consumers must be able to rely on their doctor's advice for medication without having to worry about drug companies manipulating their advertising to promote their products at the expense of patients.

The U.S. Food and Drug Administration (FDA) approved the use of Abilify for treating schizophrenic adults in 2002, but has since approved various forms of the drug for other uses, the complaints said. BMS began to market the drug as a schizophrenia treatment in 2002, but also for a number of uses not approved by the FDA, including off-label use by children. The company also promoted Abilify for use by elderly patients with symptoms consistent with dementia and Alzheimer's disease without first establishing whether the drug was safe or effective in such situations.

In 2006, Abilify received a “black box” warning that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death. Texas Attorney General Ken Paxton said in a statement:

BMS put Texans' lives at risk when it marketed Abilify for uses not approved by the FDA. The integrity of our health care system depends on patients and doctors being able to trust the representations made by pharmaceutical companies.

Each state received hundreds of thousands of dollars, with some getting \$1 million or more. Texas will take \$1 million from the settlement, while California will take \$1.3 million. The eight states that were not part of the case or settlement are Alaska, Idaho, Mississippi, New Mexico, South Carolina, Utah, Virginia and Wyoming. Arkansas Attorney General Leslie Rutledge, in a statement, added these comments:

The deceitful actions by Bristol-Myers Squibb were unlawful and irresponsible. Arkansans needing antipsychotic medications have a level of trust in the companies making these drugs, and unfortunately Bristol-Myers Squibb misrepresented Abilify with their marketing practices.

The investigation underlying the settlement is related to a 2007 civil settlement between BMS and the federal government regarding Abilify and some 2008 civil Medicaid-focused settlements between the company and a number of states. The cases were filed by each state's attorney general in state court.

Source: Law360.com

TEVA REACHES \$519 MILLION SETTLEMENT WITH U.S. GOVERNMENT

Teva Pharmaceutical Industries Ltd. has reached a settlement with the U.S. authorities in which it will pay a \$519 million fine. The settlement concludes negotiations between the company and the government concerning violations of the Foreign Corrupt Practices Act (FCPA). Teva admits in the agreement that it took part in unacceptable practices aimed at promoting its products in various countries, including Russia, Ukraine and Mexico. Teva said in a statement:

The resolution involves conduct occurring in the past, and none of the employees involved in the improper payments are still employed by Teva, including in Russia, where the entire leadership team was replaced in 2013. None of the conduct in question involved Teva's U.S. sales.

I fear this sort of thing goes on much more than is reported by the media or caught by the government. Based on our dealings with the powerful drug industry, I am not at all surprised that a drug company would bribe its way into a profitable drug deal. The FCPA must be vigorously enforced.

Source: Globes English

IV. PURELY POLITICAL NEWS & VIEWS

JEFF SESSIONS WILL BE THE U.S. ATTORNEY GENERAL

I believe that Jeff Sessions will be confirmed as the next U.S. Attorney General. I am convinced Jeff will do a good job in this new endeavor. It's good to see an Alabamian in such an important position. Hopefully, the confirmation process will take place in a fair and impartial manner and, if that happens, it will be good for all concerned.

A NEW U.S. SENATOR FOR ALABAMA

Gov. Robert Bentley will appoint a replacement for Jeff Sessions in the U.S. Senate. It appears that the Governor will have some very good individuals to choose from. Attorney General Luther Strange has announced that he will run for the seat regardless of who gets the interim appointment. He is also being considered for the appointment. I suspect Gov. Bentley has a group of new friends to deal with as we enter the New Year. It will be most interesting to see who is chosen to join Richard Shelby in Washington.

JUDGE GENE REESE RETIRES

Montgomery Circuit Judge Gene Reese retired effective Dec. 31 after a long and distinguished career on the bench. Gene has been an outstanding judge and was fair and impartial in all matters that came before him. We wish Gene the very best in the next chapter in his professional life.

V. COURT WATCH

U.S. SUPREME COURT WON'T HEAR APPEAL OVER NFL HEAD INJURY SETTLEMENT

The U.S. Supreme Court refused to take another look at an uncapped settlement between former National Football League (NFL) players and the league that would end a long-running dispute over concussions and head injuries, clearing the way for an agreement that could wind up paying out up to \$1 billion. The high

court, without an explanation, denied a challenge by a group of players who claimed the settlement did not go far enough. A group of more than 30 players asked the high court to review a unanimous Third Circuit decision earlier this year affirming the settlement, arguing it leaves out retirees whose chronic traumatic encephalopathy (CTE) afflictions are not yet apparent.

Both the NFL and a larger group of settling players had signed off on the settlement, which offered a bottomless fund over a 65-year period to compensate a class of some 22,000 former NFL players. The settlement offers payments ranging from \$1.5 million to \$5 million for each retired player diagnosed with some of the most serious degenerative conditions connected to traumatic brain injuries, including dementia, Alzheimer's disease and Parkinson's disease. In a statement, Christopher Seeger of Seeger Weiss LLP, a co-lead counsel for the retired players, said that the settlement will finally give the former players care and support for their injuries. He added:

These courageous men and their families, who in the face of great adversity took on the NFL, have made history. Despite the difficult health situations retired players face today, and that many more will unfortunately face in the future, they can take comfort in the fact that this settlement's significant and immediate benefits will finally become available to them and last for decades to come.

Former Buffalo Bills player Carlton Chester "Cookie" Gilchrist and another 31 former players had asked for the review. They said the settlement suffered from a lack of scientific discovery, as is evidenced by the recent Kevin Turner CTE diagnosis. Turner, who is from Prattville, Ala., a former New England Patriots player, died in March. The condition can still only be diagnosed after a post-mortem analysis of a patient's brain. The NFL had also urged the high court not to take up the petitions, claiming that throwing out the settlement would jeopardize the claims of the 20,000 class members who signed on to the agreement.

The settling Plaintiffs are represented by Seeger Weiss; Anapol Schwartz Weiss Cohan Feldman & Smalley and Podhurst Orseck, among other firms. The other petitioners are represented by Richard Coffman of The Coffman Law Firm, Mitchell Toups of Weller Green Toups & Terrell; Jason Webster of The Webster Law Firm;

and Deepak Gupta, Matthew Wessler and Jonathan Taylor of Gupta Wessler PLLC.

Source: Law360.com

VI. THE NATIONAL SCENE

NEW ACCUSATIONS AGAINST FORMER FOX NEWS HEAD AILES IN LAWSUIT

Another lawsuit has been filed that involves former Fox News network chief Roger Ailes. He faces new sexual harassment accusations in the lawsuit filed against 21st Century Fox. The lawsuit comes just months after Fox News agreed to pay \$20 million to settle separate allegations of sexual harassment of female staff at Fox News by Ailes. The federal discrimination lawsuit filed in New York alleges that Ailes offered Lidija Curanaj, whose legal name is Lidija Ujkic, an interview to join the Fox News Network after meeting her at a dinner in 2011.

It's alleged in the complaint that after being interviewed in a group setting, Ailes invited the woman to a private interview. Allegedly, he then told her it was "important [for female talent] to look good from head to toe," and asked her to stand and turn around for him. The suit also alleged that Ailes later contacted a man Ms. Curanaj previously dated asking if she would "put out" sexually. The man told Ailes she likely would not, the suit said, after which she was turned down for the job.

Ailes has consistently denied similar sexual harassment allegations, but lots of money has been paid out to his alleged victims. Curanaj's lawsuit does not name Ailes or Fox News as a Defendant, but rather alleges gender, age, race and pregnancy discrimination on the part of her employer, New York Fox TV station WNYW.

The suit claims that when Ms. Curanaj confronted the station's news director about not being promoted to anchor despite her journalistic experience and successes, he replied she was "not attractive enough to be an anchor." A spokeswoman for Fox TV Stations, a subsidiary of 21st Century Fox (FOXA.O), denied fault in an emailed statement. It should be noted that Fox News in September agreed to pay \$20 million to settle a sexual harassment lawsuit brought by former anchor Gretchen Carlson. A subsequent internal investigation of the company turned up

more than two dozen women who described harassment by Ailes, according to *New York Magazine*.

Source: Reuters

SORRY I CANNOT HELP YOU

"Sorry, I cannot help you." These are words you will likely hear if you contact an attorney about an injury or other wrong suffered at a Casino on Indian land or by an Indian owned business. This is because the Alabama Constitution and Alabama law do not apply to jurisdictions under Indian control. Customers who visit tribal casinos are usually unaware that they have entered a jurisdiction where Alabama law does not generally apply. Federally recognized Indian tribes, which are separate sovereigns under the U.S. Constitution, operate tribal casinos in Alabama and also own businesses.

Indian casinos and adjoining hotels, which are located on tribal land, enjoy what is called sovereign immunity. Tribal sovereign immunity protects Indian tribes from suits absent express authorization by congress or a clear waiver by the tribe. Sovereign immunity extends to bar claims for injuries or death, even to persons who have never set foot in an Indian casino or on Indian land.

Josh Harvey, his pregnant wife and their three children were on their way home from a Halloween party. A casino patron who had been gambling and drinking for approximately five hours rear-ended the Harvey's vehicle while travelling at approximately 90 miles per hour with no evidence of braking prior to impact. Josh Harvey, his wife, their unborn child and two of their three children were killed. The patron was sentenced to 15 years in prison for manslaughter. The court dismissed the Harveys' civil suit against the casino holding that the casino, owned by the Otoe-Missouria Tribe, enjoyed sovereign immunity from claims that it served alcohol to a visibly intoxicated patron. So, if you or a family member are injured or killed by a drunk driver who was over-served at a casino, sorry.

If you enter onto casino property and one of the gaming machines malfunctions or you believe you have been treated unfairly as it relates to claims for winnings or other promotions or prizes, sorry. If you are assaulted or robbed in the parking lot by another patron due to inadequate security measures, sorry. If someone gains access to your hotel room and you are robbed or assaulted, sorry. If you enter into any type of contract or prospective contract with the casino or the hotel and a

dispute arises, sorry. If an intoxicated casino employee in a casino vehicle injures you in a crash, sorry. These are all examples of scenarios where sovereign immunity acts as a complete bar to any claim or recovery.

If you apply for a loan from a lending institution, you will need to research whether that lender is an "arm of the tribe." If you have a dispute with a lender that is an arm of the tribe and want to file suit, sorry. The Circuit Court for the Seventh Judicial Circuit for St. Johns County, Fla., recently held that Great Plains Lending LLC was entitled to sovereign immunity in an action alleging violation of the Florida Consumer Collection Protection Act. The Court found that Great Plains Lending was an "arm of the tribe" and thus immune from suit. Great Plains Lending is wholly owned by the Otoe-Missouria Tribe of Indians, an Oklahoma tribe.

In addition to the above, sovereign immunity also protects the tribe from suits governed by Federal Law. As an example, if you are employed by a tribe and they fire you based on your age, sorry. A recent ruling by the U.S. Court of Appeals for the 11th Circuit held that The Poarch Creek Band of Indians is immune from suits brought under the Age Discrimination in Employment Act of 1967.

As mentioned above, a tribe may expressly waive sovereign immunity. The Poarch Band of Creek Indians waived its sovereign immunity for certain very limited claims that occur on tribal lands. Some examples would be where a patron slips and falls or where a person becomes sick due to the negligence of a tribal employee in food preparation. However, because these claims arise on tribal land, they are governed by Indian law and must be filed in the tribal court. Tribal courts have different notice provisions, procedural rules, liability limitations, damage caps and limited appellate opportunities. Some specific limitations are that no claim may be made and no award may be granted in excess of \$100,000.00 per person; no punitive damages or attorneys fee may be awarded; no award for pain and suffering or for mental anguish.

You will not see conspicuous signs outside an Indian Casino that state "Warning—Enter at Your Own Risk." Nor will you see disclaimers on documents notifying you that the business is Indian owned and may be subject to different laws. However, you need to know that is exactly what you are doing. If you are unfortunately injured or wronged while on Indian casino land, or at the hands of a Tribe owned business, hopefully you will

not have to hear the words “Sorry—I cannot help you.”

VII. WHISTLEBLOWER LITIGATION

WHISTLEBLOWERS HELPED FEDERAL GOVERNMENT RECOVER ABOUT \$5 BILLION LAST YEAR

Whistleblowers helped the United States recover more than \$4.7 billion in taxpayer funds in fiscal year 2016 (ending Sept. 30), according to a Department of Justice (DOJ) news release. This represents the third highest annual recovery in the history of the False Claims Act (FCA), the primary vehicle for federal whistleblower lawsuits. Whistleblowers in fiscal year 2016 were awarded \$519 million for uncovering the fraud that greatly benefited the government and U.S. taxpayers.

Since 2009, whistleblowers have helped the United States recover a total of \$31.3 billion, averaging almost \$4 billion a year, under the False Claims Act. The largest areas of recovery have been health care fraud, and housing and mortgage fraud. During this period the government has recovered more than \$19 billion from health care fraud actions and more than \$7 billion related to housing and mortgage fraud.

Successful health care fraud cases included schemes for overbilling government health programs, falsely marketing the benefits of pharmaceutical products, paying kickbacks to health care providers by drug and device manufacturers, and overbilling in the hospice and home health industry. Other areas of recovery included fraud in defense contracting, for-profit education, various government contracts and grants, customs fraud, and fraud involving the storage of nuclear waste or dumping of environmental contaminants.

A whistleblower represented by lawyers at Beasley Allen uncovered and stopped a multimillion-dollar scheme to defraud the federal government by a company paid to conduct background checks related to high-level security clearances. Other whistleblowers represented by our firm successfully reported fraud related to the unlawful marketing of off-label drug products, kickbacks paid to physicians by big drug companies, and fraudulent procurement of federal student loan funds by a corrupt for-profit college. The whistleblower litigation has become a significant

part of our firm's work in the Consumer Fraud & Commercial Litigation Section.

For those who may not understand, the False Claims Act provides incentives for individuals to report fraud against the United States. These incentives include 15 to 30 percent of the funds recovered by the government, as well as protection against retaliation. Whistleblowing individuals typically have first-hand, inside information that is not publicly available and has not been previously revealed to the government by some other source. The monies recovered through the False Claims Act replenish the tax pool and deter others from committing fraud. Deputy Assistant Attorney General Benjamin C. Mizer said in a news statement:

The beneficiaries of [the False Claims Act] include veterans, the elderly, and low-income families who are insured by federal health care programs; families and students who are able to afford homes and go to college thanks to federally insured loans; and all of us who are protected by the government's investment in national security and defense. In short, Americans across the country are healthier, enjoy a better quality of life, and are safer because of our continuing success in protecting taxpayer funds from misuse.

If any of you are aware of fraud being committed against the federal government, or against a state government, you should consider being a whistleblower. The FCA can protect and reward you for doing the right thing by reporting the fraud. If you have any questions about whether you qualify as a whistleblower, please contact a lawyer on Beasley Allen's Whistleblower Litigation team for a free and confidential evaluation of your claim. There is a contact form on our website, or you may contact one of the lawyers on our whistleblower litigation team: Archie Grubb, Larry Golston, Lance Gould or Andrew Brashier at 800-898-2034 or by email at Archie.Grubb@beasleyallen.com, Larry.Golston@beasleyallen.com, Lance.Gould@beasleyallen.com or Andrew.Brashier@beasleyallen.com.

Source: U.S. Department of Justice

SUPREME COURT RULES THAT VIOLATING THE FCA SEAL REQUIREMENT DOES NOT MANDATE DISMISSAL

On Dec. 6, 2016, the U.S. Supreme Court released its opinion in *State Farm*

Fire & Casualty Co. v. United States ex rel. Rigsby, 137 S. Ct. 436 (2016), the first decision of its November argument session. This case dealt with the seal requirement of the False Claims Act (FCA), and the High Court rejected a categorical rule requiring mandatory dismissal in instances where the seal requirement has been violated.

When a relator files a FCA complaint alleging that a government contractor has committed fraud, the complaint remains under seal while the government decides if it wants to intervene in the litigation. In this case, however, the relator's former lawyer leaked details of the complaint to several media outlets, violating the automatic seal. All agreed that this was an intentional violation of the seal requirement. The question became what penalties should arise from this violation.

The FCA instructs that a suit “shall” be kept under seal until allowed to be made public by a judge. But the Act says nothing in particular about penalties for breaking that seal. State Farm argued that, because the seal requirement was included in the section of the FCA creating a private right of action, the two clauses should be considered together and the case should be automatically dismissed.

The district court decided not to dismiss the complaint, noting that the violation did not prejudice the government and the offending lawyer had already been removed from the case. The U.S. Court of Appeals for the 5th Circuit affirmed, rejecting a 6th Circuit holding that dismissal is mandatory for any violation of the seal requirement. The Supreme Court unanimously (8-0) affirmed, ruling that the FCA does not “enact so harsh a rule” as automatically requiring dismissal when the seal is broken.

In his opinion, Justice Kennedy rejected State Farm's argument, holding that the seal requirement and the private right of action clause are not tied in conditional terms. He further noted that the FCA's own structure indicates that Congress did not intend for a seal violation to mandate dismissal, as the statute contains a number of provisions that do explicitly require dismissal if violated, allowing for an inference that lawmakers “would have said so” if they wanted automatic dismissals to extend to seal violations. And, “[i]n the absence of congressional guidance regarding a remedy, [a]lthough the duty is mandatory, the sanction for breach is not a loss of all later powers to act.” *Rigsby*, 137 S. Ct. at 442 (quoting *United States v. Montalvo-Murillo*, 495 U.S. 711, 718 (1990)).

Additionally, the seal requirement was enacted as part of FCA reforms intended

to encourage more private enforcement. The legislative history connected to such reforms shows that lawmakers were mostly concerned that breaking the seal could tip off a Defendant about any related investigation and harm the government's interests. For these reasons, the Court held that "it would make little sense to adopt a rigid interpretation of the seal provision that prejudices the Government by depriving it of needed assistance from private parties." *Id.* at 443.

Justice Kennedy remarked that dismissal still remains a discretionary option for district courts, alongside other remedial options that can be used to punish and deter seal violations. But the Court did not rule on whether another penalty would be warranted in the *Rigsby* case, as State Farm did not request any alternative sanction and thus had not preserved the issue for appeal.

Sources: Law360.com and scotusblog.com

SUPREME COURT UPHOLDS KATRINA FRAUD VERDICT AGAINST STATE FARM

As discussed above, the U.S. Supreme Court ruled in favor of two whistleblower sisters in their lawsuit against State Farm. The justices upheld a jury verdict that found State Farm defrauded the U.S. government when the insurance company assessed damage caused by Hurricane Katrina along the Gulf of Mexico coast in 2005. The court ruled 8-0 to reject State Farm's challenge to a 2015 lower court decision upholding the verdict in a 2006 lawsuit brought by sisters Cori and Kerri Rigsby under the False Claims Act (FCA). Here are some additional details about the case. The suit accused State Farm of improperly seeking to foist the costs of covering Katrina-related damage to a Biloxi, Miss., home onto the government rather than covering the costs itself.

State Farm argued that the claims brought by the sisters, former claims adjusters who worked for the company after the hurricane, should be voided because their lawyer violated a court order requiring that details of the case to be kept under seal. The women's former lawyer, Dickie Scruggs, had distributed information about the lawsuit to members of the news media. False Claims Act lawsuits are required to be filed under seal and remain private for 60 days. In 2008, Scruggs was convicted of conspiring to bribe a judge in a different case. He was sentenced to five years in prison. But the Supreme Court concluded that Scruggs' disclosures to the media did not merit throwing out the 2013 jury verdict. None

of the media organizations disclosed the lawsuit's existence to the public.

Justice Anthony Kennedy, writing for the court, said the seal requirement is intended to benefit the government because it prevents those suspected of defrauding it from being alerted about a potential case alleging that fraud took place. As a result, "it would make little sense to adopt a rigid interpretation of the seal provision that prejudices the government by depriving it of needed assistance from private parties," Kennedy wrote. The Obama administration had backed the sisters in the case.

The jury found that the federal government had been defrauded of \$250,000. State Farm was ordered to pay \$758,000 in damages. The sisters were awarded \$227,000 for disclosing the fraud under the False Claims Act and almost \$3 million in attorney's fees and expenses. The Rigsbys said the damage was caused by wind, which would be covered by the owners' insurance policy with State Farm. But State Farm concluded the damage was flood-related, which instead was covered by the federal government's flood insurance program. In 2015, the New Orleans-based 5th U.S. Circuit Court of Appeals upheld the jury verdict.

Source: Lawrence Henley, *Insurance Journal*

OLYMPUS EXECUTIVES REFUSE TO ANSWER KEY QUESTIONS ABOUT THE DEADLY OUTBREAKS TIED TO THE COMPANY'S MEDICAL SCOPES

Three senior executives at medical scope maker Olympus Corp. repeatedly invoked their 5th Amendment right against self-incrimination when questioned recently about internal company emails dealing with its role in superbug outbreaks. The executives declined to answer questions in depositions taken in a U.S. civil case against Olympus filed by a Seattle hospital and the widow of a patient. The company emails—first reported by the *Los Angeles Times* and *Kaiser Health News*—are key evidence in several pending civil suits against Olympus. The emails also could be relevant to an ongoing federal investigation.

The emails show that Susumu Nishina, one of the three executives deposed, told the company's U.S. managers in February 2013 not to issue a broad warning to American hospitals despite reports of scope-related infections in Dutch, French and U.S. hospitals. At least 35 patients in American hospitals have died since 2013 after developing infections tied to tainted Olympus duodenoscopes—flexible, lighted tubes used to peer deep inside the

body. More than 25 patients and families, including the Seattle-area widow, have sued Olympus alleging wrongful death, negligence or fraud.

In addition to Nishina, the company's chief manager for market quality administration at the Tokyo headquarters, the other two executives questioned were Hisao Yabe and Hiroki Moriyama. Yabe appears to be the highest ranking official among the three, serving as an executive officer in charge of the medical manufacturing improvement division. Moriyama is a key figure in the company's regulatory affairs and quality assurance unit. He is listed on several company patents for endoscopes. Also, he was the manufacturer's contact on numerous injury reports filed with U.S. regulators about scope-related infections.

The three executives were recently deposed at the U.S. Embassy in Tokyo by lawyers representing Virginia Mason Medical Center in Seattle and Theresa Bigler. Her 57-year-old husband, Richard, died in 2013 after he was infected by a contaminated Olympus scope, according to the family's lawsuit in King County Superior Court in Washington. Mrs. Bigler has sued Olympus for wrongful death and is seeking damages.

The separate federal investigation into Olympus surfaced in March 2015, when the company said it received a subpoena from investigators that "seeks information relating to duodenoscopes that Olympus manufactures and sells." A year later, in March 2016, Paul Fishman, the U.S. attorney for the District of New Jersey, said the scope-related investigation was continuing. The focus of the probe was not specified. The emails could be relevant in both the civil case and the federal investigation because they show that a month after Olympus alerted European customers in January 2013 a scope it manufactured could become contaminated, the company decided not to issue a broad warning to U.S. customers.

For those who are not familiar with the procedure, duodenoscopes are threaded down a patient's throat to diagnose and treat digestive tract problems such as gallstones, cancers and bile duct blockages. The tip of the snake-like device has proven difficult to clean, even when following the manufacturer's instructions, and antibiotic-resistant bacteria known as superbugs can spread from one patient to another, with possibly life-threatening consequences. Although infections have been tied to scopes made by other companies, Olympus dominates the market and its scopes remain in wide use.

It would appear that Olympus in Japan knew of the dangers of the duodenoscopes not being able to be adequately disinfected, even when Olympus guidelines are followed. It appears Olympus failed to notify health care providers in the U.S. of this problem. This appears to be a very strong case. Rando Wick represents the hospital and John Gagliardi represents the Bigler family.

Source: *Los Angeles Times*

EX-MAQUET COMPLIANCE OFFICER FILES WHISTLEBLOWER SUIT

A former compliance supervisor with Maquet Getinge Group has filed a whistleblower lawsuit against the medical device manufacturer in New Jersey state court. The suit claims she was fired about a year ago for objecting to the company's investigation into a product used in cardiac surgery. The whistleblower, Soila Borrero, alleges in her complaint that she is among several compliance officers terminated by Maquet for whistleblowing conduct related to U.S. Food and Drug Administration (FDA) regulations, claiming that the company "maintains and perpetuates a corporate culture of non-compliance with FDA rules and regulations." The complaint filed Dec. 9 in Essex County Superior Court states:

Maquet has terminated several other compliance supervisors for their protests and objections to Maquet's failure to adhere to FDA rules, regulations and laws.

The complaint identifies four such former compliance officers, including Oscar Sanchez, who is pursuing a separate lawsuit against Maquet over similar allegations in the same state court. Sanchez, Maquet's former chief quality regulatory and compliance officer, has alleged in his lawsuit that the company fired him because he protested regulatory violations and other improper conduct surrounding the company's products. The Sanchez case was filed in July 2015 and remains pending. The following comes from the new complaint filed by Ms. Borrero:

As a director of Quality Systems at Maquet, Ms. Borrero said she oversaw quality assurance activities to ensure that company products complied with regulatory and legislative requirements. In March 2015, she "objected to Maquet's improper testing and failure to investigate involving the Ultima Stabilizer, a violation of federal law." Her objec-

tions included that the final investigation involving the product "did not include tests performed on different samples with failed results."

It's alleged that after receiving Ms. Borrero's objections, her supervisor, David Rose—who also is named as a Defendant in the lawsuit—tried to pressure and coerce Borrero to drop her objections and protests. When she refused to do so, Rose removed her from the investigation and stopped providing her with any information related to the inquiry. The complaint alleges a series of actions that were said to be retaliation against the whistleblower for reporting the fraud.

Ms. Borrero said she was terminated on Dec. 27, 2015, because of her whistleblowing activities in violation of New Jersey's Conscientious Employee Protection Act. Ms. Borrero is represented by Paul S. Foreman. The case is *Soila Borrero v. Maquet Getinge Group and David Rose* in the Superior Court of New Jersey, County of Essex.

Source: Law360.com

VIII. SOME AREAS OF OUR FIRM'S PRACTICE

The following are some of the cases our lawyers are currently concentrating on at this juncture. To learn more, you can visit www.beasleyallen.com. I will give a brief summary below of these cases. Several of the cases will be discussed in more detail in other parts of this issue.

Personal Injury And Products Liability

Lawyers in our Personal Injury & Products Liability Section continue to focus on accident cases involving automobiles, heavy equipment and consumer products. Some of these auto cases involve single-vehicle crashes, while others involve multiple-vehicle accidents. Cole Portis heads up this Section and Sloan Downes is the Section Head Administrator. Our lawyers will review any case involving catastrophic injury or death. Contact: Cole.Portis@beasleyallen.com or Sloan.Downes@beasleyallen.com for more information on any of the matters described below.

Takata Airbags Recall—The largest automotive recall in history centers on the defective Takata airbags found

in millions of vehicles manufactured by BMW, Chrysler, Daimler Trucks, Ford, General Motors, Honda, Mazda, Mitsubishi, Nissan, Subaru, and Toyota. The defect results in shrapnel-like metal shards and airbag components being propelled throughout the vehicle interior. This frequently results in lacerations and blunt force trauma that can cause injury or death. Contact: Cole.Portis@beasleyallen.com

Honda Airbag Claims—As mentioned above, millions of vehicles are now under recall due to faulty airbag inflators. Many of these faulty inflators are in Honda vehicles. We are handling Honda airbag cases with smaller injuries that normally would not qualify for claims under our usual review process. Contact: Cole.Portis@beasleyallen.com or Chris.Glover@beasleyallen.com.

Defective Tires—Tire failure can result in a serious car crash and even a vehicle rollover accident, causing serious injury or death to vehicle occupants. Air, heat and sunlight can cause the rubber in tires to break down. When a tire is defective, potentially serious problems like detreads and blowouts can occur long before the tire would be expected to wear out. If the tire failure is the result of design or manufacturing defects, and the manufacturer is aware of the problem, they have an obligation to alert consumers to the potential danger. Contact: Cole.Portis@beasleyallen.com or Ben.Baker@beasleyallen.com.

Big Truck Accidents—There are significant differences between handling an interstate trucking case and other car wreck cases. It is imperative to have knowledge of the Federal Motor Carrier Safety Regulations, technology, business practices, insurance coverages, and to have the ability to discover written and electronic records. Expert testimony is of utmost importance. Accidents involving semi-trucks and passenger vehicles often result in serious injuries and wrongful death. Trucking companies and their insurance companies almost always quickly send accident investigators to the scene of a truck accident to begin working to limit their liability in these situations. Our lawyers, staff and in-house accident investigators immediately begin the important task of documenting and

preserving the evidence. Contact: Cole.Portis@beasleyallen.com or Chris.Glover@beasleyallen.com.

Heavy Truck Product Liability Claims—Tractor trailer and other heavy trucks are not required to contain many of the same protections for occupants as smaller passenger cars. They can contain dangerous defects putting the truck driver or passengers at risk of serious injury or death. These trucks many times have particularly weak roofs that crush in rollovers. The passenger compartments are often not protected by effective cab guards, and this allows loads to shift into the truck cab. Contact: Cole.Portis@beasleyallen.com.

On-the-job Product Liability—Many times product claims arise from worker's compensation claims. After we investigate the circumstances that caused the injuries, many times we discover a defective machine may be the cause of the injuries. Contact: Cole.Portis@beasleyallen.com or Kendall.Dunson@beasleyallen.com.

E-cigarette Explosions—We are currently investigating cases involving severe injuries caused by exploding e-cigarette devices and exploding e-cigarette batteries. These explosions have been linked to faulty e-cigarette products, defective lithium-ion batteries, and insufficient warnings for users. With few regulations to ensure their safety, e-cigarette devices have been aggressively marketed and sold in stores throughout the United States. Contact: William.Sutton@beasleyallen.com.

Nursing Home Abuse and Neglect—Nursing homes are supposed to be in the business of providing skilled nursing care to elderly and disabled residents. Unfortunately, statistics indicate residents in nursing homes suffer abuse and neglect more and more frequently at the hands of nursing home corporations. In many cases residents have died or have been severely abused as a result of neglect. They may suffer physical abuse, emotional or psychological abuse, or neglect. Our lawyers are investigating cases involving serious injury or death resulting from nursing home abuse or neglect. Contact: Ben.Locklar@beasleyallen.com

Mass Torts Section

Lawyers in our Mass Torts Section have been very busy in litigation involving the powerful drug industry during the past year and much of that work is going over into 2017. Andy Birchfield is the Section Head and Melissa Prickett is the Section Head Administrator. They can be reached at Andy.Birchfield@beasleyallen.com or Melissa.Prickett@beasleyallen.com. The following are areas where our lawyers in the Section are currently working.

Pharmaceuticals And Medical Devices

Talcum powder and ovarian cancer—As many as 2,200 cases of ovarian cancer diagnosed each year may have been caused by regular use of talcum powder. Talc is a mineral made of up various elements including magnesium, silicon, and oxygen. Talc is ground to make talcum powder which is used to absorb moisture and is widely available in various products including baby powder and adult products including body and facial powder. Talc products used regularly in the genital area increase the risk of ovarian cancer. In February 2016, a jury found Johnson & Johnson knew of the cancer risks associated with its talc products but failed to warn consumers, and awarded the family of our client \$72 million. She died of ovarian cancer after using J&J talc-containing products for more than 30 years. There have subsequently been two more jury verdicts against Johnson & Johnson. Contact: Ted.Meadows@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Xarelto—Lawsuits filed against Johnson & Johnson subsidiary Janssen Pharmaceuticals and Bayer Corp. over the blood thinner Xarelto have been consolidated in Louisiana federal court. Xarelto has been linked to serious side effects including internal bleeding, gastrointestinal bleeding, brain bleed, and death. The Xarelto lawsuits come on the heels of the recent \$650 million Pradaxa settlement. Researchers linked Pradaxa, also a blood thinning medication, to more than 500 deaths. Xarelto blood thinner litigation has been consolidated before U.S. District Judge Eldon Fallon in the Eastern District of Louisiana, who presided over suits against Merck & Co. over its medication Vioxx. The Vioxx litigation resulted in a \$4.85 billion settlement in 2007.

Contact: Andy.Birchfield@beasleyallen.com, David.Byrne@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Invokana—Approved in March 2013, Invokana (canagliflozin) is an SGLT2 Inhibitor used to treat adults with Type 2 diabetes, manufactured by Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson. SGLT2 inhibitors work by preventing high blood sugar by helping the patient's kidneys remove excess sugar through their urine. In May 2015, the U.S. Food and Drug Administration (FDA) issued a warning the drug has been linked to cases of ketoacidosis, a serious condition where there is too much acid in the blood. Complications of diabetic ketoacidosis include difficulty breathing, nausea/vomiting, abdominal pain, confusion and unusual fatigue or sleepiness. The condition can lead to diabetic coma and/or death. Contact: Melissa.Prickett@beasleyallen.com.

Testosterone Replacement Therapy (TRT) products for men have been linked to an increased risk of death, heart attack and stroke. Researchers found men who used testosterone therapy were 30 percent more likely to have a heart attack, stroke, or die after three years of use. A second study found that men had a significant increase in risk of heart attack and stroke in just the first 90 days of testosterone therapy use. Furthermore, men who started the study with clear, unobstructed coronary arteries were just as likely to have a heart attack, stroke or die as men who entered the study with established coronary artery disease. Testosterone therapy, such as the prescription topical treatments Androgel, Testim and Axiron, are used to help boost testosterone levels in men who have a deficiency of the male hormone. Symptoms of low testosterone include decreased libido and low energy. Contact: Matt.Teague@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Viagra—A preliminary study indicates the erectile dysfunction drug Viagra (sildenafil) may increase the risk of developing melanoma, the deadliest form of skin cancer. The study, published in JAMA Internal Medicine, analyzed data from nearly 26,000 men, 6 percent of whom had taken Viagra. The men who used

Viagra at some point in their lives had about double the risk of developing melanoma compared to men who had never taken the drug. Men who were currently taking Viagra were at an 84 percent greater risk of developing melanoma. We are currently investigating cases involving men who are taking or have taken Viagra and were diagnosed with melanoma. Contact: Melissa.Prickett@beasleyallen.com or Frank.Woodson@beasleyallen.com.

Risperdal, an atypical antipsychotic drug used to treat schizophrenia and certain problems caused by bipolar disorder, has been linked to the development of gynecomastia in boys and young men. Gynecomastia is a condition that causes boys to grow breasts. The drug is manufactured by Johnson & Johnson. Contact: James.Lampkin@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Zofran—Manufactured by GlaxoSmithKline, Zofran (ondansetron) was approved to treat nausea during chemotherapy and following surgery. Zofran works by blocking serotonin in the areas of the brain that trigger nausea and vomiting. Between 2002 and 2004, GSK began promoting Zofran off-label for the treatment of morning sickness during pregnancy, despite the fact the drug has not been approved for pregnant women and there have been no well-controlled studies in pregnant women. The FDA has received nearly 500 reports of birth defects linked to Zofran. Birth defect risks include cleft palate and septal heart defects. Contact: Roger.Smith@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Metal-on-Metal Hip Replacement parts—The FDA has ordered a review of all metal-on-metal hip implants due to mounting patient complaints. Problems with metal-on-metal include, but are not limited to loosening, metallosis (i.e.: tissue or bone death), fracturing, and/or corrosion and fretting of these devices, which require revision surgery. Many patients that require revision surgery due to these devices suffer significant post-revision complications. We are investigating all cases involving metal-on-metal hip implants, including the DePuy Orthopaedics ASR XL Acetabular System and the DePuy ASR Hip Resurfacing System, recalled in August 2010; the Stryker Rejuvenate and ABG II modular-neck stems, recalled in July 2012;

the DePuy Pinnacle, the Zimmer Durom Cup, the Wright Conserve, and the Biomet M2A “38mm” and M2A-Magnum hip replacement systems, which have not been recalled. Reported problems include pain, swelling and problems walking. Contact: Navan.Ward@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

3M Bair Hugger—The 3M Bair Hugger is a forced hot air warming blanket, used primarily to help maintain a patient’s body temperature during surgery. The 3M Bair Hugger pushes warm air through a flexible hose into a blanket draped over a patient. However, warming blankets can recirculate contaminated air over a patient’s body, including over an open surgical site. This may result in infections like MRSA or sepsis. In particular, patients undergoing knee or hip replacement surgery are at risk of infections deep in the joint, which are very difficult to treat. Complications from these infections include hospitalization, implant revision surgery, limited mobility, permanent disability, amputation and death. Contact: Melissa.Prickett@beasleyallen.com.

IVC Filters—Retrievable IVC filters are wire devices implanted in the vena cava, the body’s largest vein, to stop blood clots from reaching the heart and lungs. These devices are used when blood thinners are not an option. Manufacturers include Bard, Cook, and Johnson & Johnson. While permanent IVC filters have been used since the 1960s with almost no reports of failure, retrievable IVC filters were introduced in 2003, promoted for use in bariatric surgery, trauma surgery and orthopedic surgery. Risks associated with the retrievable IVC filters include migration, fracture, and perforation, leading to embolism, organ damage and wrongful death. Contact: Melissa.Prickett@beasleyallen.com.

Proton Pump Inhibitors—Proton pump inhibitors (PPIs) were introduced in the late 1980s for the treatment of acid-related disorder of the upper gastrointestinal tract, including peptic ulcers and gastrointestinal reflux disorders, and are available both as prescription and over-the-counter drugs. Beasley Allen is currently investigating PPI-induced Acute Interstitial Nephritis (AIN), which is a

condition where the spaces between the tubules of the kidney cells become inflamed. The injury appears to be more profound in individuals older than 60. While individuals who suffer from AIN can recover, most will suffer from some level of permanent kidney function loss. In rare cases individuals suffering from PPI-induced AIN will require kidney transplant.

Contact: Roger.Smith@beasleyallen.com or Melissa.Prickett@beasleyallen.com

Taxotere—Taxotere (docetaxel) is a chemotherapy drug approved in the treatment of breast cancer along with other forms of cancer. It is administered intravenously, and is a member of a family of drugs called taxanes. In 2007, manufacturer Sanofi-Aventis issued a press release touting the efficacy of Taxotere based on a clinical study. However, Sanofi-Aventis failed to inform the FDA, health care providers, and the public that permanent hair loss was observed in a number of the patients taking Taxotere. In December 2015, the FDA announced it had ordered Sanofi-Aventis to change Taxotere’s label to warn patients of the risk of permanent hair loss. While hair loss during chemotherapy is expected, patients undergoing chemotherapy with Taxotere were not warned they could potentially experience permanent hair loss. Permanent hair loss is an extremely debilitating condition, especially for women. We are currently investigating claims for women who suffered permanent hair loss following chemotherapy with Taxotere for breast cancer. Contact: Beau.Darley@beasleyallen.com or Melissa.Prickett@beasleyallen.com.

Consumer Fraud & Commercial Litigation Section

Lawyers in our Consumer Fraud & Commercial Litigation Section are working on a number of areas. Dee Miles heads up the Section and Michelle Fulmer is the Section Head Administrator. They can be reached at Dee.Miles@beasleyallen.com or Michelle.Fulmer@beasleyallen.com. The following are areas where our lawyers are working.

Fraud And General Litigation

Life Insurance Fraud—Our lawyers have uncovered alleged fraudulent

accounting practices by life insurance companies concerning premium increases. The accounting method may result in the policyholders being charged excessive insurance premiums. A client who has a life insurance policy and has been notified of a substantial increase in premium payments, or if they have been told their policy's "cost of insurance" has increased, may have a valuable legal claim. Contact: Dee.Miles@beasleyallen.com, Andrew.Brashier@beasleyallen.com or Rachel.Boyd@beasleyallen.com.

Self-funded Health and Pharmacy Insurance Plans—Third Party Administrators and Pharmacy Benefit Managers may have been charging unauthorized fees to self-funded insurance health and pharmacy benefit plans. These extra fees may be in violation of the contracts with the self-funded plan and a breach of fiduciary duty under the Employee Retirement Income Security Act of 1974 (ERISA). We are looking into these cases on behalf of self-funded plans. Contact: Rebecca.Gilliland@beasleyallen.com.

Pharmaceutical Pricing—Our lawyers are continuing to handle claims involving chain pharmacies falsely reporting their generic pricing transactions to state Medicaid agencies. This misconduct has led to millions of dollars in overpayments by Medicaid agencies for generic drugs to the chain pharmacies. Contact: Roman.Shaul@beasleyallen.com, Alison.Hawthorne@beasleyallen.com, or Rebecca.Gilliland@beasleyallen.com.

Health Care Fraud—Our lawyers are looking into cases of fraud within the health care industry. These may include cases dealing with pricing, off-label prescriptions, or other health care abuse. Contact: Roman.Shaul@beasleyallen.com, Clay.Barnett@beasleyallen.com, or Rebecca.Gilliland@beasleyallen.com.

Auto Defect Class Actions—We are continuing to work on numerous auto defect class actions against many of the major automobile manufacturers like VW, Toyota, General Motors, Ford and even some suppliers like Takata. These cases continue to be filed because of corporate misconduct in designing and manufacturing unsafe vehicles that are purchased by consumers, corporations and state agen-

cies. We continue to investigate these automobile problems for class relief treatment. Contact: Dee.Miles@beasleyallen.com, Archie.Grubb@beasleyallen.com or Clay.Barnett@beasleyallen.com

Antitrust—We are handling claims related to the violation of federal and state antitrust laws. We are currently involved in claims alleging a wide array of anticompetitive conduct, including illegal tying, exclusive dealing, monopolization, and price fixing. Contact: Archie.Grubb@beasleyallen.com, Roman.Shaul@beasleyallen.com or Alison.Hawthorne@beasleyallen.com.

Fair Labor Standards Act (FLSA)—We are working several cases involving Fair Labor Standards Act (FLSA) violations. The FLSA cases are brought on behalf of clients whose job title is misclassified by their employers so that employees are not compensated for overtime worked. Cases may also involve unequal pay, where women are paid less for doing the same job as men. Contact: Lance.Golston@beasleyallen.com or Larry.Golston@beasleyallen.com.

State and Municipalities Litigation—Our firm has represented numerous states throughout the country. These cases have been handled through the Attorneys General and have involved various civil actions. Many times, individuals are barred from bringing a consumer fraud type claim but the state government is not. We recently concluded litigation in six of eight states for a recovery dealing with medical fraud, with still two states remaining. For more information, contact Dee.Miles@beasleyallen.com, Roman.Shaul@beasleyallen.com or Alison.Hawthorne@beasleyallen.com.

Employment Law—We are handling employment cases. Situations that may be addressed in this area include minimum wage and overtime pay, unfair labor practices, all types of discrimination, employee benefits, and whistleblower claims. Contact: Larry.Golston@beasleyallen.com

Whistleblower Litigation

False Claims Act—Whistleblower Litigation—Our lawyers are handling and investigating whistleblower claims of government fraud ranging

from Medicare/Medicaid to military contracts, and any other type of fraud involving a government contract. Under the False Claims Act (FCA) the whistleblower is entitled to a percentage of the recovery. Studies show that as much as 10 percent of Medicare/Medicaid charges are fraudulent. Common schemes involve double-billing for the same service, inaccurately coding services, and billing for services not performed. Additionally, the Commission on Wartime Contracting has warned that the lack of oversight of government contractors has led to massive fraud and waste. Contact: Lance.Golston@beasleyallen.com, Larry.Golston@beasleyallen.com, or Andrew.Brashier@beasleyallen.com.

Toxic Torts Section

Lawyers in our Toxic Torts Section are working on cases in a number of important areas. Rhon Jones is the Section Head and Sandra Walters is the Section Head Administrator. They can be reached at Rhon.Jones@beasleyallen.com or Sandra.Walters@beasleyallen.com. The following are some of the areas our lawyers are working on.

Toxic Torts Litigation

Mesothelioma—Mesothelioma is a highly aggressive and rare form of cancer usually affecting the lining of the lungs (pleural) or abdominal cavity (peritoneal). Occasionally, it also may affect the lining of the heart (pericardial). The only known cause of mesothelioma is exposure to asbestos. About 2,000 new cases of mesothelioma are diagnosed in the United States each year. For years, asbestos was widely used in many industrial products and in building construction for insulation and fire protection. When asbestos is broken or disturbed it can release microscopic fibers that can be inhaled or ingested, posing a health risk, including the development of asbestos diseases and mesothelioma. Contact: Rhon.Jones@beasleyallen.com.

Benzene—Benzene is widely used in a number of industries and products, yet many people remain unaware of the toxic danger of this chemical substance. Exposure to products containing benzene, whether through inhalation or skin absorption, can cause life-threatening diseases including Acute Myeloid Leukemia (AML),

Myelodysplastic Syndrome (MDS), lymphomas and aplastic Anemia. Some of these diseases do not manifest themselves until several years after exposure to benzene. Due to certain statute of limitations for bringing a claim of this nature it is important to contact an attorney as soon as possible if you believe your condition is a result of benzene exposure. Contact: John.Tomlinson@beasleyallen.com

Severe Lung Disease—Our lawyers are investigating numerous cases involving severe lung disease, including where a client has received any of the following diagnoses: any interstitial lung disease, pulmonary fibrosis (whether idiopathic or not), silicosis, black lung, bronchiolitis obliterans, sarcoidosis, berylliosis or chronic beryllium lung disease, metal lung disease, hypersensitivity pneumonitis, pneumoconiosis, and non-smoker's lung cancer and emphysema. These are grave diseases that often-times result in either death or a lung transplant, and they are frequently caused by exposure to dusts, fibers, metals, chemicals, vapors, food flavoring additives or other tiny particles in the workplace or as a result of a defective product. Often overlooked by some lawyers, these can be very good cases. Contact: Chris.Boutwell@beasleyallen.com

Roundup / Glyphosate Litigation—Our firm is actively investigating cases where landscapers, farmers, groundskeepers or commercial gardeners used commercial grade Roundup and developed Non-Hodgkin's Lymphoma (NHL). Plaintiffs across the country have filed lawsuits after having been diagnosed with NHL after using Monsanto's herbicide. Contact: Rhon.Jones@beasleyallen.com and John.Tomlinson@beasleyallen.com.

IX. PRODUCT LIABILITY UPDATE

IKEA REACHES \$50 MILLION WRONGFUL DEATH SETTLEMENT OVER FALLING DRESSERS

The IKEA group, a furniture manufacturer and retailer, has agreed to pay \$50 million to the families of three children

who were killed when their Ikea dressers tipped over and crushed them. The settlement will be divided evenly among the families of Curren Collas of West Chester, Penn.; Camden Ellis of Snohomish, Wash.; and Ted McGee of Apple Valley, Minn.

After the death of Ted McGee, the third child killed by a Malm dresser, IKEA announced in June that it would recall at least 29 million dressers. At the time, the furniture retailer also announced it would stop selling its popular "Malm" series of products. Prior to the recall, IKEA had launched a sweeping public relations campaign, urging customers who have unsecured IKEA dressers to request a free kit from the company to secure them.

However, despite the millions of dressers in the United States, IKEA reported it had distributed just 300,000 kits to customers. "It is clear that there are still unsecured products in customers' homes," the company had said in a statement to NBC News in June. The statement added: "We believe that taking further action is the right thing to do."

In addition to the \$50 million settlement, IKEA has also agreed to donate \$50,000 to a children's hospital in each of the boys' home states and \$100,000 to Shane's Foundation NFP, an organization devoted to children's safety with a focus on furniture tip-over prevention, the company said. Further, the company has agreed to only sell chests and dressers in the U.S. that meet or exceed heightened performance requirements and increase awareness of the risk of tip-overs.

Unsecured furniture can be a silent and dangerous hazard in homes, particularly with young children who like to climb. One child dies every two weeks from furniture tipping over in the home, according to the Consumer Product Safety Commission. There are there injuries reported every hour—adding up to 25,400 per year. The manufacturer of furniture—and in this case dressers—has to stay up to date on what is happening in the real world and take the steps necessary to protect consumers and, especially as in this case, children.

The Plaintiffs are represented by Alan M. Feldman, Daniel J. Mann and Edward S. Goldis of Feldman Shepherd LLP. Ikea is represented by White & Williams LLP. The cases are *McGee at al. v. The Ikea Group et al.*; and *Collas v. The Ikea Group et al.*, in the Court of Common Pleas of the State of Pennsylvania, County of Philadelphia.

Sources: NBC News and Law360.com

X. MASS TORTS UPDATE

Beasley Allen Lawyer Will Serve As Co-Lead Counsel For Multidistrict Litigation Involving The Johnson & Johnson Talc Litigation Consolidated In Trenton, N.J.

Leigh O'Dell, a lawyer in our firm's Mass Torts Section, has been selected to serve as Co-Lead Counsel for consolidated multidistrict litigation (MDL) in New Jersey federal court concerning talcum powder's link to ovarian cancer. Michelle Parfitt of Ashcraft & Gerel, a firm based in Washington, D.C., will also serve as Co-Lead Counsel.

The lawsuits allege that Defendant Johnson & Johnson is liable for personal injuries or wrongful deaths that resulted from ovarian or uterine cancer in women who used the company's talc products for feminine hygiene. More than 60 Plaintiffs in the MDL are ready to make their case based on decades of scientific research linking talc to cancer. The MDL is being tried in the court of Judge Freda L. Wolfson, United Stated District Judge for the District of New Jersey in Trenton. Leigh had this to say:

I feel very honored to serve on behalf of the thousands of women who are suffering and many dying of ovarian cancer as a result of their long-term use of talcum powder. Despite numerous credible scientific studies showing an increased risk of ovarian cancer, Johnson & Johnson has never warned users of their Baby Powder or other talcum-powder based products. Internal documents make clear that J&J and its principal supplier of talc have been aware of the risks of ovarian cancer for many years. Rather than act responsibly and warn consumers, Johnson & Johnson suppressed safety information and actively misled women about the dangers of genital talc use. The company's conduct is reprehensible, and we look forward to continuing to pursue justice on behalf of these deserving women and their families.

Already this year, three juries have found Johnson & Johnson liable for injuries or wrongful death resulting from the use of its talc-containing products such as Johnson's Baby Powder and Shower to Shower body powder for feminine hygiene.

- In February, another jury awarded the family of Jacqueline Fox \$72 million, holding Johnson & Johnson liable for her ovarian cancer death. In that verdict, \$62 million was punitive damages. The purpose of awarding punitive damages is to punish a company for wrongdoing and to compel it to change its actions.
- On May 2, a jury awarded Gloria Ristesund \$55 million, which included \$5 million in actual damages and \$50 million in punitive damages.
- In October, a jury awarded Plaintiff Deborah Giannecchini \$70.075 million after agreeing the products contributed to the development of her ovarian cancer. The verdict included \$575,000 in medical damages, \$2 million in compensatory damages, and \$65 million in punitive damages against Johnson & Johnson and \$2.5 million in punitive damages against Imerys, which supplies talc to Johnson & Johnson. This was the first jury verdict against Imerys in this litigation.

Three decades of scientific research, including more than 20 well-executed studies, shows that women who regularly use talcum powder for genital hygiene are three times as likely to develop ovarian cancer compared to those who do not. In the U.S., ovarian cancer affects about 21,000 women a year and is the fifth leading cause of cancer death among women. One medical expert calculates that this use of talcum powder leads to nearly 45 percent of the new ovarian cancer cases reported annually. Johnson & Johnson has ignored and attempted to discredit these scientific studies for years, and still refuses to provide warning labels on talc-containing products about the potential risks linking talc and ovarian cancer. When you consider that Imerys, the company that mines the talc, places a cancer warning label on the containers delivered to J&J, it is shameful that J&J still refuses to warn the ultimate user—women.

JOHNSON & JOHNSON AND SUBSIDIARIES HIT WITH MONUMENTAL VERDICTS IN 2016

2016 has been a rough year for many in corporate America (brought about by their own wrongdoing), but it appears the prize for worst year ever may go to Johnson and Johnson and its subsidiaries, which have been continually hit with verdicts against the companies for claims that certain products manufactured and mar-

keted by J&J are unsafe and have caused the injuries and deaths of thousands of folks worldwide.

In a February 2016 J&J talcum powder trial, a St. Louis jury returned a verdict in favor of the family of Jaqueline Fox for \$72 million. Beasley Allen lawyer Ted Meadows, who is leading the firm's talcum powder litigation, along with the trial team, put forth expert evidence proving that the daily use of J&J talcum powder products by Ms. Fox over many years caused her ovarian cancer and ultimately her death. Two more talc jury verdicts came in May and October 2016, with verdicts of \$55 and \$70 million, respectively, being returned.

In March 2016, a federal jury in Dallas found Johnson & Johnson and its subsidiary, DePuy Orthopedics, liable for injuries resulting from the DePuy "Pinnacle" metal-on-metal hip devices. The jury awarded five Plaintiffs a total of \$498 million after agreeing the products caused complications, including metal poisoning and revision surgeries. The verdicts were reduced due to punitive damages caps in the Plaintiffs' respective states. The trial started on Jan. 11, 2016, and took more than eight weeks before it concluded. This was the second bellwether case tried in the Pinnacle multidistrict litigation (MDL). The first was a win for the Defense in late 2014.

On Dec. 1, 2016, the third Pinnacle bellwether verdict was handed down, slamming J&J with a \$1 billion combined verdict for the six Plaintiffs. There are no punitive damages caps in California, the home state of each of the six representative Plaintiffs. These cases were tried in the DePuy Pinnacle MDL before Judge Ed Kinkeade in the Northern District of Texas.

J&J will continue to appeal these verdicts and rulings and has not made any overtures of settling the remaining thousands of claims, ignoring the evidence against it and the public outcry that it take responsibility for the deleterious effects of its products.

The message to Johnson and Johnson seems clear to everyone but the dysfunctional "family company" that continues to maintain the safety of the products mentioned above and stand behind its delusions.

INVOKANA/INVOKAMET UPDATE

In March of 2013, the U.S. Food and Drug Administration (FDA) approved Invokana (canagliflozin) to treat Type 2 diabetes. Invokana is a new class of drug, an

SGLT2 Inhibitor, which is a sodium glucose co-transporter 2 inhibitor. Invokana is manufactured by Janssen Pharmaceuticals, Inc., which is a subsidiary of Johnson & Johnson. SGLT2 inhibitors prevent high blood sugar by forcing the patient's kidneys to remove excess sugar through urine excretion in an "emergency" evacuation mode. The drug became a blockbuster drug, generating at least \$1 billion in sales, within two years of being on the market.

Invokana is a prescription medicine that is used along with diet and exercise to lower blood sugar. Invokana is normally taken in combination with another drug, like Metformin or Glucophage, to decrease insulin resistance, because Invokana alone does not lower blood sugars enough to make it an effective single agent for the treatment of diabetes. In studies, Invokana lowered A1C (a 3-month average of the amount of sugar in the blood) by only .5 to .7 percentage points, making it a weak glucose lowering agent. Invokana has also been prescribed for off label uses of lowering blood pressure and promoting weight loss.

Invokana was approved for sale by the FDA in a January 2013 Advisory Committee Meeting by an 8:7 vote. This drug barely passed the vote for approval by the Committee. The reason for the narrow margin for approval is because in the first month of clinical trials for Invokana, 13 participants receiving the drug had a heart attack or stroke and only one participant in the placebo group had a heart attack. Unbelievably, the Committee asked Janssen to continue studying the drug *while at the same time approving the drug for sale to the general public*. Adding to this already problematic scenario is the fact that Janssen's Canagliflozin Cardiovascular Assessment Study (CANVAS) clinical trial, which commenced in 2009, *is still ongoing at this time*, and will not even be available until June of 2017.

Invokana has been linked to a number of serious side effects including diabetic ketoacidosis (DKA). DKA is a type of acidosis that develops when insulin levels are too low or during prolonged fasting. Complications of DKA include difficulty breathing, nausea, vomiting, abdominal pain, confusion and unusual fatigue or sleepiness. The condition can result in a diabetic coma, extended hospitalization and even death.

In a Diabetes Care Study published in September of 2015, Invokana was associated with a much higher risk of DKA than other SGLT2 inhibitors. From March of 2013, when Invokana was first approved,

to October of 2015, the FDA received reports of 101 confirmable cases of acute kidney injury, some requiring hospitalization and dialysis. In approximately half of the cases, the acute kidney injury occurred within only one month of starting the drug.

The crux of claims against Janssen include failure to adequately test Invokana and properly warn consumers about the risk of medical problems associated with the drug. On May 15, 2015, the FDA issued a Safety Announcement warning that SGLT2 Inhibitors like Invokana may lead to diabetic ketoacidosis. On Dec. 4, 2015, the Safety Review conducted by the FDA resulted in the label being changed to warn of too much acid in the blood and that SGLT2 Inhibitors may cause serious urinary tract infections. On Sept. 10, 2015, the FDA strengthened the warning for SGLT2 Inhibitors to include an increased risk of bone fractures. On June 14, 2016, the FDA revised the warnings for SGLT2 Inhibitors to include information about acute kidney injury, specifically kidney failure.

Lawsuits have been filed in federal courts in California, Georgia, Illinois, Kentucky, Louisiana, Minnesota, New Jersey, and Tennessee. Lawsuits have also been filed in state courts in Illinois, Missouri and Delaware. On Dec. 7, 2016, the Judicial Panel on Multidistrict Litigation (JPML) issued an order consolidating 55 lawsuits against Janssen in New Jersey federal court. U.S. District Judge Brian R. Martinotti will preside over the multidistrict litigation (MDL), which will handle Invokana and Invokamet cases only. The MDL litigation is *In Re Invokana (Canagliflozin) Products Liability Litigation*, MDL No. 2750.

Lawyers in Beasley Allen's Mass Torts Section are investigating claims on behalf of individuals and families injured by Invokana and Invokamet, specifically cases involving diabetic ketoacidosis and acute kidney injury. If you would like more information, contact Danielle Ward Mason, a lawyer in the Mass Torts Section. She can be reached at (800) 898-2034 or by email at Danielle.Mason@beasley-allen.com.

Source: Law360.com

ABILIFY & COMPULSIVE BEHAVIORS

Abilify is an antipsychotic medication used to treat symptoms of a variety of mental disorders, including bipolar disorder, depression, and schizophrenia. It works by changing the actions of chemicals in the brain that regulate mood and

behavior. Specifically, it may either increase or decrease dopamine or serotonin in the brain when there is an imbalance. It is intended to help decrease hallucinations, mood swings and depressive thoughts.

Abilify was first approved by the U.S. Food and Drug Administration (FDA) to treat schizophrenia in November 2002. Marketed in the U.S. by Bristol-Myers Squibb and the Otsuka Pharmaceutical Company, it is the top-selling antipsychotic. In 2013, it was a top selling drug in the U.S. with sales of nearly \$6.9 billion.

Since its introduction to the market, there have been reports of an association between Abilify and compulsive behaviors, such as compulsive gambling, eating, shopping and sexual behaviors. Earlier this year, the FDA warned that Abilify had been linked to impulse-control problems, most commonly pathological gambling. The FDA indicated that these urges cease when usage is discontinued, suggesting a close correlation. Further, the FDA ordered that the Abilify label be updated to warn of the relationship between Abilify and pathological gambling and other compulsive behaviors. The consequences of compulsive behaviors are oftentimes devastating.

We are currently investigating cases involving Abilify and compulsive gambling. If you have any questions regarding the litigation, or if you would like for us to review your potential claim, please contact Melissa Prickett at 800-898-2034 or by email, Melissa.Prickett@beasley-allen.com.

ETHICON PHYSIOMESH FLEXIBLE COMPOSITE MESH

On May 25, 2016, Ethicon, a Johnson and Johnson subsidiary, recalled its Physiomech flexible composite mesh (for laparoscopic use) from the global market. This Physiomech is a flexible composite mesh used for hernia repair by reinforcing the abdominal wall and preventing the hernia from re-opening. Ethicon recalled the product following the release of unpublished data from two separate independent European hernia registries. The studies suggest that the recurrence/reoperation rates after laparoscopic ventral hernia repair using the Ethicon Physiomech composite mesh were higher when compared to other similar hernia meshes. Ethicon Physiomech was also shown to fail earlier than competitors in the market.

Physiomech, made of polypropylene, was found to break down in structure causing the layers of the mesh to separate,

leaving the polypropylene exposed. This breakdown in structure causes the hernia to recur or causes other serious bacterial infections at the site of surgery, potentially making additional surgeries necessary. Some common symptoms of Physiomech failure include problems such as: bacterial infections, internal organ damage, chills, fever, pain and swelling at the site of surgery, fluid filled abscesses in the abdomen, and perforation of blood vessels.

Ethicon issued a field safety notice stating that it believes the higher rates of recurrence/reoperation to be a multifactorial issue; however it still has not been able to characterize the issue. Ethicon noted these issues could possibly be product characteristics or operative and patient factors. However, Ethicon is unable to identify ways for doctors to prevent hernia recurrences and complications due to use of the Physiomech. Thus, Ethicon has indicated it will not be returning the Physiomech Flexible Composite to the market.

Physiomech was approved under 510(k) clearance April 9, 2010, by the U.S. Food and Drug Administration (FDA). This process does not require clinical trials for safety and efficacy. This program allowed Ethicon to skip many pre-market studies and research by demonstrating that the Physiomech was "substantially equivalent" to another product that was already approved by the FDA. Ethicon used its own Proceed mesh device as its substantially equivalent device to fast-track the process.

Ethicon denies that the product was actually recalled, but maintains the stance that they merely "voluntarily withdrew" the Physiomech after the independent studies were released. In June 2012, Ethicon also removed four transvaginal meshes from the market claiming "business reasons" as the motive for recall. These transvaginal mesh products were also made from polypropylene.

There are at least three Physiomech cases already filed nationwide. These cases claim severe reactions to the Physiomech including severe infections, abscesses, intestinal fistula, abdominal pain, diminished bowel obstruction, and the Physiomech pulling away from the abdominal wall leading to additional surgeries.

To find out which mesh was used during their laparoscopic surgery patients should ask their doctor or hospital for an operative reports and/or device tags. If you suffered complications after hernia surgery using Physiomech, contact Melissa Prickett, a lawyer in our Mass Torts

Section, at 800-898-2034 or by email at Melissa.Prickett@BeasleyAllen.com.

Sources: Swiss Medic, FDA, Lawyers & Settlements

UPDATE ON RISPERDAL LITIGATION

Beasley Allen lawyers continue to pursue Risperdal claims on behalf of individuals who have been injured as a result of taking Risperdal. Risperdal is the brand name drug manufactured by Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson. The drug went on the market in 1993 after receiving approval from the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia. In 2003, the drug was approved for short term treatment of acute manic/mixed episodes associated with Bipolar I Disorder in adults. I will give a brief history of the Risperdal litigation.

Until 2006, the drug was not approved for any indication to treat minors. In fact, in 1997, the FDA denied Janssen's request for a pediatric indication for the drug. Despite this denial, Janssen marketed the drug for the treatment of depression, anxiety, Attention Deficit Disorder (ADD), Attention Deficit and Hyperactivity Disorder (ADHD), conduct disorder, sleep disorders, anger management, and mood enhancement/stabilization.

In 2006, Janssen finally obtained approval to market the drug for autistic irritability for children and adolescents between the ages of 5 to 16 years old. The following year, Janssen obtained approval to market the drug for treatment of schizophrenia in adolescents between the ages of 13 to 17 years old and short-term treatment of manic or mixed episodes of Bipolar I Disorder in children and adolescents between the ages of 10 to 17 years old.

Use of Risperdal can cause gynecomastia (enlarged breasts in males), galactorrhea (milky nipple discharge), weight gain, hyperglycemia, diabetes, and inhibited reproductive function.

From 1993 until 2006, the Risperdal label stated that the risk of gynecomastia (enlarged breasts in males) was "rare" and defined "rare" as "less than 1 in 1,000." In 2006, Janssen modified the gynecomastia warning to state that the risk of gynecomastia in adolescent males was 2.3 percent (more than a 2,300 percent increase in risk from the previous warning). There is evidence that Janssen knows that the actual risk exceeds the 2.3 percent risk that has been stated in the label since 2006. Additionally, from 1993 until 2006, Risperdal was not approved for any use for children or adolescents. There

is evidence that Janssen actively promoted Risperdal to physicians treating children and adolescents during this period of time despite knowing that such promotion was not allowed.

There have been a couple of recent developments in the Risperdal litigation occurring in Philadelphia since our update in July 2016. In early November, Janssen settled a case that was set to begin trial in Philadelphia. Despite the settlement of the November trial setting, Janssen has not given any indication that it is willing to seek resolution of the Risperdal litigation in Philadelphia and California.

Janssen's recalcitrance in seeking resolution of this litigation was bolstered by a Dec. 13, 2016, ruling by the trial judge in another Philadelphia trial that began on Dec. 2, 2016. The trial judge granted judgment in favor of Janssen after concluding the Plaintiff's expert did not establish either general or specific causation under Texas law. In other words, the trial judge concluded that the Plaintiff's expert's testimony did not establish that Risperdal caused the Plaintiff's enlarged breasts. Counsel for the Plaintiff has indicated that the ruling will be appealed.

Our firm has a Risperdal case involving one Plaintiff pending in the Western District of Tennessee that is currently scheduled to start trial in late February 2017. We also have a Risperdal case involving two Plaintiffs pending in the Middle District of Alabama that is currently scheduled to start trial in June 2017.

To date, there have been six Risperdal trials in Philadelphia, including the one discussed above. In four of the trials, the juries have awarded damages against Janssen totaling more than \$74 million. In one other trial, the jury found that the warnings provided by Janssen were not adequate but did not find that Risperdal usage caused that Plaintiff's injuries. There are more than 2,000 Risperdal cases filed in Philadelphia.

There is a separate group of several thousand Risperdal cases filed in California. Recently, the Judge handling those cases entered an order selecting almost 800 cases for trial work-up over the next year. Discovery in these cases has begun in phases and trials will proceed in 2017 and 2018.

If you or a loved one has suffered an injury as a result of taking Risperdal, contact James Lampkin, a lawyer in our firm's Mass Torts Section, at 800-898-2034 or by email at James.Lampkin@beasleyallen.com.

STRYKER ADDS PATIENTS TO \$1 BILLION HIP IMPLANT SETTLEMENT

Stryker Corp. and its subsidiary, Howmedica Osteonics Corp., has agreed to compensate additional Plaintiffs in the multidistrict litigation (MDL) that was settled for \$1 billion two years ago for patients who received allegedly defective metal hip replacements. Eligible U.S. Plaintiffs now include patients who had surgery to replace their Rejuvenate and/or ABG II modular-neck hip stems up until Dec. 19, according to the agreement struck between the Stryker entities and the court-appointed committees of lawyers representing Plaintiffs in multi-county litigation in New Jersey and multi-district lawsuits in federal court.

The eligible claimants will receive a base award of \$300,000 for each revised hip, subject to any applicable reductions or limitations, according to the agreement. Unrepresented claimants are eligible for 71 percent of the base award, or \$213,000. The agreement says reductions will be taken for things like obesity, smoking and age.

The new agreement follows the \$1 billion settlement agreed to in November 2014 to resolve thousands of claims centralized in Minnesota federal court and multicounty litigation in New Jersey state court. The litigation came about after Stryker recalled the modular-neck stems in June 2012, saying they could fret or corrode, harm body tissue, and cause pain or swelling.

About 95 percent of eligible patients had enrolled in the 2014 settlement. Ellen Relkin of Weitz & Luxenberg PC, a member of the settlement committee, told Law360:

Further, learning from procedural obstacles from the first settlement, we were able to change some terms to deliver a more efficient and quicker payment process for this new round of settlements. Hundreds of patients who underwent revision surgeries of their Stryker Rejuvenate and ABG II hips will be pleased that they are finally getting compensated for their injuries.

Stryker expects the majority of the payments under the expanded settlement agreement will be made by the close of 2017. While the agreement will help close "significant" litigation activity, some lawsuits still remain, the company said in a statement. The statement said:

The final outcome of this matter is dependent on many variables that

are difficult to predict. The ultimate cost to entirely resolve this matter may be materially different than the amount of the current estimate.

About 20,000 people were implanted in the U.S. with the Rejuvenate and ABG II hip products. The original settlement, which also offered a \$300,000 base award, had compensated patients who had gotten surgery up until Nov. 3, 2014, according to court documents. Gibbons PC, representing Stryker, declined to comment through its publicist. Representatives for the Plaintiffs didn't immediately respond to requests for comment. Stryker is represented by Sedgwick LLP, Stinson Leonard Street LLP and Gibbons PC. The Plaintiffs are represented by lawyers from Weitz & Luxenberg; Meyers & Flowers; Anapol Weiss; DeGaris & Rogers; Seeger Weiss; Lieff Cabraser Heimann & Bernstein; Pogust Braslow & Millrood; and Levin Papantonio Thomas Mitchell Rafferty & Proctor. The MDL is *In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation* before the U.S. Judicial Panel on Multidistrict Litigation.

Source: Law360.com

DOCTOR IN TESTOSTERONE GEL MDL MUST REVEAL DRUG COMPANY CONNECTIONS

A doctor involved in the multidistrict litigation (MDL) over the marketing of testosterone replacement drugs, who was one of the biggest proponents of the drugs' use for more conditions has been ordered to turn over records of payments he received from the drugs' manufacturers. U.S. District Judge Matthew Kennelly, an Illinois federal judge, issued this ruling last month. Pursuant to the ruling, Dr. Abraham Morgantaler will have to turn over any tax forms recording payments he received from 18 pharmaceutical companies involved in the MDL. The drugmakers are accused of aggressively marketing their products while downplaying the risks of heart attacks and stroke associated with them.

Judge Kennelly's ruling ends Dr. Morgantaler's lengthy battle against a subpoena served on him by the Plaintiffs' Steering Committee. The doctor has been portrayed as actively shaping "the science, marketing, and use of [testosterone replacement therapy] products involved in these MDL proceedings." Steering committee counsel Chris Seeger reiterated the importance of Dr. Morgantaler as a third-party witness.

Dr. Morgantaler has been one of the biggest proponents of using the products

to treat symptoms of male aging like weight gain and lowered libido. Dr. Morgantaler founded the Androgen Study Group, a multidisciplinary group that reviews studies done on testosterone therapy. In addition to the payment records, Dr. Morgantaler was ordered to turn over PowerPoints he made for presentations about testosterone replacement for other doctors and medical schools.

Bellwether trials against the Defendant drug companies are expected to begin next year. The Plaintiffs are represented by Trent Miracle of Simmons Hanly Conroy; Ronald Johnson Jr. of Schachter Hendy & Johnson; and Chris Seeger of the Seeger Weiss firm. The case is *In Re: Testosterone Replacement Therapy Products Liability Litigation* in the U.S. District Court for the Northern District of Illinois.

Source: Law360.com

FDA TO STUDY PHARMACEUTICAL SOCIAL MEDIA ADVERTISING

As you might know from seeing their advertisements on television, in addition to telling consumers what their drugs can do, pharmaceutical companies are required to provide information about a drug's potential risks. This is called fair balance, and that may be a stretch for the term. For television commercials, risk information is often disclosed at the end and often in small print, after the benefits of the drug are touted. Print advertisements frequently have the risk information on the reverse side of the ad.

The advent of social media advertising has created a dilemma for drug companies and the U.S. Food and Drug Administration (FDA). If drug companies need more time or space to communicate risk information in traditional advertisements, they can purchase additional airtime or print space. So far, social media advertising has not been that accommodating for advertising. Each social media site has character limits for posts. Most famously, Twitter limits users to 140 characters at a time. Instagram allows 2,200 characters for each image, but only 3 lines of text are visible in users' feeds. These restrictions have the FDA wondering can adequate risk information be communicated in character-limited platforms like Twitter?

The FDA recently announced plans to study the effectiveness of risk information posted on social media sites. The studies will evaluate whether social media posts should include risk information when claims about a drug's benefits are made, or if a link to the risk information is sufficient. The FDA believes that study partici-

pants who see risk information within the post will retain that information better than those who see only a link to click for risk information. However, it is possible that a person's motivations for viewing the post could affect the results. For example, someone actively searching for information about a drug is more likely to click a link for more information and therefore probably more likely to retain the risk and benefit information, while a person who simply happens across a social media posting is much less likely to follow a link to see risk information. The FDA will use the findings from these studies to issue guidelines on promoting pharmaceutical products on social media.

For now, some social media sites have their own policies in place concerning pharmaceutical advertising. Twitter restricts the promotion of prescription drugs and other health supplements. Facebook, on the other hand, has developed new features designed to help pharmaceutical companies better convey risk information on its platform, including an ad with automatically scrolling risk information.

The FDA's guidance on this issue will be extremely important. Consumers need to be fully informed of the risks of the medications they take, regardless of the number of characters required.

Sources: FDA, Law360.com, Twitter, StatNews.com

XI. BUSINESS LITIGATION

MERCK WINS RECORD \$2.5 BILLION PATENT VERDICT AGAINST GILEAD

A federal jury has ordered Gilead Sciences Inc. to pay \$2.54 billion to Merck & Co. for using a patented invention as the basis for its blockbuster drugs for the potentially deadly liver disease hepatitis C. This is the biggest patent-infringement verdict in U.S. history. The jury in Wilmington, Del., deliberated for less than two hours and rejected Gilead's arguments that Merck's patent is invalid. The judge in the case had already found that Merck's patent was infringed by Gilead's Sovaldi and Harvoni, which account for more than half the drugmaker's revenue.

The infringement also was found to be willful, meaning the judge could increase the damage award by as much as three times the amount set by the jury. The jury said that Gilead owed 10 percent royalties

on \$25.4 billion in total sales for the two drugs. Gilead plans to appeal.

The patent, issued in 2009, is for a compound that Merck's Idenix unit contends is the basis for all major treatments for hepatitis C, including ones made by Gilead. Sovaldi was approved by the U.S. Food and Drug Administration (FDA) in 2013 and Harvoni got regulatory go-ahead a year later. Merck's drug, Zepatier, was approved this year.

Gilead argued that Idenix never adequately described what it claimed to have invented, and the patent didn't cover a new idea. The company said in a statement following the verdict:

We remain steadfast in our opinion that Idenix's U.S. patent is invalid, and since they made no contribution and assumed none of the risk in the discovery and development of sofosbuvir and its metabolites, do not believe they are entitled to any level of damages.

Sovaldi is based on the compound sofosbuvir, while Harvoni combines sofosbuvir with the compound ledipasvir. Gilead, based in Foster City, Calif., got the compounds as part of its 2012 acquisition of Pharmasset Inc.

This is the second trial between the two companies. The first, over different patents, ended in a disaster for Merck. A jury in California said that Gilead should pay \$200 million in royalties, but that verdict was thrown out because the judge said a key Merck witness lied. In that case, Merck may have to pay Gilead's legal fees.

Hepatitis C is a virus that attacks the liver and can lead to cirrhosis or liver cancer. The disease affects 130 million to 150 million globally, according to the World Health Organization, and the Centers for Disease Control has said as many as 4 million Americans may have chronic hepatitis C infections.

The drugs are effective at curing the virus with fewer side effects than earlier treatments, but they have been controversial because of their costs. A complete treatment with Sovaldi costs \$84,000, while Harvoni's price tag is \$94,500, though the drugs are typically discounted. A newer version that can treat more genotypes of the virus, called Epclusa, has a list price of \$74,760 for a 12-week treatment.

Harvoni generated \$4 billion in U.S. sales in the first nine months of the year, and Sovaldi brought in \$1.78 billion. Revenue from the two drugs is falling, however, because Gilead has been forced to offer discounts to insurers due to competition from Merck and AbbVie Inc. Merck sells Zepatier for \$54,600.

Gilead and Idenix have been engaged in a global fight since 2012 over which company was first to invent certain compounds for treating hepatitis C. Merck had claims demanding patent royalties on sales of Sovaldi and Harvoni even before it bought Idenix in 2014, absorbing this case as part of the deal. The case in California was Merck's own suit against Gilead, filed in 2013 by the Whitehouse Station, N.J., based drugmaker.

Gilead also had been engaged in a patent fight with AbbVie over ways to treat hepatitis C. The companies resolved their disputes in August. The previous top verdict was a \$1.67 billion judgment Johnson & Johnson won against Abbott Laboratories. It was later thrown out on appeal.

The case is *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 14-846, U.S. District Court, District of Delaware (Wilmington). It's rather interesting that corporate giants really like the courts when they are the victims of wrongdoing.

Source: *Bloomberg News*

FEDERAL JUDGE APPROVES DEUTSCHE BANK SETTLEMENT FOR GOLD PRICE-FIXING

A New York federal judge gave preliminary approval last month to an agreement by Deutsche Bank AG to pay investors and others \$60 million to settle claims that it engaged in illegal price-fixing of the gold market. U.S. District Judge Valerie Caproni said the agreement between Deutsche Bank and investors and traders who brought the suit against the bank and others appeared adequate. The order said: "The court preliminarily finds that the settlement encompassed by the Settlement Agreement raises no obvious reasons to doubt its fairness."

Judge Caproni also appointed Quinn Emanuel Urquhart & Sullivan LLP and Berger & Montague PC as co-lead counsel for the settlement class for settlement purposes only. The settlement class includes anyone who sold physical gold or derivatives based on gold or bought gold put options on COMEX or other exchanges from Jan. 1, 2004, through June 30, 2013. The parties had asked Judge Caproni to grant preliminary approval to the settlement on Dec. 2, saying it would potentially benefit thousands of class members. The agreement also calls for Deutsche to provide information to assist with the ongoing action.

Documents provided by Deutsche have already led to further claims against the banks. The investors have asked the court's permission to file a third amended

complaint to incorporate information they said would show Deutsche and UBS AG traders engaged in coordinated activities and exchanges of confidential information as well as the existence of a conspiracy prior to 2006, even though Judge Caproni has already dismissed such claims.

UBS has fought back against the request, saying the investors are trying to retool their theories about UBS' role in the alleged scheme and are changing the fundamental nature of the suit from a benchmark manipulation case to one over spot market order manipulation.

The putative antitrust class action was originally filed in March 2014 alleging that big banks conspired to manipulate the London gold fix, which is used as a benchmark to determine the price of gold and gold derivatives.

In addition to UBS and Deutsche, the investors have alleged that HSBC, Societe Generale SA, The Bank of Nova Scotia and Barclays participated in the scheme. The banks set the London gold fix—which dates to 1919—twice per day through conference calls, once in the morning and once in the afternoon. The chairman proposes an opening price, and firms declare how many bars of gold they want to buy or sell at that price based on client orders and their own proprietary needs. The price is increased or decreased until supply matches demand, at which point the price is declared fixed.

The Plaintiffs are represented by Daniel L. Brockett, Daniel P. Cunningham and Steig D. Olson of Quinn Emanuel Urquhart & Sullivan; and Merrill G. Davidoff, Michael C. Dell'Angelo and Zachary D. Caplan of Berger & Montague. The multi-district litigation (MDL) is *In Re: Commodity Exchange Inc., Gold Futures and Options Trading Litigation* in the U.S. District Court for the Southern District of New York.

Source: *Law360.com*

XII. AN UPDATE ON SECURITIES LITIGATION

EDWARD JONES FACES ERISA-BASED EXCESSIVE FEE LITIGATION

Edward Jones has been sued for a second time this year in a complaint alleging excessive fees and self-dealing in its 401(k) plan. In addition to those two suits,

there have been a large number of other cases targeting financial services companies for their own retirement plans. This lawsuit, *Schultz et al v. Edward D. Jones & Co., L.P. et al*, alleges the broker-dealer and several employees overseeing the retirement plan breached their fiduciary duties by selecting high-cost mutual funds when identical, lower-cost ones were available, choosing “an unreasonable number” of high-risk investment options, and including a “poorly performing” money market fund in place of a stable value fund.

Plaintiffs also claim Edward Jones engaged in self-dealing through a distribution relationship with several fund companies such as American Funds, Franklin Templeton Investments, Goldman Sachs and BlackRock. Specifically, they allege Edward Jones entered into arrangements with such “product partners” whereby fund companies paid for access to the “captive market” of 401(k) participants by giving revenue-sharing fees to Edward Jones in return for “shelf space” on the retail side of the brokerage business.

According to the Plaintiffs in the proposed class-action, these revenue-sharing arrangements were “contingent upon” Edward Jones offering the partners’ investment options in the roughly \$4 billion Edward D. Jones & Co. Profit Sharing and 401(k) Plan. The complaint alleges:

Edward Jones was able to negotiate and secure these acknowledged Revenue Sharing Agreements with its Product Partners in part by guaranteeing them access to the billions of assets under managements in the Plan, where Edward Jones, through its designees, could choose all of the investment options.

These incentivized arrangements clouded fiduciaries’ decision-making and ultimately cost participants millions of dollars in excessive fees, according to Plaintiffs. Edward Jones denies any wrongdoing.

The Edward Jones suits fit within a broader theme of the Plaintiff’s bar suing financial services companies over fiduciary breach in their own 401(k) plans. Firms such as Morgan Stanley, Neuberger Berman, Franklin Templeton, New York Life Insurance Co. and American Century Investments are among those targeted this year. Allegations centering on Edward Jones’ retail distribution relationships and revenue-sharing payments influencing its 401(k) fund selection seem unique among the lot, though.

Litigation against retirement plan sponsors has also been extending to different

corners of the defined contribution market. If you need more information relating to this litigation, contact Rebecca Gilliland, a lawyer in our firm’s Consumer Fraud & Commercial Litigation Section, at 800-898-2034 or by email at Rebecca.Gilliland@beasleyallen.com.

Source: InvestmentNews.com

XIII. AN ANNUAL REPORT ON MULTIDISTRICT LITIGATION BY LAW360

WHERE THE 5 TOP MDLS ARE SAID TO STAND AT THE END OF 2016

Law360 issued a report in December on the multidistrict litigations (MDLs). Among the hundreds of pending MDLs across the country, the report says some stand out for the large jury awards returned against major companies such as Johnson & Johnson. The report also says there have been some MDLs, like the General Motors ignition-switch MDL, where there were not many verdicts at all. Other MDL were said to be notable for their “longevity.” As 2016 draws to a close, Law360 reported on what they describe as “five highly visible MDLs that will be most active in 2017.” We will set out the information below for each of the five as reported by Law360.

General Motors Ignition-Switch MDL

In this MDL before Southern District of New York Judge Jesse Furman, General Motors is accused of selling cars it should have known were dangerous. An ignition switch placed in a number of makes and models throughout the auto empire—including Pontiacs, Chevys and Saturns—could flip out of the “run” slot while a vehicle was in motion, disabling the power steering, the power brakes and, most dangerously, the air bags. Well over a thousand cases have settled; 325 cases remain in the federal MDL, according to the most recent statistics from the Judicial Panel on Multidistrict Litigation. There is also a state MDL over the switches in Texas. An initial set of six bellwethers ended in 2016 after only one completed a trial. The single

verdict came in March and was for GM, although there was an asterisk in the form of the jury’s finding that the GM vehicle at issue was unreasonably dangerous. Of the five others, one was dismissed by the Plaintiff before trial, one was dropped partway through trial by a Plaintiff facing claims of falsifying financial documents, and three were settled.

Next up in this MDL is a second set of six bellwethers. They’ll involve accidents that occurred after July 2009, when Old GM went through a restructuring and sold its assets to New GM, the entity defending against the suits. Each side is currently selecting a wish list of cases for inclusion, and those lists are due to Judge Furman in January. The outcome of the first set of bellwethers “raises the question of whether there may be a handful of cases that from the perspective of the Plaintiff might have significant value [but] the rest of the cases may not have significant value in terms of potential verdicts,” says Diane Lifton of Hughes Hubbard & Reed LLP. “In which case you might see the whole MDL proceed toward settlement either during or after 2017. “If they keep settling out like that and cases keep dropping away, I would expect to see a resolution, especially with a leadoff win for GM,” Lifton said. The MDL is *In re: General Motors Ignition Switch Litigation*, case number 1:14-md-02543, in the U.S. District Court for the Southern District of New York.

DePuy Pinnacle Hip MDL

It was a big year for Plaintiffs with DePuy artificial hips. On Dec. 1, a Texas federal jury found Johnson & Johnson’s DePuy Orthopaedics Inc. unit liable for more than \$1 billion in a six-Plaintiff bellwether trial targeting metal-shedding artificial hips in its Pinnacle line, dwarfing the \$150 million verdict J&J is on the hook for after a previous bellwether. At the MDL’s heart are allegations that friction between the device’s metal socket and metal ball head rubs away billions of microscopic particles with every step, polluting the bloodstream and surrounding tissue with “wear debris” over time. The Plaintiffs alleged J&J knew the device was riskier than others available but still pushed it aggressively, even paying kickbacks to amenable surgeons.

J&J maintains it acted appropriately and responsibly in the development, testing and marketing of the Ultamet product. During its opening, the company questioned whether the patients might have had hypersensitive responses to the implants, and suggested the devices were wrongly positioned in their bodies because of doctor error, which it said would lead to the excessive wear. J&J has objected to proceeding with more trials until the appeals from the second bellwether trial have been resolved. This MDL has “garnered a great deal of press because of the size of the verdict and the concern over evidentiary rulings at the trial court level and how quickly the Fifth Circuit might get to the appellate issues,” Lifton said. “All of the indicators point toward the likelihood that these significant verdicts are not going to lead to a global settlement anytime soon.”

After the verdict was read, U.S. District Judge Ed Kinkeade urged the parties to appoint a settling lawyer for discussions of a potential end to the MDL, which has more than 6,000 cases. The next bellwether is set to begin in September 2017, with the parties preparing for 10 plaintiffs, all from New York. The MDL is *In re: DePuy Orthopaedics Inc. Pinnacle Hip Implant Products Liability Litigation*, case number 3:11-md-02244, in the U.S. District Court for the Northern District of Texas.

Xarelto (Rivaroxaban) MDL

Lawsuits over internal bleeding allegedly caused by Xarelto, a blood thinner developed by Johnson & Johnson unit Janssen Pharmaceuticals Inc. and Bayer Corp., were first consolidated in December 2014. The MDL now has almost 14,000 cases pending before U.S. District Judge Eldon Fallon in the Eastern District of Louisiana, and suits have also been filed in state court. Xarelto was approved in the U.S. in 2011 for a number of uses, including reducing the risk of deep vein thrombosis in the legs of knee- or hip-replacement recipients and reducing the risk of stroke in atrial-fibrillation patients. Both companies submitted new drug applications in 2011 for both uses, according to filings. The drug made \$582 million in sales in its first full year of market availability, rising a

few years later to \$2 billion for fiscal 2013—a mega-blockbuster. Dates have been set for four bellwether trials, and the specific cases for them have been chosen. The bellwethers will try a mixture of gastrointestinal-bleed and brain-bleed claims under Louisiana, Mississippi and Texas law.

In the first bellwether, slated for March, Plaintiff Joseph Boudreaux will argue that he started taking Xarelto to control his atrial fibrillation in January 2014 and less than a month later was hospitalized for dangerous gastrointestinal bleeding requiring multiple blood transfusions. He says Janssen and Bayer misrepresented the safety of the drug both to the public and to the U.S. Food and Drug Administration and that there are issues surrounding certain clinical trial results. After Boudreaux’s trial, starting March 13, bellwether trial dates are set for April 24 and May 30. Watch for tweaks in bellwether start dates, however; Judge Fallon has been notified of a conflict with the NBA All-Star Game. The MDL is *In re: Xarelto (Rivaroxaban) Products Liability Litigation*, case number 2:14-md-02592, in the U.S. District Court for the Eastern District of Louisiana.

Volkswagen “Clean Diesel” MDL

Legendary Plaintiffs’ attorney Elizabeth Cabraser told a California federal court in October that this litigation had “set the land-speed record” for turning around the largest automotive settlement in U.S. history in about a year. Volkswagen’s emissions troubles began when the U.S. Environmental Protection Agency (EPA) launched an investigation into its “clean diesel” cars’ true output of pollution-causing emissions. Although the manufacturer claimed that its diesel cars were a “cleaner” option than nondiesel cars, Volkswagen’s programmers had installed devices meant to deceive regulators about the actual emissions output. Those so-called defeat devices caused a vehicle’s reported output of nitrogen oxides to meet U.S. standards during testing, but the cars actually emitted up to 40 times more pollutants during real-world driving. About 650 dealerships and about 475,000 customers in two different classes reached deals with Volkswagen this year.

Final approval of the consumer settlement was granted by U.S. District

Judge Charles Breyer in October. The settlement includes just over \$10 billion to buy back cars from consumers and provide cash compensation to the owners, \$2.7 billion for environmental remediation and \$2 billion to build zero-emission vehicle infrastructure. Only weeks after final approval, a number of appeals were filed with the Ninth Circuit. As for the dealer plaintiffs, preliminary approval of their \$1.2 billion settlement was granted in October, and a hearing on final approval is set for Jan. 18. Seven dealerships have opted out and eight have objected. On Dec. 20, Judge Breyer announced Volkswagen had reached a tentative deal worth at least \$1 billion over 80,000 3.0-liter cars; the previous settlements had been regarding 2.0-liter cars. Still remaining are securities claims over stock drops in the wake of the revelations. The MDL is *In re: Volkswagen “Clean Diesel” Marketing, Sales Practices and Products Liability Litigation*, case number 3:15-md-02672, in the U.S. District Court for the Northern District of California.

Pelvic Mesh MDLs

The most sprawling medical-device MDL grouping by far is also one in which “the bellwether process is not viable,” U.S. District Judge Joseph Goodwin ruled in 2014. Judge Goodwin, of the Southern District of West Virginia, is overseeing 62,000 active cases in seven different MDLs. More than half the cases are against Ethicon Inc. Many thousands of other suits against American Medical Systems Inc., C.R. Bard Inc. and Boston Scientific Corp. have already been settled, according to Leigh O’Dell of Beasley Allen, a lead lawyer involved in the litigation on the Plaintiffs’ side.

In October, Boston Scientific asked the Eleventh Circuit to overturn a \$27 million jury verdict for four women who said the company’s mesh caused infection, organ perforation, nerve damage, blood loss and chronic pelvic pain. Defense lawyers are watching closely to see what view the appeals court takes on the use of multiple Plaintiffs in one trial. In his April 2014 consolidation order, Judge Goodwin had said that the cases made identical legal claims and that the interest of fairness both for these four women and for the thousands

more waiting in the wings demanded consolidation. “The more cases that are tried together in this MDL totaling over 11,000 cases, the sooner the parties will come to understand the true nature of these cases, their values, the weaknesses and strengths in their cases and the cost of trying them. At this time, the bellwether process is not viable in this MDL,” he said. The trial took place in November 2014. O’Dell said that “it’s been pretty protracted and very hard-fought litigation. There have been many cases worked up through Judge Goodwin’s discovery process—hundreds of cases, which would make it distinct from other MDL proceedings.” She called that exhaustive workup roster “helpful in some sense for learning in very granular detail the strengths and weaknesses of specific cases.”

A trial in the 31-plaintiff Mullins case, which sits within the larger Ethicon mesh MDL, is set for March 6. The Ethicon MDL is *In re Ethicon Inc. Pelvic Repair System Products Liability Litigation*, 2:12-md-02327, and the Boston Scientific MDL is *In re Boston Scientific Corp. Pelvic Repair System Products Liability Litigation*, 2:12-md-02326, both in the U.S. District Court for the Southern District of West Virginia.

Source: Law360.com

XIV. WORKPLACE HAZARDS

WRONGFUL DEATH LAWSUIT FILED BY BEASLEY ALLEN IN CHAMBERS COUNTY, ALABAMA

Lawyers in our firm have filed a wrongful death lawsuit involving the tragic death of a young worker at an Alabama manufacturing plant. The lawsuit was filed on behalf of the family following the death Regina Allen Elsea, a 20-year-old worker, who was crushed while cleaning a robotics machine at a manufacturing plant located at Cusseta, Ala.

Ms. Elsea, a resident of Five Points, Ala., was sent with three coworkers to re-activate a robotics machine on June 18, 2016, after the assembly line stopped production. While Ms. Elsea was inside, the robot abruptly restarted, crushing her. She died from her injuries.

Due to this tragically preventable accident, the Elsea family is mourning the loss of their young family member, rather than celebrating her planned marriage, which should have occurred just weeks after her death.

It is most significant that the Cusseta manufacturer and two staffing agencies currently face a combined \$2.5 million in fines by the U.S. Department of Labor’s Occupational Safety and Health Administration (OSHA). An investigation found the companies in violation of worker protection policies. Ajin USA manufactures metal parts for Hyundai and Kia vehicles. Alliance Total Solutions LLC and Joynus Staffing Corp. are staffing agencies that helped place Ms. Elsea with Ajin.

“This senseless tragedy could have been prevented if Regina Elsea’s employers had followed proper safety precautions,” according to Dr. David Michaels, Assistant Secretary of Labor for OSHA. Dr. Michaels added, “In addition, it is unfortunate that Hyundai and Kia, who set strict specifications on the parts they purchase from their suppliers, appear to be less concerned with the safety of the workers who manufacture those parts.”

OSHA cited Ajin USA for willfully failing to use energy control procedures; exposing workers to “caught-in, struck-by or crushing hazards;” failing to provide safety locks and exposing employees to crushing and amputation hazards among other violations. Dr. Michaels made this interesting observation:

Kia and Hyundai’s on-demand production targets are so high that workers at their suppliers are often required to work six and sometimes seven days a week to meet the targets. It appears that—to reduce its own costs in meeting these targets—this supplier cut corners on safety, at the expense of workers’ lives and limbs.

Among the citations to Ajin USA were:

- Failing to utilize energy control procedures to prevent machinery from starting up during maintenance and servicing.
- Exposing workers to caught-in, struck-by and crushing hazards by allowing them to enter a robotic cell without shutting down and securing hazardous stored energy according to safety procedures.
- Failing to provide safety locks to isolation hazardous energy.

- Exposing employees to crushing and amputation hazards due to improper machine guarding.

The complaint has been filed in the Circuit Court of Chambers County, Alabama. Kendall Dunson, a lawyer in our firm’s Personal Injury & Products Liability Section, will lead the litigation team in this case. This writer will be on the team along with Warner Hornsby from our firm and Tripp Walton, a lawyer from Auburn, Ala.

SECOND PIPELINE EXPLOSION DEATH HIGHLIGHTS IMPORTANCE OF WORKPLACE SAFETY

Quite often it’s not until a situation turns bad that safety is brought to the forefront. The Occupational Safety and Health Administration (OSHA) has confirmed the death of a second victim in the Oct. 31 Colonial Pipeline explosion, bringing the fatality count to two. The explosion occurred while contractors were working to repair a gas leak in a remote location 30 miles south of Birmingham, Ala., that affected Georgia-based Colonial Pipeline’s Line 1, which pushes an estimated 1.3 million gallons of gasoline a day through the state, according to AL.com.

Nine contractors—all but one from L.E. Bell Construction—were working a mile west of the original leak when a worker accidentally stuck the line while excavating. The subsequent explosion left one contractor fatally injured and sent four more to UAB’s burn center. Two fires caused by the explosion burned 31 acres of land, though no residences were close by. Fire crews had to build an earthen dam to contain the flames. Brigham McCown, former administrator of the federal Pipeline and Hazardous Materials Safety Administration, told AL.com:

Typically, we don’t see external damage to a pipeline from ground-level activity, whether it’s human or weather-related, except for some third party striking the pipeline with a piece of excavation equipment. That’s now the leading cause of pipeline spills and accidents.

A Forbes article about the explosion poses the question, “Do we need fewer pipelines—or more?” The question relates to one of the main concerns associated with oil and gas pipelines: safety. What—if anything—could have been done to prevent this? Were all persons observing protocol when this occurred? Even though there is no evidence of wrongdoing in the Colonial Pipeline Explosion at

this time, all too often our lawyers find that when serious injuries or death occurs on the job, the incident was preventable. Disasters like the explosion make clear how important safety regulations are for the safety of workers and those who live in the communities in which they work.

If you have any questions about whether a serious work-related injury could qualify for compensation, contact Kendall Dunson, a lawyer in our firm's Personal Injury and Product Liability Section, for a free and confidential evaluation of your claim. He can be reached at 800-898-2034 or email Kendall.Dunson@beasleyallen.com.

Source: AL.com

FIREFIGHTER'S ESTATE FILES SUIT OVER FAULTY GEAR

The family of a Philadelphia firefighter who was killed in a 2014 fire has filed a lawsuit against several companies involved in the manufacture and sale of a self-contained breathing apparatus (SCBA) and manufacturers of protective garments, blaming them for her death. Joyce Craig was the first female firefighter to die while fighting a fire. The estate of Ms. Craig said the pressure hoses in the breathing apparatus had been the subject of a recall prior to the fire that took her life. The family said a faulty personal alert system and her garments were also responsible for her death. It's alleged in the complaint that "an adequately functioning SCBA would have prevented firefighter Craig's death."

Ms. Craig was killed in the line of duty on Dec. 9, 2014, while fighting a house fire in Philadelphia. She is survived by her two children, a son now aged 18 and a daughter who is now 3. The lawsuit targets equipment manufacturers Scott Health and Safety, Cairns and Brother Inc., MSA Safety Inc., Global Secure Safety Products Inc., Goodyear Tire and Rubber Co., Municipal Energy Services Inc., Pro-Am Safety Inc., Total Safety Inc., Fisher Scientific Co. LLC, Smith Fire Service Inc. and Safeware Inc.

The lawsuit alleges that the companies failed to inform users of the device that it included pressure hoses, manufactured by Goodyear, that had been recalled. The hoses are intended to bring pressurized air to the firefighters' gas masks. The complaint said Ms. Craig ran out of air and died while fighting the fire.

The Plaintiffs also blamed the personal alert safety system on Craig's breathing apparatus, saying that it failed to alert other firefighters to her location. It's

alleged that the safety system lacked distinguishable audio and video signals and was designed in a way that made it prone to failing at high temperatures. Also, it was added that the entire apparatus and its component parts fell short of several National Fire Protection Association standards. Fire protection garments made by Safeware, Lion Group Inc. and Majestic Fire Apparel Inc. were said to have lacked appropriate heat resistance and prevented Ms. Craig's breathing apparatus from functioning properly.

The Plaintiffs are represented by Bob Mongeluzzi, David Kwass and David Langsam of Saltz Mongeluzzi Barrett & Bendesky. The case is *Johnson et al. v. Scott Health and Safety et al.* in the Philadelphia County Court of Common Pleas.

Source: Law360.com

XV. TRANSPORTATION

DOT EXPANDS DRUG TESTING REGULATION TO TEMP TRUCK DRIVERS

The U.S. Department of Transportation (DOT) has expanded drug and alcohol testing requirements for truck drivers to include commercial drivers employed by staffing agencies. The DOT's Federal Motor Carrier Safety Administration (FMCSA) made clear in a notice of enforcement guidance published in the Federal Register that the department's existing controlled substances and alcohol testing regulations extend to commercial driver staffing agencies that employ commercial drivers who are supplied to motor carriers to operate commercial motor vehicles.

According to the notice, commercial driver staffing agencies supply the motor carrier industry with intermittent, casual or occasional drivers to help meet industry business demands. The staffing agency directly employs the driver, and pays the driver's wages and employment taxes so they would also fall under the FMCSA's regulatory umbrella. FMCSA said it defines a "casual, intermittent, or occasional driver" as one who works for another employer for any period of less than 30 consecutive days.

If a leased driver operates or is expected to operate for a motor carrier employer for more than 30 consecutive days, the driver should be included in that motor carrier employer's random testing pool and that motor carrier employer should assume full responsibility for the driver under its own

DOT drug and alcohol testing program, FMCSA said.

These employers and staffing agencies would also be subject to recordkeeping requirements. The FMCSA said that employers using such drivers must verify the driver's participation in a DOT drug and alcohol testing program every six months and maintain records verifying that.

The expanded drug-testing requirements came weeks after the FMCSA issued its long-awaited final rule establishing a drug and alcohol clearinghouse for commercial bus and truck drivers that would serve as a central location to find violations of the administration's testing program for the substances. The database will be a central repository for records of violations of the alcohol and drug testing program by those who hold commercial driver's licenses. Once it is established, motor carrier employers will have to look at the system for information about prospective and current employees who have unresolved federal drug and alcohol testing regulation violations that would keep them from operating a commercial motor vehicle, FMCSA said in its announcement.

The trucking industry had spent nearly two decades lobbying for the creation of a national repository for drug and alcohol test results in order to close a regulatory loophole that made it possible for a driver with a history of drug or alcohol abuse to be hired by a carrier without that carrier being informed of the driver's history.

The clearinghouse rule goes into effect this month, but industry stakeholders have until January 2020 to get in compliance. The rule requires motor carriers, medical review officers, designated representatives and substance abuse professionals to report positive drug and alcohol test results, drivers' refusal to be tested, traffic citations for impaired driving, drivers who have undergone the return-to-duty drug and alcohol rehabilitation process and actual knowledge of drug or alcohol use to FMCSA.

Source: Law360.com

UNAPPROVED AVIATION PARTS LINKED TO NEARLY 24 CRASHES SINCE 2010

It is alarming to know that some private airplanes are soaring through the skies while relying on unapproved aviation parts—those that have not been rigorously tested and inspected by the Federal Aviation Administration (FAA). However, it is beyond frightening to know that these unapproved aviation parts have even made

their way onto commercial aircraft. A recent investigation by San Francisco's NBC (KNTV) Bay Area Investigative Team revealed that "unapproved aviation parts played a role in nearly two dozen crashes that killed seven and injured 18 others since 2010." The team got this information by compiling and analyzing data from the National Transportation and Safety Board (NTSB).

Despite its regulation of the aviation industry, the FAA has recorded 135 cases of unapproved parts falling through the cracks since 2011. The information is collected for the general and commercial segments of the industry through the FAA's National Tracking and Reporting Systems. The agency contended that only a few unapproved parts investigations indicated an unsafe condition. Yet, the FAA agreed that using an "unapproved part increases risk, reduces safety, and could introduce an unexpected threat to an operating aircraft."

Ken Gardner, a retired FAA inspector and expert on unapproved parts, agrees and said the bottom line is that there is no way to know when the parts will fail nor how many lives will be jeopardized when the failure occurs.

The news team successfully purchased several aviation parts over the internet, which were significantly underpriced. One item, an electronic decoder panel, cost the team \$60, but Mr. Gardner estimates that a new decoder costs more than \$1,000. The decoder arrived with a yellow tag showing its history. Although it previously failed in a commercial DC-10 aircraft, someone signed off on the part and indicated it could be put back into a DC-10. Gardner said he, personally, would not use or sell the part on the open market given its questionable history and the tragic impact it could have on countless lives.

As air traffic grows and commercial airlines are faced with aging fleets, the demand for surplus or aftermarket parts will only continue to grow. At the same time, commercial airlines are reducing their on-hand supplies of surplus parts and relying more on used serviceable material. The Oliver Wyman agency reports that the global aviation industry spends more than \$5 billion annually to maintain, repair and overhaul aircraft.

Mr. Gardner believes that because unapproved parts are cheaper (they do not bear the added cost of the rigorous testing measures) they are enticing to repair shops and aviation mechanics. Still, the FAA will criminally charge anyone who intentionally puts an unapproved part in an airplane, and mechanics or companies

that do so can face up to a \$32,140 fine for each violation. If you need more information on this subject, contact Mike Andrews, a lawyer in our Personal Injury & Products Liability Section at 800-898-2034 or by email at Mike.Andrews@beasleyallen.com. Mike handles aviation litigation for the firm.

Sources: NBC (KNTV) Bay Area, Locatory.com

RUNWAY CLOSE CALLS CONTINUE TO CLIMB IN U.S.

Aviation experts agree that the most dangerous time during any airliner flight occurs while it is on the ground. The twenty-five (25%) percent increase in hazardous runway incidents at U.S. airports during fiscal year 2016 supports this consensus. Many of the lawyers in our firm fly out of Atlanta on a regular basis.

Commercial jet passengers leaving Hartsfield-Jackson International Airport in Atlanta experienced a close call last April. As the jet raced down the runway for takeoff the pilot was forced to brake suddenly which reaches 138 miles per hour. An air-traffic controller cleared the jet to take off from a runway then immediately realized it would cross the path of another plane, which had just landed. The controller quickly told the jet's pilot to abort the takeoff. Fortunately, there was enough runway left for the plane to completely stop safely. The two airliners were just over a mile apart and at high speeds at that time.

Even political candidates are not immune to runway mishaps. Vice President-elect Mike Pence, his staff, crew and the press pool were all thankful to be safe after the campaign's chartered plane slid off a LaGuardia Airport runway near the end of the campaign. These are just two examples of tarmac incidents the Federal Aviation Administration (FAA) tracks through its Aviation Safety Reporting System (ASRS).

The Wall Street Journal, citing FAA data, reported that there were more than 1,560 tarmac incidents nationwide in fiscal 2016 and 19 close calls "resulting in significant chances of accidents or collisions that were narrowly avoided." The number of close calls is up from 15 in fiscal 2015. The total number of reported tarmac incidents increased for the third consecutive year, up from 1,450 in fiscal 2015 and around 1,250 in 2013 and 2014. The data is based on 50 million flights across the country including commercial, private and personal flights.

The number of incidents continues to climb despite the significant efforts over

the years to prevent the most dangerous types of incidents. Regulators and industry leaders have adopted proactive measures such as better pilot education and providing more assistance to help airport operators reduce certain risks. Still, researchers are not certain of the cause of the persistent trend. However, they believe that enhanced collection and analysis of data from incident reports is critical to bringing the numbers down.

Airline operators, service companies and unions agree to submit the incident reports to the FAA. To encourage reporting, incident reports can be filed anonymously—without fear of reprimand. While information from incident reports is also paired with corresponding data sent automatically from the aircraft, the quality of incident report data is limited by a witness's recall and the excessive focus on certain types of incidents.

The FAA investigates all reports to determine the severity of unexpected mishaps. An incident that could affect the safety of the flight crew, ground crew and passengers is deemed "serious." Incidents are "not serious" if they do not involve serious personal injury or substantial aircraft damage, according to The Atlantic. However, there are no clearly defined characteristics for each category, nor are there specific guidelines for making the determination.

Georgetown University professor Robin L. Dillon-Merrill believes incident data can more effectively spot trends, allowing the causes of the current upward trend of incidents to be identified and corrected. Dr. Dillon-Merrill and her team researched the thoroughness and effectiveness of information obtained from incident reports. She suggests that by simplifying the incident reporting process and expanding the focus of unexpected mishaps to include smaller and "less obvious incidents," commercial aviation can improve the data authorities rely upon to improve U.S. runway safety.

Dr. Dillon-Merrill advises that maintaining a balance in data collection is crucial, but tricky. Collecting too much data and issuing warnings too frequently could diminish their effectiveness. However, pulling the reins too tightly around data collection and narrowing the focus only on easily discernible incidents could reinforce dangerous behavior and dissuade efforts to find safer tactics to prevent or correct runway mishaps.

If you need more information on this subject, contact Mike Andrews, a lawyer in our Personal Injury & Products Liability Section at 800-898-2034 or by email at

Mike.Andrews@beasleyallen.com. Mike handles aviation litigation for the firm.

Sources: *Wall Street Journal* and *The Atlantic*

**ANOTHER U.S. MARINE CORPS V-22 OSPREY
CRASH TEMPORARILY GROUNDS AIRCRAFT
STATIONED IN JAPAN AND REIGNITES SAFETY
CONCERNS**

A U.S. Marine Corps V-22 Osprey tilt-rotor helicopter crashed on Dec. 13, injuring two of the five Marines on board. However, all five were safely airlifted from the crash site off the coast of Okinawa, Japan, according to the *Nikkei Asian Review*.

Japanese daily newspaper *The Mainichi* reported that the Marines' were conducting an aerial refueling training operation at the time of the crash and, although the investigation is ongoing, U.S. military officials say they "are highly confident" the crash occurred when the Osprey's rotor blades struck the refueling line and damaged the aircraft. Following the deadly aircraft's latest mishap, news outlets reported that military officials grounded the entire fleet at the urging of Japan Defence Minister Tomomi Inada. However, less than a week after the mishap and despite an active investigation, officials cleared the fleet to resume operations Dec. 19.

Military officials commended the pilots for recognizing there was a problem and choosing an option that reduced the risk to civilians. The pilots opted to keep the aircraft offshore rather than exposing more lives to danger by flying over a populated area in order to reach the air station. Regardless, the crash deepened local residents' fears about the aircraft's questionable safety record.

The Osprey has been plagued with safety issues since its inception. It was designed to function as both an airplane and a helicopter, yet the two types of aircraft perform completely differently. The design's compromise prevents the Osprey from effectively performing either function safely. Additionally, the aircraft is cursed with a defect that causes significant dust intake and "turbine blade glassification," which is an erosive condition that can lead to engine failure. Risks of an Osprey malfunctioning due to these defects are heightened when it hovers too long in one area. At the time of the crash, the Osprey was hovering as it waited for the refueling process to finish.

Osprey helicopters have been forced into several emergency landings since the vehicle's first deployment in 2007. Three of those landings occurred in December

2016. On the same night as the Dec. 13 crash landing, another V-22 experienced landing gear problems as it was landing at the same air station in Futenma. *The Marine Corps Times* reports that it suffered an electrical system failure, which affected the signals on the landing gear.

Earlier in the month, an Osprey based at Marine Corps Air Station Miramar in San Diego, Calif., was forced to make an "unplanned landing," according to San Diego's NBC 7. The San Diego-based aircraft landed in an open field in the Cleveland National Forest safely—without injuries to any of the six crewmembers or damage to the aircraft. One pilot reportedly attributed the cause of the mishap to "an engine malfunction with the hydraulics."

Mike Andrews, the lawyer at Beasley Allen who handles aviation litigation and has handled several Osprey cases, is familiar with past issues involving hydraulics. After identifying problems with the aircraft's hydraulic lines and aircraft operational software, the military responded with revisions to the aircraft to increase its safety.

The aircraft has also been involved in a number of fatal crashes. Most recently, two U.S. Marines, 21-year-old Lance Cpl. Matthew Determan and 24-year-old Cpl. Joshua Barron, who were stationed at Bellows Air Force Station in Hawaii, were killed in May 2015 when their Osprey crashed during a training operation. Determan's family hired our Law firm and Honolulu lawyer Melvin Y. Agena to represent them in a wrongful death lawsuit. We will prove that this aircraft is defective and highly dangerous. Following the May 2015 fatal crash in Hawaii, NBC News reported that the V-22 Osprey helicopter has claimed 37 lives and injured many more.

Fortunately, no lives were lost during these latest three V-22 Osprey mishaps, but members of the Nago Municipal Assembly believe that if the aircraft continue training in or near their prefecture, it is just a matter of time before a crash or other tragedy occurs. If you need more information on this subject, contact Mike Andrews, a lawyer in our Personal Injury & Products Liability Section at 800-898-2034 or by email at Mike.Andrews@beasleyallen.com. Mike handles aviation litigation for the firm.

Sources: *Nikkei Asian Review*, *The Mainichi*, *Marine Corps Times*

XVI. ENVIRONMENTAL CONCERNS

**FIRST STATE PCB SUIT FILED AGAINST
MONSANTO**

Washington became the first state to sue Monsanto Co. over pollution from a once widely used chemical now known to cause cancer and immune system problems in humans and devastate wildlife populations. The state's damages may reach into the hundreds of millions of dollars. Washington is joining a number of cities that have already sued Monsanto under a public nuisance theory—saying the company produced and widely sold polychlorinated biphenyl (PCB) even though it knew it was toxic—in the hopes of collecting millions to pay for cleanup of the pollutant.

The pollution has accumulated for decades in humans, plants and animals. The company produced PCB—essentially an insulation product that improves fire safety and durability in a wide range of products, including those purchased by the military—for four decades and didn't stop until Congress passed the Toxic Substances Control Act (TSCA) in 1979, the state's complaint said. The complaint says Monsanto knew long before it was ordered to stop making the substance that it was damaging to the environment. Gov. Jay Inslee said in a statement:

Monsanto is responsible for producing a chemical that is so widespread in our environment that it appears virtually everywhere we look—in our waterways, in people and in fish—at levels that can impact our health. It's time to hold them accountable for doing their fair share as we clean up hundreds of contaminated sites and waterways around the state.

The suit has claims for public nuisance, negligence and product liability. At least eight cities—including Spokane and Seattle—have filed similar claims against Monsanto. The governmental entities filing the suits are represented by the same Plaintiffs' firms, Baron & Budd PC and Gomez Trial Attorneys. The suits allege that from about 1935 to 1980, Monsanto was the only manufacturer in the U.S. that intentionally produced PCBs for commercial use; the chemicals were made in Illinois and Alabama. Monsanto's commercially produced PCBs were used in

many industrial products, including electrical equipment such as transformers, motor start capacitors and lighting ballasts, among other things, the lawsuits say.

In January, San Jose, Berkeley, Oakland and San Diego in California, and Spokane and Seattle in Washington sought to have their suits combined in multidistrict litigation (MDL), court records show. The U.S. Judicial Panel on Multidistrict Litigation (JPML) in April declined, however, saying the facts in the cases will be different because they all address different bodies of water.

In August, Monsanto sought for dismissal of the Portland case, saying those claims were “absolutely time-barred.” In October, a judge mostly upheld Spokane’s case, but dismissed a product liability claim because the city isn’t a consumer.

Washington is represented by Attorney General Robert W. Ferguson and William R. Sherman and Jonathan C. Thompson of the attorney general’s office; John P. Fiske of Gomez Trial Attorneys; and Scott Summy, Carla Burke Pickrel and Celeste Evangelisti of the Baron & Budd firm. The case is *State of Washington v. Monsanto Co. et al.* in the State of Washington’s King County Superior Court.

Source: Law360.com

SPRAY FOAM INSULATION PRESENTS HEALTH HAZARDS

Spray polyurethane foam (SPF) is used as an effective insulator of residential and commercial buildings throughout the world. It is sprayed onto walls, ceilings, and other spaces to seal gaps to make structures more comfortable, energy efficient, and quiet. SPF involves a chemical reaction whereby isocyanates mix with polyol (among other proprietary chemicals) to create the foam, which eventually hardens into the insulation.

Although effective, it can cause various health issues in both building occupants and workers who apply it. The key contaminant is isocyanate which can cause skin, eye, and lung irritation as well as asthma and immune-sensitization. Both the National Institute of Occupational Safety and Health (NIOSH) and the U.S. Environmental Protection Agency (EPA) have classified isocyanates as the leading attributable chemical cause of work-related asthma. Indeed, the EPA has concluded that manufacturers’ claims that SPF is “non-toxic,” “safe” or “environmentally friendly” are inaccurate.

In addition to asthma, exposure to isocyanates may cause sensitization in some people after a single exposure to a rela-

tively high concentration or repeated exposures to lower concentrations over time. The EPA has concluded there is no safe level of exposure after sensitization meaning an individual will be permanently impacted by the chemical. Even where sensitization does not result, long-term lung and respiratory problems may occur.

Lawyers in our firm’s Toxic Torts Section are currently investigating potential claims by homeowners and construction workers who suffer adverse health effects from exposure to toxic chemicals contained in SPF. If you would like more information, please contact Chris Boutwell at 800-898-2034 or by email at Chris.Boutwell@beasleyallen.com

EPA PROPOSES BANNING TCE IN THE DRY CLEANING INDUSTRY

The Environmental Protection Agency (EPA) has proposed banning the toxic chemical trichloroethylene (TCE) when used as a degreaser and spot removal agency in the dry cleaning industry. TCE is a non-flammable liquid chlorinated hydrocarbon used as a solvent to remove grease from metal parts and as a cleaner in many industries. It is a common environmental contaminant found at a majority of listed Superfund sites throughout the United States.

TCE exposure typically occurs via inhalation at the workplace or from consuming contaminated drinking water. Short-term effects to small doses can cause dizziness, headaches, and sleepiness while exposure over the long-term can cause scleroderma (a systemic autoimmune disease), neurotoxicological issues, and even cancer. Both the National Toxicology Program and the International Agency for Research on Cancer have concluded that TCE is carcinogenic and, in particular, linked with kidney and liver cancer.

The EPA appears to be acting under increased authority to regulate certain chemicals after a revision to the Toxic Substances Control Act (TSCA) earlier this year. Before this overhaul, the agency did not have much power to regulate chemicals, with only a few hundred having been adequately tested for their impact on the public health. The bipartisan measure now permits the EPA to restrict chemicals already in commerce that pose health risks to humans and the environment. TCE was among the first 10 chemicals the EPA chose to evaluate under this expanded authority. It is currently evaluating other uses of the chemical to determine

whether a more widespread ban is warranted.

Source: Law360.com

JUDGE ENDS CAMP LEJEUNE DRINKING WATER MDL

A federal judge in Georgia dismissed 17 lawsuits in the multidistrict litigation (MDL) filed by military families over the contamination of drinking water at the Camp Lejeune military base in North Carolina. U.S. District Judge Thomas W. Thrash rejected the Plaintiffs’ motion to transfer the cases after the Eleventh Circuit determined that North Carolina’s 10-year statute of repose applied to their personal injury claims and rejected arguments there was an exception for latent illnesses based on a recent North Carolina law. The Court found that the law, which exempted groundwater contamination suits from the statute of repose, could not be applied retroactively.

Plaintiffs then requested the cases be transferred to North Carolina where the Fourth Circuit had interpreted the North Carolina law differently, thus warranting jurisdiction. Judge Thrash refused, concluding that a more favorable venue for the Plaintiffs was not a proper basis for transfer. Noting there was no dispute that the contamination issue was solved in 1987, Judge Thrasher concluded that the earliest claim made in 1999 was untimely and dismissed the lawsuits.

The United States Department of Veterans Affairs has acknowledged Camp Lejeune’s water supply was contaminated with industrial solvents such as perchloroethylene, trichloroethylene, vinyl chloride and benzene that leaked from storage tanks. Service members and their families who resided at the base have suffered from an increased risk of cancer, adverse birth outcomes, and other health effects.

This decision illustrates the difficulty many face when filing suit for a latent illness, which may take years to manifest. Some states have a discovery rule that tolls the statute of limitations until the Plaintiff suspects the illness is attributable to a Defendant’s wrongful conduct. Others, like North Carolina, may have an exception to the statute of repose which allows certain actions to be brought later than previously required. Thus, one must pay close attention to the applicable laws governing toxic tort cases.

Source: Law360.com

Mesothelioma is a rare and aggressive cancer that is caused by exposure to asbestos. Mesothelioma forms on the thin layer of tissue covering the internal organs (called the mesothelium), most commonly on the lining of the lungs and chest wall. There is no cure for mesothelioma, and the current five-year survival rate following diagnosis is approximately 8 percent in the United States. Treatment options have been limited, but significant advances in detection were made in 2016. Given that an early diagnosis is the single best way to improve a patient's diagnosis, these advances are positive news.

The first new method of detection is a type of blood test using exomes, which are microscopic substances that can be used to detect cancer. Previously, exomes have been used to detect prostate, colorectal and ovarian cancer. Building on the processes used for those tests, scientists have been able to use exomes to detect the presence of mesothelioma in the body. While this new method of detection does not establish the stage to which the cancer has progressed, the development of a new positive/negative test is a major advancement.

Another new detection method developed in 2016 comes in the form of a breath test. As noted above, the most commonly diagnosed form of mesothelioma involves the lining of the lungs, known as pleural mesothelioma. In current testing, this new breath test was able to distinguish between individuals who had pleural mesothelioma and those who did not with nearly 90 percent accuracy.

A third new method involves the use of a specific type of protein, known as high-mobility group box 1 (HMGB1). Using this protein, researchers were able to distinguish between:

- those who had mesothelioma,
- those who had been exposed to asbestos but had not yet developed mesothelioma, and
- those who had no asbestos exposure.

This test has a very high sensitivity rate, making it especially promising to those working in high risk fields.

If you would like more information about these cases, you can contact Grant Cofer, a lawyer in our firm's Toxic Torts Section. He can be reached at 800-898-2034 or by email at Grant.Cofer@beasleyallen.com.

Source: Mesothelioma+Asbestos Awareness Center

Recently it was revealed that thousands of emergency response personnel from all over the country were exposed to the toxic substance known as ricin while undergoing disaster response training at the Center for Domestic Preparedness (CDP) in Anniston, Ala. The Center, which trains firefighters, paramedics and other first responders from all over the country, is part of the Federal Emergency Management Agency (FEMA). The Center provides hands on training to first responders to enable them to better respond to terrorist attacks. Trainees were unknowingly exposed to the deadly form of the chemical, rather than a less toxic form, due to a mix-up with a vendor. Use of some form of ricin is necessary to train students on the chemical detection equipment.

Ricin is a toxin derived from castor beans and is lethal if even a small amount of the substance is inhaled or ingested. The toxin has been used in the past in terrorist acts that attempted to send ricin-laced letters through the mail.

Students may have been exposed to the toxin as far back as 2012, when the unnamed vendor began shipping the toxin to CDP for training purposes. As many as 10,000 students may have been exposed to the chemical during training exercises. Thankfully, it is not believed that any students or personnel at the CDP were harmed by the exposure. The CDP asserts that safety equipment and protocols were adhered to, including storing the toxin in biosafety cabinets. However, one anonymous source has indicated that respirators may not have been used by students when handling the substance.

The lethal version of ricin is a toxin made up of two protein chains—an A-chain and a B-chain. The vendor supplied the CDP with the lethal form of ricin, ricin-holotoxin, containing both protein chains, rather than the less deadly ricin A-chain. The A-chain is poisonous, but it is not lethal without the presence of the B-chain.

Since the CDP discovered the error, it has ceased all "live fire" training activities. Internal and external investigations are being conducted into the CDP's safety protocols. If you need more information on this subject, contact Rhon Jones or Jeff Price, lawyers in our Toxic Torts Section, at 800-898-2034 or by email at Rhon.Jones@beasleyallen.com or Jeff.Price@beasleyallen.com.

An Ohio jury has found DuPont liable for sickening a resident who developed testicular cancer after drinking water contaminated by the company's dumping of toxins near his community's water source. Jurors awarded Plaintiff Kenneth Vigneron \$2 million in what is the first of approximately 40 upcoming trials. Vigneron is one of nearly 3,500 Plaintiffs whose lawsuits were filed by residents in Ohio and West Virginia and have been consolidated in the Southern District of Ohio.

The Plaintiffs accuse DuPont of sickening residents through decades of releasing perfluorooctanoic acid, also known as PFOA or C8, into both the air and the Ohio River at the Washington Works site. C8 was an integral chemical in the manufacture of nonstick cookware for decades but has since been phased out in the United States. The lawsuits allege that DuPont's internal studies from decades ago acknowledge that C8 was hazardous to human health.

Six bellwether cases concluded earlier this year, with two of them resulting in jury verdicts of \$1.6 million and \$5.6 million, the latter of which included punitive damages. U.S. District Judge Edmund Sargus recently ordered DuPont to turn over documents related to a Dutch investigation over similar pollution allegations to the American multidistrict litigation (MDL) Plaintiffs to assist in subsequent trials.

Contaminants can also overload wastewater treatment systems that may not be equipped to treat certain levels of chemicals wrongfully dumped by another party. Such an incident occurred in Gadsden, Ala., where the Water Works and Sewer Board is striving to treat water that was allegedly contaminated with PFOAs and perfluorooctane sulfonates (PFOS) by upstream carpet and textile companies. Beasley Allen filed suit on behalf of the Board, claiming it should not be held responsible for the higher readings of these chemicals in order to comply with the EPA's new lifetime health exposure guidelines.

In addition to representing wastewater treatment systems, we are investigating personal injury cases involving residents exposed to PFOA and PFOS who have been diagnosed with certain diseases. If you have any questions about these cases, contact Chris Boutwell or Ryan Kral, lawyers in our Toxic Torts Section, at 800.898.2034 or by email at Chris.Boutwell@beasleyallen.com.

XVII. UPDATE ON NURSING HOME LITIGATION

SEPSIS IN NURSING HOMES IS A MAJOR PROBLEM

In reviewing nursing home cases, a common problem that our lawyers see is elderly people who develop sepsis. According to a recent report by the Centers for Disease Control (CDC), more than half of Americans who were polled had no idea what sepsis is.

Sepsis is a very serious medical condition. Once obtained, the death rates have been reported between 28 and 50 percent. Understandably, the elderly, very young, and those with a compromised or weakened immune system are at the higher end of the fatality rates for this serious medical condition.

According to Kary Pryzmus, a CDC sepsis coordinator, "Sepsis is the body's overwhelming response to infection." Ms. Pryzmus in a recent interview with NBC, stated: "Sepsis has been known in the past as being a blood poisoning or a complication of a certain condition. When we hear someone passed away from a complication of pneumonia they won't say the word sepsis."

In the nursing home setting, sepsis is frequently associated with an open wound or sore. Once a person develops an infection, the risks of the body becoming "septic" is exponentially increased. Bacteria can also enter the body through other methods, such as through a surgical wound (like around a feeding tube) or through the lungs in the form of bacterial pneumonia.

According to the CDC, the warning signs that a person may have sepsis are the following:

- Shivering, fever or very cold.
- Extreme pain or general discomfort, often described as the "worst ever."
- Pale or discolored skin.
- Sleepiness, difficulty waking up, or extreme fatigue.
- A state of confusion.

- The feeling of impending death.
- Shortness of breath.
- Failure to improve despite high dosages of antibiotics and other medications.

Ms. Pryzmus, when asked, correctly noted that it is essential to get a person with these symptoms to an appropriate medical provider. Unfortunately, far too often, nursing homes either do not timely recognize these symptoms in patients, or the facilities' staffs believe they can treat the patient in-house. The delay in treatment can be, and often is, fatal.

Sepsis should be a rare event in nursing home settings. The best way to prevent it is to ensure that the patients/residents do not develop sores. But if sores or illness do arise, it is essential that nursing home staff promptly transfer the patient/resident to a more acute facility, such as a hospital emergency room. Because the elderly are already at a heightened risk of death from sepsis, timely and appropriate treatment is essential to their survival and recovery. If you need more information on this subject, contact Ben Locklar, a lawyer in our firm who handles Nursing Home Litigation, at 800-898-2034 or by email at Ben.Locklar@beasleyallen.com.

XVIII. AN UPDATE ON CLASS ACTION LITIGATION

CELEBREX JUDGE APPROVES \$468 MILLION SETTLEMENT

A New York federal judge has given approval to a \$468 million settlement in a long-running multidistrict litigation (MDL) against Pfizer Inc. U.S. District Judge Laura Taylor Swain said this was a "very complex" case, which accused Pfizer of misleading investors about the risks of its pain treatments Celebrex and Bextra, lasted for 12 years and involved more than 100 depositions, 65 million pages of documents and nearly 300,000 hours of legal work in its prosecution and investigation. There were three motions for summary judgment and a trip to the Second Circuit and back before arm's-length negotiation with an experienced mediator produced what Judge Swain called "an outstanding result." Judge Swain said: "The legal work in this case was done extraordinarily well and billed in an appropriate manner."

Judge Swain thanked and congratulated the lawyers on both sides after more than a decade of litigation. She told the lawyers it had been "an honor and a pleasure to work with you over the years." Jay W. Eisenhofer of Grant & Eisenhofer, representing the class, told Judge Swain the settlement, which represented about 9 percent of potential damages against Pfizer, should be allowed to settle because the case was heavily dependent on one corrective disclosure and had the case been lost, it would have been "devastating for the class." He urged Judge Swain to approve the approximately \$130 million in fees and more than \$20 million expenses, noting that 45 percent of the lawyers' time was spent on fact discovery. Jay said that it would take 500 lawyer-years to get through all of the documents reading at one page per minute. He added:

This was a very, very hard-fought case. Every stop was pulled out, everybody did their utmost, everybody did their best. We really gave everything we had to this case.

Lynn K. Neuner of Simpson Thacher & Bartlett LLP, representing Pfizer, asked Judge Swain to approve the settlement and said the company took no position on the issue of fees and expenses. This statement was issued by Pfizer:

Pfizer reached a settlement to resolve this securities class action case for all defendants. This resolution reflects our desire to avoid the distraction of continued litigation and instead, to focus on the needs of patients and prescribers. We and all other defendants deny wrongdoing as part of the agreement.

The underlying suit alleged that the company and its executives, including CEO Henry McKinnell, knew that drug safety studies conducted between 1998 and 2004 showed Celebrex and Bextra posed serious cardiovascular risks but hid the information from the public.

A consolidated class complaint was filed in February 2006, and in July 2012, Judge Swain certified a class led by the Teachers' Retirement System of Louisiana. The judge denied several motions to dismiss, and although she trimmed the suit in March 2013, she kept most of the investors' allegations. But in May 2014, she barred University of Chicago law professor Daniel Fischel from testifying on behalf of the investors, then dismissed the case after Pfizer argued that the shareholders could no longer sustain key elements of their claim. The Second Circuit ultimately found that Judge Swain was within reason

to find that Fischel improperly adjusted his study of Pfizer's stock price, but that she should have allowed him to present his findings on loss causation and damages, barring him only from testifying about his adjustment.

It was reported that the settlement is likely among the last major payments Pfizer will make over the two drugs. It has already paid \$894 million to settle product liability and consumer fraud suits brought by drug users and state attorneys general, \$1 billion to settle civil allegations it fraudulently promoted and marketed Bextra, and a \$1.3 billion criminal fine—at the time the largest ever imposed in the U.S.—for the same fraudulent misbranding.

The investors are represented by Gregory P. Joseph, Douglas J. Pepe and Sandra M. Lipsman of Joseph Hage Aaronson LLC, Jay W. Eisenhofer, Richard S. Schiffrin, James J. Sabella, Charles T. Caliendo, Brenda F. Szydlo, Geoffrey C. Jarvis and Mary S. Thomas of Grant & Eisenhofer PA, Jonathan S. Massey of Massey & Gail LLP, and David Kessler, Andrew L. Zivitz, Matthew L. Mustokoff and Michelle M. Newcomer of Kessler Topaz Meltzer & Check LLP.

The case is *In re: Pfizer Securities Litigation* in the U.S. District Court for the Southern District of New York.

Source: Law360.com

XIX. THE CONSUMER CORNER

U.S. CONSUMER PRODUCT SAFETY COMMISSION DEMANDS TRANSPARENCY IN PROTECTIVE ORDERS AND SETTLEMENT AGREEMENTS AGAINST MANUFACTURERS

The Consumer Product Safety Commission (CPSC) is a federal public-health authority that protects the public from unreasonably dangerous consumer products. To do its job, the CPSC must receive timely information regarding consumer product-related safety hazards. The CPSC relies on manufacturers to report potential product hazards. Despite a mandatory reporting requirement, manufacturers may fail to report hazards in a timely manner—if the hazards are reported at all. In fact, manufacturers often use confidentiality provisions in protective orders and settlement agreements to make sure the public never learns of the injuries and death its products are causing. These protective orders and settlement agreements

prevent anyone from reporting the defective product to the CPSC.

The CPSC has now recommended that “all parties seek to include a provision in any private protective order or settlement agreement that—despite whatever restrictions on confidentiality are imposed, and whatever entered into by consent or judicial fiat—specially allows for disclosure of relevant [consumer product] safety information to [the CPSC] and other applicable authorities.” This applies to parties that are in the process of agreeing to or have already agreed to confidentiality provisions. The CPSC recommends that each protective order or settlement agreement contain the following language to allow parties to report defects to the CPSC:

- nothing herein shall be construed to prohibit any party from disclosing relevant consumer product safety information to the Consumer Product Safety Commission; or
- nothing herein shall be construed to prohibit any party from disclosing relevant safety information to a regulatory agency or government entity that has an interest in the subject matter of the underlying suit.

The CPSC found that manufacturers of playground equipment, collapsible cribs, and all-terrain vehicles have kept defects from the CPSC through protective orders. This means that these manufacturers could have received incident reports on their equipment, but the CPSC would be kept in the dark if those incident reports were covered by the protective order. The CPSC believes its recommendation to add a provision allowing disclosure to the agency to protective orders and settlement agreements will prevent cover-ups of defects through litigation. If you need more information on this subject contact Stephanie Monplaisir, a lawyer in our firm's Personal Injury & Products Liability Section, at 800-898-2034 or by email at Stephanie.Monplaisir@beasleyallen.com.

AT&T ISSUING \$88 MILLION IN REFUNDS TO 2.7 MILLION CUSTOMERS

AT&T will soon start refunding more than \$88 million to customers as part of a settlement over unauthorized charges. The Federal Trade Commission (FTC) said 2.7 million current and former AT&T mobile phone service subscribers will receive refunds averaging \$31 per person. Current AT&T subscribers—the vast majority of those affected—will see refunds on their bills in the next 75 days.

Former customers, which account for about 300,000 people, will receive refunds in the mail.

The funds come from a 2014 FTC settlement over claims that AT&T was charging up to \$9.99 per month for things like horoscopes, wallpapers, ringtones and fun facts. These were being pushed to customers' phones from third-party companies, a process known as “cramming.” The FTC said AT&T kept 35 percent of the revenue from the providers. FTC Chairwoman Edith Ramirez stated:

AT&T received a high volume of complaints related to mobile cramming prior to the FTC and other federal and state agencies stepping in on consumers' behalf. I am pleased that consumers are now being refunded their money and that AT&T has changed its mobile billing practices.

You can call 877-819-9692 for more information on the settlement. The most recent settlement is the second one involving AT&T and cramming charges. In August, AT&T agreed to pay a \$7.5 million fine related to unauthorized charges. Of that amount, \$6.8 million was refunded to customers and \$950,000 was paid as a fine to the U.S. Treasury.

Source: AL.com

GNC TO PAY \$2.25 MILLION FOR SELLING MISLABELED SUPPLEMENTS

The U.S. Department of Justice (DOJ), the Food and Drug Administration (FDA), and the U.S. Attorney's Office for the Northern District of Texas have been investigating GNC Holdings, Inc. for the company's failure to ensure that GNC's retail products are actually legal in the U.S. As a result of the government's recent investigation, it has been discovered that GNC allowed a misbranded supplement, OxyElite Pro Advanced Formula, to be sold at its stores nationwide. The supplement is manufactured by USP Labs LLC, who GNC claims made false assurances and provided fake documentation representing that the supplement contains the natural plant extracts listed on the label, when in fact it contains synthetic stimulants made in China.

According to state and federal investigations into USP Labs LLC, the company allegedly was involved in a conspiracy to import ingredients from China using false certificates of analysis and false labeling. USP Labs LLC allegedly represented that it used natural plant extracts in some of its

products, when in fact it was using synthetic stimulants manufactured in a Chinese chemical factory. Despite USP Labs LLC's fraudulent conduct, GNC should have taken the necessary steps to ensure that the retail products on its shelves are safe and legal. Instead, GNC did not take any action to verify that the ingredients in the supplement stocked on GNC shelves were as represented, nor did GNC conduct any testing on the supplement or require additional certifications.

As a result of the investigation into GNC, the company agreed to pay \$2.25 million to settle the allegations that it sold mislabeled dietary supplements. In exchange for an agreement from the government not to prosecute the company, GNC also agreed to improve its practices regarding potentially illegal ingredients in supplements to better determine which products should be approved for sale, and further agreed to focus on improving the quality and purity of supplements in the industry. According to the DOJ, if the FDA issues a public notice that OxyElite Pro Advanced Formula is not legal or safe, GNC has agreed that it will immediately remove the product from its shelves. Benjamin C. Mizer, Principal Deputy Assistant Attorney General for the DOJ, said in a statement:

Unlawful dietary supplements are an important enforcement priority for the department. Today's resolution is a significant step forward in reforming an industry rife with alarming practices.

Lawyers at Beasley Allen have handled many cases involving fraud and deceit with respect to a manufacturer's representations of its products. If any of our readers are aware of these type of "alarming practices," contact Ali Hawthorne, a lawyer in our firm's Consumer Fraud & Commercial Litigation Section, at 800-898-2034 or by email at Alison.Hawthorne@beasleyallen.com.

Source: Law360.com

XX. RECALLS UPDATE

We are again reporting a large number of safety-related recalls. We have included some of the more significant recalls that were issued in December. If more information is needed on any of the recalls, readers are encouraged to contact Shanna Malone, the Executive Editor of the Report. We would also like to know if we

have missed any safety recalls that should have been included in this issue.

HYUNDAI RECALLS 41,000 MINIVANS OVER HOODS THAT CAN FLY OPEN

Hyundai Motor America Inc. has recalled more than 41,000 minivans over fears that the vehicles' hood latches could corrode and cause the vehicles' hoods to fly open while driving. The recall affects 41,264 model year 2007 and 2008 Hyundai Entourage minivans equipped with secondary hood latches that could remain in the open position even if the hood is closed, due to corrosion. If the vehicle's hood is not closed properly, or if the primary hood latch is released while driving, it is possible the hood could open and obscure the driver's view and increase the risk of a crash. To fix the issue, Hyundai will replace the latches free of charge to Entourage owners. The affected vehicles were either sold or registered mostly in Northern, cold weather states, including Alaska, Illinois, Maine and New York. The states at the southern end of the affected range are Kansas, Kentucky, Missouri and West Virginia. In total, the recall encompasses vehicles in 27 states and the District of Columbia.

For vehicles in any other state, Hyundai dealers will inspect the secondary latches and will either lubricate or, if necessary, replace the component. All new hood latches will incorporate an enhanced corrosion coating. According to documents filed with the National Highway Traffic Safety Administration (NHTSA), Hyundai said that it first discovered the issue in June when an Entourage owner in Pennsylvania notified the automaker of a hood latch detachment. Although Hyundai found no evidence of corrosion on the primary or secondary latch, it continued to investigate the issue, finding two incidents of corrosion on the secondary latches in September and October. The automaker decided to conduct the recall in early November. Hyundai said it is not aware of any injuries or accidents related to the issue. Hyundai notified dealers of the recall in late November and started notifying Entourage owners Dec. 9.

The Entourage is not the only vehicle manufactured by the Korean automaker's U.S. arm to have experienced hood latch problems. In June Hyundai recalled 81,000 model year 2016 Tucson SUVs. Hyundai unit Kia Motors America Inc. also recalled 220,000 model year 2006 to 2014 Kia Sedona minivans because of the same issue. Other automakers have also experienced hood latch issues, including Nissan

North America Inc., which recalled more than 1 million Altima sedans to fix corrosion problems in three campaigns between 2015 and 2016.

DOOR LOCKSETS MANUFACTURED BY STANLEY SECURITY SOLUTIONS TAIWAN RECALLED DUE TO RISK OF ENTRAPMENT IN AN EMERGENCY

Stanley Security Solutions Taiwan, Ltd. of Taiwan, has recalled about 70,000 door locksets. The latches can fail and the door cannot be unlocked from the inside, posing an entrapment risk. This failure could lead to the inability to vacate a location in an emergency. This recall involves Stanley's commercial cylindrical series BMHA/ANSI Grade 1 heavy duty locksets with dead-latch components. The recalled locksets have brass, bronze, nickel, chrome or satin chrome finish. They were sold under 18 different brands and with the following model or part number, located on the packaging: View brand and model information here: <https://www.cpsc.gov/Recalls/2017/Door-Locksets-Recalled>. The company has received four reports of the latches failing. No injuries have been reported.

The locksets were sold at Stanley Commercial Hardware and other lock distributor and retailers nationwide and online at Amazon.com and Grainger.com from February 2016 through September 2016 for between \$170 and \$320. Consumers should immediately stop using the recalled locksets. For Stanley Commercial Hardware-branded locksets, consumers should contact Stanley Commercial Hardware and for all other brands, consumers should contact Stanley Security Solutions Taiwan to receive a free replacement latch or to schedule an appointment to have the latches replaced free of charge if the lockset is already installed. Contact Stanley Commercial Hardware toll-free at 855-885-1296 from 8 a.m. to 5 p.m. ET Monday through Friday or www.stanleyhardwarefordoors.com and click on Products, then on Recall for more information. Stanley Security Solutions Taiwan toll-free at 855-655-5750 from 8 a.m. to 5 p.m. ET Monday through Friday or <http://tw.stanleysecuritysolutions.com> and click on Products, then on QCL-100 Recall Notice for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Door-Locksets-Recalled>.

ATRIUM RECALLS SAFEHARBOR WINDOWS DUE TO IMPACT INJURY HAZARD

Atrium Windows and Doors Inc., of Welcome, N.C., has recalled about 580 SafeHarbor vinyl impact windows. The glass can separate from the frame during hurricane conditions, posing an impact injury hazard. This recall involves SafeHarbor Series 65 and 265 vinyl impact windows that are custom manufactured and installed by contractors to meet building specifications and vary in size and shape. The windows are installed with a removable label with the "SafeHarbor" brand name on it.

The windows were sold at ABC Supply, Absolute Installation, Builder's First Source, Gulf Coast Lumber, Jupiter Industries, Lansing, Lowe's, and Lumberman's stores nationwide from March 2016 through September 2016 for between \$350 and \$750. Consumers should avoid areas with the recalled windows during hurricane conditions and contact Atrium to schedule a free repair. Contact Atrium at 800-377-6524 from 8 a.m. and 5 p.m. ET Monday through Friday, email at 65impact-products@atriumwindows.com or online at www.atriumwindows.com and click on "Safety Alert" for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Atrium-Recalls-SafeHarbor-Windows>

TARGET REANNOUNCES RECALL OF MENORAHS DUE TO FIRE HAZARD

About 2,600 Menorahs have been recalled by Target Corp., of Minneapolis. The menorahs can melt when the candles are burning, posing a fire hazard. This recall involves clear acrylic Hanukkah menorahs in a pyramid design that are 10.5 inches long, 1.2 inches wide and 2.3 inches high. Model number 240-14-0169 and bar code can be found on a round white label on the side of the menorah. The company has received eight reports of the product melting, including three reports of fire. No property damage or injuries have been reported.

The Menorahs were sold exclusively at Target stores nationwide from October 2015 through December 2015 for about \$20. Consumers should immediately stop using the recalled menorahs and return them to Target for a full refund. Contact Target at 800-440-0680 from 7 a.m. to 6 p.m. CT daily, online at www.target.com and click on "School/Stationery/Seasonal" on the product recalls page or the "Product Recalls" tab on Target's Facebook page for more information. Photos

available at: <https://www.cpsc.gov/Recalls/2017/Target-Reannounces-Recall-of-Menorahs>

REMINGTON BRAND CHAINSAWS RECALLED BY MTD SOUTHWEST DUE TO FIRE HAZARD

About 8,000 Remington gasoline chainsaws have been recalled by MTD Southwest Inc, of Tempe, Ariz. The chainsaws can leak fuel, posing a fire hazard. This recall involves Remington-branded chainsaws powered by a two-cycle gasoline engine ranging in size from 42cc to 46cc and with either a 14 inch, 18-inch or 20-inch bar. The chainsaw's housing is orange and black and Remington is printed on the side of the unit and on the bar. Chainsaws included in this recall have model numbers RM4214, RM4218 and RM4620 and serial numbers 1K155XQ0198 through 1F076XQ0200; and were manufactured between Nov. 15, 2015 and June 7, 2016. Model and serial numbers and the manufacture date are located on a white label above the rear handle. The second through fifth characters of the serial number identify the manufacturing date. The second character is the month with A= January, B= February, C = March, etc. The third and fourth characters are the day of the month. The fifth character is the last digit of the year of manufacture (e.g. C286= March 28, 2016).

The chainsaws were sold at Bi-Mart, Farmer's Furniture, Lowe's and Mid-States Distributing Co. and other retailers nationwide and online at Amazon.com and Lowe.com from February 2016 through July 2016 for between \$160 and \$280. Consumers should immediately stop using the recalled chainsaws and contact MTD Southwest's Remington recall line for instructions on obtaining a free replacement chainsaw. Contact MTD Southwest's Remington recall line toll-free at 888-848-6038 from 8 a.m. to 5 p.m. ET Monday through Friday or online www.remingtonpowertools.com and click on the Product Recall tab at the bottom of the main page. Photos available at <https://www.cpsc.gov/Recalls/2017/Remington-Brand-Chainsaws-Recalled-by-MTD-Southwest>

MASTERBUILT RECALLS LP GAS SMOKERS DUE TO FIRE HAZARD

Masterbuilt Manufacturing, LLC of Columbus, Ga, has recalled about 41,000 Masterbuilt and Cabela's 7-in-1 gas smokers. The smoker's gas hose can disconnect posing a fire hazard. The recalled

Masterbuilt 7-in-1 smoker comes in green or stainless steel with a Cabela's logo, or black with Masterbuilt logo. The three-piece cylindrical body design consists of a lid, center body, and base which sits on the LP gas burner stand. It also has a porcelain flame disk bowl, water bowl, cooking grates, 10- quart pot and basket, thermometer, burner, a PVC hose and weighs about 32 pounds. Masterbuilt has received five reports of the PVC gas hose becoming disconnected during use, including one report of property damage from a fire. There have been no reports of injuries.

The smokers were sold at Army, Air Force Exchange, Cabela's, Gander Mountain and other stores nationwide and online at <http://www.Amazon.com> from April 2011 to October 2016 for about \$150 to \$200. Consumers should immediately stop using the recalled smoker and contact Masterbuilt for a free replacement rubber LP gas hose. Contact Masterbuilt at 800-489-1581, from 8 a.m. to 5 p.m. ET Monday through Friday, or online at www.masterbuilt.com and click on Support then choose Contact on the upper right hand corner of the page for more information. Photos available at: <https://www.cpsc.gov/Recalls/2017/Masterbuilt-Recalls-LP-Gas-Smokers>.

4 SIZZLE RECALLS PROMOTIONAL CHARCOAL GRILLS DUE TO FIRE HAZARD

4 Sizzle LLC, of Stateline, Nev., has recalled about 1,700 charcoal grills. The grill can catch on fire, posing a fire hazard. This recall involves wooden barrel-shaped charcoal grills with the Shock Top logo at the front. The grills are used as display enhancers in retail, liquor, convenience and other stores or were received by consumers as promotional giveaways and at charity auctions. The grill measures approximately 20 inches in diameter and 33 inches high. Item number 1089930 and PO number CMD8051855 are printed on the product packaging. The company has received two reports of the grills catching on fire. No injuries have been reported.

The grills were sold at used as display enhancers in retail, liquor, convenience and other stores and received by consumers as promotional giveaways and purchased at charity auctions from November 2015 through October 2016. Consumers should immediately stop using the recalled grills and contact 4 Sizzle to return the grill in exchange for a \$200 incentive or a full refund. Contact 4 Sizzle online at www.4sizzle.com and click on Barrel Grill Recall or toll-free at 888-847-

8716 from 7 a.m. to 6 p.m. CT Monday through Friday for more information. Photos available here: <https://cpsc.gov/Recalls/2017/4-Sizzle-Recalls-Promotional-Charcoal-Grills>.

ZEBRA TECHNOLOGIES RECALLS POWER SUPPLY UNITS FOR THERMAL PRINTERS DUE TO FIRE HAZARD

Zebra Technologies Corp., of Lincolnshire, Ill., has recalled about 166,000 power supply units for Zebra brand thermal printers. The power supply units can degrade and corrode over time when exposed to moisture and overheat, posing a fire hazard. This recall involves power supply units that serve as the power source for models of Zebra brand thermal industrial printers used to make bar codes and other commercial labels. The power supply units were either sold as after-market kits or included with the sale of the following models of Zebra brand printers: G-Series (GK420D/T, GX420D/T, GX430D/T), GT Series (GT800, GT810, GT820, GT830), ZP455, HC100, PIXX Series (P100, P110, P120), and ZXP3. The Zebra logo or FSP North America logo, date code and part number are printed on the power supply. Date codes between 1039XX through 1052XX and 1101XX through 1152XX are included in the recall for the following power supply units:

Printer Model	Zebra Power Supply Unit Part Number	Power Supply Unit Type
GK420d	808099-001	70W Brick
GK420t	808099-001	70W Brick
GX420d	808101-001	100W Brick
GX420t	808101-001	100W Brick
GX430d	808101-001	100W Brick
GX430t	808101-001	100W Brick
GT800	808099-001	70W Brick
GT810	808099-001	70W Brick
GT820	808099-001	70W Brick
GT830	808099-001	70W Brick
HC100	808099-003	70W Brick (Medical Brick)
PIXX	808099-002	70W Brick
ZXP3	808101-001	100W Brick

The company has received three reports of the power supply units overheating or catching fire, including a fire that spread from the connector to the printer, damaging the printer and surrounding work space. No injuries have been reported. The power supply packs were sold through direct sales from Zebra and through Zebra distributors and resellers, including BlueStar Inc., Ingram Micro Data Capture Point of Sale Division, ScanSource and Wynit Distribution LLC, to businesses, hospitals and end-users nation-

wide from July 2010 through June 2012 for between \$400 and \$4,750 with Zebra printers and for about \$11 as an after-market accessory. Printer owners should immediately stop using the recalled power supply units and contact Zebra for a free replacement power supply. Contact Zebra at 800-658-3795 anytime Monday through Friday, email PSUrecall@zebra.com or online at www.zebra.com and click on "Power Supply Recall" for more information.

CRAFTSMAN BRAND CHAINSAWS RECALLED BY MTD SOUTHWEST DUE TO FIRE HAZARD

MTD Southwest Inc, of Tempe, Ariz., has recalled about 19,500 Craftsman gasoline chainsaws. The chainsaws can leak fuel, posing a fire hazard. This recall involves Craftsman-branded chainsaws powered by a two-cycle gasoline engine ranging in size from 42cc to 46cc and with either a 16-inch, 18-inch or 20-inch bar. The chainsaw's housing is red and black and Craftsman is printed on the side of the unit and on the bar. Chainsaws included in the recall have model numbers 41AY427S799 316.38070, 41AY429S799 316.38090, 41AY462S799 316.38098 and 41AY469S799 316.38188, and serial numbers 1K155XQ0198 through 1F076XQ0200; and were manufactured between Nov. 15, 2015 and June 7, 2016.

Model and serial numbers and the manufacture date are located on a white label above the rear handle. The second through fifth characters of the serial number identify the manufacturing date. The second character is the month with A= January, B= February, C = March, etc. The third and fourth characters are the day of the month. The fifth character is the last digit of the year of manufacture (e.g. B196 = February 19, 2016).

The chainsaws were sold at Ace Hardware, Atwoods, Orchard Supply Hardware

and Sears and online at OSH.com and Sears.com from February 2016 through July 2016 for between \$160 and \$280. Consumers should immediately stop using the recalled chainsaws and contact MTD Southwest's Craftsman recall line for instructions on obtaining a free replacement chainsaw. Contact MTD Southwest's Craftsman recall line toll-free at 866-864-2949 from 8 a.m. to 5 p.m. ET Monday through Friday or online at www.craftsman.com and click on the Customer Care tab and then on Product Recalls under Warranty and Returns. Photos available at <https://www.cpsc.gov/Recalls/2017/Craftsman-Brand-Chainsaws-Recalled-by-MTD-Southwest>

GREE REANNOUNCES DEHUMIDIFIER RECALL FOLLOWING 450 FIRES AND \$19 MILLION IN PROPERTY DAMAGE

Gree Electric Appliances, of China, has recalled about 2.5 million Dehumidifiers in the United States. In addition, 55,000 were sold in Canada. This recall was first announced in September 2013, updated in October 2013 and expanded in January 2014. The dehumidifiers can overheat, smoke and catch fire, posing serious fire and burn hazards to consumers. This recall involves 20, 25, 30, 40, 45, 50, 65 and 70-pint dehumidifiers with brand names Danby, De'Longhi, Fedders, Fellini, Frigidaire, GE, Gree, Kenmore, Norpole, Premiere, Seabreeze, SoleusAir and SuperClima. The brand name and the pint capacity are printed on the front of the dehumidifier. The model number and date code are printed on a sticker on the back, front or side of the unit. The dehumidifiers are white, beige, gray or black plastic and measure between 19 and 24 inches tall, 13 and 15 inches wide, and 9 and 11 inches deep. View model information here: <https://www.cpsc.gov/Recalls/2017/Gree-Reannounces-Dehumidifier-Recall-Following-450-Fires-and-19-Million-in-Property-Damage>. There have been more than 2,000 reported incidents of dehumidifiers overheating. About 450 fires have been reported, resulting in more than \$19 million in property damage.

The dehumidifiers were sold at AAFES, HH Gregg, Home Depot, Kmart, Lowe's, Menards, Mills Fleet Farm, Sam's Club, Sears, Walmart and other stores nationwide and in Canada, and online at Amazon.com and Ebay.com, from January 2005 through August 2013 for between \$110 and \$400. Consumers should immediately unplug and stop using recalled dehumidifiers and contact Gree for a full refund. Contact Gree toll-free at 866-853-

2802 from 8 a.m. to 6 p.m. ET Monday through Friday or online at www.greecusa.com and click on Recall for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Gree-Reannounces-Dehumidifier-Recall-Following-450-Fires-and-19-Million-in-Property-Damage>.

WORLD TRADING RECALLS ORBIT SELF-BALANCING SCOOTERS/HOVERBOARDS DUE TO FIRE HAZARD

World Trading, of Valencia, Calif., has recalled about 1,900 self-balancing scooters/hoverboards. The lithium-ion battery packs in the self-balancing scooters/hoverboards can overheat, posing a risk of smoking, catching fire and/or exploding. This recall involves Orbit brand self-balancing scooters/hoverboards. The hoverboards have two wheels at either end of a platform and are powered by lithium ion battery packs. Orbit brand hoverboards were sold in the following six colors: black, blue, gold, green, red and white. "Orbit" is printed on a black sticker on the underside of the hoverboard.

The hoverboards were sold at Evine's televised shopping programs and online at evine.com in December 2015 for about \$300. Consumers should immediately stop using these recalled products and contact World Trading to exchange their hoverboard for a free UL-certified replacement hoverboard. Contact World Trading toll-free at 877-498-8697 from 9 a.m. to 5 p.m. PT Monday through Friday or email support@worldtrading23.com for more information. Photos available at: <https://www.cpsc.gov/Recalls/2017/World-Trading-Recalls-Orbit-Self-Balancing-Scooters-and-Hoverboards>

IMUSA RECALLS ESPRESSO MAKERS DUE TO IMPACT AND BURN HAZARDS

About 17,500 Espresso makers have been recalled by IMUSA USA, LLC, of Doral, Fla. The filler cap at the top of the unit can crack and allow steam to escape, posing a risk of burns to the user. In addition, the cap can pop off unexpectedly as a result of pressure buildup, posing an impact injury risk to a bystander. This recall involves IMUSA espresso makers. The black or gray and black espresso makers have model numbers GAU-18200 and GAU-18201. The caps on the recalled espresso makers have date codes "201407" to "201411" The model number and date code are printed on a rating label on the bottom of the espresso maker. "IMUSA" is printed on the on front of the espresso

maker. The company has received 43 incidents including one report of a consumer who sustained burns to his hand from steam escaping through a crack in the cap.

The makers were sold at Kmart, Sears, Target and other stores nationwide from July 2014 through November 2014 for between \$30 and \$45. Consumers should immediately stop using the recalled espresso makers and contact IMUSA for a free replacement filler cap. Contact IMUSA toll-free at 844-750-4165 from 8:30 a.m. to 5 p.m. PT Monday through Friday, email at recall@bowlesverna.com or online at www.imusausa.com and click on "Recall" at the top of the page for more information. Photos available at: <https://www.cpsc.gov/Recalls/2017/IMUSA-Recalls-Espresso-Makers>.

LED LAMPS RECALLED BY TECHNICAL CONSUMER PRODUCTS DUE TO ELECTRICAL SHOCK HAZARD

Technical Consumer Products Inc., of Aurora, Ohio, has recalled about 39,000 Technical Consumer Products (TCP) LED lamps. The lamps can overheat exposing an energized heat-sink and wires, posing an electrical shock hazard. This recall involves 10 watt LED A19 Shape lamps sold under the TCP brand name. These lamps are white and produce a soft white (2700 Kelvin) color temperature. Recalled units have item number "LED10A19 DODLCHP" and the date code printed directly on the white plastic heat-sink of the lamp, just above the screw in the base. Consumers will need to shut off power to the lights and disengage the lamp to check the item number and date code. More information available here: <https://www.cpsc.gov/Recalls/2017/LED-Lamps-Recalled-by-Technical-Consumer-Products>

The lamps were sold exclusively at Habitat for Humanity of San Joaquin County in Stockton, Calif. from August 2016 through September 2016 for about \$3. Consumers should immediately stop using recalled lamps, shut off power to lights and contact TCP for instructions on receiving a refund or a free replacement lamp. Contact TCP at 800-324-1496 from 8 a.m. to 5 p.m. ET Monday through Friday, or email at recall@tcpi.com or online at www.tcpi.com and click on "Recall" for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/LED-Lamps-Recalled-by-Technical-Consumer-Products>

VALSPAR RECALLS WOOD CLEANER AND WOOD BRIGHTENER PRODUCTS DUE TO CHEMICAL HAZARD

About 10,300 Cabot wood cleaner and wood brightener products have been recalled by The Valspar Corporation, Cabot brand owner, of Minneapolis, Minn. A faulty cap seal can cause the containers to leak contents, posing a chemical hazard to consumers. Inhaling, ingesting or skin contact with the product can cause burning and other injuries. This recall involves Cabot-branded wood cleaner and wood brightener products, sold in one gallon (3.78 L) white bottles with a handle that are about 9 inches tall. The bottles have the Cabot logo and the name of the product on the front. Products included in the recall have the following badge alphanumeric identifier printed on the back of bottle: More information available here: <https://www.cpsc.gov/Recalls/2017/Valspar-Recalls-Wood-Cleaner-and-Wood-Brightener-Products>.

The wood cleaners were sold at Menards in Minnesota, North Dakota and Wisconsin in August 2016 for about \$10. The wood brighteners were sold at Blain Supply, Do It Best, L&M Fleet Supply, Menards and Orgill in California, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, North Carolina, North Dakota and South Dakota from August 2016 through September 2016 for about \$15. Consumers should stop using the recalled products and keep them away from children and immediately contact Valspar for disposal and refund instructions. Contact Cabot Stains toll-free at 877-755-3336 from 8 a.m. to 8 p.m. ET or online at www.cabotstain.com and click on the Information on Cabot Cleaner and Brightener Recall link at the top of the page. Photos available here: <https://www.cpsc.gov/Recalls/2017/Valspar-Recalls-Wood-Cleaner-and-Wood-Brightener-Products>

SUMMIT RECALLS CLIMBING TREESTANDS DUE TO FALL HAZARD

Summit Treestands LLC, of Decatur, Ala., has recalled about 270 climbing treestands. A weld in the treestand's frame can break during use, posing a fall hazard. This recall involves Summit Treestands Explorer SD closed front climbing treestands used for hunting. The treestands have a metal frame, a suspended foam-padded seat in a camouflage pattern material and weighs about 20 pounds. The seat platform on the stand measures about 38 inches long by 22 inches wide and the foot platform on the stand measures 36 inches

long by 20 inches wide. The recalled stand can be distinguished from other models by the size of the platform and by a bar that encircles the user and folds down flat for packing. The model also includes folding stirrups.

The tree stands were sold at sporting goods stores nationwide during August 2016 for about \$360. Consumers should immediately stop using the climbing tree-stands and contact Summit for instructions on returning the recalled product for a free replacement. Contact Summit Tree-stands toll-free at 800-353-0634 from 8 a.m. to 5 p.m. CT Monday through Friday, or online at www.summitstands.com and click on recalls for more information. Photos available at: <https://www.cpsc.gov/Recalls/2017/Summit-Recalls-Climbing-Treestands>.

BARNETT OUTDOORS RECALLS CROSSBOWS DUE TO INJURY HAZARD

Barnett Outdoors LLC, of Tarpon Springs, Fla., has recalled 3,300 Crossbows. The sensor that senses whether an arrow is properly loaded can malfunction, which can cause the crossbow to fire unexpectedly, posing an injury hazard to the user or bystander. This recall involves six models of Barnett crossbows that can be identified by their model numbers printed on the limbs of the riser and dome label on the bow. Name of products available here: <https://www.cpsc.gov/Recalls/2017/Barnett-Outdoors-Recalls-Crossbows>. Barnett has received three reports of the crossbow firing unexpectedly, resulting in one report of a hand laceration.

The crossbows were sold at Cabela's, Bass Pro Shops, Dicks Sporting Goods and other retailers and dealers nationwide from April 2016 through November 2016 for between \$800 and \$1,600. Consumers should immediately stop using the recalled crossbows and contact the company for a free replacement trigger with a nock sensor. Contact Barnett Outdoors at 800-234-4907 from 9 a.m. to 5 p.m. ET or online at www.barnettoutdoors.com and click on "Crossbow Recall" for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Barnett-Outdoors-Recalls-Crossbows>

MASCO CABINETRY VOLUNTARILY RECALLS MOBILE KITCHEN ISLANDS AND FREESTANDING CABINETS

Masco Cabinetry of Ann Arbor, Michigan, has recalled their Floating Island

Base, Peninsula Floating Island Base, Chopping Block Table; freestanding base, vanity and tall cabinets with Void Toe Kick options. The recalled cabinets pose a potential tip-over hazard when the drawer(s) or roll-out tray(s) are extended. This voluntary recall involves the Floating Island Base, Peninsula Floating Island Base, Chopping Block Table, and freestanding base, vanity and tall cabinets specified with the Void Toe Kick option that are not secured to the wall or to the floor. The Floating Island Base and Peninsula Floating Island Base are wood cabinets with wood tops, and have one or more drawers and a roll-out tray and shelving behind one or more doors. Each model is on caster wheels. The models range in width from 24 inches up to 36 inches, and are 36 inches high. The Chopping Block Table is a wood cabinet on decorative legs with a wood top, and has one drawer and one open shelf. The tables range in width from 24 inches up to 42 inches, and are 36 inches high.

Also included in the recall are wood base, vanity and tall cabinets specified with the Void Toe Kick option that are not secured to the wall or the floor. The cabinets may feature doors, drawers and/or roll-out trays. This could include a variety of cabinet height and width configurations, but most cabinets subject to this recall will have casters, decorative legs, or decorative feet, and all are freestanding (i.e., movable) cabinets that are not permanently affixed to a wall or to the floor. There is one known incident of a tip over and no injury was reported.

The products were sold under the Kraft-Maid® and Merillat Masterpiece® brands. The brand names appear on the inside panel of the drawer(s). The recall includes any model numbers beginning in FIB, PFIB, or CBT; or any model number ending in -VTK. They were sold at Lowe's®, The Home Depot®, and other home-improvement retailers and kitchen and bath dealers nationwide. The Floating Island Base and Peninsula Floating Island Base were sold from 1999 through July 2016 for an average retail price of \$661 (Floating Island Base) and \$821 (Peninsula Floating Island Base). The Chopping Block Table was sold from 2000 through July 2016 for an average retail price of \$1,222. Base, vanity and tall cabinets with Void Toe Kick option were sold from March 2004 through the present for between \$98 and \$1,697. Consumers should immediately stop using the recalled cabinets and contact Masco Cabinetry for a repair kit containing parts and instructions for how to modify the product for safe use, or a full or partial refund. Masco Cabinetry

toll-free at 855-891-7076 from 8:00 a.m. to 6:00 p.m. ET Monday through Friday or anytime online at www.mascocabinetry.com/safety-notice for more information on how to receive a repair or refund.

TREK RECALLS BICYCLE LIGHTS DUE TO INJURY HAZARD

About 600 bicycle lights have been recalled by Trek Bicycle Corporation, of Waterloo, Wis. The bicycle light can operate intermittently when paired with a remote transmitter, reducing the visibility of and for the rider, posing an injury hazard. This recall involves Trek Bontrager Flare RT and Ion 700 RT bicycle lights. Both models of lights come in black. "Bontrager" and "Transmtr" are printed on the front of the Bontrager Flare RT lights and the date code is printed on the back. "Ion 700 RT," "700 Lumen" and "Transmtr" are printed on the side of the Ion 700 RT lights and the date code is printed on the bottom under the charging port cover. The recalled lights have the following date code: view at: <https://www.cpsc.gov/Recalls/2017/Trek-Recalls-Bicycle-Lights>. The company has received seven reports of the lights functioning intermittently when paired with a remote transmitter. No injuries have been reported.

The bicycles were sold at bicycle stores nationwide and online at www.trekbikes.com from July 2016 through October 2016 for between \$60 and \$240. Consumers should immediately stop using the recalled lights with a remote transmitter and return the lights to the store where purchased or contact Trek to receive a free replacement bicycle light. Contact Trek at 800-373-4594 from 8 a.m. to 6 p.m. CT Monday through Friday or online at www.trekbikes.com and click on "Safety & Recalls" at the bottom of the page for more information. Photos available at: <https://www.cpsc.gov/Recalls/2017/Trek-Recalls-Bicycle-Lights>.

YANKEE CANDLE RECALLS LUMINOUS CANDLES DUE TO LACERATION HAZARD

About 31,000 Luminous Candle Collection have been recalled by The Yankee Candle Company Inc., of South Deerfield, Mass. When the candle is lit, the glass jar can crack, posing a laceration hazard. This recall involves Yankee Candle's Luminous Collection fragrance candles. The square glass candles contain a fragrant wax with three wicks. The item number is printed on the bottom of glass candle jar. The

recalled candles are approximately 4 inches wide by 5 inches high. Item Numbers available here: <https://www.cpsc.gov/Recalls/2017/Yankee-Candle-Recalls-Luminous-Candles>. The company has received 16 reports of the glass jar cracking. No injuries have been reported.

The candles were sold exclusively at Yankee Candle stores nationwide and online at www.yankeecandle.com from September 2016 through November 2016 for about \$35. Consumers should immediately stop using the recalled candles and contact Yankee Candle to receive a full refund. Contact Yankee Candle toll-free at 877-803-6890 from 8 a.m. to 11 p.m. ET Monday through Friday, 9 a.m. to 9 p.m. ET Saturday & Sunday or online at www.yankeecandle.com and click on “Luminous Candle Collection: Safety Notice” at the top of the page for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Yankee-Candle-Recalls-Luminous-Candles>

CUISINART FOOD PROCESSORS RECALLED BY CONAIR DUE TO LACERATION HAZARD

Conair Corp., of Stamford, Conn., owner of the Cuisinart brand has recalled about 8 million Cuisinart® food processors. The food processor’s riveted blade can crack over time and small, metal pieces of the blade can break off into the processed food. This poses a laceration hazard to consumers. This recall involves the riveted blades in Cuisinart food processors with model numbers that begin with the following: CFP-9, CFP-11, DFP-7, DFP-11, DFP-14, DLC-5, DLC-7, DLC-8, DLC-10, DLC-XP, DLC-2007, DLC-2009, DLC-2011, DLC-2014, DLC-3011, DLC-3014, EV-7, EV-10, EV-11, EV-14, KFP-7 and MP-14. The model number is located on the bottom of the food processor. The blades have four rivets and are silver-colored stainless steel and have a beige plastic center hub. Only food processors with four rivets in the blades are included in this recall. Cuisinart is printed on the front and on the bottom of the food processors. Conair has received 69 reports of consumers finding broken pieces of the blade in processed food, including 30 reports of mouth lacerations or tooth injuries.

The processors were sold at department, gourmet and specialty stores nationwide and on various websites from July 1996 through December 2015 for between \$100 and \$350. Consumers should immediately stop using the food processor’s riveted blade and contact Cuisinart for a free replacement blade. Contact Cuisinart

toll-free at 877-339-2534 from 7 a.m. to 11 p.m. ET Monday through Friday and from 9 a.m. to 5 p.m. ET Saturday and Sunday or online at www.cuisinart.com and click on Product Recalls at the bottom of the page for more information on the voluntary recall. Photos available at: <https://cpsc.gov/Recalls/2017/Cuisinart-Food-Processors-Recalled-by-Conair>

ARIA CHILD RECALLS STROLLERS DUE TO LACERATION AND FALL HAZARDS

About 29,400 Qbit strollers have been recalled by Aria Child Inc. of Dedham, Mass. A gap in the stroller’s folding side hinge can pinch a caregiver’s hand during unfolding, posing a laceration hazard. In addition, the stroller can fold unexpectedly during use, posing an injury and fall hazard to the caregiver and child. This recall involves the gb Qbit lightweight stroller for children up to 50 pounds. The recalled strollers have 4 sets of two wheels, a five-point harnessed restraint system, a full-sized reclining seat, a storage basket, a removable cup holder and a travel storage bag. The strollers can also be used as a travel system with infant carriers. The strollers are mostly black with an accent color. The “gb” red box logo is printed on the harness and on both sides of the stroller legs and “Qbit” is printed in white on the stroller legs. The model number and date of manufacture are printed on a sticker on the rear leg of the stroller, directly above the wheels, next to the storage basket. Model number and the date of manufacture here: <https://www.cpsc.gov/Recalls/2017/Aria-Child-Recalls-Strollers>. The company has received five reports of consumers being pinched by the stroller hinge mechanism, resulting in four consumers needing stitches for cuts. In addition, there were 71 reports of the stroller unexpectedly folding during use, resulting in 12 minor bumps or bruises to a child or caregiver and one fractured wrist and elbow to an adult due to a fall.

The strollers were sold at Babies R US and other retail stores nationwide and Albeebaby.com, Amazon.com, Dmart-stores.com, Medbroad.com and other online retailers from May 2015 through November 2016 for about \$180. Consumers should immediately stop using the recalled strollers and contact Aria Child for a free replacement stroller. Contact Aria Child toll-free at 888-591-5540 from 8 a.m. to 5 p.m. ET Monday through Friday or online at www.ariachild.com and click on “Qbit Lightweight Stroller Voluntary Recall Information” for more information.

Photos available here: <https://www.cpsc.gov/Recalls/2017/Aria-Child-Recalls-Strollers>

CARBON EXPRESS RECALLS CROSSBOWS DUE TO INJURY HAZARD

About 3,800 Crossbows have been recalled by Eastman Outdoors Inc., dba Carbon Express, of Flushing, Mich. The crossbow can fire unexpectedly when the safety is engaged, posing an injury hazard to the user or bystander. This recall involves two Carbon Express Blade crossbows in black (model 20292) or camouflage (model 20240). Both crossbows have “Blade” printed on the sides of the bow. The bows have a half aluminum rail and a die cast riser. All models have a black pistol grip with a black butt stock and weigh about 6.5 pounds. The crossbows shoot 320fps and have a 13-inch power stroke. The model number is printed on a metallic sticker on the bottom left limb of the crossbow. The company has received one report of a crossbow firing unexpectedly, resulting in a thumb laceration.

The crossbows were sold at Bass Pro, Ellett Brothers and other hunting and sporting goods stores nationwide and online at Amazon.com and Carbonexpresscrossbows.com from July 2016 through October 2016 for between \$250 and \$300. Consumers should immediately stop using the recalled crossbow, and return them to Carbon Express to receive a free repair. Contact Carbon Express at 800-211-5982 from 8 a.m. to 5p.m. ET Monday through Friday or online at www.carbonexpresscrossbow.com and click on Resource/Blade Recall for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Carbon-Express-Recalls-Crossbows>

PUBLIX RECALLS PANCAKE AND WAFFLE MIXES OVER SALMONELLA

Publix Supermarkets is recalling some Publix Premium Pancake and Waffle Mixes after being informed by the supplier that milk powder used as an ingredient may contain Salmonella. The mixes were sold at Publix stores in Florida, Georgia, Alabama, South Carolina, Tennessee and North Carolina. All lot codes of the following items are affected by this recall:

- Publix Premium Banana-Flavored Chocolate Chip Pancake & Waffle Mix 16 Oz.

- Publix Premium Pumpkin Pancake & Waffle Mix 16 Oz.
- Publix Premium Blueberry Flavored Pancake & Waffle Mix 16 Oz.

Salmonella is a bacterium that can cause diarrhea, fever, and abdominal cramps and most individuals recover without treatment. In some cases, diarrhea may be so severe that the patient needs to be hospitalized. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness. If you have the mixes you can return them to a Publix store for a full refund or call the Customer Care Department at 800-242-1227

SCHURMAN RETAIL GROUP RECALLS GIFT BOXES DUE TO RISK OF MOLD EXPOSURE

About 8,400 VIVID Red Wine Crush Gift Boxes have been recalled by Schurman Retail Group, of Fairfield, Calif. Mold can be present on the boxes, posing a risk of respiratory or other infections in individuals with compromised immune systems, damaged lungs or an allergy to mold. This recall involves decorative gift boxes constructed with metallic decorative papercoverings. The boxes are red, packaged in a clear cellophane sealed bag and have the phrase "VIVID handmade" printed on the bottom in gold-colored ink. Model info here: <https://www.cpsc.gov/Recalls/2017/Schurman-Retail-Group-Recalls-Gift-Boxes>. The company has received nine reports of respiratory irritation from contact with the boxes.

The boxes were sold at POPYRUS, Paper Destiny and Carlton Cards Stores in October 2016 for between \$5 and \$7. Consumers should immediately stop using the recalled paper boxes and return them to POPYRUS, Paper Destiny or Carlton Cards Stores for a full refund or contact Schurman Retail Group for instructions on how to return the product. Contact Schurman Retail Group toll-free at 855-730-7998 from 7 a.m. to 4 p.m. CT Monday through Friday, or online at www.papyrusonline.com and click on "Recall Information" for more information. Photos available here: <https://www.cpsc.gov/Recalls/2017/Schurman-Retail-Group-Recalls-Gift-Boxes>

Once again there have been a large number of recalls since the last issue. While we weren't able to include all of them in this issue, we included those of the highest importance and urgency. If you need more information on any of the recalls listed above, visit our firm's web site at www.BeasleyAllen.com or www.RightingInjustice.com/Recalls. We would

also like to know if we have missed any significant recall that involves a safety issue. If so, please let us know. As indicated at the outset, you can contact Shanna Malone at Shanna.Malone@beasleyallen.com for more recall information or to supply us with information on recalls.

XXI. FIRM ACTIVITIES

LASONYA LUCAS

LaSonya Lucas has worked in our firm's Mass Torts department for 11 years. While she has stayed in the same section all of these years, she is now a Legal Secretary and received her bachelor's degree from Troy University.

LaSonya has been married to her husband Tyrone Lucas for seven years and has had two sons with him—Lathan, 5, and Teagan, 3. She enjoys being active at the family's church and her son's school, as well as spending time with her friends and family.

LaSonya is a very good employee. She works hard, is totally dedicated, and is an asset to the firm. We are blessed to have her with us.

MELINDA HENDERSON

Melinda Henderson, in July 2009, began her career in Beasley Allen's Personal Injury & Products Liability Section as a clerical assistant. Nearly seven years later, Melinda now works as the Legal Secretary to Greg Allen—the firm's Lead Products Liability lawyer.

Melinda graduated from Troy University with a B.S. in Broadcast Journalism and a minor in Public Relations. She is also the proud mother of one son, Nicolas, who is 13 years old and who attends Johnnie Carr Middle School. In her spare time, Melinda enjoys reading, traveling and spending time with her son, especially on their annual trip to Disney World.

Melinda is a dedicated and hard-working employee who says she really enjoys her work. She has been involved in some very high profile product liability litigation in her job. We are fortunate to have Melinda with us.

XXII. SPECIAL RECOGNITIONS

SPECIAL LAWYER AWARDS PRESENTED AT BEASLEY ALLEN CHRISTMAS PARTY

Annually, our firm recognizes lawyers whose work has been exceptional and productive for clients during the year. The lawyers recognized are selected by our board. This year there were a huge number of lawyers in play and it was very difficult to select the winners. However, after a great deal of study and consideration, the choices were made.

Litigators Of The Year

Beasley, Allen, Crow, Methvin, Portis & Miles, P.C., announced that Ted Meadows and Rhon Jones were selected as the firm's Litigators of the Year for 2016. The annual recognition is presented to the lawyer who demonstrates exceptional professional skill throughout the course of the year and best represents the firm's ideal of "helping those who need it most." This year two lawyers were selected. Ted Meadows practices in the firm's Mass Torts Section and has been key in leading the litigation against Johnson & Johnson for ovarian cancer illnesses and deaths related to the company's talcum powder products. Rhon Jones is head of the firm's Toxic Torts section, and headed up the massive litigation related to the BP oil spill.

Lawyers Of The Year

In addition to selecting the overall "top lawyers," Beasley Allen recognized excellence in each of its sections. The Beasley Allen Lawyer of the Year was named in each Section. Honorees for 2016 are Chris Glover, Personal Injury Lawyer of the Year; LaBarron Boone, Products Liability Lawyer of the Year; Archie Grubb, Fraud & Commercial Litigation Section Lawyer of the Year; David Dearing and Danielle Ward Mason, Mass Torts Section Lawyers of the Year; and John Tomlinson, Toxic Torts Section Lawyer of the Year.

We have extremely talented lawyers working at the firm. The lawyers who were recognized this year have displayed outstanding abilities and talents in their profession. We are blessed to have them as part of our team. Part of what makes these lawyers successful is their appreciation that our work is a team effort, and that they couldn't do what they do without the

support of their fellow lawyers and staff at the firm. To be honored in this manner his is a recognition that is well-deserved.

The Chad Stewart Award

In addition to the professional awards given each year, our Board of Directors elect to recognize a lawyer each year in memory of Beasley Allen lawyer Chad Stewart, who passed away in 2014. "The Chad Stewart Award" was established by the firm to recognize a lawyer who best exemplifies Chad's spirit of service to God, his family and the practice of law in the task of "helping those who need it most." The 2016 Chad Stewart Award was presented to Roman Shaul. Roman practices in the firm's Consumer Fraud & Commercial Litigation Section, and Roman worked alongside Chad in their Section and actually worked on important cases together. Roman is a lawyer dedicated to his clients, and focused on helping others. He is certainly deserving of this award.

XXIII. FAVORITE BIBLE VERSES

One of our lawyers, Parker Miller, sent in a statement he reads frequently, along with a verse for this issue. The statement reads as follows:

Resolve to be tender with the young, compassionate with the aged, sympathetic to the striving, and tolerant with the weak and the wrong. Sometimes in life you will have been all.

The verse below ties directly into this statement:

Carry each other's burdens, and in this way you will fulfill the law of Christ. Galatians 6:1-5.

Janie Cantey, who is working as a staff assistant in our Mass Torts Section, supplied a verse along with an explanation of why it's so special to her. With her permission, I will give her reasons. First, let's read the scriptures she supplied.

Peace I leave with you; my peace I give you. I do not give to you as the world gives. Do not let your hearts be troubled and do not be afraid. John 14:27

This is what Jamie had to say:

I have had so much heartache in my life over the past two years and this verse gives me such peace when I turn to it. I know God led me to it when He knew I needed it the most. When I was a baby, my grandparents adopted me and raised me as their own. February 2015, my "father" gave up his fight for his earthly life and journeyed to his real "Home." I was brokenhearted, along with my "mother." Little did we know that just 14 months later, she would join him. The pain I felt when I got the call that she had passed away was immeasurable. Mother lived in Mobile and had spent the 17 days before that with me and had not been sick or anything. Her heart just stopped beating while she sat in her chair the day after I took her home. This verse helps me because I have been troubled by her death and I know that God sent this verse to me at the right time to remind me that I will see her again one day and so every time I read it I become less and less afraid and look forward to our reunion!

But Jesus looked at them and said to them, 'With men this is impossible, but with God all things are possible. Matthew 19:26

This has been my go-to verse for many, many years! Being given up by my birth parents. I have always had very low self-esteem and self-worth. I grew up thinking my parents did not love me and wondered why. I felt like I was not good enough or worthy of their or anyone else's love. It took me 30-something years to figure out that they did love me. They loved me enough to know that they were not capable of giving me the life I deserved. They were very young and wild and knew nothing about raising a child. Even though I finally figured that out, it did not really help with my self-esteem issues. They were already too imbedded in me. Through the years it has gotten somewhat better because I have had this verse to go to....and the love of a wonderful husband, children and my "parents" or grandparents, as some would call them. But I still go to this verse when I need reminding that I CAN do ALL things through Christ and that I AM worthy because I AM worthy of HIS love and at the end of the day, my

heart's desire is to bear, "Well done, my good and faithful servant."

Chris Glover, one of the lawyers in our firm who will be in our Atlanta office, supplied scriptures for this issue. Chris was teaching on this group of scriptures when he was asked by our board if he was interested in moving to Atlanta to open our Atlanta office. Chris says he knows God planned that so he would be open to His calling. Chris says "wherever He leads, I will follow."

Now listen, you who say, Today or tomorrow we will go to this or that city, spend a year there, carry on business and make money. Why, you do not even know what will happen tomorrow. What is your life? You are a mist that appears for a little while and then vanishes. Instead, you ought to say, "If it is the Lord's will, we will live and do this or that." James 4:13-15 New International Version (NIV)

XXIV. CLOSING OBSERVATIONS

PORTION OF HIGHWAY 431 NAMED "GENERAL EDWARD F. CROWELL HIGHWAY"

A portion of Highway 431 in Russell County was recently renamed in honor of Edward F. Crowell, a decorated serviceman and a celebrated businessman and a very good friend of this writer. I have known the honoree since the early 1970s and can attest to the fact that Ed Crowell is an outstanding person and worthy of this honor.

The road between mile markers 91 and 98 on Highway 431 now boasts signage identifying the section of highway as the General Edward F. Crowell Highway in honor of its namesake, "who has made the lives of his fellow citizens better and has brought honor and respect to Alabama through his tireless and dedicated contributions to this state and the country," according to the state legislature's joint resolution approving the naming.

Ed served 35 years in the United States Air Force, becoming a Brigadier General in 2004. He retired from the USAF in 2009 after serving as Commandant of the Air War College and Vice Commander of Air University, both located at Maxwell Air Force Base in Montgomery. He has

received numerous awards for his service, including the U.S. Air Force Distinguished Service Medal, the third highest honor given by the service branch. He has also received the Legion of Merit, Meritorious Service Medal, Air Force Commendation Medal, Air Force Achievement Medal, National Defense Service Medal, Global War on Terrorism Service Medal, Air Reserve Forces Meritorious Service, Air Force Longevity Service, Air Force Outstanding Unit Award, Armed Forces Reserve Medal with Silver Hour Glass, Joint Meritorious Unit Award, Small Expert Marksmanship Ribbon and Air Force Training Ribbon.

Ed has worked as a civilian for more than 20 years at VT Miltope, a technology company for military, industrial and commercial aviation applications. He is currently its president and CEO and is universally respected for his leadership and work.

In addition, he was appointed by former Gov. Bob Riley as a Trustee to the Troy University Board and was appointed by Gov. Robert Bentley to the State Health Planning and Development Agency's Certificate of Need Review Board and the Commission for Efficiency in State Government.

Ed received his bachelor's from Alabama State University, a master's of business administration from Troy State University, and during his military service, received degrees from the Squadron Officer School, the Air War College and the Air Command and Staff College.

As a young man, Ed says he journeyed daily along Highway 431 to work with his brother in the textile industry in Columbus, Ga., "never envisioning that one day this highway would bear my name." Ed had this to say of the recognition:

I am deeply humbled and truly honored that a highway of any sorts would bear my name, particularly one as well traveled as Highway 431. I have never aspired anything other than doing my duty for God and Country, expecting nothing in return.

To officially commemorate the honor, a sign bearing the highway's new name was unveiled on Dec. 16. We all will run into

"special people" during our lives and Ed Crowell is certainly one of those persons for me. I am very proud of my friend and wish him well in all of his future endeavors.

Sources: U.S. Air Force Biographies, AL-SJR94, Alabama Ethics Commission

XXV. OUR MONTHLY REMINDERS

If my people, who are called by my name, will humble themselves and pray and seek my face and turn from their wicked ways, then will I hear from heaven and will forgive their sin and will heal their land.

2 Chron 7:14

All that is necessary for the triumph of evil is that good men do nothing.

Edmund Burke

Woe to those who decree unrighteous decrees, Who write misfortune, Which they have prescribed. To rob the needy of justice, And to take what is right from the poor of My people, That widows may be their prey, And that they may rob the fatherless.

Isaiah 10:1-2

I am still determined to be cheerful and happy, in whatever situation I may be; for I have also learned from experience that the greater part of our happiness or misery depends upon our dispositions, and not upon our circumstances.

Martha Washington (1732—1802)

The only title in our Democracy superior to that of President is the title of Citizen.

Louis Brandeis, 1937
U.S. Supreme Court Justice

The dictionary is the only place that success comes before work. Hard work is the price we must pay for success. I think you can accomplish anything if you're willing to pay the price.

Vincent Lombardi

XXVI. PARTING WORDS

My prayer is for all of you to have a good, healthy, prosperous and blessed New Year. Many Americans have made New Year's resolutions and I suspect some have already been broken. I have a suggestion that will work much better for you than making resolutions for the New Year.

I have mentioned before the message I give to all new lawyers who come to work at our firm. It's so important that I will mention the message again. It's a good way for us to prepare for the New Year. The message deals with setting our priorities for all areas in our life.

We all need to set priorities in our lives. Putting God first in all things—with our families next in line, followed by our work—is absolutely necessary. Don't worry about your work being in third place. When God is truly your top priority, the other two areas will be taken care of for sure. Those priorities are not just for lawyers, but are needed for everybody regardless of their profession or occupation.

When we let our priorities get out of kilter, problems will always follow. The problems may not show up right away, but rest assured in time they will surely come. We all need to be reminded of the need to set and keep the proper priorities in our lives, I will wind up 2016 and start 2017 by saying:

May God bless each of you and your family during 2017.

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