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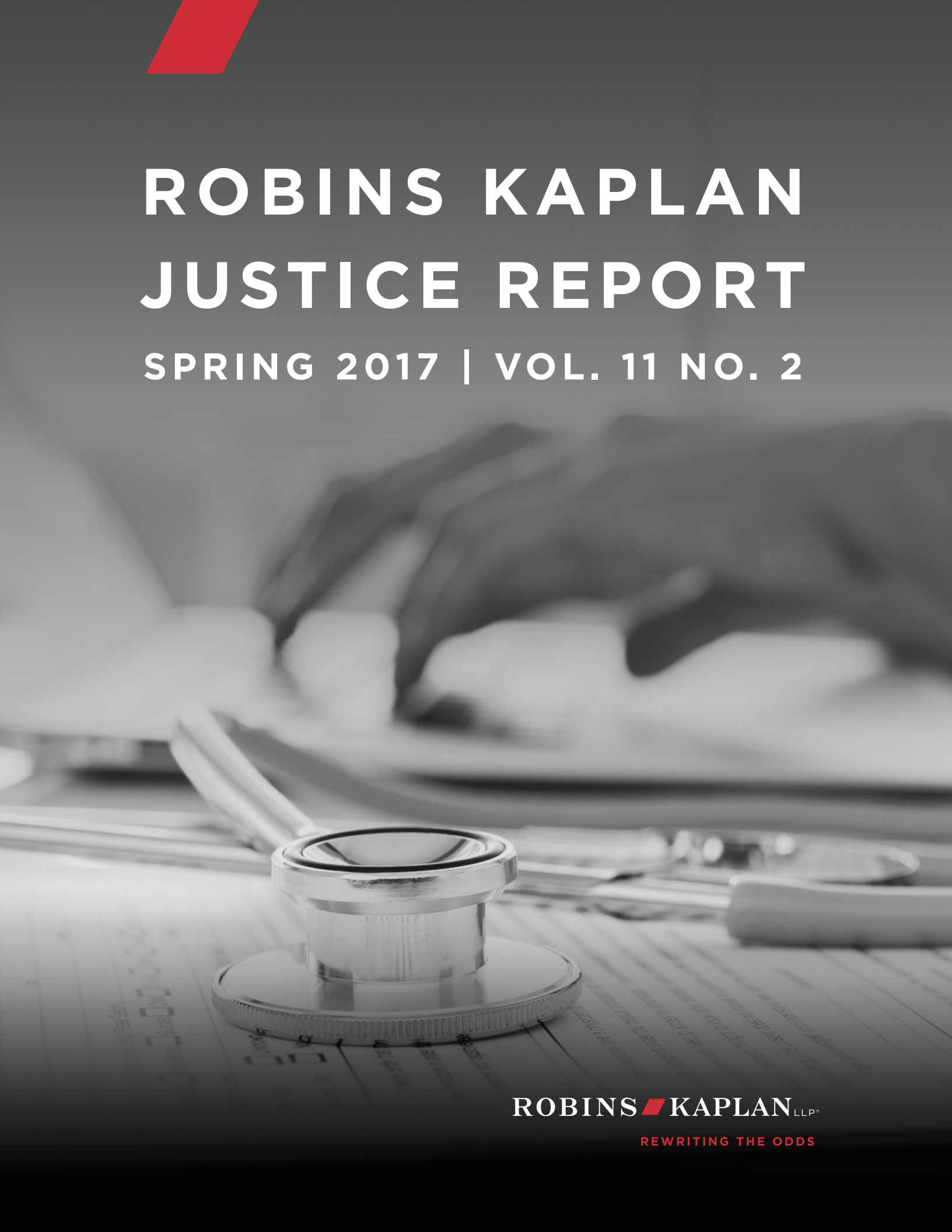


ROBINS KAPLAN LLP®

REWRITING THE ODDS

INSIDE THIS ISSUE

MEDICARE SET-ASIDES

BY COLIN PETERSON AND TERESA FARISS MCCLAIN

COLIN PETERSON

TERESA FARISS MCCLAIN

At Robins Kaplan LLP, we often represent individuals who have suffered catastrophic injuries that will require ongoing medical care for the rest of their lives. Our primary objective in resolving these cases is to ensure our clients will have the resources they need to access the best care possible and meet all of their future needs. When representing injured clients facing future healthcare needs, we must fully understand how a settlement may affect the client's eligibility to receive healthcare benefits from government programs.

For clients receiving Medicare benefits, the legal landscape may be shifting. A recent announcement issued by the Centers for Medicare & Medicaid Services ("CMS") signals an intention to expand enforcement of existing federal regulations. These enforcement actions would affect all Medicare beneficiaries who settle liability claims (i.e., medical malpractice or personal injury claims) that include compensation for future medical expenses.

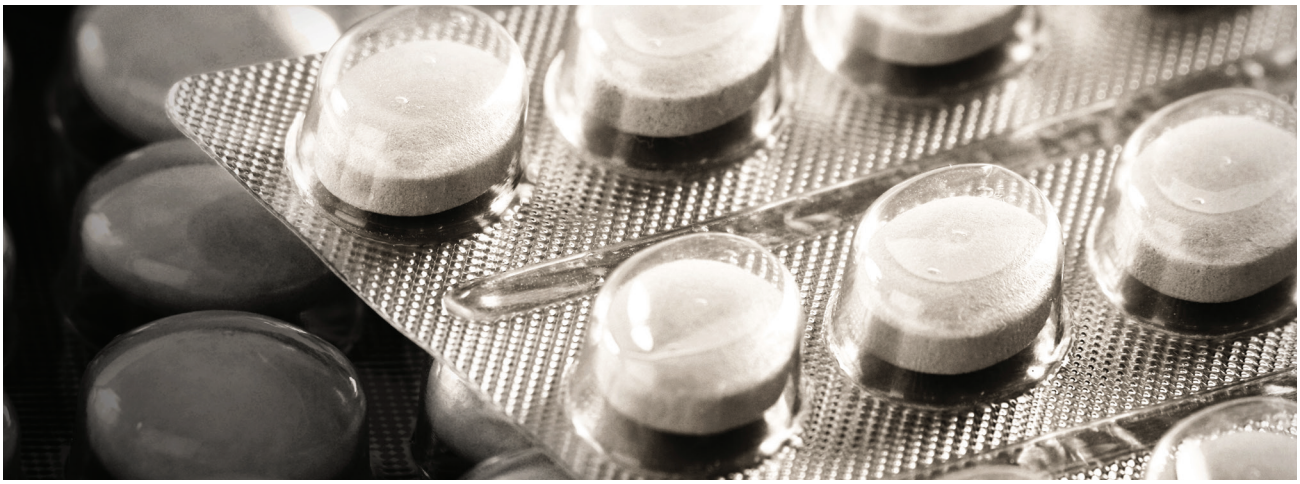
Existing federal law requires that plaintiffs who receive Medicare benefits and settle lawsuits have a duty to protect Medicare's future interests. A mechanism frequently used to protect Medicare's future interests is the creation of a Medicare Set Aside Fund (MSA)—a dedicated fund established at the time of settlement for the purpose of paying for future medical care needs that Medicare otherwise would have covered when those future needs are related to the client's injuries.

For reasons explained below, plaintiff attorneys have generally taken the position that there is no requirement to establish MSAs in liability cases. CMS's proposed policy change, therefore, would impose yet another obstacle for attorneys to overcome in attempting to resolve medical malpractice or personal injury cases. Though vigorous lobbying efforts are expected in opposition to this change, attorneys should prepare to deal with the consequences if CMS enforces these actions and implements the related regulations.

Attorneys representing Medicare beneficiaries in liability cases must understand how the program functions, and they must understand the relevant federal regulations and other guidance that will define their legal duties under the program. With this knowledge, we can properly advise our clients on how best to use their settlement proceeds to pay for future care costs while at the same time avoiding the risk of any adverse action by the federal government.

IS YOUR CLIENT A MEDICARE BENEFICIARY?

Medicare is one of the largest programs in the federal government and provides benefits to over 55 million Americans. Though it is often thought of as a program meant only for Americans aged 65 or older, Medicare covers people of all ages with certain disabilities. Accordingly, there is a high likelihood that a client in a personal injury or medical malpractice case will be enrolled in the Medicare program and therefore subject to its rules and regulations. Even if your client is not a beneficiary at the time of settlement, the fact that they may become one in the future will also require consideration of Medicare's interests whenever the client requires future care.



HOW DOES MEDICARE DECIDE WHO PAYS FOR YOUR CLIENT'S FUTURE MEDICAL CARE?

In 1980, Congress enacted the Medicare Secondary Payer Act (MSPA) as a strategy to reduce spending and protect the financial stability of the Medicare program. The MSPA provides that Medicare may not make payment where "payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan . . . or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance." The MSPA therefore made Medicare a "secondary payer" when the beneficiary has other insurance coverage that would pay for future care needs.

Then, in December 2007, Congress enacted the Medicare, Medicaid and SCHIP Extension Act, adding mandatory reporting requirements regarding Medicare beneficiaries who receive settlements or other payments from liability insurance, no-fault insurance, or workers' compensation. See 42 U.S.C. 1395y(b) (Section 1862(b) of the Social Security Act) and 42 C.F.R. Part 411. An organization required to report under Section 111 is referred to as a responsible reporting entity (RRE).

RREs include liability insurers, no-fault insurers, and workers' compensation plans and insurers. RREs may also be organizations that are self-insured with respect to liability insurance, no-fault insurance, and workers' compensation. The passage of this legislation enabled CMS for the first time to track settlements on behalf of beneficiaries. Medicare then used this information to determine when it should assume secondary- payer status and could withhold benefits in accordance with the MSPA.

WHAT GUIDANCE HAS CMS GIVEN TO ATTORNEYS WHO REPRESENT MEDICARE BENEFICIARIES?

CMS has a statutory obligation to ensure that Medicare does not unnecessarily assume the role of primary payer for a beneficiary party to a lawsuit who has received a settlement that includes funding for future medical expenses. As such, CMS will require such settlements to include MSAs in certain circumstances.

CMS defines an MSA as a "financial agreement that allocates a portion of [a client's settlement proceeds] to pay for future medical services" related to their injuries that were the subject of their lawsuit. CMS requires depletion of MSA funds before Medicare will pay for services related to those injuries.

Two types of Medicare set-aside procedures currently exist: one for workers' compensation cases and another for liability claims. Beginning in 2001, CMS issued a series of memos further defining Medicare Set Asides in Workers Compensation (WCMSA) cases. CMS has also organized a structured approval process for these allocations. Attorneys who settle workers' compensation cases can follow this process to ensure their compliance with federal regulations.

Attorneys who handle liability cases, however, face some uncertainty, given the fact that CMS has not issued any binding guidance on Liability Medicare Set Asides (LMSAs). Specifically, CMS has not established any formal approval process for LMSAs, nor will CMS even agree to review proposed LMSAs.

One of the few issues that has been settled with respect to LMSAs is that they are not required where a beneficiary will not require any future medical care related to their injuries. In September 2011, CMS's Financial Services Group issued a memo stating that Medicare would consider its interests satisfied if a beneficiary's treating physician certified in writing that (1) the treatment for an injury related to a liability insurance settlement had been completed as of the date of the settlement and (2) future medical treatment would not be required.

Despite some informal statements from CMS personnel regarding LSMAs for clients with future care needs, it is unclear which jurisdictions, if any, should follow that guidance. CMS is divided into 10 regional offices, and only one has issued any formal guidance on LMSAs. A CMS regional coordinator for Region 6 in Dallas, Texas, issued a memo in 2011 stating their belief that the plaintiff bears the responsibility in liability cases to address the MSA issue. The memo further stated that the defendant bears the responsibility to report settlements under Section 111 reporting. Because this memo reflects only one person's opinion, however, attorneys remain without any legally binding direction for handling LSMAs.

WHAT IS THE FUTURE OF LMSAS?

Earlier this year, CMS issued Change Request 9893, explaining to private healthcare insurance companies that, beginning in October 2017, it would start to track the existence of LMSAs and deny payments for medical services that CMS concludes should be paid by LMSAs. In other words, beneficiaries who receive compensation resulting from someone else's negligence may soon experience a denial of Medicare coverage for negligence-related medical care.

Unfortunately, Change Request 9893 fails to provide any guidance to attorneys on how to ensure that their clients can avoid the denials of Medicare coverage that will result from this new policy. Among other issues, CMS has not announced whether this policy would have any retroactive effect, has not explained how the process of LMSA approval would work, and has provided no guidance whatsoever on the criteria it would use to evaluate whether a particular LMSA would be approved. Attorneys who represent Medicare beneficiaries in personal injury or medical malpractice cases should be on the lookout for further guidance on these and other issues in the coming months.

Though many questions remain, this much is clear: If CMS moves forward with enforcement of LMSAs, there will be an increased risk for both plaintiff's attorneys and their clients, and settling liability claims will become more difficult. Because of the mandatory reporting requirements, Medicare will be on notice of any liability settlement and the ICD codes that may be related to the plaintiff's injuries. That could trigger a denial of care and a lengthy internal appeals process before Medicare payments could be reinstated by a Federal District Court. In addition, plaintiff's counsel may face legal malpractice risks if they fail to properly advise their Medicare eligible client regarding the LMSA issue. It is therefore incumbent upon plaintiff's attorneys to consider Medicare's future interest, determine whether an LMSA is required, educate their client on the issues, and then document the steps taken to comply with the Medicare requirements.

Because liability cases often resolve for a compromised amount, LMSAs could end up accounting for a disproportionately large percentage of a plaintiff's settlement proceeds. And given the uncertainty involved in predicting future care needs, there is a risk that more money will be set aside than is actually needed for future negligence-related medical care. Whether these excess funds would be available to a plaintiff remains an open question. If LMSAs result in a drastic reduction of a plaintiff's ability to access settlement funds, liability cases will inevitably become more difficult to settle. While the policy underlying LMSAs—cost shifting from Medicare to a negligent party—may be sound, the reality is that it may prevent injured people from obtaining the justice that they deserve.

SELECTED CASE RESULTS

$1.3 MILLION SETTLEMENT FOR FAILURE TO DIAGNOSE INTERNAL BLEEDING

PETER SCHMIT

COLIN PETERSON

Peter Schmit and Colin Peterson settled a wrongful death case against a northern Minnesota hospital that failed to diagnose and treat massive internal bleeding in a 50-year-old woman following a routine back surgery. The hospital did not have the ability to repair the bleeding even though it was a known risk of the surgery. By the time the bleeding was diagnosed, there was very little time to accomplish the necessary transfer to another facility where the bleeding could be stopped. The transfer was frantic, chaotic, and ultimately the woman did not arrive at the accepting facility in time to save her life. This settlement, combined with a previous settlement that had been obtained against the surgeon who performed the surgery, resulted in a total recovery of $1.3 million on behalf of the woman's family.

JUSTICE FOR FOUR-YEAR-OLD BOY WHO LOST HIS MOTHER

CHRIS MESSERLY

PHILIP SIEFF

ELIZABETH FORS

Megan was a 24-year-old single mother to Brayden, age four. She was on her way to work one icy morning, when her vehicle was struck by another car on I-94 in the northern Twin Cities suburbs. Her car was sent careening into a construction crane that was parked too close to the freeway. The crane decapitated her. We sued the construction project's general contractor as well as the company responsible for leaving the crane in a dangerous position. We settled with these two companies, the driver who started the chain of events, and Megan's own underinsured motorist carrier. Economic loss was less than $400,000. In addition to her little boy, Megan's parents, brother, sister, and grandfather survive her. The $1,655,000 settlement will help provide for little Brayden's future.

$7.3 MILLION SETTLEMENT FOLLOWING INADEQUATE POST-OPERATIVE MONITORING

BRANDON THOMPSON

Brandon Thompson recently settled a malpractice case that involved a 35-year-old father of three who died mysteriously less than 12 hours after having gallbladder surgery. The autopsy gave no clues, simply concluding that there was "no anatomical cause of death." After an extensive investigation, Brandon and his team learned the man had died from "opioid-induced respiratory depression" – he had received significant but certainly not toxic levels of pain medication in the overnight hours, was left unmonitored, and slipped into a deep sleep from which he never woke up. Brandon and his team proved that the hospital's policies governing post-operative monitoring were inadequate, and that the staff had violated even the inadequate education and training that the hospital had provided.

The case settled shortly before trial for $7.3 million, providing future financial security for the man's wife and three young children.

MASS TORT NEWS

GARY WILSON, TARA SUTTON, AND MUNIR MEGHJEE APPOINTED TO ABILIFY MDL LITIGATION LEADERSHIP

In December 2016, Chief Judge M. Casey Rodgers of the Northern District of Florida appointed three Robins Kaplan partners to the leadership team in the Abilify Compulsivity Cases multidistrict litigation ("MDL"). Gary Wilson is the plaintiffs' co-lead counsel and a member of the plaintiffs' Executive Committee, Tara Sutton is a member of the Joint Settlement Committee, and Munir Meghjee is the plaintiffs' federal/state liaison counsel.

Abilify is prescribed to treat a variety of disorders, including schizophrenia, irritability, agitation, depression, and mania. The Abilify Compulsivity litigation involves claims that Abilify distorts the reward-seeking behaviors in patients, causing them to compulsively gamble or engage in other compulsive activities, such as hyper-sexuality, compulsive shopping, and binge eating. In August 2016, FDA ordered that the Abilify label include warnings about these behaviors.

HOLLY DOLEJSI APPOINTED TO INVOKANA MDL LITIGATION LEADERSHIP

In January 2017, Judge Brian R. Martinotti of the District of New Jersey appointed Robins Kaplan associate Holly Dolejsi to the Plaintiffs' Steering Committee for the Invokana MDL.

Invokana, a drug used to treat Type 2 diabetes, has been linked to diabetic ketoacidosis, a serious condition characterized by high levels of acid in the blood, which can lead to coma or death if untreated. Symptoms that may indicate the onset of ketoacidosis include nausea, vomiting, abdominal pain, tiredness, and trouble breathing. Ketoacidosis may be present even if a patient's blood glucose levels are not very high. In December 2015, the FDA required the Invokana manufacturer to warn about the risk of ketoacidosis on its label, after reviewing the adverse events of ketoacidosis and noting that all patients required hospitalization or emergency treatment.

KATE JAYCOX APPOINTED CO-LEAD OF AAJ'S STOCKERT 3T HEATER-COOLER DEVICE LITIGATION GROUP

In February 2017, Robins Kaplan principal Kate Jaycox was appointed co-lead of the American Association for Justice's (AAJ) newly formed litigation group concerning the Stöckert 3T heater-cooler device. The goal of the group is to cooperatively litigate and to educate other attorneys who may represent clients harmed by the 3T device.

Heater-cooler devices are designed to regulate a patient's body temperature during open-chest surgeries. According to the FDA and CDC, the Stöckert 3T heater-cooler device may have been contaminated during manufacturing, which could put patients at risk for nontuberculous ("NTM") infections, which are rare, very difficult to treat, and life-threatening. One type of slow-growing NTM infection associated with the device can take up to five years to develop after exposure during surgery. The Stockert 3T heater-cooler device is used in about 60% of hospitals, and over the past several months, many hospitals have sent out warning letters to patients who have been exposed to this device during surgery over the past five years.

OTHER DRUG AND DEVICE INVESTIGATIONS

Robins Kaplan LLP is currently investigating many new potential cases. Please contact our Mass Tort team if you have any questions or know of any individuals whose case should be evaluated.

- **Abilify** – This atypical antipsychotic—used to treat a variety of disorders, including schizophrenia, bipolar, and depression—may cause impulse-control behaviors, including compulsive gambling.[1]
- **Benicar** – Popular blood pressure medication can cause intestinal problems known as sprue-like enteropathy, with chronic diarrhea, weight loss, nausea, and vomiting.[2]
- **Premature Hip Implant Failures** – Litigating cases involving DePuy ASR, DePuy Pinnacle, Stryker Rejuvenate, Stryker LFIT COCR V40, Wright Profemur, Wright Conserve, and Biomet M2a-Magnum.[3]
- **Invokana, Farxiga, and Jardiance** – These Type 2 Diabetes drugs can cause ketoacidosis—very elevated blood acid levels—which may require hospitalization.[4]
- **Stockert 3t Heater-Cooler Device** – This device used during open-heart surgery has been linked with a specific type of rare, nontuberculous mycobacterium infections, which can occur up to 5 years after exposure.[5]
- **Taxotere** – Studies and reports have associated permanent hair loss (alopecia) with the use of chemotherapy drug Taxotere (docetaxel).[6]
- **Viagra** – Use is associated with increased risk of melanoma.[7]
- **Xarelto** – Anticoagulant (blood thinner) linked to serious bleeding complications, intracranial hemorrhaging, gastrointestinal bleeding, wound infections from inhibited clotting, and lack of effectiveness in preventing dangerous clotting.[8]
- **Zofran** – This anti-nausea drug prescribed "off label" for morning sickness is associated with increased risk of cleft palate and congenital heart defects.[9]

Footnotes on Page 8 >

THREE ATTORNEYS INDUCTED INTO THE INTERNATIONAL SOCIETY OF BARRISTERS

PETER SCHMIT

CHRIS MESSERLY

BRANDON THOMPSON

We're pleased to announce that three of the Personal Injury and Medical Malpractice Group's most experienced litigators, Peter Schmit, Chris Messerly, and Brandon Thompson, have been inducted into the International Society of Barristers (ISOB).

Founded in 1965, the ISOB promotes an independent judiciary and works to preserve the right to a trial by jury. Membership in the organization is highly exclusive: Only existing fellows can nominate new members, and candidates are admitted only after an exhaustive inquiry into the nominee's professional integrity and skill as a trial lawyer. The ISOB's membership includes fellows from every state in the U.S., as well as members in Australia, Canada, England, Scotland, and Ireland.

Peter, Chris, and Brandon are joined in the organization by longtime member Kathleen Flynn Peterson.

TROY TATTING AND BRANDON VAUGHN NAMED PRINCIPALS

BRANDON VAUGHN

TROY TATTING

Two talented attorneys, Brandon Vaughn and Troy Tatting, were recently named Principals by Robins Kaplan's board of directors.

Troy Tatting focuses his practice on representing individuals harmed by defective pharmaceutical drugs and medical devices. Notably, he was part of the bellwether trial and litigation team in the multi-district litigation (MDL) involving the smoking-cessation drug Chantix. Since 2013, Super Lawyers has recognized Mr. Tatting as a "Minnesota Rising Star."

Brandon Vaughn is a personal injury, medical malpractice, and product liability attorney who provides advocacy and justice to those who have been harmed by the medical system. Mr. Vaughn is an active member of numerous professional organizations, including the American Association for Justice, and sits on the Board of Directors of the Hennepin County Bar Association. He has been included on Super Lawyers' "Minnesota Rising Stars" list every year since 2013, and Minnesota Lawyer named him an "Up and Coming Attorney" in 2016.

BISMARCK
1207 West Divide Avenue
Suite 200
Bismarck, ND 58503
701 255 3000 TEL

BOSTON
800 Boylston Street
Suite 2500
Boston, MA 02199
617 267 2300 TEL

LOS ANGELES
2049 Century Park East
Suite 3400
Los Angeles, CA 90067
310 552 0130 TEL

MINNEAPOLIS
800 Lasalle Avenue
Suite 2800
Minneapolis, MN 55402
612 349 8500 TEL

NAPLES
711 Fifth Avenue South
Suite 201
Naples, FL 34102
239 430 7070 TEL

NEW YORK
399 Park Avenue
Suite 3600
New York, NY 10022
212 980 7400 TEL

SILICON VALLEY
2440 West El Camino Real
Suite 100
Mountain View, CA 94040
650 784 4040 TEL

SIOUX FALLS
101 South Main Avenue
Suite 100
Sioux Falls, SD 57104
605 335 1300 TEL

< Continued From Page 7

1. http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/55668a-eng.php
2. http://www.fda.gov/Drugs/DrugSafety/ucm359477.htm; http://www.ncbi.nlm.nih.gov/pubmed/22728033
3. *Concerns about Metal-on-Metal Implants*, available at www.fda.gov
4. *http://www.fda.gov/drugs/drugsafety/ucm446845.htm*
5. See https://www.cdc.gov/hai/outbreaks/heater-cooler.html
6. See, e.g., *Kluger, Permanent Scalp Alopecia Related to Breast Cancer Chemotherapy by Sequential Fluorouracil/Epirubicin/Cyclophosphamide (FEC) and Docetaxel: A Prospective Study of 20 Patients*, Annals of Oncology at 1 (May 9, 2012); *Prevezas et al., Irreversible & Severe Alopecia Following Docetaxel or Paclitaxel Cytotoxic Therapy for Breast Cancer,* 160 Br. J. Dermatology 883-885 (2009); Tallon et al., *Permanent Chemotherapy-Induced Alopecia; Case Report and Review of the Literature,* 63 J. Am. Academy of Derm. 333-336 (2010).
7. Wen-Qing Li, et al. *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*. JAMA Intern. Med. (June 2014)
8. Lassan, M.R., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Athroplasty. N. Engl. J. Med. 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty. Lancet 2008: 372:31-39; Ericksson, B.I., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. N. Engl. J. Med. 2008; 358;2765-75; Jameson SS, et al. Wound complications following rivaroxaban administration. J. Bone Joint Surg. Am. 2012; 1554-8
9. M. Anderka et al. *Medications Used to Treat Nausea and Vomiting of Pregnancy and Risk of Selected Birth Defects.* Birth Defects Res A Clin Mol Teratol. (Jan. 2012); JT Anderson et al. *Ondansetron use in Early Pregnancy and the Risk of Congenital Malformations – A Register Based Nationwide Cohort Study*. Pharmacoepidemiology and Drug Safety. (Oct. 2013)

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