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IHA/MAPS PSO Legal Webinar

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IHA/MAPS Caselaw Updates and National Patient Safety Initiatives

Michael R. Callahan
Senior Counsel
Katten Muchin Rosenman LLP
312-902-5634
michael.callahan@katten.com
https://katten.com/Michael-Callahan

Agenda

- Recent Patient Safety Act Case Law Updates
  - —Veltri v. AMITA Health Alexian Brothers Medical Center
  - —Franco v. Yale New Haven Hospital, Inc.
  - —Payton v. Columbia St. Mary's Hospital
  - —Shands Teaching Hospital and Clinics v. Beylotte
- Lessons Learned and Recommendations
- Options for Sharing PSWP within a Hospital/Healthcare System
- CANDOR/CRP Program and the Patient Safety Act
- Recent National Patient Safety Efforts

Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1st) 230073-U (Sept. 29, 2023)

Background

- This case involves a medical malpractice lawsuit in which the patient alleges that she suffered a fractured left distil femur during a surgical procedure by physicians acting as agents of the hospital.
- Plaintiff filed a Motion to Compel the discovery of three documents which the hospital claimed were privileged under both the Illinois Medical Studies Act (IMSA) and the Patient Safety Act (PSA).

  —Patient Safety Event Report (Veltri's RL Datix Report)

  —Acesis Peer Review Committee Case Write Up

  —SERT Event Review Team Case Notes

Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1st) 230073-U (Sept. 29, 2023)

- Plaintiff argued that IMSA did not apply because the hospital failed to establish that the documents "were used, requested, or generated by any peer review committee, or its designee, in the course of an internal peer review process."
- Regarding the PSA, the plaintiff argued that the hospital "had not asserted that the documents were generated strictly for submission to an approved" PSO.
- The privilege log actually implies "the documents were used for internal quality control and review separate and distinct from any PSO reporting."
- The log also failed to "state that the documents … were in fact submitted to a PSO" as the PSA requires.

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- The trial court judge, which was the same judge in the *Daley* case, granted the plaintiffs Motion to Compel because the affidavit submitted in support of both privileges was "insufficient" and further: "It is the burden of the defendant in these cases to indicate or to prove when the Committees met and when they ended … [and] that's not found here in the Affidavit. So, therefore I'm finding that these documents which were prepared prior to any Review Committee Meeting were made in the ordinary course of business."
- The court denied the hospital's Motion for Reconsideration.
- Upon the hospital's refusal to produce the documents, it was held in civil contempt. The hospital subsequently appealed.

Veltri v. AMITA Health Alexian Brothers Medical Center, 2023 IL App (1st) 230073-U (Sept. 29, 2023)

Appellate Court Decision

- The only document which the hospital claimed was patient safety work product (PSWP) under the PSA was Veltri's RL Datix Report under the "reporting pathway".
- Because the trial court did not make any findings of fact regarding this Report and whether it did or did not meet the PSA requirements, the appellate court addressed this question de novo.
- The Report was submitted both to the trial court and on appeal for in camera inspection.
- The court relied on the *Daley* decision in determining whether the report was "created for the purpose of reporting to a patient safety organization" and noted that the affidavit in that case stated that the documents in dispute were created "solely" for submission to the PSO.

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- The appellate court ruled that the hospital had failed to meet its burden of establishing that the report was PSWP for the following reasons:
  - —The affidavit submitted "is silent as to whether such reports are generated specifically for the purpose of submission to the [Ascension Health PSO] AHPSO.
  - —The affidavit states only that the hospital "used the RL Datix electronic reporting system within its designated [PSES] and provides RL Datix reports to [the AHPSO]"
  - —The affidavit actually suggests that "referral to the AHPSO is not the only use, as the patient safety specialist analyzed it for referral to the SERT Committee and MSQOC"

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- The hospital's contention that these committees are subparts of AHPSO and/or that the reports were created only for reporting for AHPSO is not supported by the affidavit or the record which was established during the trial court.
- As a result, the hospital's argument that the report was privileged under the PSA was rejected.

Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

Background

- The plaintiff in this lawsuit was accidentally injured when resisting efforts by the hospital's protective services officers to address his threatening and aggressive behavior when attempting to remove a woman from the emergency room.
- The lawsuit against the hospital alleged assault and battery, negligence, negligent training and supervision and unlawful forceable detention leading to false arrest.
- During discovery, the plaintiff deposed the hospital's Patient Safety Coordinator and requested that she produce "any and all records, (including any written reports, videos, email communications, interoffice memos consuming the incident, etc.) … wherein [Plaintiff] was injured and subsequently arrested."

Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

- In response, the hospital argued that the materials requested were created within its PSES as part of the investigation into the incident. Because they were reported to its contracted PSO, they therefore were privileged under the Patient Safety Act and Connecticut statutes.

Trial Court's Decision

- The trial court relied heavily on the Illinois Appellate Court decision in *Daley*, and also on the unrebutted representation in the Patient Safety Coordinator's affidavit, which included the following:
  - —As Patient Safety Coordinator, she conducted an investigation of the incident within the hospital's PSES.
  - —She was one of the "designated leaders responsible for collecting, analyzing and managing [PSWP] for the purpose of submitting to a PSO.

Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

- The investigation notes she prepared were reported to the PSO and were not prepared, maintained or distributed outside of its PSES.
- The hospital contracted with an AHRQ certified PSO during the time of the incident.
- The Coordinator participated in a safety huddle with other employees to discuss the incident and interviewed an emergency nurse who witnessed the event.
- The purpose of the huddle and interview was to obtain information to report to the PSO in order to improve the quality and safety of patient care.
- "The results of the investigation and interview led to the creation of a subcommittee to work on an alert process designed to manage incoming aggressive behavior in patients in order to better manage the care and safety of these patients."

Franco v. Yale New Haven Hospital, Inc., Docket No. CV-20-6103795-S (New Haven Judicial District) (March 31, 2023)

- —"The affidavit … establishes that the documents were assembled and prepared by her solely for submission to the [PSO] … and were reported to the [PSO]."
- —The court further concluded that "the documents had the ability to improve patient safety and quality healthcare, and … were submitted to the PSO."

- Trial court rejected the plaintiff's argument that the Patient Safety Act and Connecticut statutes only apply to medical malpractice cases.
- It noted that there was no specific provisions in the Patient Safety Act or Connecticut statutes to limit the protections to med mal cases.

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- The court also cited to *Tinal v. Norton Healthcare, Inc.* involving an alleged employee discrimination under the American with Disabilities Act in which the court extended the privilege protections in that non-medical malpractice case.
- The *Tinal* court concluded that "an absence of any explicit exception to the plain language of [the PSQIA] for civil rights actions, it is clear to the Court that the privilege created for patient safety work product is intended to apply across the board to all other types of claims."

Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

Background

- Plaintiff brought a negligence action against the hospital after being beaten and stabbed in the hospital's parking garage.
- During discovery, the plaintiff requested "all documents, communication or correspondence as it relates to [Hospital's] "Serious Event Review Team(s)" (SERT) which were generated over a specific period of time.
- The plaintiff filed a motion to compel after the hospital refused to produce any materials arguing that they were privileged under the Patient Safety Act and Wisconsin statutes.
- Through affidavits and the hospital's memorandum in support of its motion for a protective order, it established the following:

Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

—The minutes were entered into the hospital's event reporting system (ERS) and were discussed at the SERT meetings.

—SERT and ERS are both components of the hospital's PSES policy which describes a process of collecting, utilizing, sharing and reporting PSWP or treating PSWP as deliberations or analysis.

—It was the hospital's routine practice during the relevant time frame that event reports were "prepared by and submitted to SERT for review and were reported to the hospital's PSO.

—Both the date on which the minutes entered into the PSES and were reported to the PSO were included.

—The minutes related to the medical care provided to the plaintiff.

Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

Trial Court's Decision

- After quoting from the definition of PSWP in the Patient Safety Act, the court determined that the minutes were "assembled or developed by a provider for the purpose of reporting to a PSO and are actually provided" as demonstrated through the affidavits.
- The court further held that the minutes were privileged because they "identify the discussions and analyses conducted by SERT … meetings"
- The minutes were privileged under both the reporting pathway and the deliberations or analysis pathway, and therefore, were privileged from discovery under the Patient Safety Act.

Payton v. Columbia St. Mary's Hospital, Case No. 20CV1108, Wisconsin Circuit Court (July 8, 2022)

- The court rejected the plaintiff's arguments that the minutes were created separately from the hospital's PSES.
- The court further determined that the minutes were privileged under the Wisconsin peer review statute.

Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1st District Court of Appeals (March 8, 2023)

Background

- Plaintiff filed a negligence suit against the hospital while visiting a patient when she slipped and fell claiming she was injured on some clear liquid while walking through a hallway.
- During discovery she sought "an investigation report that was prepared by the hospital as a result of her fall."
- In response to the plaintiff's motion to compel, the hospital argued that the report was placed in the hospital's PSES and "prepared solely for submission to [a] patient safety organization" and in fact was submitted and therefore was PSWP under the Patient Safety Act.
- The trial court ruled against the hospital, concluding that the Patient Safety Act only applies to patients and not incidents involving staff or visitors.

Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1st District Court of Appeals (March 8, 2023)

- The hospital's *petition for certiorari* was granted by the Florida First District Court of Appeals.

Appellate Court's Decision

- In reversing the trial court's decision, the appellate court pointed to an "uncontracted affidavit" from the hospital "certifying that the subject report was assembled for reporting to a patient safety act organization under the Act and that the report was in fact submitted" utilizing the confidential reporting pathways set forth under the Patient Safety Act.
- The court agreed with the hospital's arguments that efforts to improve conditions that would have caused slip and fall injuries meets the requirement under the Act that the report "could result in improved patient safety, health care quality or health care outcomes."

Shands Teaching Hospital and Clinics v. Beylotte, Fla. 1st District Court of Appeals (March 8, 2023)

- Because these safety efforts apply to all persons, including patients, visitors and employees, the court stated that it did not matter that the plaintiff was not a patient at the time.
- Because the Patient Safety Act was not limited to reports which only involved patients, the court held that the disputed report was privileged and that the trial court's order requiring a disclosure of the report be quashed.

Lessons Learned and Recommendations

- Consider revising PSES policies to extend to employees and visitors as long as the identified patient safety activities and reviews can also cover patients.
- The Patient Safety Act privilege and state peer review privileges are not mutually exclusive. Both can apply, depending on the documents which the hospital or health care provider are seeking to protect.
- The decisions emphasize the importance of introducing affidavits, relevant PSES policies and legal memorandums in support of a motion for protective order or effort to quash a subpoena.
- Supporting affidavits should specifically describe the following:
- The process by which the PSWP was collected or generated in the PSES and the date on which this occurred.

Lessons Learned and Recommendations

- How it was shared, reviewed and utilized to improve patient care and/or reduce patient, employee or visitor risk.
- If utilizing the reporting pathway, state that the PSWP was collected for the purpose of reporting to a PSO and when it was reported.
- If relying on the deliberations or analysis pathway, establish how and when the PSWP was being deliberated and analyzed within the context of the PSES.
- The affidavit should specifically cite to the relevant provisions in the PSES to support compliance with the Patient Safety Act.
- That the PSWP was not created outside of the PSES.
- That the PSWP was created for the purpose of improving patient care and reducing risk.

Lessons Learned and Recommendations

- PSES policy should specifically identify which PSWP is being actually reported to the PSO and which is being treated as deliberation or analysis.
- As a best practice, the PSES policy should identify the names of reports, analyses, committees, minutes and other work product utilized or created through identified quality assurance, quality improvement, peer review or other patient safety activities.
- In order to further support privilege arguments, be prepared to turn documents over for an *in camera* inspection which can be accomplished under the permissible disclosure exception under Section 3.206(b)(3) of a Final Patient Safety Rule which allows a provider to disclose its own PSWP.

Lessons Learned and Recommendations

- If appealing an adverse discovery ruling, make sure that the record on appeal, including supporting affidavits, policies, legal arguments, etc., are included.
- Red Herring Arguments
  - PSWP was not prepared for the "sole purpose" of reporting to a PSO.
  - PSWP was shared outside of the PSES.
  - Claimed PSWP only included factual information.
  - Claimed PSWP was created in the normal course of business.
  - Privilege was waived because it was improperly shared or disclosed.

Sharing PSWP Within a Hospital

- The Patient Safety Act allows a PSO participating provider to share PSWP within a hospital or participating provider entity for any “use”. There are no limitations.
- That said, PSWP should only be shared and used by workforce members or others who need access to PSWP in order to carry out their identified responsibilities.
- PSWP, like HIPAA, must be kept privileged and confidential and not inappropriately shared with outside or other parties who do not need access to PSWP to carry out any legal or other responsibilities.
- HR and risk managers can access PSWP in order to carry out their employment and claims and litigation management responsibilities but should not place PSWP in files unrelated to a patient safety activity.

Sharing PSWP Within a Hospital

- Instead, HR and risk should create separate forms and, if necessary, separate interviews outside of the PSES which can then be used for appropriate employment, claims and litigation management purposes.
- This information, created outside of the PSES, will not qualify as PSWP or for the privilege protections under the Illinois Medical Studies Act.
- Because this information is not privileged, it can be used in defending against employment claims or introduced into evidence in the defense of the med mal or other litigation if not otherwise privileged under, for example, attorney client work product or insurer-insured privileges.

Sharing PSWP Within a Healthcare System

- The Patient Safety Act has a number of exceptions which would permit the disclosure of PSWP, including a "disclosure among affiliated providers (Section 3.206)(b)(4)(iii) and disclosure authorized by identified providers under Section 3.206(b)(3).
- The disclosure among affiliated providers' exceptions will allow all participating healthcare providers which are owned, controlled, or managed by a parent organization to share identifiable PSWP among, for example, the hospitals within the healthcare system.
- In other words, if there are three hospitals within a healthcare system, that are controlled affiliates of a parent organization, each of the hospitals can share identifiable PSWP amongst themselves, as well as with the parent organization.

Sharing PSWP Within a Healthcare System

- Such disclosures do not waive any of the privilege protections and would be important in terms of tracking trends, outcomes, the results of other patient safety activities which can be used by the system for the purpose of improving patient care and reducing risk.
- The disclosure authorization for identified providers is important in the context of being able to track physicians and other healthcare providers which serve as members of multiple hospitals or provider entities within the system.
- In other words, assume Dr. Callahan is a member of the medical staff of three affiliated hospitals within a healthcare system.

Sharing PSWP Within a Healthcare System

- It is important that Dr. Callahan's quality, behavior and other activities affecting patient care be tracked and shared by the three medical staffs and hospitals consistent with privacy and confidentiality requirements.
- However, under the Medical Studies Act and the Patient Safety Act, Dr. Callahan would have to authorize the disclosure and sharing of identifiable peer review and PSWP by and among the hospitals and medical staffs.
- This typically is achieved by including the written authorization in Dr. Callahan's appointment and reappointment application and/or employment agreement, keeping in mind that the disclosure authorization should be very specific in citing to the Medical Studies Act and to the Patient Safety Act as well as describing the purpose for which the authorization is being requested/required.

CANDOR/CRP Programs Background

Background

- Before the publication of the Institute of Medicine Report "To Err is Human," which identified that over 100,000 deaths occurred from medical errors. Hospitals and physicians often used a "delay, defend and deny" approach, when unintended adverse patient events occurred.
- This approach largely was based on concerns about legal liability, loss of reputation, refusing to acknowledge error, reports to the Data Bank and licensing boards and similar implications.
- Over the years, however, it has been universally recognized by state and federal governments, accrediting bodies, health care associations and agencies such as the National Institute of Health and the Agency for Healthcare Research and Quality, that programs were needed to engage in honest and forthright discussions with patients and their families about these adverse events.

CANDOR/CRP Programs

- It is in this context that programs such as Communications and Optimal Resolution), and other Communications and Resolutions Programs were developed so as to address the following:
  - — What happened and why?
  - — Acceptance of responsibility for the adverse event
  - — The provision of a true and honest apology
  - — How the identified problem is going to be fixed going forward
  - — How the patient and family will be actively engaged in this particular effort

Applying CRP Programs within a PSES Policy

Background

- All hospitals have events reporting systems and policies in place which identify the occurrence of an adverse event that could have been or was harmful to patients.
- Most hospitals participating in a PSO such as MAPS, collect adverse event reports in their PSES and either report them to the PSO or treat them as deliberators or analysis.
- Information which is reported to a PSO or treated as deliberations on analysis is privileged patient safety work product under the Patience Safety Act.
- Such Incident reports can be considered CANDOR/CRP reports which then typically trigger an internal investigation consistent with existing quality improvement/quality performance peer review investigations, committee reviews, reports, analyses, etc.

Applying CRP Programs within a PSES Policy

- If designed correctly, all such investigations and reviews can be privileged at a minimum under the Patient Safety Act and possibility under the Illinois Medical Studies Act.
- Under CANDOR/CRP programs, the communications with the patients and family members regarding the facts and cause of an adverse event along with the investigations can be kept privileged and confidential under the Patient Safety Act.
- The question is how much information does the hospital need to reveal to the patient and family that is considered PSWP, if any?
- Non-privileged information which can be disclosed and discussed include the following:

  —Any information in the medical record

Applying CRP Programs within a PSES Policy

- —Any and all facts relating to the adverse event including the cause of the adverse event
- —The results of any investigation, including a root cause analysis
- —The actions the the hospital intends to avoid the occurrence of future adverse events such as the one affecting the patient
- —Communications with the patient and family as to the outcome of remedial actions being taken by the hospital.

- Given the scope non-privileged information which can and should be disclosed to the patient and family it is probably not necessary to also disclose PSWP.

Applying CRP Programs within a PSES Policy

- In a rare event that the judgment is made to disclose PSWP, the hospital can exercise the written authorization disclosure exception under the Final Rule (Section 3.206(b)(3)) without protections waiving the privilege.

Recommendations

- Review your PSES Policy to determine whether the types of investigations and subsequent work product relating to adverse events is covered in order to be considered privileged under the Patient Safety Act.
- Add to the Policy a specific reference to CRP program including discussions with the family which are to be treated as PSWP to make sure that no PSWP is being disclosed to the family unless you are using the written disclosure exception under the Patient Safety Act.

Recent National Patient Safety Efforts

A Transformational Effort on Patient Safety

- In September 2023, the President's Council of Advisors on Science and Technology issued a Report to the President – A Transformational Effort on Patient Safety
- The Report made the following recommendations:
  - —Establish and maintain federal leadership for the improvement of patient safety as a national priority
  - —Ensure that patients receive evidence-based practices for preventing harm and addressing risks.
    - This will require that appropriate federal agencies develop a list of high-priority harms, evidence-based practices, and system-level mitigation strategies to eliminate preventable harms including "never events" that should never occur in healthcare.

Recent National Patient Safety Efforts

- —Partner with patients and reduce disparities and medical errors and adverse outcomes.
- —Accellerate research and deployment practices, technologies and exemplar systems of safe care.

- The Report also contains the following:
  - —"To ensure standards for timely communication to patients and families of harm events and immediate root cause analysis of the harm – with dissemination of the findings internally and with appropriate medical bodies, CMS should require within five years that hospitals demonstrate their efforts to communicate with families and appropriate medical bodies after future adverse events occur as a Condition of Participation. Hospitals should consider, as a model, prior efforts aimed at communication and resolution, including a communication and optimal resolution program (CANDOR) and communication resolution program (CRP).

Recent National Patient Safety Efforts

—Another example in carrying out the recommendations includes the following:

- "Building upon existing work by AHRQ to collect data from Patient Safety Organizations (PSOs), HHS, DoD, and VA could establish mandatory reporting to a national repository for patient safety events data which could support access to and interoperability of healthcare data as well as enable disparity stratification efforts."

Executive Order on the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence (Executive Order)

- The President's Executive Order was issued on October 30, 2023.
- The Executive Order requires HHS to establish an "HHS AI Task Force" by January 28, 2024.
- The Task Force has 365 days to develop a regulatory action plan for predictive and generative AI-enabled technologies in healthcare that include:
  - —The organization and implementation of an AI Safety program by September 30, 2024.
    - In partnership with federally listed Patient Safety Organizations, the program will be tasked with creating a common framework that organizations can use to monitor and track clinical errors resulting from AI use in healthcare settings.

Executive Order on the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence (Executive Order)

- The Program also will create a central tracking repository to track complaints from patients and caregivers who report discrimination and bias related to the use of AI.

Firm Bio

Michael R. Callahan

Senior Counsel
Health Care

Chicago Office
+1.312.902.5634

michael.callahan@katten.com

https://katten.com/michael-callahan

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory compliance, policy and litigation standpoint, including the development of patient safety organizations (PSOs).

The knowledge to identify efficient and practical solutions

Health systems, hospitals and physician groups large and small across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues, which he can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to provide better and comparative solutions.

He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression, he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.

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Michael R. Callahan

Senior Counsel
Health Care

Chicago Office
+1.312.902.5634

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https://katten.com/michael-callahan

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Katten Locations

CHARLOTTE
550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO
525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS
2121 North Pearl Street
Suite 1100
Dallas, TX 75201-2591
+1.214.765.3600 tel
+1.214.765.3602 fax

LONDON
Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

LOS ANGELES – CENTURY CITY
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN
515 South Flower Street
Suite 4150
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK
50 Rockefeller Plaza
New York, NY 10020-1605
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY
100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI
Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC
1919 Pennsylvania Avenue NW
Suite 800
Washington, DC 20006-3404
+1.202.625.3500 tel
+1.202.298.7570 fax