Conducting Ethical and Effective Investigations in Health Care

Wiggin and Dana 2017
Health Care Roundtable
November 8, 2017

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Today's Presentation

- Investigation structure, timing and first steps
- *Kovel* - Use of outside assistance
- Deputizing non-lawyers
- *Upjohn* – Warnings for employee interviews
- Yates Memo
- Disclosures

Investigation Triggers

- Government subpoena or request for information
- Search warrant
- Regulatory requirement
- Employee complaint – "formal" and "informal"
- Compliance hotline call
- Audit or compliance review
- Change to existing law
- Media scrutiny
- Company policy

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Whistleblowers under the FCA

- The FCA authorizes the United States, or "relators" acting on behalf of the United States to recover monetary damages from parties who submit, or cause others to submit, fraudulent claims for payment by the federal government.
- Penalties include treble damages, $10,781.40 - $21,562.80 per claim, and program suspension, debarment and exclusion.
- Take all complaints seriously - "Even a broken clock is right twice a day."
- If government intervenes, relator receives between 15 and 25% of total recovery.
- If government declines, relator typically can move forward on behalf of government is he/she so chooses. Relator will receive between 25 and 30%
- FCA mandates defendant pay reasonable relator's counsel fees if relator prevails.
- Anti-retaliation provisions.

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Timing

- 60-Day Medicare Reporting and Returning of Self-Identified Overpayments
- An overpayment has been identified when the provider or supplier has, or should have, "through the exercise of reasonable diligence," determined that an overpayment has been received and quantified the amount of the overpayment.
- *State of Florida ex rel. Malie v. First Coast Cardiovascular Institute, P.A., et al.*, Case No. 3:16-cv-10548-J-34MCR
- Medicaid may want refunds even sooner

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Forming the Team

- Lawyers must lead the team
- Non-lawyers (e.g., internal audit) have valuable roles to play
- Consider need for outside help, e.g., investigators, forensic accountants, public relations consultants
- Ensure independence of all team members from the matter being investigated

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Who Should Conduct Investigation?

- In-house counsel
  - Non-lawyers working under the supervision of in-house counsel (ex: HR, compliance, accounting, IT)
- Regular outside counsel
- Outside counsel with no prior connection to company or management

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If Deputizing Non-Lawyers

- Provide training
- Document deputization
- Give instructions to:
  - Keep all information learned confidential
  - Mark all notes, memoranda, reports and emails as "Privileged and Confidential"
  - Avoid extraneous comments in notes or memoranda
  - Turn over original notes and memoranda to supervising counsel

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Document Preservation

- Written Litigation Hold / Preservation Notice
- Distributed to custodians of potentially relevant documents
- Applies to hard copy and electronic records
- Re-visit extent of Hold Notice distribution during investigation

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Privilege and Work Product

- **Who is the client?**
  - The company (at direction of management)?
  - Board of Directors, Audit Committee, Special/Independent Committee of the Board?
- **Attorney-client privilege**
  - To obtain legal advice
  - Document it and protect it throughout investigation
- **Work product protection**
  - In anticipation of litigation

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The *Kovel* Doctrine

- **To maintain privilege when counsel uses outside assistance**
  - *US v. Kovel*, 296 F.2d 918 (2d Cir. 1961) – no waiver where disclosure to accountant was *in furtherance of providing of legal advice*
  - *Perino v. Edible Arrangements Intern. Inc.*, 2015 WL 1442737 (D. Conn. Mar. 27, 2015) – no waiver for forensic audit conducted at request of litigation counsel
- **Often rejected as to PR firms**; provision of legal advice is key
  - *Compare Haugh v. Schroder Inv. Mgmt. N. Am. Inc.*, 2003 WL 21998674, at 3 (SDNY Aug. 25, 2003) ("[a] media campaign is not a litigation strategy") *with In re Grand Jury Subpoenas*, 265 F. Supp. 2d 321, 332 (SDNY 2003) (privilege found where counsel hired PR firm to advise on swaying public opinion to lessen pressure on prosecutors)

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12

The *Kovel* Doctrine

- Outside counsel retains expert
- Engagement letter should indicate
  - Services being provided at the request, and under the direction of counsel
  - Purpose of the service is to assist counsel in providing legal advice to the client
  - The services provided are meant to be confidential and protected by privilege

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13

Additional Initial Considerations

- Prompt follow up with complainant
- Consider preliminary employment actions
- Consider early reporting obligations
  - Law enforcement if criminal conduct
  - Mandatory disclosure under consent decree or cooperation agreement
  - Insurance
- Media/Public Relations

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Employee Notification

- Initial communication to employees
- Set forth expectation of "cooperation"
- Explanation of employee rights
- Advancement of fees, indemnification

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15

Interviews

- Upjohn warning
- Try to make employee comfortable with brief explanation of process
  - High-level description of issue being investigated
  - No conclusions until all facts gathered
  - Why *they* are being interviewed
  - Outline of the interview
- Reiterate anti-retaliation policy
- Avoid assurances (ex: "don't worry; you're not in trouble")

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Confidentiality Requests: Navigating Between *Upjohn* and *Banner Health*

- ***Upjohn Co. v. United States*, 449 U.S. 383 (1981)** – recognizes that companies are entitled to attorney-client privilege, and that communications with employees for the purpose of providing legal advice to the company can be privileged – ***if kept confidential***
- ***Banner Health System* (358 N.L.R.B. No. 93, July 30, 2012)** – blanket confidentiality instructions to non-supervisory employees may violate the National Labor Relations Act

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Upjohn

***Upjohn Co. v. United States*, 449 U.S. 383 (1981)**

- Preserving the company's privilege requires adequate warnings:
  - "I am a lawyer for the company. I do not represent you personally."
  - "The purpose of this interview is to discuss [ ] with you so that I can provide proper legal advice to the company."
  - "Our conversation is privileged. The privilege however belongs to the company, -- not you."
  - "It is up to the company to either invoke the privilege or waive the privilege"
    - Request to maintain confidentiality to preserve the privilege

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Upjohn (Cont.)

- Confirm interviewee's understanding
- Document Upjohn warnings and understanding
  - United States v. Ruehle, 606 F.Supp.2d 1109, rev'd, 583 F.3d 600 (9th Cir. 2010) (company counsel referred to State Bar)

The Yates Memo

- September 9, 2015 memorandum from the Deputy Attorney General Sally Yates
  - "One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing . . . [Accountability] deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system."

The Yates Memo (cont.)

- **DOJ's Key Steps to Implementing Yates Memorandum**
  - Corporations must provide all relevant facts relating to individuals responsible for misconduct in order to qualify for cooperation credit
  - Focus on individuals from the inception of criminal or civil corporate investigation
  - Close coordination between DOJ criminal and civil attorneys
  - DOJ will not release culpable individuals from civil or criminal liability when resolving a matter (absent extraordinary circumstances or DOJ policy)
  - Resolution with corporation should not occur without clear plan to resolve related individual cases
  - Civil attorneys should focus on individuals and evaluate whether to bring suit against individual based on consideration beyond individual's ability to pay

The "Soft Repeal" of Yates?

- Deputy U.S. Attorney General Rod J. Rosenstein stated that the Yates Memo is formally "under review" by DOJ
- "The solutions of the past are not necessarily the right solutions today. Circumstances change. We should not blindly accept past practices."
- Speculated changes:
  - the continued resolve to hold individuals accountable for corporate wrongdoing
  - an affirmation that government should not use criminal authority unfairly to extract civil payments
  - any changes to Yates will make the policy more clear and more concise
  - such changes will reflect input from stakeholders inside and outside the DOJ

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Yates Memo – Key Implications

- Company must now focus its internal investigation on individuals
- More stern "Upjohn Warnings" to employees
- May receive less cooperation from employees
- Increased pressure to waive privilege/work product with respect to individuals
- Whistleblowers may increase

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Banner Health System

***Banner Health System,* 358 N.L.R.B. No. 137 (2015), *enforcement denied in relevant part*, Banner Health System v. NLRB, 851 F.3d 35 (D.C. Cir. 2017)**

- Employer requested employees involved in workplace investigations not to discuss the matter with co-workers while the investigation was ongoing.
- NLRB held that employer violated Sec. 7 of National Labor Relations Act by maintaining this blanket confidentiality policy.
- Employer's concern with protecting its investigation does not outweigh employees' rights under NLRA to discuss the terms and conditions of their employment with coworkers.

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24

Banner Health System (Cont.)

- Employer has burden to justify need for confidentiality, for example:
  - witnesses need protection
  - evidence is in danger of being destroyed
  - testimony is in danger of being fabricated
  - there is a need to prevent a cover up

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Banner Health System (Cont.)

- *Banner Health* requires an employer to determine if confidentiality is warranted at the outset of each and every investigation.
  - Eliminate any blanket rule requiring confidentiality in all investigations.
  - Implement policies that assess confidentiality on a case-by-case basis.
  - If confidentiality is warranted, document the justification for it.
- According to Board holdings, words like "request" and "recommend," even though not mandatory, still have a tendency to coerce employees in the exercise of their Section 7 rights.

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Interview Technique

How to respond to interviewee questions

- Do I –
  - Have to talk to you?
  - Have to talk to you now?
  - Need a lawyer?
- Will I –
  - Lose my job?
  - Be prosecuted?

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27

Disclosures

- Company disclosure policy
- Disclosures to auditors, insurers, board/committees
- Voluntary disclosure to government
  - OIG Self Disclosure Protocol
  - The CMS Voluntary Self-Referral Disclosure Protocol
  - Cooperation credit for disclosure of "relevant facts"
  - Government may not request waiver of privilege for "non-factual or 'core' attorney-client communications or work product"

Questions and Discussion

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Counsellors at Law

Grand Rounds

Year in Review
2016-2017

2016-17 VERDICTS AT A GLANCE

- 26 Verdicts
- 14 Defense
- 12 Plaintiff

Some real head-turners…

Some real head-turners…

$6.8M	$12M	$5.8M
• 13 yo male • Wrongful Death • Medication -> lymphoma • Lack of informed consent	• 55 yo male • Suicide • $5M pain and suffering • $5M death itself • $2M loss of life's enjoyment	• 68 yo male • Wrongful Death • Complications post open heart surgery • $1.2M economic and noneconomic • $4.5M loss of consortium

4

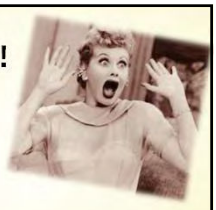
Another head-turner…

- Shoulder dystocia $4.2M

a. Past loss of enjoyment of life's activities	$ 60,000
b. Future loss of enjoyment of life's activities	$ 2,300,000
c. Past pain and suffering	$ 40,000
d. Future pain and suffering	$ 800,000
e. Permanent injury	$ 1,000,000
Total Non-economic Damages	$ 4,200,000

5

SURPRISE OF THE YEAR!!!



$25 Million Dollar Verdict

- ❖ 18 yo female
- ❖ Failure to diagnose and treat popliteal artery clot
- ❖ Amputation
- ❖ $4 M economic damages
- ❖ $21 M non-economic damages
- ❖ Escalators…

6

NOT ALL PLAINTIFF VERDICTS ARE THE SAME…

- $6.5M demand
- Radiologist settles before trial
- $1.2M…..but

- Neurologist & Group: $240,000

7

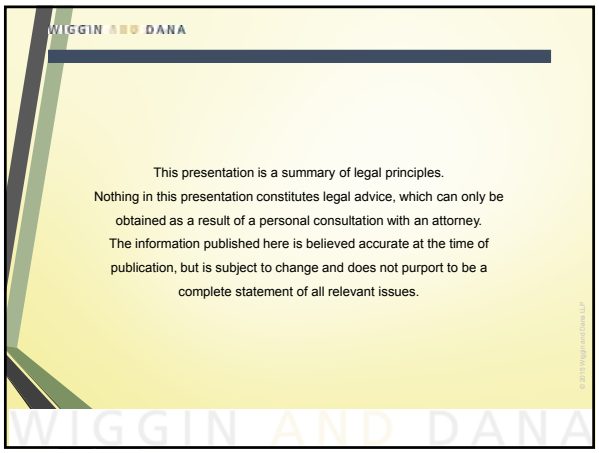
DEFENSE VERDICTS

- Pelvic Mesh – Failure to warn
- Lab Error – Termination of Pregnancy
- Failure to Properly Treat – Vision Loss
- Surgical Error – Paralysis

8

WHAT WE'RE WATCHING

- Collateral Source – Marciano Decision
- Challenges to Peer Review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Nothing in this presentation constitutes legal advice, which can only be obtained as a result of a personal consultation with an attorney.
The information published here is believed accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.
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Advisory

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Unretained Health Care Providers May Not Be Compelled to Render Opinion Testimony

Physicians, skilled nursing care providers, rehabilitation facilities, mental health providers, and other health care professionals are often confronted with a time consuming and uncomfortable situation. A patient becomes a plaintiff in a lawsuit and asks her treating provider to testify in an adversary proceeding regarding expert issues in the case, including the standard of care, the cause of injuries, and future prognosis. If the treating provider does not want to get involved, he or she is often subpoenaed by a party's counsel, who will then try to elicit opinion testimony during the treating provider's deposition. Frequently, providers are not even compensated for their time.

Six years ago, in *Milliun v. New Milford Hospital*, the Connecticut Appellate Court decided that nonparty physicians did not have an absolute privilege to refuse to testify as expert witnesses regarding medical opinions formed during their treatment of a plaintiff. This month, in *Redding Life Care, LLC vs. Town of Redding* (AC 37928), the Appellate Court considered whether nonparty experts have a qualified privilege not to voice their opinions. In a carefully reasoned decision, the Appellate Court recognized a qualified privilege for unretained expert witnesses in Connecticut.

The *Redding* case arose in the context of a real estate tax appeal. The plaintiff in the tax appeal had been pursing financing of its property with two different lenders, both of whom ordered appraisals of the property. David Salinas, a professional real estate appraiser, provided opinions to both banks. The Town sought to compel Mr. Salinas to testify as to the property's value at a deposition in the tax appeal, which was wholly unrelated to the financing transaction. The trial court had granted the Town's motion for a commission to take Mr. Salinas's deposition, and it denied his motion for a protective order. Mr. Salinas filed a writ of error with the Connecticut Supreme Court, which transferred the case to the Appellate Court.

Although *Redding* involved a non-medical expert, the Appellate Court discussed several trial court decisions that had recognized a qualified unretained expert privilege for treating healthcare providers, including *Hill v. Lawrence & Memorial Hospital* (2008) and *Drown v. Markowitz* (2006). In *Hill*, which the Appellate Court cited extensively in its decision, the trial court noted policy reasons for recognizing a privilege for treating providers, including "the heavy strain on relationships in health care facilities when one health care provid-

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Unretained Health Care Providers May Not Be Compelled to Render Opinion Testimony

er is required to make a public assessment under oath about another's professional performance." The Appellate Court also considered, as persuasive authority, the Wisconsin Supreme Court's decision in the medical malpractice case of *Burnett v. Alt.* The Appellate Court quoted the Wisconsin decision's reasoning that "[u]nlike factual testimony, expert testimony is not unique and a litigant will not be usually deprived of critical evidence if he cannot have the expert of his choice." Furthermore, because the court cannot compel a person to be an expert against his or her will, the Appellate Court noted that it would be illogical to allow litigants to be able to do so.

The unretained expert privilege is qualified in that a witness may be compelled to provide opinion testimony if (1) under the circumstances, the individual reasonably should have expected that, in the normal course of events, he or she would be called upon to provide opinion testimony in subsequent litigation; and (2) there is a compelling need for the individual's testimony in the case. The Court also noted that other considerations may be relevant, such as "whether he was retained by a party with an eye to the present dispute." Nevertheless, given the weight afforded the *Hill* decision in the Appellate Court's opinion, the parameters of the qualified privilege, and that the *Hill* court held that nonparty treating experts could not be compelled to offer expert testimony, the *Redding* decision is good news for treating providers who would prefer to spend their time and energy treating patients and do not want to be distracted by the litigation process. It is also an important clarification of the existing precedent in *Milliun*, which seemed to suggest the opposite.

Importantly, the unretained expert privilege must be invoked by the treating provider, and, like other privileges, can unwittingly be waived. Treating providers who are subpoenaed and who wish to assert the unretained expert privilege should consult with counsel immediately so that they can take appropriate steps to preserve this privilege.

If you have any questions about the unretained expert privilege or have received a subpoena from a third party's attorney, please feel free to contact Erika Amarante or Kevin Budge.

Advisory

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Connecticut Appellate Court Upholds the Preclusion of Plaintiff's Nursing Standard of Care Expert

In *Ruff v. Yale-New Haven Hospital*, No. AC 37749 (*officially released* May 2, 2017), the Connecticut Appellate Court unanimously affirmed the trial court's preclusion of a nursing expert who lacked "active involvement in the practice or teaching of [nursing] within the five-year period before the incident giving rise to the claim." The *Ruff* decision gives teeth to the statutory "five year" rule for non-specialist expert witnesses, such as nurses, who seek to testify in medical malpractice cases. See Conn. Gen. Stat. § 52-184c. Importantly, the *Ruff* decision, which resulted from the efforts of Wiggin and Dana partners Erika Amarante and Kim Rinehart, sends a message that standard of care experts must have relevant, real-world experience before they may judge their peers.

THE TRIAL COURT'S PRECLUSION OF PLAINTIFF'S NURSING EXPERT

The trial court granted the Defendant's motion to preclude Plaintiff's sole standard of care expert, Donna Maselli, after carefully reviewing her deposition testimony. Ms. Maselli had been disclosed by the Plaintiff in a lawsuit alleging that a registered nurse had negligently inserted a foley catheter, which is a device that drains a patient's urine directly from the bladder. Although the Plaintiff's expert was licensed as a registered nurse, she had been employed by a state agency in a purely administrative role for fifteen years prior to the date of the alleged malpractice. She admitted during her deposition that her job did not involve the clinical care of patients and that she had not inserted a foley catheter since the 1980s. Ms. Maselli also had a side business devoted to litigation consulting, but that also involved no clinical patient care. Although she claimed to provide private duty nursing care to friends and family, she acknowledged that this was usually done free of charge and that such care did not include medications or treatments and was not rendered under the direction of a physician or APRN.

Because Ms. Maselli was not a specialist such as a board-certified physician, the trial court considered whether she was qualified to testify as a "similar health care provider" under § 52-184c(b), or under § 52-184c's catch-all provision, subpart (d). Section 52-184c(b) defines "similar health care provider" as "one who: (1) is licensed by the appropriate regulatory agency of this state or another state requiring the same or greater qualifications; and (2) is trained and experienced **in the same discipline or school of practice and such training and experience shall be as a result of the active involvement in the practice or teaching of medicine within the five-year period before the incident giving rise to the claim**." (Emphasis added). Section 52-184c(d) is a residual provision that gives the trial court additional discretion to permit expert testimony. It permits expert testimony from a witness who does not meet the statutory definition of "similar healthcare provider," but, "to the satisfaction of the court, possesses sufficient training, experience and knowledge as a result of practice or

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Connecticut Appellate Court Upholds the Preclusion of Plaintiff's Nursing Standard of Care Expert

teaching in a related field of medicine, so as to be able to provide such expert testimony as to the prevailing professional standard of care in a given field of medicine. **Such training, experience or knowledge shall be as a result of the active involvement in the practice or teaching of medicine within the five-year period before the incident giving rise to the claim**."

The trial court concluded that Ms. Maselli failed both tests because she did not meet the five-year active practice requirement – the so called "five year rule" – applicable to both subsections of the statute. The Plaintiff rested his case without a standard of care expert. Defense counsel moved for a directed verdict because the Plaintiff could not meet his burden of proof, and the trial court directed a defense verdict.

THE APPELLATE COURT DECISION

The Appellate Court affirmed the trial court's decisions on both the motion to preclude Ms. Maselli and the motion for directed verdict. The Appellate Court first emphasized that the decision of whether or not to preclude an expert witness is a matter left to the sound discretion of the trial court, which is not overturned absent abuse of discretion. The Appellate Court agreed that the trial court properly precluded Ms. Maselli under the "five year rule," opining that although the nurse who placed the foley catheter and Ms. Maselli were both trained and licensed as registered nurses, Ms. Maselli was no longer involved with the type of "clinical care nursing" practiced in the hospital setting. Further, Maselli had not actively practiced nursing for "far more" than five years prior to the incident. The court rejected Plaintiff's claim that providing "private duty nursing care" to family and friends qualified as active practice, noting that such care was not rendered at the direction of a physician and citing the nursing scope of practice statute, Connecticut General Statutes § 20-87a(a). The Appellate Court next affirmed the trial court's directed verdict for the defense, opining that "[a] directed verdict is justified if the plaintiff fails to present any evidence as to a necessary element of his or her cause of action." In *Ruff*, the Plaintiff presented no evidence regarding the nursing standard of care.

Ruff makes it clear that Connecticut courts will not shy away from requiring expert witnesses to walk a mile in a healthcare provider's shoes before they may criticize his or her care in a malpractice lawsuit.

Wiggin and Dana partner Erika Amarante served as trial counsel in *Ruff*, and Wiggin and Dana partner Kim Rinehart served as appellate counsel.

Advisory

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CMS Issues Revised Stark Self-Disclosure Form

On March 28, 2017, the Centers for Medicare and Medicaid Services ("CMS") announced that effective June 1, 2017, all disclosures made pursuant to Self-Referral Disclosure Protocol ("SRDP") must use new Form CMS-10328 available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol-Original.pdf.

WHAT IS THE SRDP?

The SRDP was first established by CMS in 2010 in response to the Affordable Care Act's provision requiring the establishment of a formal process for providers and suppliers to self-disclose actual or potential violations of the physician self-referral law, commonly called The Stark Law. The Affordable Care Act gave the Secretary of the U.S. Department of Health and Human Services authority to reduce the amount "due and owing" for Stark Law violations that have been self-disclosed. Given the Stark Law's dizzying complexity, strict liability standard, and severe penalties, the opportunity to disclose and resolve actual and potential violations has been welcomed by health care providers and suppliers.

From its inception in 2011 through 2016, there have been a total of 233 settlements pursuant to CMS's SRDP, and settlements have been steadily increasing over time: (See figure 1 below)

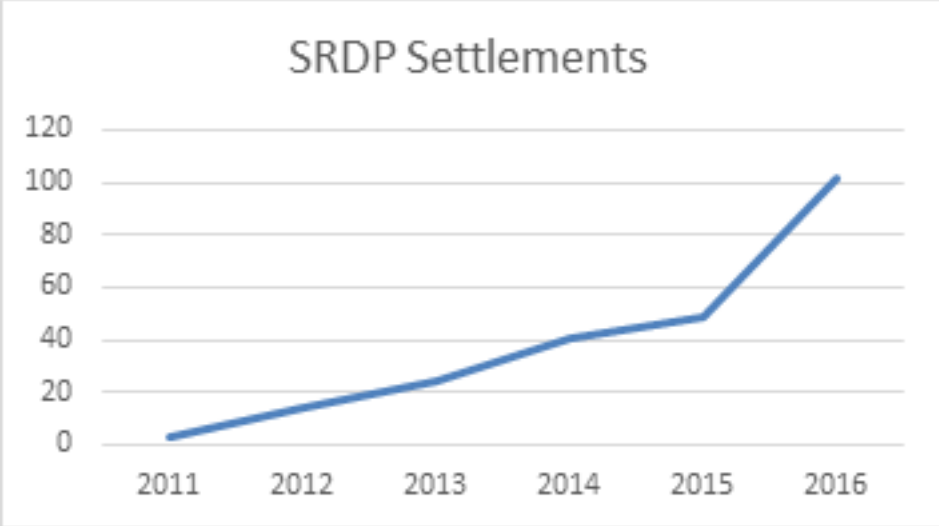

FIGURE 1

https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html

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CMS Issues Revised Stark Self-Disclosure Form

In addition, as of March 1, 2017, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement, or settled by CMS's law enforcement partners. The dollar amounts of these settlements have varied widely from as low as $60.00 to as high as $1,195,763. Because CMS neither publicizes the facts involved in each case nor explains how it determines the amount of each settlement, it is difficult to ascertain in advance how CMS might resolve a particular self-disclosure. However, the general consensus is that, when considered in proportion to the potential liabilities involved, CMS has been settling these cases favorably for disclosing providers and suppliers.

WHAT DOES THE NEW SRDP FORM REQUIRE?

In March 2017, CMS issued a required electronic form for SRDP submissions. CMS stated that the electronic form is intended to "reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information." Prior to the issuance of this new form, parties utilizing the SRDP drafted detailed narrative descriptions describing the violation and associated potential liabilities. Use of the new form will be mandatory starting on June 1, 2017. Until then, parties submitting self-disclosures pursuant to the SRDP are encouraged by CMS but not required to use the new SRDP form.

The new SRDP form has 4 parts:

1. SRDP Disclosure Form: On this form, the disclosing party provides information about itself; the pervasiveness of noncompliance; whether the disclosing party has knowledge that the disclosed conduct is under current inquiry by a government agency or contractor; whether the disclosing entity has a history of conduct similar to that being disclosed or any prior criminal, civil or regulatory enforcement action against it; and steps that the disclosing part has taken to prevent future noncompliance.
2. Physician Information Form(s): For each physician included in the disclosure, the disclosing party must submit a separate Physician Information Form providing details of the noncompliant financial relationship(s) between the physician and the disclosing party.
3. Financial Analysis Worksheet: The Financial Analysis Worksheet quantifies the overpayment for each physician who made referrals in violation of The Stark Law.

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CMS Issues Revised Stark Self-Disclosure Form

4. Certification: The initial disclosure and any related supplemental submission must include a certification signed by the disclosing party or, in the case of an entity, its Chief Executive Officer, Chief Financial Officer, or other individual who is authorized by the disclosing party to disclose the matter to CMS and to certify the truthfulness of the information contained in the disclosure. The signed certification must state that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS's attention for the purpose of resolving the disclosed potential liabilities relating to the physician self-referral law.

WHAT CHANGED?

This new form standardizes the SRDP process and is meant to make the process simpler for both disclosing parties and CMS. However, the new form also requires the disclosing party to include certain information that was not previously required, such as a description of the "pervasiveness of noncompliance," which "means how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians." According to the instructions on the new form, the disclosing party must "report the pervasiveness of the noncompliance relative to the disclosing party's similar financial relationships or similar services furnished." The expectation is that the disclosing party will be able to state that the noncompliant arrangement being disclosed represents a certain percentage of all of the disclosing party's similar arrangements. Disclosing the pervasiveness of compliance may be a complicated exercise for providers that have many different types of arrangements with physicians, especially since the analysis must incorporate the "stand in the shoes" analysis in order to determine how arrangements with physician organizations should be counted. For example, according to CMS, the disclosure of a noncompliant lease arrangement with a physician organization that consists of three owners and two non-owners might have to be counted as three separate arrangements if the arrangement with the organization is deemed to be an arrangement with the physicians standing in the shoes of the organization.

The new form also does not require a description of the disclosing party's compliance program or information regarding the specific financial benefit of the noncompliant relationship to the applicable physician – two elements that were previously required to be part of the disclosure.

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CMS Issues Revised Stark Self-Disclosure Form

Perhaps most significantly, the revised SRDP explicitly requires the disclosing party to adopt a 6-year lookback period, meaning that the disclosing party must review the last six years of payment data in order to calculate the overpayment that resulted from the Stark Law violation. Previously, the SRDP required the disclosing party to look back only four years. This change was a result of CMS's final rule on the 60-day reporting and returning of overpayments obligation which established a 6-year lookback period for the reporting and returning of overpayments under 42 CFR 401.305(f). Although that 60-day rule became effective on March 14, 2016, CMS was prohibited from mandating that disclosing parties provide six years' worth of financial data in their SRDP disclosures before the formal OMB approval for and issuance of this new SRDP form.

If you have questions about this advisory or want to learn more about the Health Care Compliance, Fraud and Abuse Practice Group, contact Maureen Weaver at mweaver@wiggin.com or Jody Erdfarb at jerdfarb@wiggin.com.

Advisory

MARCH 2017

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New DOJ Guidance On Evaluation of Corporate Compliance Programs

In February 2017, the Fraud Section of the United States Department of Justice ("DOJ") released new guidance, entitled Evaluation of Corporate Compliance Programs, on how it evaluates corporate compliance programs in the context of a criminal investigation. For many years, the DOJ, as well as other federal and state agencies, have emphasized the importance of implementing robust compliance programs, especially in heavily regulated industries, such as health care. In fact, for many health care providers, having a compliance program is mandated by law. The new DOJ guidance does not necessarily set forth new concepts; it is more a conglomeration of corporate compliance rubrics found in sources such as the United States Attorney's Manual, the United States Sentencing Guidelines, the Securities and Exchange Commission, and the Organization for Economic Cooperation and Development Council, among others. However, it provides added insight into the elements of compliance programs that are considered the most important by the DOJ and, therefore, health care providers should pay close attention and revise their compliance programs as needed.

The DOJ guidance sets forth eleven topics, along with sample questions, that the DOJ considers in evaluating the efficacy of a particular compliance program. These topics focus on the following:

1. Analysis and Remediation of Underlying Misconduct – how the company prevents, analyzes, and responds to discovered misconduct;
2. Senior and Middle Management – involvement of the company's senior leaders in the compliance program and how they respond to misconduct;
3. Autonomy and Resources – the value of the compliance program within the organization and whether the compliance function is provided sufficient resources to perform adequately;
4. Policies and Procedures – the design and accessibility of compliance policies, as well as their integration into the company's operations;
5. Risk Assessment – the methodology used to identify risk, collect data, and investigate risks;
6. Training and Communications – the extent to which employees receive compliance training and communication from top management to employees regarding compliance;
7. Confidential Reporting and Investigation – effectiveness of the com-

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New DOJ Guidance On Evaluation of Corporate Compliance Programs

pany's reporting mechanisms, the scope of internal investigations, and the appropriateness of response to investigations;

8. Incentives and Disciplinary Measures – the extent to which individuals are held accountable for misconduct and how compliance and ethical behavior are incentivized;
9. Continuous Improvement, Periodic Testing and Review – the company's internal auditing, control testing, and compliance program review.
10. Third Party Management – whether the company has implemented adequate control of its vendors; and
11. Mergers and Acquisitions – the role of compliance in the due diligence process and corporate transactions.

Although the guidance is couched in terms of DOJ investigation of misconduct, organizations can use DOJ's sample lines of questioning to proactively review their current compliance programs. Of note, the guidance focuses on what specific actions the company took to analyze misconduct, whether the company could have identified the misconduct previously, and what steps the company has taken to remediate the misconduct. The guidance specifically asks whether the company performed a "root cause analysis of the misconduct at issue," highlighting the DOJ's emphasis on finding the impetus of misconduct as a way to prevent future misconduct.

The guidance also set forth specific topic headings and corresponding questions for compliance inquiries related to third-party vendors and mergers and acquisitions. The sample questions indicate DOJ's desire for compliance programs to include an evaluation of third-party vendors at all stages of the relationship, including due diligence in selecting vendors, subsequent on-going compliance oversight of such vendors, and remediation of any discovered misconduct by the vendors. The guidance also highlights compliance pitfalls in the context of mergers and acquisitions, focusing on whether compliance risk was reviewed during the due diligence process and whether the compliance function was identified as an integral part of the transaction more generally.

Organizations should review the new DOJ guidance closely and use it as an opportunity to evaluate their current compliance programs and to strengthen areas of potential weakness. Doing so now, and continuing to review and modify compliance programs in light of subsequent guidance and individual compliance experience and challenges, will help organizations more effectively monitor potential fraud and abuse and put them in a better position to respond in the event of any future DOJ investigation.

Advisory

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Connecticut Supreme Court Permits Tort Liability For the Acts of an Apparent (Not Actual) Agent

In Cefaratti v. Aranow, No. SC 19443 (June 14, 2016), the Connecticut Supreme Court resolved a dispute among lower Connecticut courts and recognized tort liability for the acts of an apparent agent. See 321 Conn. 593. The Court spelled out the parameters for apparent agency liability in a medical malpractice case. In so doing, the Court expressly overruled a series of Connecticut Appellate Court decisions spanning three decades.

Cefaratti involved a surgeon, Dr. Jonathan Aranow, who had left a surgical sponge in the patient's abdominal cavity during gastric bypass surgery at Middlesex Hospital. The hospital argued that it could not be liable for the surgeon's alleged malpractice because the surgeon, who had hospital privileges, was not the hospital's agent or employee.

Ms. Cefaratti had herself selected Dr. Aranow as her surgeon based on her research to find the best gastric bypass surgeon in the state. Ms. Cefaratti, however, also attended several informational sessions at the hospital, conducted by Dr. Aranow's staff, as well as a seminar that the surgeon conducted at the hospital. The patient received a pamphlet, prepared by the hospital, referring to the education program developed by "the health care team who will be caring for you" and the importance of the program in which "(w)e will discuss" preparation for the operation. The patient alleged that these actions by the hospital made her believe that the surgeon was a hospital employee because he had privileges there.

The Superior Court granted the hospital's summary judgment motion and the Appellate Court affirmed on the ground that apparent agency is not a ground for tort liability. By a 4-3 vote, the Supreme Court reversed, recognizing apparent agency as a basis for tort liability. The Court eased the way to imposing liability on a hospital if it holds out an independent physician or group as having authority to act for the hospital, and the patient relied on the hospital to select the physician, as might happen for emergency or radiology services (to name just two examples). The Court nevertheless imposed strict limits on apparent agency authority if the patient selected the independent physician, as happened in Ms. Cefaratti's case. In that instance, the plaintiff must prove that she detrimentally relied on the appearance that the physician was a hospital agent or employee, and the Court opined that it would be the "rare" case where a tort plain-

CONTINUED ON NEXT PAGE

Connecticut Supreme Court Permits Tort Liability for the Acts of an Apparent (Not Actual) Agent

tiff can prove that reliance. Ms. Cefaratti must still prove that reliance on remand to the trial court.

APPARENT AGENCY AND APPARENT AUTHORITY

In Cefaratti, the Supreme Court first addressed the meaning of apparent agency and a related but distinct doctrine, apparent authority. The doctrines are rooted in contract law, but the Court held that apparent authority was recognized in tort law in its earlier 1941 decision in Fireman's Fund Indemnity Co. v. Longshore Beach & Country Club, Inc., where the club's customer tipped an employee to retrieve his car, the car was driven into a body of water, and the auto insurer brought a subrogation action against the club for the employee's negligence. The Supreme Court described the doctrine of apparent authority but found under the facts that the club could not be held liable for its employee's actions, which fell outside of his actual or apparent authority as a watchman. The Supreme Court in Cefaratti read Fireman's Fund as implicitly recognizing the doctrine of apparent authority in negligence actions, even if rejected in that case.

Middlesex Hospital countered that there's a difference between apparent authority and apparent agency, with the former applicable to an actual agent under the employer's control but who is acting beyond the scope of his authority, and the latter applicable to a person who was never an agent for any purpose. The Court in Cefarrati rejected the distinction and ruled that the two doctrines have merged, adopting the test set forth in the Restatement (Third) of Agency § 2.03 (2006). The Restatement provides: "Apparent authority is the power held by an agent or other actor to affect a principal's legal relations with third parties when a third party reasonably believes the actor has authority to act on behalf of the principal and that belief is traceable to the principal's manifestations." Under that test, it makes no difference whether the alleged tortfeasor was an "agent" who exceeded actual authority "or" was an "other actor" and never an agent. In either instance, the key ingredient to holding the principal liable for actions taken beyond an actual agency relationship is that the principal and not the alleged agent took steps in public view to portray the alleged agent as possessing authority to act for the principal in the particular transaction, and the affected person justifiably believed that the principal, by its actions, had conferred agency authority. As emphasized by the Court, it is the principal who must cloak the actor with the public appearance of authority to act for the principal, and that doctrine can bind the principal whether the actor was never an agent or employee or, instead, was an agent or employee going beyond the scope of actual authority.

CONTINUED ON NEXT PAGE

Connecticut Supreme Court Permits Tort Liability for the Acts of an Apparent (Not Actual) Agent

DETRIMENTAL RELIANCE

The hospital argued that even if apparent agency is recognized in a tort action, the injured party must still allege and prove detrimental reliance on the appearance of agency or authority—that is, Ms. Cefaratti must show she relied on the hospital's actions in allegedly cloaking the surgeon with the appearance of being an agent or employee. Ms. Cefaratti, however, argued that detrimental reliance is not a traditional factor in an apparent agency relationship. On this question, the Court agreed with the hospital . . . sort of.

Apparent agency often arises in contract disputes, where the parties have chosen to interact with each other, and implicit in the principal's actions in giving someone the appearance of authority is that the other person will detrimentally rely on that appearance. The Supreme Court illustrated that point through a hypothetical car sale: "[I]f A agrees to pay B $1000 for a car, and A gives the $1000 to C, reasonably believing B's representations that C was his agent, it reasonably may be presumed that A would not have given the money to C but for B's representations." Person A certainly would not have handed $1000 to a stranger with no expectation of receiving B's car in return.

The analysis is more difficult in tort cases, where reliance on the appearance of an agency relationship is not implicit in the behavior of the parties. No one chooses to have an accident with a truck because the brand name on the side of the truck made it appear that the truck driver acted for the owner of the brand.

The Supreme Court nevertheless dispensed with detrimental reliance as a required element of proof in situations it analogized to contract cases, i.e., where the patient chooses the hospital, and the hospital selects the physician to treat the patient. This could arise, for example, if a patient arrives at the hospital to use emergency or radiology services or a patient chooses a hospital for the reputation of its cardiology programs and meets caregivers when first visiting the hospital. In these cases, where a patient chooses a medical facility and is assigned health care providers, the Supreme Court held that it will presume detrimental reliance. Therefore, a plaintiff may establish apparent agency by proving: "(1) the principal held itself out as providing certain services; (2) the plaintiff selected the principal on the basis of its representations; and (3) the plaintiff relied on the principal to select the specific person who performed the services that resulted in the harm complained of by the plaintiff."

The Supreme Court then recognized a different scenario, where the patient selects a community physician, perhaps based on reputation, and is treated at the hospital where the physician has privileges. In that case, the Supreme Court will not presume that the patient relied on a reasonable belief that the hospital has appeared to confer agency authority on the physician.

CONTINUED ON NEXT PAGE

Connecticut Supreme Court Permits Tort Liability for the Acts of an Apparent (Not Actual) Agent

The Court explained: "It would make little sense to hold a principal vicariously liable for the negligence of a person who was not an agent or an employee of the principal when the plaintiff would have dealt with the apparent agent regardless of the principal's representations." In this second scenario, the plaintiff must prove that: "(1) the principal held the apparent agent or employee out to the public as possessing the authority to engage in the conduct at issue, or knowingly permitted the apparent agent or employee to act as having such authority; (2) the plaintiff knew of these acts by the principal, and actually and reasonably believed that the agent or employee or apparent agent or employee possessed the necessary authority; and (3) the plaintiff detrimentally relied on the principal's acts, i.e., the plaintiff would not have dealt with the tortfeasor if the plaintiff had known that the tortfeasor was not the principal's agent or employee." The Court emphasized that this is a narrow path to establishing tort liability for the acts of an apparent agent, and it will be the "rare tort action" where the plaintiff can prove detrimental reliance under this scenario.

Because Ms. Cefaratti had chosen Dr. Aranow as her surgeon, the Supreme Court treated her case as falling within this second scenario. Because the Court had minted a new standard in its opinion, it reversed the hospital's summary judgment but remanded the case to the trial court to give the plaintiff a chance to prove that she detrimentally relied on her belief that Dr. Aranow was the hospital's agent or employee. The Court "emphasize[d] that, to meet this burden, the plaintiff must set forth facts and evidence capable of raising a reasonable inference that she would not have allowed Aranow to perform the surgery if she had known that he was not Middlesex' agent or employee."

WHAT CAN BE DONE?

After Cefaratti, what can a hospital, or other potential apparent principal, do to avoid the effects of apparent agency? The answer to that is not clear in circumstances where the patient has not chosen the physician providing the services. Some jurisdictions have allowed hospitals to rebut the appearance of an agency relationship by posting signs indicating that medical providers are not agents or employees of the hospital or by requiring potential patients to sign disclaimers to that effect. However, that disclaimer may not be effective in an emergency situation or other situations where the court believes there is no informed patient choice of provider. The Supreme Court, while acknowledging the differences between jurisdictions in this area, stated that it need not answer this question at this time. The issue will undoubtedly arise and have to be decided in other cases.

Despite the lack of clarity in the law, hospitals and other medical institutions may want to post signs.

CONTINUED ON NEXT PAGE

Connecticut Supreme Court Permits Tort Liability for the Acts of an Apparent (Not Actual) Agent

It may also make sense to have doctors disclose to patients, in non-emergent situations, that the doctor is not an agent or employee of the hospital and that the patient may choose to go elsewhere or, where available, choose another doctor. In this way the hospital can try to categorize a future lawsuit as one where the patient either did not have a reasonable belief that the physician was an agent or employee or has selected the physician and so must prove detrimental reliance. It will also allow the health care institution to pursue in court the open question of whether signs and disclaimers are effective to rebut a claim of apparent agency.

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Erika Amarante is a partner in the firm's Litigation Department. She represents hospitals, physicians and other health care providers in cases alleging professional negligence, lack of informed consent and negligent credentialing. She has extensive experience defending claims of wrongful death, birth trauma, delayed diagnosis of cancer, and brain injuries, as well as the catastrophic injuries that often arise in such claims. Erika also has had the unique experience of serving in a claims management position, setting reserves and valuing cases. She regularly counsels health care providers on issues of liability and risk reduction strategies. Erika has tried cases to verdict and recently secured a defense judgment after a bench trial in a case alleging lack of informed consent, and a directed verdict in a jury trial in a medical negligence case.

In addition to health care litigation, Erika's practice also includes litigation, arbitration and counseling on a wide variety of complex commercial and civil litigation issues. A seasoned franchise litigator, Erika has arbitrated and litigated dozens of franchise cases and has been chosen by her peers for listing in *The Best Lawyers in America* in the Franchise category (for more information on the standards for inclusion in *The Best Lawyers in America*, see www.bestlawyers.com/about/ct_methodology.aspx). Erika has extensive experience litigating environmental disputes in state and federal courts. She also regularly counsels the firm's clients on the requirements of federal and state antitrust law.

Erika serves on the Board of Directors of the Connecticut Defense Lawyers Association and the Executive Committee of the Connecticut Bar Association's Litigation Section. She was Editor-in-Chief of the *Connecticut Bar Journal* from 2010-2013, and is a James W. Cooper Fellow of the Connecticut Bar Foundation.

Erika received a BA with distinction from Cornell University in 1995, and in 1998 received her J.D. *cum laude* from New York University School of Law, where she was Editor-in-Chief of the *Environmental Law Journal*. After law school Erika served as law clerk to Justice Richard N. Palmer and Justice Francis M. McDonald on the Connecticut Supreme Court, and later served as Executive Assistant to Chief Justice Francis M. McDonald on the Connecticut Supreme Court.

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Kevin S. Budge is a Partner in the firm's Litigation Department. His practice focuses on the defense of healthcare providers in alleged professional negligence matters. He represents healthcare providers in all areas of professional liability and most extensively in complex large damage exposure matters such as birth trauma, delayed diagnosis of cancer, and wrongful death. Kevin also regularly represents physicians and other healthcare providers before the State Department of Public Health in investigations, inquiries and administrative proceedings. In addition, Kevin has substantial experience in claims management, setting reserves and valuing cases.

Kevin has appeared in the majority of Superior Courts in the State of Connecticut, many of the Probate Courts in the State, as well as in each of the District Courts for the State of Connecticut. Kevin regularly counsels healthcare providers regarding managing risks and limiting liability. He has extensive experience counseling clients regarding conservatorships, psychiatric commitments, electroconvulsive shock therapy and psychiatric medication proceedings. Before joining Wiggin and Dana, Kevin was in private practice concentrating on insurance defense, personal injury defense and commercial litigation.

Kevin graduated *magna cum laude* from the University of Connecticut. He received his J.D. from Western New England College School of Law. Kevin is admitted to practice in Connecticut and the U.S. District Court, District of Connecticut and is a member of the Connecticut Bar Association, New Haven County Bar Association and the American Bar Association, Connecticut Defense Lawyers Associate and Defense Research Institute (DRI).

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Joseph W. Martini, is a Partner and Chair of the firm's White Collar Defense, Investigations and Corporate Compliance Group. In 2014, 2015 and 2016, the White Collar Group was awarded the Litigation Department of the Year for Government Investigations and Corporate Compliance by the *Connecticut Law Tribune*. Mr. Martini, a member of the firm's Executive Committee, maintains offices in New York, Stamford, and Washington, D.C.

A Fellow of the American College of Trial Lawyers, Mr. Martini is an accomplished trial lawyer. He has successfully represented public and privately held companies, government officials and individuals in sophisticated criminal and commercial matters in federal and state courts, and before arbitration panels. Mr. Martini regularly represents clients in investigations conducted by the Department of Justice (and U.S. Attorney's Offices throughout the United States), the Securities and Exchange Commission, FINRA, FAA and OSHA, and other federal and state regulators and prosecutors. Prior to joining Wiggin and Dana, Mr. Martini served for nine years as an Assistant United States Attorney in Connecticut, investigating and prosecuting a broad range of federal crimes.

Throughout his 30 year career as a prosecutor and defense attorney, Mr. Martini's criminal matters have involved allegations of health care and financial fraud, political corruption, insider trading and securities fraud, violations of the Foreign Corrupt Practices Act, RICO, tax, mortgage and bankruptcy fraud, mail and wire fraud, money laundering, currency transaction and Bank Secrecy Act matters, environmental crimes, theft of trade secrets, municipal corruption, fraud in the defense contracting industry and occupational safety and health (OSHA) matters.

Mr. Martini is often retained by entities facing crisis situations to conduct internal investigations, and has regularly done so in the financial, health care, manufacturing, construction and defense industries. Mr. Martini also has experience representing clients in matters involving the United Nations, and before hospital boards of directors and hearing panels in connection with disciplinary matters and other administrative proceedings. He also advises educational institutions in connection with Title IX investigations.

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As a federal prosecutor, Mr. Martini received numerous awards and commendations, including the Department of Justice's prestigious Director's Award for Superior Performance as an Assistant U.S. Attorney. He was also an instructor at the FBI Sensitive Operations and Undercover School at the FBI Academy in Quantico, Virginia.

Mr. Martini has received an AV® Preeminent™ peer rating from *Martindale-Hubbell* (for more about the standards for inclusion in *Martindale-Hubbell*, please click here). Mr. Martini is individually listed in *Chambers USA* in the category of Litigation: White Collar Crime and Government Investigations. *Chambers* USA has listed Wiggin and Dana's litigation department in Band 1 and has listed Mr. Martini as a notable practitioner. Sources say he is "an excellent trial lawyer," and "very capable, bright and determined." (For more about the standards for inclusion in *Chambers* USA, please click here). Mr. Martini also has the distinction of having been chosen by his peers for inclusion in *The Best Lawyers in America* in the category of White Collar Criminal Defense (for more about the standards for inclusion in *The Best Lawyers in America*, please click here). Benchmark Litigation has recognized Mr. Martini as a *Litigation Star* in the area of White Collar Crime (for more about the standards for inclusion in Benchmark Litigation, please click here. Mr. Martini has also been recognized by Super Lawyers as a top rated attorney in the area of White Collar Crime.

Mr. Martini is also an accomplished appellate lawyer, having briefed and argued over 20 cases before the United States Court of Appeals and New York and Connecticut state appellate courts.

Mr. Martini frequently lectures on white collar matters before groups in the health care and defense industry, including the Society for International Affairs and the Connecticut Hospital Association.

Before joining the U.S. Department of Justice, Mr. Martini was a litigation associate in the New York office of White & Case LLP.

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Mr. Martini graduated *cum laude* with a B.A. from Gettysburg College and received his J.D. *cum laude* from Brooklyn Law School.