Vol. 2 No. 3 July 2009

PRO TE: *Solutio*

SOLUTIONS FOR YOU

Preparing Your Sales Force

Legal Issues From Training To Trial — Part II

E-Discovery

A Powerful Tool For The Defense

Dear Clients:

As ever, within the legal arena of healthcare, changes continue to come from all directions — government agencies and lawmakers, the impact of court decisions, even from new and unexpected areas. And with those changes comes a need for adaptation and creative thinking. Hopefully, this issue of *Pro Te: Solutio* will help you discover new ways of addressing familiar situations and map out what may be previously unexplored territory.

In part two of *Preparing Your Sales Force, Keeping Legal Issues in Mind, from Training to Trial*, you will find some advice on preparing medical sales representatives for deposition at trial. From tips on preparing sales reps for the trial experience to highlighting matters of addressing an audience, this article should help allay common concerns going into a deposition.

But what if a sales rep has been fraudulently joined into a case? This issue's article *Sales Representatives, Diversity Jurisdiction, and Fraudulent Joinder* provides guidance into dealing with this increasingly popular attempt to avoid removal to federal court though research — both traditional research and current-by-the-hour website searches.

As the internet becomes a more common part of daily life, e-discovery becomes a more likely part of evidence submission. If electronic evidence is gathered or submitted improperly, however, it can be omitted just as any other type of evidence can. *Using E-Discovery to Pop the Hot Air from Plaintiff's Case* examines how and why e-discovery should be used against exaggerated claims.

Staying current with innovative approaches and newly emerging tools is just one of the many ways our Pharmaceutical, Medical Device, and Healthcare Industry Group works to make a difference for those dedicated to making a difference in the lives of others.

Christy D. Jones
Co-Chair — Litigation

Charles F. Johnson
Co-Chair — Business and Corporate Healthcare

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Sharing Solutions

It's human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client's anxiety into relief and even triumph. That's why we created this magazine, *Pro Te: Solutio*, which explores how real-life legal problems have been successfully solved.

That's also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you're invited to contact group co-chairs Christy Jones and Charles Johnson, as well as any of the attorneys listed on the inside back cover of this publication.

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WARNING!

COMPLIANCE FORECAST CALLS FOR SUNSHINE

Senators Charles Grassley (R-Iowa) and Herb Kohl (D-Wisconsin) recently re-introduced the Physician Payments Sunshine Act ("Sunshine").[1] The 2009 Sunshine Act requires manufacturers to report annually to the U.S. Department of Health and Human Services (HHS) payments to physicians in excess of $100 per year. Unlike previous versions of Sunshine that were stalled in order to accumulate and incorporate industry recommendations, the current, more aggressive version is expected to sail through Congress this year, in some form, on the strong political winds of healthcare reform. To avoid getting burned by Sunshine, pharmaceutical and medical device manufacturers need to take immediate steps to develop a Sunshine preparedness plan.

If passed, Sunshine would require manufacturers of any drug, device, biological, or medical supply that is eligible for Medicare, Medicaid, or State Children's Health Insurance Program (SCHIP) coverage to disclose, on an annual basis, any payment or other transfer of value to a physician, medical practice, or group practice that exceeds $100 per year. The first report would be due March 31, 2011.[2] Sunshine defines payment broadly to include one or more transfers having an aggregate value of more than $100 per year, including food, entertainment, travel expenses, education, gifts, charitable contributions, grants, consulting fees, honoraria, research, royalty or license, other compensation, profit distributions, and ownership/investment interest held by physicians or their immediate family members (but excludes publicly traded securities or mutual funds as long as such were purchased by the physician and not provided by the manufacturer) and other transfer as defined by the HHS Secretary.[3] Manufacturers would not be required to report educational materials that directly benefit patients, product samples for patient use that may not be sold, or in-kind contributions used for charity care.[4] Additionally, under the proposed legislation, manufacturers would be allowed to delay reporting payments made pursuant to a product development agreement for services provided in conjunction with the development of a new drug, device, biological, or medical supply or in connection with a clinical trial until the first report after FDA approval or two years, whichever is earlier.[5] HHS would then make all of the reported information available via the internet in a searchable, user-friendly format.[6]

Sunshine includes fines ranging from $1,000 to $10,000 for each payment that is not reported (up to $150,000 annually) and additional penalties of $10,000 to $100,000 for each payment for intentionally violating reporting requirements (up to $1 million annually).[7] Actual fines and penalties under Sunshine are not the biggest risk, since presumably the reports will be scrutinized for potential violations of federal and state laws by government investigators and *qui tam* hopefuls who should benefit from the "searchable, user-friendly format" to reduce greatly their fact-gathering burden.

Regrettably, Sunshine does not incorporate the crucial state law preemption provisions that the industry had secured in prior Sunshine drafts.[8] Instead, as introduced, Sunshine only preempts duplicate state reporting requirements but allows states to impose additional reporting obligations.[9] Some states have already adopted disclosure laws that impose additional requirements beyond Sunshine, and additional states are slated to introduce disclosure legislation this year.[10] The inadequate preemption provisions make Sunshine seriously flawed and significantly increase the complexity of the compliance systems that will be required to track contradictory state and federal reporting requirements. For instance, Massachusetts state law reporting requirements begin July 1, 2010, and extend far beyond Sunshine's application to physicians by requiring disclosure of payments to anyone authorized to prescribe, dispense, or purchase drugs or medical devices licensed in Massachusetts as well as officers, employees, agents, or contractors of the prescriber who, in the course and scope of their employment, support the provision of healthcare.[11] The breadth of this statute may extend to hospitals, nursing homes, pharmacists, and health benefit plan administrators, as well as healthcare professionals who are licensed in Massachusetts but practice in other states. States like Massachusetts will create a much bigger burden than Sunshine and emphasize the need for well thought out, flexible data collection systems.

In defense of the Sunshine drafters, the goal of transparency is laudable. Tracking of monetary transfers between manufactures and physicians seems like a reasonable request to provide a mechanism to evaluate monetary transfers to ensure that healthcare decisions are not influenced by improper payments. After all, how hard can it be to track payments? Unfortunately, Compliance Officers who have implemented effective tracking systems know that implementation of such systems is time consuming, labor intensive, and expensive. Ironically, companies with the most experience in implementing such systems are companies who were forced to implement tracking systems pursuant to Corporate Integrity Agreements (CIA) or Deferred Prosecution Agreements (DPA) with the government. Under such circumstances, it is relatively easy to convince senior management that significant resources must be allocated to comply with the CIA/DPA. In today's economic downturn, it may be more difficult to obtain the widespread support and financial commitment needed to implement an effective process to comply with Sunshine. However, failure to properly plan and integrate data collection processes into daily

operations may create a superficial system that not only fails to capture essential information necessary for state disclosure law compliance (leading to fines, penalties, and reputational damage), but one that will require costly re-engineering of the process at a later date. Leadership and appropriate financial support are crucial to navigate safely through Sunshine and prepare for increasing state disclosure obligations.

The Business Travel Forecast for Healthcare Professionals is Treacherous

To illustrate the complexity of the tracking, let's evaluate a typical interaction between a medical device company and a physician engaged to promote training and education on the safe and effective use of its products.

Dr. Don Doright was engaged by Good Care Device Company to provide training and education on the safe and effective use of Good Care's device. The program was designed to teach physicians how to implant the device safely according to FDA labeling.

Dr. Doright lives in Phoenix but agreed to fly to Good Care's corporate headquarters in Minot, North Dakota, to teach a training program. Dr. Doright will be paid $400 per hour for his services. He arrived in Minot and took a taxi to the Good Care facility. Two hundred physicians registered for Good Care's training program, but due to an unseasonably late snow creating hazardous driving conditions, only 150 arrived on the day of the program. The program lasted for six hours, and modest meals were provided. Dr. Doright provided the training and participated in a subsequent question and answer session. Although he planned to fly back to Phoenix immediately after the program, his afternoon flight was cancelled due to weather, so he was provided a hotel room by Good Care and rescheduled on a flight home to Phoenix the following morning. Some additional physicians who attended the program were provided hotel and airfare since the program was not within driving distance for all attendees.

Before we discuss the practical steps that are needed to collect the data to comply with Sunshine or similar state disclosure laws, note that Sunshine does not prohibit any otherwise legal payment to a physician. Therefore, Sunshine does not require that any existing arrangements be restructured; it *simply* requires disclosure.

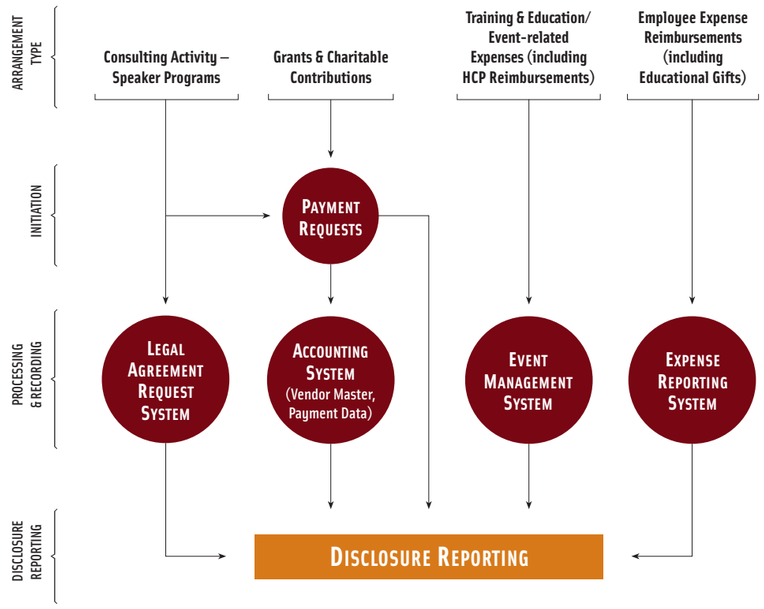
Of course, the challenge is that developing a disclosure system that is sustainable over time is anything but *simple*. For example, to accomplish the reporting required by Sunshine to track the interaction between Dr. Doright and Good Care outlined above, Good Care will need to develop a system that includes the following:

- An event identification number specific to the training and education program, to be assigned to all airfare, lodging, and any other transfer of value provided at the program, the purpose being to ensure the costs for the program are reconciled to the event file.
- A unique identification number for Dr. Doright, all faculty, and each physician attending the training program.
- A procedure/work instruction to reconcile all meals, airfare, lodging, and transportation and assignment of each transfer of value to the unique identification numbers assigned to each physician for this specific event.
- A check point to ensure that Dr. Doright has an active consulting agreement and a method to track any payment for the consulting activity to ensure the consulting payment will be captured and reported.
- A procedure to address any no shows for meals and a reconciliation process to ensure each transfer of value is accurately captured. Specifically, if 200 plates of food were charged based on the number of expected attendees, but only 150 attendees showed up for the meal, an accounting process must be in place to either adjust the price per person or account for the no shows. Since no one's plate of chicken got bigger because of the no shows, it would seem reasonable to account for the no shows separately rather than to increase the price per head reported as a payment for Sunshine purposes. On the other hand, if the event planner negotiated steak for the 150 actual attendees, for the budgeted price of chicken for the 200 expected guests, the system must collect and report the higher price per head. A process must be in place to deal with all potential variances consistently. Such as if a vegetarian attendee stepped out to grab his own vegetarian sandwich, will the system report no monetary transfer for this attendee or allocate all attendees the food and beverage cost for the program whether or not they accept the meal, thus, technically over-reporting the value of payments to the attendees?
- A system to ensure that all payments were processed with appropriate triggers to be tracked in the disclosure database. The system used must be capable of producing reports by a physician-unique identifier that details the type of value transfers and provides aggregate totals by type of interaction.

This example illustrates that, while disclosures of payments to physicians may sound simple, implementation of reliable systems to collect the information to be disclosed is complex. It will require re-engineering of processes and significant training of personnel across all areas of the organization to ensure that the processes are followed.

How will your organization prepare for Sunshine?

The best answer is to integrate the data collection process into daily operations of the business rather than retroactive collection of data by compliance personnel. Every



business unit and employee must take responsibility for compliance, and those closest to the business function are in the best position to design workable processes. For instance, to properly track payments, a limited number of company employees may need to make travel arrangements directly. Past policies of reimbursing physicians and employees for certain types of expenses on personal credit cards may need to be halted. Undoubtedly, serious information technology solutions need to be considered to aggregate data. While a simple spreadsheet-type database may seem like the quickest path to disclosure compliance, it is not sustainable over time for most companies, considering the volume of entries that will be required and that state law requirements will continue to expand. Our example was one training and education program; large companies with multiple products may have hundreds of these programs each year.

Sunshine compliance will require aggregation of data from multiple operating departments. The following chart illustrates the complexity of the flow of information and the variety of operational departments that may need to contribute data to the disclosure data base.

Successful implementation of a long-term disclosure strategy will require assembling a cross-functional team that includes (at a minimum) business partners from the following areas:

- Compliance
- Legal
- Information Technology
- Medical Education/Training and Education Department/Event Management
- Customer Contact Management

- Sales
- Marketing
- Finance
- Accounts Payable (including employee expense processing)
- Communications
- Research and Development
- Clinical
- Office of Medical Affairs

After the team designs the disclosure reporting database, completeness testing and data integrity testing will need to be developed and performed to ensure the universe of data captured is complete and accurate. For instance, once a company believes that it has developed a system to collect all of the information required for Sunshine and state law compliance, auditing should be conducted on expenses in the accounting data that are not included in the disclosure database to be sure that the excluded data is indeed unrelated to payments to healthcare professionals. Additionally, companies will need to audit for appropriate inclusion criteria, to ensure transfers of value captured in the database are accurate. A company could bring unwarranted scrutiny on a healthcare professional if a payment is entered incorrectly as $100,000.00 instead of $100.00. There are potentially serious ramifications for both over-reporting and under-reporting of payment data. Compliance Officers also need solid auditing and monitoring processes to have confidence in the data prior to signing annual certifications required under some state laws.

While the scope of this article is to address Sunshine compliance, our Dr. Doright example should illustrate a need for compliance professionals to make mental lists of the many compliance procedures beyond the disclosure issues that are triggered by this common interaction:

- Does the organization have a prospective planning process that documents the need for the consulting services to be provided (were the services necessary)?
- Does the organization have an active consulting agreement for Dr. Doright that is compliant with the federal anti-kickback statute?
- Does the company have documentation containing the fair market value analysis of the consulting arrangements?
- Prior to payment for the consulting services, was there a reasonableness review, and was it approved by the individual who engaged the service(s)?
    - Was the number of hours for preparation reasonable?
    - Does the number of hours invoiced for the presentation match the agenda time?
    - Was the amount of travel time reasonable based on flight schedule or driving distance?
- Was the presentation reviewed and approved by the appropriate company representative to ensure it met all regulatory, trademark, legal requirements (on-label, etc.)?
- Did Dr. Doright alter the presentation on the plane while traveling to the meeting without approval of the company's coordinator/regulatory reviewer?
- Does the company have a process to ensure that the presentation was not altered?
- Did Dr. Doright deviate from the approved FDA indications during the presentation?
- Was airfare the lowest logical fare?
- Was the meeting location appropriate?
- Was the hotel for the overnight stay an approved hotel?
- Were any inappropriate expenses included in the hotel bill?
- Was the meal within reasonable limits?
- Were all expenses captured and submitted?
- Was the provision of this consulting agreement unduly influenced by sales rather than educational needs?

Perhaps prompting the additional substantive compliance questions that will arise while implementing a Sunshine compliant disclosure program will be the "silver lining" to Sunshine. Transparency is good for public trust in the industry and will level the playing field for organizations that strive to operate within legal boundaries. Essentially, Sunshine is forcing companies to invest in more effective compliance processes to track and monitor their relationships with physicians and other healthcare providers. For the first time in the history of the industry, most companies will have access to databases to evaluate the total costs of training and education programs and will aggregate costs across departments to know the total company compensation to a particular healthcare provider or entity. Presumably, better data will lead to better decisions, and in that regard, perhaps, with thoughtful preparation, Sunshine will be enlightening.[12] However, if Congress fails to re-incorporate meaningful state preemption provisions into the final version of Sunshine, even with diligent preparation, manufacturers are in for a stormy course through frequently shifting state disclosure requirements.

[1] Physician Payments Sunshine Act of 2009, S. 201, 111th Cong. (2009).

[2] Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009), §1128G(a)(1)(A).

[3] *Id.* at §1128G(a)(1)(A)(vi), §1128(g)(10).

[4] *Id.*

[5] *Id.* at §1128G(e).

[6] *Id.* at §1128G(c)(1)(c).

[7] *Id.* at §1128G(b)(1-2).

[8] *See* Proposed Physician Payment Sunshine Act of 2008 at §2.

[9] Physician Payments Sunshine Act of 2009, S. 201, 111th Cong. (2009), §1128G(d)(3).

[10] *See generally*, Cal. Health & Safety Code §§119400 – 119402; D.C. Code Ann. §§48-833.01 – 48-833.09; Maine Rev. Stat. Ann. tit. 22, §2698-A; Minn. Stat. §§151.461, 151.47; Nev. Rev. Stat. §639.570; Vt. Stat. Ann. tit. 22, §4632; W. Va. Code §5A-3C-13.

[11] 105 Mass. Code Regs. §§970.000 – 970.101.

[12] It is not the intent of this article to set forth all of the provisions of the Act or to outline a method of compliance.

Written *by* Denise D. Burke & Machelle D. Shields

THE OTHER SIDE OF THE SUN: COMPLIANCE FOR HEALTHCARE PROVIDERS

As explained in the preceding article, Congress is in the process of formulating additional reporting requirements for pharmaceutical and medical device manufacturers. Although healthcare providers have no direct reporting obligations under the proposed statute absent an ownership interest in a private company subject to the statute, providers will be affected as information on received compensation will be publicly available. This article offers suggestions to protect providers and ensure the accuracy of any information ultimately disclosed pursuant to the proposed statute.

Recommended Actions

1) Compliance Plan Update

Although not directly responsible for reporting, healthcare systems, hospitals, and physician offices should take actions to help satisfy their own compliance obligations. Certainly, the first order of business is to include appropriate language in the organization's compliance plan. From there, policies and procedures should be established to provide guidelines for contract approval and review — including legal review — and appointing the individual(s) with ultimate authority for executing the contract. By limiting the number of individuals authorized to execute agreements, accompanied with those individuals requiring legal review as a condition precedent to signing, healthcare providers can substantially decrease their risk. Contemporaneous staff education is crucial to this process. Healthcare providers should not only properly educate their staff regarding any such updates, documentation of such efforts should be maintained in support thereof.

Inherent in this process is a decision-making opportunity. Coupled with recent industry moves such as the recently-revised PhRMa *Code on Interactions with Healthcare Professionals*, organizations should engage in an extensive review of current practices to help ensure proper compliance.

2) Physician Self-Disclosure Form

Further recommended steps include maintaining appropriate documentation and records evidencing any applicable financial arrangement(s). To that end, healthcare providers specifically should require their medical staff members to disclose any and all such reportable relationships. Healthcare providers that employ physicians may incorporate these activities through their human resource functions in addition to, or in lieu of, the medical staff route. Such disclosures should occur at least once during each re-credentialing cycle, if not annually, with physicians required to report additions and/or deletions immediately. All such disclosures should be noted and tracked, in conjunction with the healthcare provider's current conflict of interest management activities, so that purchases can be properly monitored and handled.

3) Contract Negotiations

When negotiating purchase agreements, healthcare providers should be mindful of these reporting requirements. Including contractual language whereby the manufacturer represents and warrants that any and all applicable financial relationships have been disclosed is advisable. Doing so will bolster the organization's compliance efforts. Similarly, doing so will help the organization manage not only its agreements with manufacturers, but also its agreements with physicians who may have a financial relationship with a particular manufacturer from whom the organization seeks to make purchases. To help avoid potential Stark and/or Anti-Kickback Statute entanglements, proper documentation of the products purchased and the fair market value of such is extremely important — yet another good reason to have sound contract review, approval, and execution policies in place.

4) Monitoring Websites

In an effort to bolster the proffered goal of transparency, the government ultimately intends to post reportable transactions on a website, and several manufacturers have already voluntary begun this process. Healthcare providers would do well to monitor these websites. Doing so will help confirm the accuracy of the information gathered as well as provide a helpful defense should a transaction arise that, for some reason, does not appear on any of the various website postings. To the extent such information will be readily available, it must be monitored, mined, and properly utilized.

Conclusion

As currently drafted, the Sunshine Act will require hospitals, health systems, and physician offices to be even more diligent in their compliance efforts. The days of not knowing or not asking for such information are already gone. Taking (at least) the steps outlined above will increase healthcare providers' knowledge regarding their financial dealings with physicians and manufacturers. This knowledge should help healthcare providers make more informed decisions while managing their organizations.

Written *by* Jim Stanzell

Even a sales representative *who is well prepared for the deposition* process, tuned into potential *areas of inquiry, and ready to convey* the company's themes can *fall prey to plaintiff's counsel's* verbal traps. Questions that *appear innocuous may come back* to haunt the company.

Preparing *your* Sales Force

Keeping Legal Issues in Mind, From Training to Trial

Part II of II

Preparing Your Sales Force to Testify[1]

No one likes to be deposed. Court reporters, cameras, and lawyers combined with forced conversation can send even the most experienced professional into a panic. Although your sales representatives have demonstrated excellent communication when acting as a resource to physicians, performing well in the artificiality of the deposition process requires a different set of skills. Effective preparation on both the general process and the case-specific issues can minimize the stress and turn a potentially adversarial encounter into a positive experience for both the individual testifying as well as your company.

Allay Fears and Explain the Process

At this stage in their lives, most sales representatives have never spent a day with a lawyer, and if they have, the odds are that they have not had to meet with an attorney in the context of preparing to testify at a deposition or trial. To the extent possible, put the sales representative at ease by explaining what her role will be in the litigation. Explain the nature of the case and the parties involved, and let the representative know that she is an important witness because she is the company's primary contact with the physician(s).

Although you want to assure the sales representative that the company is looking out for her best interests and is taking action to ensure she will be prepared for deposition, you also need to be aware of and guard against potential conflicts. The company should only provide counsel for the sales representative so long as there are no conflicts of interest. For this reason, you should review the sales representative's employment file and be prepared to address any past or future potential compliance issues.

Provide your sales representative with the contact information for the outside counsel who will prepare the sales representative for deposition. Define your role versus the role of outside counsel. For example, who should they call if they identify documents in their file related to the case? Indicate that outside counsel will meet personally with the sales representative and most likely run through anticipated deposition questions. (A list of potential deposition topics accompanies this article.) Let the sales representative know that preparing for deposition requires at least two meetings: One meeting to go over potential topics that may be covered and to review documents and another close to, if not the day before, the deposition to refresh the sales representative on both substantive and procedural concerns.

Instruct the sales representative not to discuss this matter with family, friends, or work colleagues and that any calls or inquiries she may receive should be directed to legal counsel. Explain that the sales representative will likely be asked with whom she discussed the case and that any of the persons who were privy to these discussions may be subject to depositions themselves.

You should also inform the sales representative's immediate supervisors — e.g. district and regional managers — of the sales representative's upcoming deposition. Not only could they have particular knowledge about relevant marketing issues in their territory, but they also need to know that their sales representative will be pulled from the job on multiple occasions for preparation and the deposition itself.

Gather Relevant Documents

If a deposition subpoena has already been served on your sales representative, it most likely includes a listing of the categories of documents the sales representative will have to bring to deposition. Even if not listed, for preparation purposes, the sales representative will need to collect all of his or her documents along with laptops, jump drives, or any other electronic storage devices containing information about the drug and physician at issue and bring those documents to the meeting with counsel.

By this point in the litigation, key sales and marketing documents may have been identified. Local counsel should maintain copies of these documents and identify which documents could be helpful in preparing the sales representatives. Conversely, there will likely be internal documents that the sales representative has not been privy to and that should not be used when preparing the sales representative to testify.

If the court has required the production of call notes and/or IMS data relating to the plaintiff's prescribing physician, the sales representative should be prepared to explain what the notes and data mean and how they are used. Pull a copy of the sales representative's employment file noting all awards, accolades, counseling, and reprimands. Although the sales representative has likely already received your company's document retention letter, remind her there should be no destruction of documents, sales pieces, or electronic data related to the drug or physician at issue.

Emphasize Your Company's Themes

Notwithstanding plaintiff's counsel's attempts to gain key concessions from your sales representative to aid his client's case, the deposition can also be an opportunity to present the company's story. Good politicians know how to "stay on point." Your sales representative should be similarly prepared to stress the underlying themes of your case. Although your themes will hinge on the issues presented in your particular case, a few ideas appear as leitmotifs throughout pharmaceutical and products litigation.

> The company should only provide *counsel for the sales representative so* long as there are no conflicts of *interest. For this reason, you should* review the sales representative's *employment file and be prepared to* address any past or future *potential compliance issues.*

A Sales Representative's Credibility is Job Security

Sales representatives are employed by the company to be a resource to physicians. They are responsible for discussing the benefits and limitations of their company's drug so that physicians can determine whether or not a product is appropriate for their patients. To do their jobs well, sales representatives need to be informed, knowledgeable, and honest. Only through consistent, accurate communication will they gain the credibility and goodwill necessary to build a long-term relationship with a physician; they are not interested in making the hard pitch to achieve a one-time sale.

Dishonesty is not only severely punished by the company, but it does not make economic sense for the sales representative. Any short-term gain through over-promotion would be outweighed by the damage to the sales representative's reputation and possible termination by the company. The sales representative should be prepared to offer examples of company policy, demonstrating that termination can result from inaccurate advertising. For example, what are the repercussions for a sales representative using a "homemade" sales aid or detailing off-label?

Sales Representatives as One of Many Resources to Physicians

Although your sales representative provides accurate and helpful information to the physician, a sales representative is not a medical doctor and cannot be considered a complete source of information for physicians. Your sales representative should be prepared to address how your company handles physician information requests and whether the prescriber(s) at issue ever requested additional material. Other sources for physicians include package inserts, medical journals and articles, medical conferences, press releases, peer to peer education, and their own experience. A physician would need to review many sources to have complete information on a drug.

Physicians, Not Sales Representatives, Prescribe Medications

The final decision to prescribe a drug to a patient is the physician's individualized medical judgment based on the patient's individual medical history and risks. A sales representative is not attempting to convince physicians that her company's drug is appropriate for any one patient — that is a determination only the physician can make. A large part of what sales representatives do is distinguish their product from competitors' products so that when a physician determines a patient will benefit from a given drug class, the physician will choose to prescribe the company's drug, rather than other drugs in the same class.

Science, Not Marketing, Guides Sales Representatives

All of the training given to sales representatives and the material they use in the course of detailing physicians has been developed based on valid scientific studies and approved by the research division of the company. Although the marketing department may determine appropriate ways to communicate and package the company's message, the message itself is developed by the research arm of the company.

The FDA Has the Final Word

The business of making and selling prescription pharmaceuticals is highly regulated and tightly controlled. All sales and marketing activities are subject to FDA review and approval. In addition to the FDA's supervision of marketing, Congress is considering passing new legislation to require disclosure of most payments, including meals over a certain threshold, to physicians (*see* "Warning! Compliance Forecast Calls for Sunshine," p.2 of this issue). Given the federal government's level of monitoring, it is disingenuous for plaintiff's counsel to suggest that the company's marketing department attempted to deceive the FDA.

Avoid Traps

Even a sales representative who is well prepared for the deposition process, tuned into potential areas of inquiry, and ready to convey the company's themes can fall prey to plaintiff's counsel's verbal traps. Questions that appear innocuous may come back to haunt the company.

Acknowledge Skills

A variety of skills are necessary to communicate all components of a sales presentation. A strong background in science is not a required trait. Acknowledging plaintiff's counsel's statement to the contrary may act as an admission that the company's sales force is undereducated for their task.

Sales representatives should openly discuss their education and training and not try to oversell their substantive knowledge.

> Performing well at deposition *requires a great deal of preparation and* focus. Educating your sales *representative about the process, the* substance, and the potential *pitfalls of a deposition helps ensure* that your sales representative *will perform as admirably in the* deposition room as she does *in the physician's office.*

Consistent with the themes above, the research arm of the company and the scientists who work there have already prepared the message. The sales representative's job is to convey that message in an effective way and provide approved information to accommodate individual physician's prescribing habits.

Know Limits

Sales representatives need to answer questions based on their own understandings and experience. They should not purport to speak on behalf of the company as a whole or, more narrowly, other sales representatives within their territory. Often, plaintiff's counsel may present sales aids in draft rather than final form or fail to distinguish between material that may be used as an aid and material that may be left with the physician. For this reason, a sales representative should not testify that a particular aid was used unless he or she is certain of that fact from personal experience.

Similarly, sales representatives should candidly acknowledge that they are not medical or regulatory experts. Sales representatives need to know that they do not have to have definitive answers to regulatory questions and that "I don't know" is an acceptable answer. For example, whether or not a given marketing piece is consistent with the label is a complex determination. The representative may answer, "I am not a regulatory expert or a medical doctor. My understanding is that this material was reviewed and approved by our regulatory department."

Respect the Audience

Remind your sales representative that the audience is a jury. Many jurors' experience at a physician's office is sitting in the waiting room for a while, followed by a very brief visit with the physician. While having half-hour lunches with a physician and his staff may seem routine to the sales representative, it may be viewed as unparalleled access when compared to the jurors' own experience. A deposition riddled with jargon may also turn off some jurors. For example, if a sales representative refers to a physician as a "target," the jurors may perceive her as only interested in the sale rather than acting as a resource.

Performing well at deposition requires a great deal of preparation and focus. Educating your sales representative about the process, the substance, and the potential pitfalls of a deposition helps ensure that your sales representative will perform as admirably in the deposition room as she does in the physician's office.

Potential Areas of Inquiry at Sales Representative Deposition

Sales Representative Background

- Personal (married/children/activities in community)
- Education
- Employment
- Training
- Sales Quotas/Compensation/Bonus
- Sales Aids (branded/unbranded; company logo)
- Off-label Protocols
- Order of Sales Presentations
- Labeling Changes
- Familiarity with Studies
- Sampling Policy
- Speaker Programs/Gifts
- Personal Use
- Sales Force Structure
- Detailing Generally
- Medical Literature Policy
- Key Prescribers

Prescriber History

- Any and all discussions with prescriber about drug/device at issue;
- Any comments (positive or negative) from prescriber regarding drug/device at issue;
- History of prescribing drug and device;
- Off-label inquiries from prescriber;
- Any discussions with prescriber regarding litigation associated with drug/device at issue;
- Any discussions with prescriber where issue caused or contributed to a particular health problem or disease;
- Any discussions with prescriber regarding efficacy of the drug/device at issue;
- Any discussions with prescriber regarding safety of the drug/device at issue;
- Knowledge of prescriber's litigation history (e.g., has he ever worked as an expert?);
- Prescriber's attendance at lunch and learns, company-sponsored speaking events, etc.;
- Prescriber's standing and reputation in the community; and
- Whether prescriber still uses drug or device in his practice.

[1] Part I of this series, published in the April 2009 issue of *Pro Te: Solutio*, focuses on training your sales representatives to be successful in the field while at the same time minimizing their exposure should they ever be called to testify.

Written *by* Michael Hewes & Lisa M. Martin

Case Law

Sales Representatives, Diversity Jurisdiction, and Fraudulent Joinder: Where Do the Courts Stand?

The issue of whether a sales representative has been fraudulently joined by the plaintiff to defeat diversity jurisdiction is one that is continuously evolving. When preparing an opposition to remand, we have to search Westlaw, PACER, and the internet generally because decisions on this issue are hidden in slip opinions and unreported decisions but hardly ever hammered out in the Federal Supplement. Although the subject matter has been written on in many publications and review articles, district court rulings continue to be inconsistent and the facts of individual cases overwhelmingly drive the decisions, so it is imperative to be current on the law in this area for the applicable jurisdictions. Because the issue continues to evolve, when presented with a sales representative fraudulent joinder situation, we must review the precedent for factual distinctions and conduct thorough research searches on court websites as well as traditional Westlaw/Lexis searches to ensure the removal and remand briefing contains the most up-to-date cases. This compendium is not intended to provide a complete overview of the law in each state but more to serve as a starting point for research in the states that have posted decisions and to demonstrate the varying views across the country and even intra-state on the issue.

Alabama: *Legg v. Wyeth,* 428 F. 3d 1317 (11th Cir. 2005) (finding that plaintiffs did not present sufficient evidence on remand motion to show that the sales representative had any knowledge of the risk allegedly associated with the medication and that no reasonable possibility existed to conclude that the sales representative personally breached a duty to the plaintiff); *see also In re Prempro Prods. Liab. Litig.,* No. 4:03cv1507, 2006 WL 617981 (E.D. Ark. March 8, 2006) (applying Alabama law and finding sales representatives fraudulently joined); *but see Finley v. Merck & Co., Inc.* No. 2:08cv51 (Order, M.D. Ala. March 12, 2008) (remanding case and finding that sales representative was not fraudulently joined).

California: *Vu v. Ortho McNeil Pharms., Inc.,* 602 F. Supp. 2d 1151 (N.D. Cal. 2009) (holding that sales representative was fraudulently joined and did not destroy complete diversity between the parties).

Colorado: *Nerad v. AstraZeneca Pharms., Inc.,* No. 05-6128, 2006 WL 2879057 (10th Cir. Oct. 11, 2006) (finding that remand decision was not appealable and district court properly found that sales representative was not fraudulently joined).

Connecticut: *Oliva v. Bristol-Myers Squibb Co.,* No. 3:05cv486, 2005 WL 3455121 (D. Conn. Dec. 16, 2005) (holding that sales representative was proper party with potential liability under Connecticut's product liability statute).

Florida: *Merced-Torres v. Merck & Co., Inc.,* 393 F. Supp. 2d 1299 (M.D. Fla. 2005) (finding sales representative fraudulently joined and denying remand).

Georgia: *Faison v. Wyeth, Inc.*, 353 F. Supp. 2d 1273 (S.D. Ga. 2004); *Catlett v. Wyeth, Inc.,* 379 F. Supp. 2d 374 (M.D. Ga. 2004) (finding sales representative fraudulently joined and that the learned intermediary doctrine does not extend to sales representatives).

Hawaii: *McClelland v. Merck & Co., Inc.,* No. 06-543, 2007 WL 18293 (D. Haw. Jan. 19. 2007) (denying remand and granting motion to stay pending transfer to multi-district litigation proceedings).

Illinois: *Kennedy v. Medtronic,* 851 N.E.2d 778 (Ill. App. 2006) (finding that Medtronic's clinical specialist attended the surgery to provide technical support and ensure that the lead parameters were correctly calibrated and the lead was functioning properly and that this limited role did not entail her voluntarily assuming a duty, under section 324A of the Restatement (Second) of Torts, for the placement of the lead into the correct ventricle of the patient's heart).

Indiana: *McDaniel v. Synthes, Inc.,* No. 2:07cv245, 2007 WL 3232186 (N.D. Ind. Oct. 29, 2007) (finding that sales representative who sold pain pump to medical device company and was present in operating room during surgery was not fraudulently joined).

Kansas: *Jochim v. Wyeth-Aherst Labs. Div.,* No. 01-2304, 2001 WL 950785 (D. Kan. July 13, 2001) (remanding case in which plaintiffs amended complaint adding local sales representative and physician).

Kentucky: *Anderson v. Merck & Co., Inc.,* 417 F. Supp. 2d 842 (E.D. Ky. 2006) (finding sales representative was fraudulently joined and denying remand).

Mississippi: *Omobude v. Merck & Co., Inc.,* No. 3:03cv528, 2003 WL 25548425 (Oct. 3. 2003) (holding that sales representative was improperly joined); *but see Coker v. Merck & Co., Inc.,* No. 4:07cv100, 2007 WL 2363398 (N.D. Miss. Aug. 16, 2007) (finding sales representative properly joined).

Nevada: *Elmore v. Merck & Co., Inc.,* No. 3:06cv557, 2007 WL 956893 (March 29, 2007) (holding that sales representative was proper party and granting remand to state court).

New Mexico: *Spataro v. Depuy Orthopaedics, Inc.,* No. 08-00274, 2009 WL 382617 (Jan. 9. 2007) (holding that defendant did not meet burden to show that sales representative was fraudulently joined).

Oregon: *DaCosta v. Novartis AG,* No. 01-800, 2002 WL 31957424 (D. Ore. March 1, 2002) (denying remand and dismissing sales representative as party).

Pennsylvania: *Crutchley v. I-Flow,* No. 09-35, 2009 WL 650358 (E.D. Pa. March 12, 2009) (finding sales representative a proper party and granting remand).

Texas: *Del Bosque v. Merck & Co., Inc.,* No. 06-510, 2004 WL 3487400 (S.D. Tex. Dec. 1, 2006) (finding that sales representative was properly joined and granting remand to state court); *see also Rape v. Medtronic, Inc.,* No. 9:04cv225, 2005 WL 1189826 (E.D. Tex. May 19, 2005).

West Virginia: *Jones v. Purdue Pharma L.P.,* No. 5:01cv1246, 2002 WL 32097528 (S.D. W. Va. Feb. 27, 2002) (holding that sales representative was fraudulently joined).

Wisconsin: *Stibor v. Ethicon, Inc.,* No. 04-C-1255, 2005 WL 1793589 (E.D. Wis. July 27, 2005) (granting remand and finding that the Complaint stated a claim against sales representative).

Written *by* Alyson Jones

Using E-Discovery *to* Pop *the* Hot Air from Plaintiff's Case

Hot Air or Nightmare? How often have you heard from opposing counsel that their client is the Mother Theresa of plaintiffs? You know the spiel. It begins with *my client is a fine upstanding person, selflessly giving to others, protecting children, the elderly, and homeless dogs from cruelty and abuse and would have done even more for this world but for your company's fatally flawed product.…* The pitch ends with a request for a sizeable check to compensate the plaintiff for egregious, irreparable, and life-altering injuries. Wanting something more balanced than this one-sided tale of horror, you move forward to find out what the plaintiff's case is really about — hot air or nightmare?

E-Discovery

One of the sharpest tools in the discovery drawer for deflating a puffed-up and seemingly impenetrable plaintiff is e-discovery. Traditionally, the spear of e-discovery has been aimed against corporate defendants, causing a trail of anguish to comply with the unwieldy demands created by the electronic format. But that tool can be equally effective for the defense. Depending upon age, geographic residence, and other factors, the likelihood is in your favor that the plaintiff has left an e-trail.

According to a 2009 Gallup report, internet usage among Americans has doubled over the last five years, and nearly half of all Americans are *frequent* internet users: "While the most educated, most affluent, and youngest Americans are those more likely to say they use the internet more than one hour per day, the less affluent, non-working, and unmarried are increasing their usage at noteworthy rates."[1]

The e-discovery plan begins with a simple search of the plaintiff's name on Google. This initial search alone can produce some wonderful results. For instance, a Google search on the plaintiff in a pharmaceutical product liability action showed that the plaintiff was able to go boating, fishing, and energetically participate in many other activities that were in stark contradiction to his trial testimony. Another quick Google search showed that a plaintiff in a medical device action engaged in a public chat forum, where the plaintiff stated that his counsel did not believe in his case. With the proliferation of home videos and public airings, YouTube may also provide motion picture impeachment.

Discovery of Social Networking Websites

Another potentially fertile area is publicly available information from social networking websites. Social networking websites allow individuals to form online social communities. Within such sites, members communicate by public or private messaging, file-sharing, and/or discussion boards. The benefits of these sites are building relationships, information-sharing, education, grassroots advocacy, and expressing and sharing different forms of arts and entertainment.

Social networking websites attract a wide variety of individuals from different age groups and backgrounds, and different sites have different constituents. For instance, Facebook, the most popular social networking website,[2] began as a university site and has grown to 200 million active users around the world.[3] MySpace attracts a young crowd, which according to one author, has made the site "a low-rent teenage hangout."[4] MySpace, however, has taken aggressive steps in 2009 to attract older folks in a battle for popularity against Facebook,[5] while LinkedIn is specifically geared to professionals.

To participate in a social networking website, an individual fills out a profile with contact information, personal information such as gender and interests, and agrees to abide by the website's terms of service and privacy policy. While each website has its own requirements, most of the popular sites require the user: (a) to provide accurate, current, and complete information as may be prompted by any registration forms on the site; (b) to maintain and promptly update registration data so as to keep the information accurate, current, and complete; and (c) to be fully responsible for all uses and actions taken on the user's account. Accordingly, against a requirement of honesty and accuracy, publicly accessible user information may be relevant to a plaintiff's bias, credibility, and even substantive issues depending on what information is listed.

> Even when you have obtained e-discovery to pierce an exaggerated claim, a bigger hurdle remains. How to get the e-discovery admitted into evidence?

Not many cases directly address third-party discovery from social networking sites. In *Mackelprang v. Fidelity National Title Agency, Inc.*,[6] plaintiff sued defendants for sexual harassment, claiming that her superior sent her inappropriate and sexually explicit emails on her office computer on at least a weekly basis.[7] After her husband became employed at the same company, plaintiff alleged that another supervisor coerced her into having sexual relations with him under a threat that if she did not do so, her husband would be fired.[8] Plaintiff then engaged in unwanted sexual acts.[9] After plaintiff complained to human resources, she was told the situation would be handled but if she brought it up again, she would be fired, and in her distressed state, plaintiff attempted suicide on two separate occasions.[10]

Defendants took affirmative investigative action after plaintiff filed the sexual harassment lawsuit. One of those steps included serving a subpoena on MySpace.com to produce information regarding two accounts maintained by the plaintiff.[11] MySpace.com produced the "public" information but refused to produce private email messages on either account absent a search warrant or letter of consent to production by the account holder.[12] The two MySpace accounts publicly showed that plaintiff identified herself as a single woman who didn't want kids and alternately as a married woman with six children she loves.[13]

Defendants moved to compel plaintiff to consent to the production, arguing that plaintiff was using the private messaging functionality of MySpace to facilitate the same type of electronic and physical relationships she has described as harassment in her complaint.[14] Defendants also argued that such evidence, if discovered in the private emails, was relevant to plaintiff's claim for emotional damages.[15] The court denied without prejudice defendant's motion to compel. Consistent with other sexual harassment cases, the court drew the line by permitting discovery of the plaintiff's work-related sexual conduct, but not permitting inquiry into plaintiff's private sexual conduct.[16] The court reasoned "what a person views as acceptable or welcomed sexual activity or solicitation in his or her private life, may not be acceptable or welcomed from a fellow employee or a supervisor."[17]

However, the court found that any statements plaintiff may have made about her two suicide attempts or contemporaneous emotional distress claims on MySpace would be relevant to her claim for emotional distress.[18] Also, the court allowed discovery on any online statements plaintiff made about her

lawsuit and on the online accounts she maintained. The discoverable information included both the plaintiff's own emails and her MySpace private messages.[19] The court pointed out that the "proper method for obtaining such information" was to serve upon plaintiff" properly limited requests for production of relevant email communications" and threatened to sanction plaintiff if she engaged in wrongful and bad faith denial that the MySpace accounts belonged to her.[20] Discoverable information "d[id] not include private email messages between Plaintiff and third persons regarding allegedly sexually explicit or promiscuous emails not related to Plaintiff's employment."[21]

In sum, requesting e-discovery, including social networking communication, should be the standard part of any defendant's discovery package on plaintiff, but care should be taken to craft the document request to the issues of the case.

Admissibility of E-Discovery

Even when you have obtained e-discovery to pierce an exaggerated claim, a bigger hurdle remains. How to get the e-discovery admitted into evidence? Chief Magistrate Grimm's opinion in *Lorraine v. Markel American Insurance Co.*[22] provides an excellent comprehensive "how-to" analysis under the Federal Rules of Evidence. He provides a simple checklist for getting e-mails and other electronic systems information (ESI) into evidence, either at trial or in summary judgment:

- Is the ESI relevant under Rule 401, meaning does the ESI tend to make some fact that is of consequence to the litigation more or less probable than it would otherwise be?
- Has the ESI been authenticated as required by Rule 901(a), meaning is the ESI what it purports to be?
- Is the ESI being offered for the truth of the matter asserted? If so, does the ESI fall within one of the exceptions to hearsay in Rules 803, 804, or 807?
- Is the form of the ESI that is being offered into evidence an original or duplicate under the original writing rule set forth in Rules 1002 and 1003? If not an original, is there admissible secondary evidence to prove the content of the ESI?
- Is the probative value of the ESI substantially outweighed by the danger of unfair prejudice or one of the other factors identified by Rule 403 such that it should be excluded despite all of the above?[23]

The magistrate judge pointed out the ubiquitous nature of e-mails: "Although courts today have more or less resigned themselves to the fact that '[w]e live in an age of technology and computer use where e-mail communication now is a normal and frequent fact for the majority of this nation's population, and is of particular importance in the professional world [...] it was not very long ago that they took a contrary view — '[e]-mail is far less of systematic business activity than a monthly inventory printout.'"[24] The court observed that people now "tend to reveal more of themselves in emails […] than in other more deliberative forms of written communication. For that reason, e-mail evidence often figures prominently in cases where state of mind, motive, and intent must be proved."[25]

An email message may be authenticated directly or indirectly by "its 'contents, substance, internal patterns, or other distinctive characteristics, taken in conjunction with circumstances.'"[26] E-mails may even be self-authenticating if they contain labels or tags affixed in the ordinary course of business.[27] The most frequent means to authenticate email evidence is through a person with personal knowledge, expert testimony, or comparison with authenticated exemplar, distinctive characteristics including circumstantial evidence, trade inscriptions, and certified copies of business records.[28]

The court also addressed internet website postings, text messages, and internet chat rooms.[29] Establishing authenticity for these types of electronic exchanges most likely requires a witness with personal knowledge, expert testimony, distinctive characteristics, public records, a system or process capable of producing reliable results, or an official publication.[30]

Because the emails and other electronic system information at issue were not properly authenticated, Chief Magistrate Grimm denied the cross-motions for summary judgment.

Conclusion

E-discovery is becoming a routine part of defense discovery requests. Planning how to authenticate the information will be the challenge.

[1] *See* Morales, Lynmari. "Nearly Half of Americans Are Frequent Internet Users." *Gallup*. 2 January 2009. Retrieved 10 June 2009. <http://www.gallup.com/poll/113638/Nearly-Half-Americans-Frequent-Internet-Users.aspx>.

[2] Bains, Lee. *Switched*. 27 January 2009. Retrieved 10 June 2009. "Facebook Overtakes MySpace as Most Popular Social Networking Site." <http://www.switched.com/2009/01/27/facebook-overtakes-myspace-as-most-popular-social-networking-sit>.

[3] *See* <http://en.wikipedia.org/wiki/Facebook>; Elliot Spagat, "Owen Van Natta, MySpace CEO: 'There's A Lot More That Can Be Done Around Innovation,'" 28 May 2009, Retreived 10 June 2009, <http://www.huffingtonpost.com/2009/05/28/owen-van-natta-myspace-ce_n_208526.html>; Caroline McCarthy, "Van Natta as My Space CEO: 'Effectively Immediately,'" <http://news.cnet.com/8301-13577_3-10226941-36.html>.

[4] *See* MacMillan, Robert. "Reinventing MySpace: A New CEO is Just the Beginning." 24 April 2009. Retrieved 10 June 2009. <http://www.reuters.com/article/ousiv/idUSTRE53N7DI20090424>.

[5] Feldon, Emily. "MySpace Courts Older Folks in Battle Against Facebook." 4 June 2009. Retrieved 10 June 2009. <http://www.nbcnewyork.com/around_town/the_scene/Myspace-Courts-Older-Folks-In-Battle-Against-Facebook.html>.

[6] 2007 WL 119149 (D. Nev. Jan. 9, 2007).

[7] *Id.* at *1.

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *Id.* at *2.

[12] *Id.*

[13] *Id.* at *3.

[14] *Id.* at *3.

[15] *Id.*

[16] *Id.* at **3-6.

[17] *Id.* at 6.

[18] *Id.* at **7-8.

[19] *Id.*

[20] *Id.*

[21] *Id.* at *8.

[22] 241 F.R.D. 534 (D. Maryland 2007).

[23] *Id.* at 538.

[24] *Id.* at 554 (internal citations omitted).

[25] *Id.*

[26] *Id.* at 554 (*quoting* Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence §900.07(3)(c), Joseph M. McLaughlin ed., Matthew Bender 2d ed. 1997).

[27] *Id.*

[28] *Id.* at 554-55.

[29] *Id.* at 555-57.

[30] *Id.*

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