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The MedLaw Update

The newsletter of the Medical Liability and Health Care Law Committee

9/21/2018

Volume 23 Issue 3

Committee Leadership

In This Issue

Leadership Note

Letter from the Chair

By J. Richard Moore

The September 2018 issue of *Atlantic* includes a lengthy piece titled, "What It Takes To Be A Trial Lawyer If You're Not A Man." It is written by Lara Bazelon, a clinical professor of criminal law at the University of San Francisco School of Law. Professor Bazelon notes that while more women than men were admitted to law schools over the last 20 years, women are still much less likely to occupy "the high-profile role of first chair at trial." She points out persistent biases on the part of judges, juries and male (and sometimes female) trial lawyers that continue to impact women litigators in the courtroom.

While Professor Bazelon's piece makes important points about the very real challenges that face women trial lawyers, her narrow focus on first-chair trial practice risks obscuring the fact that today, across the immense spectrum of opportunities in the legal field, the practice of law in America is a woman's profession. I started law school at just about the time that women law students began to outnumber men. From the very beginning of my student experience, it was apparent that women were at the leadership forefront. The top honor in our law school is the Founder's Medal, and in the year I graduated, it was awarded to my good friend Kelly Cahill Timmons. Kelly has gone on to become a popular and successful professor of law at Georgia State University. Since my graduation year, the Founder's Medal for law—which is based strictly on classroom performance, what we used to call "grades"—has been awarded to women graduates on nine occasions. At the risk of giving away my age, I will disclose that this is just under half of the time.

I have been privileged through the course of my career to work with and for exceptionally talented women lawyers. I have been mentored by woman partners whose training is part of every deposition I take, every brief I write, every negotiation I conduct, and every case I try. I have labored in the trenches with women coworkers on cases big, small and average, and have been gratified on innumerable occasions by the tenacity and ingenuity these colleagues demonstrate. I have worked for accomplished women clients in the insurance and health care industries, and for female corporate counsel whose expectations are as high for themselves as for their outside attorneys. I am certain that my experience is shared by attorneys across the country.

For me, working in our committee has been the fullest demonstration of the successful integration of the sexes in a professional setting. For years, of course, DRI has been proactive about recognizing the growing contributions of women in the law and incorporating women lawyers' talents and hard work into the organization's membership and leadership. I am proud to say that the Medical and Health Care Law Committee is a model of success in that regard. Many of our current leadership positions are occupied by women: Jodi Terranova of Washington, DC chaired the 2018 Medical Liability seminar in March; Erika Amarante of New Haven, CT, is the program chair for the 2019 Medical Liability seminar; Caroline Berdzik of Princeton, NJ, is program vice chair for our upcoming 2018 Nurse Home/ALF Litigation seminar; and Laura Eschelman is serving as our 2018 Annual Meeting liaison. And women's involvement in leadership in our committee is nothing new. Laura was program chair of the 2017 Medical Liability seminar, and was awarded DRI's Program Chair Of The Year Award for her performance. She was preceded in 2016 by Tracy Zuckett of Denver, CO. Angie Ioannou of Hartford, CT, served as program chair for the 2016 Nursing Home/ALF Litigation seminar, and was our 2017 Annual Meeting liaison. Angie also previously served as Publications Chair. I could go on and on about the contributions that the many women lawyers involved in our committee have made over the years, and continue to make to this day.

The point of these observations is not to boast about how much progress we have made (although I am indeed very proud to be involved in such an organization). The point is to recognize that our committee, and our organization, could not and would not be successful without the wisdom, imagination and generosity of the women who are the backbone of its membership and leadership. Professor Bazelon makes a strong point when she highlights the continuing challenges that women trial lawyers confront. If my DRI experience is any indicator, I am confident that the women who lead us today, the women who are our peers in the workplace and professional organizations, and the women who are in training to occupy the next levels of leadership, will all blaze through those challenges.

Feature Articles

Healthcare Vendors/Subcontractors: The Risk Is Yours!

By Adrejia L. A. Boutté Swafford

"Through the federal civil rights laws and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, [the United States Department of Health and Human Services' Office for Civil Rights] protects your fundamental nondiscrimination and health information privacy rights by …investigating civil rights, health information privacy, and patient safety confidentiality complaints to identify discrimination or violation of the law and take action to correct problems." Wonderful. But who regulates vendors and subcontractors with our health care providers/entities?

The answer is simple. The United States Department of Health and Human Services' Office for Civil Rights, state laws, and each heath care provider/entity. For an entity, cyber risk is the degree of exposure created by every individual, from employee to customer to a vendor; through regular business activities with technological devices. Travelers Insurance Company cites the following top five risks for businesses as: 1) "Human Error: Lost and Stolen Laptops and Smartphones;" 2) Hackers; 3) "Spear Phishing: Social Engineering Targeted at Employees;" 4) Extortion; and 5) "Hacktivism: Social and Political 'Hactivists'[sic]."

According to the RAND Corporation's 2015 study, "data breaches" and the "unintentional disclosure of personally identifiable information (PII) stemming from loss or theft of digital or printed information," were the most commonly reported cybercrimes. In 2017 Verizon reported that 80 percent of the breaches in the Healthcare industry were due to "privilege misuse ['Any unapproved or malicious use of organizational resources…'], miscellaneous errors ['Incidents in which intentional actions directly compromised an attribute of a security asset'], physical theft and loss." In general, "the healthcare sector is now under siege from 'rampant' attacks by 'ransomware,' malicious computer coding that essentially captures an organization's information assets until a ransom is paid." "Every aspect of the institution is tied up."

In the 2015 case, *Columbia Casualty Company vs. Cottage Health System*, No. 2:15-cv-03432 (C.D. Cal. May 7, 2015), 2015 WL 3751196, the insurer/plaintiff, Columbia Casualty Company ("Columbia"), filed a "Complaint for a Declaratory Judgment pursuant to 28 U.S.C. §2201 and for reimbursement of Defense and Settlement Payments made by Columbia on behalf of its insured" against defendant/insured, Cottage Health System ("Cottage"). Columbia sought a declaration that it was not obligated to provide Cottage with a defense or indemnification in connection with any and all claims stemming from the data breach at issue, and further, that it was entitled to reimbursement in full from Cottage for any and all attorney's fees or related costs or expenses paid or will pay in connection with the defense and settlement of the class action lawsuit and any related proceedings and an award of damages consistent with such declaration. Apparently, "between October 8, 2013 and December 2, 2013, confidential medical records of approximately 32,500 of [Cottage Health System's] Hospitals' patients that were stored electronically on [Cottage Health System's] servers were disclosed to the public via the internet." As alleged by the underlying class action, the incident occurred because:

> [C]ottage and/or its third-party vendor, INSYNC Computer Solution, Inc. ("INSYNC"), stored medical records on a system that was fully accessible to the internet but failed to install encryption or take other security measures to protect patient information from becoming available to anyone who 'surfed' the internet. And as such, [C]ottage violated its nondelegable duties under [California's Confidentiality of Medical Information Act ("CMIA")] and HIPAA to maintain the security of its patients' confidential medical records and to detect and prevent data breaches on its system that would allow such information to become available to the public through the internet.

In the underlying claim, the cyber incident—the "data breach" —was investigated by the California Department of Justice for possible violations of the HIPAA laws, and a class action was filed against Cottage and a settlement reached. *Id.* Cottage held a NET PROTECT 360 claims-made cyber liability insurance policy with Columbia and, as a result, Columbia agreed to cover the settlement, "subject to a complete reservation of rights." *Id.* Following the settlement, this suit ensued. Ultimately, the matter was handled, it went to arbitration in accordance with the terms of the insurance contract, and was presumably resolved in arbitration.

Healthcare providers/entities can avoid the troubles experienced by Cottage. To mitigate and minimize this third-party type of risk, health care providers/entities must require that their vendors and subcontractors follow the same level of cyber risk, HIPAA, and state law compliance

as they do. And, in some cases these health care providers/entities may need to require that their vendors and subcontractors access the vulnerable data through the provider's/entity's own secured networks; versus transferring the data into a foreign network. The process of transferring data creates a degree of unique vulnerability on its own. Of course, if the entity conducts or offers medical services over the internet to the European Union (EU), or simply has patients located in the EU, it will be further subjected to the regulations of the EU General Data Protection Regulation.

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Sign on the Dotted Line

Avoiding the Collapse of a Mediated Agreement

By Matthew D. Murphy and Adam J. Kost


In February of 2018, the South Dakota Supreme Court delivered an important message to parties who participate in mediation: do not leave a successful mediation without ensuring the agreement is documented in writing.

Mediation in Health Care

Mediation continues to be an effective and efficient tool for resolving all types of civil disputes, including those in health care. Mediation can have a number of benefits for all parties involved, including reduced legal costs, expedited results, direct involvement of the parties, and the potential for medical professionals to acquire information that may improve quality of care. Carol B. Liebman, *Medical Malpractice Mediation: Benefits Gained, Opportunities Lost*, Law & Contemp. Probs., Summer 2011, at 135, 139. In 2016, the ABA issued a resolution urging "lawyers and all interested parties to encourage the informed and voluntary use of alternative dispute resolution (ADR) processes as an effective, efficient and appropriate means to resolve health care disputes." https://www.americanbar.org/content/dam/aba/ administrative/ house_of_delegates/2016_hod_midyear_meeting_electronic_report_book.authcheckdam.pdf

The Issue

Many of you reading this article likely have a mediation scheduled within the next month. Maybe even next week. And, as you know from your past experience, your case will probably be resolved at that mediation. But what would happen if you and your client walked out of that mediation with what you thought was a clear oral agreement expressly discussed between the parties and mediator collectively, only to discover later that there was a major disconnect on a key term? Simple – you would make a motion to enforce the oral settlement agreement and call the mediator as a witness. Part of the rationale here might include the rule of evidence allowing in-court discussion of the terms of settlement agreements when such evidence is being introduced for "another purpose," like enforcing the terms of the settlement itself. Fed. R. Evid. 408.

Well . . . not so fast. If you are in a state that has enacted the Uniform Mediation Act, like here in South Dakota, your perceived oral agreement is not binding, and evidence of the oral agreement, including testimony from the mediator, cannot be submitted to the court.

The *Winegeart v. Winegeart* Case from South Dakota

In *Winegeart v. Winegeart*, Eryn Winegeart and her former spouse, Weston Winegeart, mediated their divorce and apparently came to an oral agreement about how the sale of their marital home would proceed. 2018 S.D. 32, 910

N.W.2d 906. After the mediation, Weston listed the home with a realtor. The listing agreement included a commission for the realtor. Soon after, a third party signed an agreement to purchase the home. Eryn refused to sign off on the purchase agreement, claiming that Weston orally agreed during the mediation to sell the property without paying a realtor. *Id.* at ¶¶2–3, at 907.

Weston sought a court order to compel Eryn to sign. At his deposition, the mediator testified it was his "understanding…that there were no Realtor commissions to be paid, that this was going to be a private sale." *Id.* ¶4, at 907. The trial court rejected this testimony, finding there had not been an enforceable oral agreement between the parties regarding payment of a realtor commission, and it ordered Eryn to sign the purchase agreement. *Id.* at ¶¶4–5, at 907–08.

Eryn appealed the trial court's decision to the South Dakota Supreme Court ("the Court"). The Court affirmed the trial court based upon multiple grounds, one being the provisions of South Dakota's Uniform Mediation Act ("the Act"). The Act has been adopted in 12 jurisdictions (the District of Columbia, Hawaii, Idaho, Illinois, Iowa, Nebraska, New Jersey, Ohio, South Dakota, Utah, Vermont, and Washington) and it has been introduced in two others (New York and Massachusetts). Mediation Act, Uniform Law Commission (2018), http://www.uniformlaws. org/Act.aspx?title=mediation Act.

The Court first considered whether or not communications made during mediation are confidential and thus cannot be used to prove the existence of an oral agreement. *Id.* at ¶8, at 908. The Act generally makes any mediation communication privileged and "not subject to discovery or admissible in evidence in a proceeding[.]" SDCL 19-13A-4(a). As defined by the Act, a mediation communication is "a statement, whether oral or in a record or verbal or nonverbal, that occurs during a mediation or is made for purposes of considering, conducting, participating in, initiating, continuing, or reconvening a mediation or retaining a mediator." SDCL 19-13A-2(2).

In analyzing this issue, the Court looked to the Act's exceptions codified at SDCL 19-13A-6. One exception permits evidence and testimony regarding "an agreement evidenced by a record signed by all parties to the agreement." SDCL 19-13A-6(1). The Court found this telling: "The specific inclusion of *written* agreements in SDCL 19-13A-6 implies that *nonwritten* agreements are not excepted from the mediation-communication privilege." *Winegeart*, 2018 S.D. at ¶10, at 909 (emphasis in original) (Citing *In re Estate of Flaws*, 2012 S.D. 3, ¶20, 811 N.W.2d 749, 754 (applying the canon of construction *expressio unius est exlcusio alterius*)). The Court went on to note an opinion from the Utah Supreme Court, also interpreting the Act, which mentioned that the Uniform Law Commission "explained in a comment to the Uniform Mediation Act that oral agreements were intentionally *not* included in the list of exceptions to mediation privilege." *Id.* (Quoting *Reese v. Tingey Constr.*, 177 P.3d 605, 609–10 (Utah 2008)).

For further analysis, the Court relied upon the five other jurisdiction that had adopted the Act and addressed this same issue, all coming to the same conclusion—an oral agreement is unenforceable under the terms of the Act. *See Billhartz v. Billhartz*, No. 5-13-0580, 2015 WL 2058961, at *8 (Ill. App. Ct. May 4, 2015) (Written agreements are enforceable, while oral agreements generally are not); *Shriner v. Friedman Law Offices, P.C., L.L.O.,* 877 N.W.2d 272, 290 (Neb. App. 2016) (Mediation communications generally are not discoverable); *City of Akron v. Carter*, 942 N.E.2d 409, 415–16 (Ohio Ct. App. 2010) (same); *Reese v. Tingey Constr.*, 177 P.3d 605, 609 (Utah Sup.Ct. 2008) (Parties must evidence an agreement in writing to be enforceable); *Willingboro Mall, Ltd. v. 240/242 Franklin Ave., L.L.C.*, 71 A.3d 888, 898 (N.J. 2013) (same). While recognizing the decisions of these other jurisdictions were not binding on the Court, "the Legislature has instructed that '[i]n applying and construing this chapter, consideration should be given to the need to promote uniformity of the law with respect to its subject matter among States that enact it.'" *Winegeart*, 2018 S.D. at ¶10, 911 N.W.2d at 910 (*Quoting SDCL 19-13A-13*).

Based on its analysis, the Court concluded that, with regard to the common form of the Act, it is clear that an oral agreement arising out of a mediation is not enforceable. However, the Winegeart Court went one step further in its analysis because South Dakota's Act has a particular nuance not found in others. It stated as follows:

> These opinions [from other jurisdictions] are premised on the evidentiary reality that if mediation communications are not subject to discovery or admissible in evidence, then generally the only way to prove the terms of an agreement is to reduce it to a signed writing. (citation omitted). But South Dakota's version of the UMA potentially provides another avenue for establishing the terms of a settlement reached during mediation that has not been reduced to writing. Under §7(b)(1) of the UMA, '[a] mediator may disclose…whether a settlement was reached[.]' But unlike every other jurisdiction that has adopted the UMA, the South Dakota Legislature modified the language of our corresponding statute; thus, in South Dakota, a mediator

> may disclose 'whether a settlement was reached and if so the terms thereof[.]' SDCL 19-13A-7(b)(1).

Id. at ¶12 (emphasis in original). After some additional statutory analysis only applicable to South Dakota's version of the Act, the Court again affirmed the position discussed above, refusing to "permit a mediator to disclose the terms of a purported *oral* settlement reached during mediation," thereby implying that the only time a mediator could testify about the terms of a mediated settlement would be in a case where such settlement was reduced to writing. *Id.* at ¶13-14, at 910–11 (emphasis added). As part of its analysis, the Court noted two important points that would be applicable to all jurisdictions operating under the Act:

> [First] As noted above, the purpose of the mediation-communication privilege is to encourage participants to be candid by shielding their negotiations from later disclosure. [citations omitted]. But if a mediator may disclose mediation communications . . ., then the purpose of the mediation-communication privilege can be easily subverted[.] . . . And, as the ULC pointed out in the model act 'nearly everything said during a mediation session could bear on either whether the parties came to an agreement or the content of the agreement." [citations omitted]. Thus, permitting a mediator to disclose the terms of a purported oral settlement also has 'the potential to swallow the rule of privilege.' Id. (citations omitted).
>
> [Second] [P]erhaps most important of all, this narrow reading harmonizes [South Dakota's statutory scheme] with its counterparts in other jurisdictions that have enacted [the Act], thereby carrying out the Legislature's directive to consider chapter 19-13A in light of other jurisdictions' treatment of [the Act]. (citations omitted).

Id. at ¶14, at 910–11.

Conclusion

Next time you head to a mediation, be prepared to leave with the terms of any resolution documented in writing. If documenting all the various terms of the agreement is not feasible on the mediation day, at a minimum, document the material ones. This is a must in any jurisdiction that has adopted the Uniform Mediation Act. In those jurisdictions that have not, this should still be considered a best practice.

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Don't Forget to Print Your Medicine

The Impact of 3D Printing on Pharmaceutical Products Liability

By Elizabeth C. Christen

Recently, three-dimensional ("3D") printing, also known as "additive manufacturing," has taken off so rapidly that some observers are calling it "the next greatest chapter in the industrial revolution." Although the technology has been around since the 1980s, recent advancements have lowered the cost of 3D printers, allowing them to be utilized in industries from medical and dental to automotive, fashion, food and more. In August 2012, President Obama recognized the potential for innovation brought about by 3D printing and launched the National Additive Manufacturing Innovation Institute to foster support and collaboration around 3D printing. As with any innovative technology, however, new concerns regarding regulations and potential liability for manufacturers abound. This article explores recent advancements in 3D-printed medicines and the intersection of new this technology with traditional medical regulations and law.

What Is 3D Printing?

3D printing generally starts with a computer-aided design ("CAD") of a digital model of the product. Then, the design is sliced into thousands of horizontal layers that will form the digital file for feeding into a 3D printer. Using different

materials, the product or end-result is printed layer-by-layer, transforming the two-dimensional layers into a 3D product. The American Society for Testing and Material ("ASTM") has recognized and set standards for seven different types of additive manufacturing.

The medical industry's most prolific use of 3D printing has been in the production of hearing aids and other medical devices such as prosthetic limbs, dental implants, and surgical screws. To date, the FDA has approved, through its 501(k) process, over 100 3D-printed medical devices, leading some experts to believe that 3D-printed pharmaceuticals may be the next area to take off.

3D-Printed Pharmaceuticals

In 2015, the FDA approved the first (and currently the only) 3D-printed medication: Spritam, an anti-epileptic seizure tablet developed and manufactured by Aprecia Pharmaceuticals. Aprecia's proprietary 3D printing process, known as the ZipDose technology, prints a porous structure that rapidly disintegrates in the patient's mouth, making it easier to swallow. The process involves first putting a powder layer containing the drug under an inkjet print-head. The print-head then prints a bonding liquid at specific locations along the powdered sheet. Depending on the size of the tablet desired, Aprecia may print upwards of 30 or 40 layers of these sheets to create one pill. However, using a single printer "the size of a room," Aprecia has reported that it is able to print tens of thousands of tablets a day.

In December 2017, Aprecia and Cycle Pharmaceuticals announced a partnership to create 3D-printed tablets to treat rare (also known as "orphan") diseases using the ZipDose technology. Experts believe that 3D printing could be particularly useful in this area, which traditionally has required pharmaceutical manufacturers to maintain expensive infrastructure for low selling medications, because it could allow manufacturers to print different types of tablets on the same printer simply by changing the powders or "ink" used. This "changing-the-ink-cartridge concept" could lead to a democratization of pharmaceutical manufacturing whereby a 3D printer is used to make medicine more locally to patients, such as in hospitals or pharmacies.

Another possibility is printing personalized medicine or medicine specifically designed to fit one patient's needs. For example, researchers in the U.K. are experimenting with "polypills" or pills containing multiple drugs in one tablet. These researchers have been able to overcome drug compatibility concerns and issues with drug release timing using commercial 3D printers to compartmentalize multiple drugs on one tablet. Advances like these have led to the theory that one day doctors may be able "hand off an algorithm for patients to go print at home on a 3D printer rather than jotting down 'take 2 and call me in the morning.'"

Regulations and Legal Developments

All of these advancements beg the question of additional regulations and potential liability concerns for pharmaceutical manufacturers. Although the FDA has seemingly embraced 3D printing, it has acknowledged that new regulations are necessary. On December 15, 2017 the FDA issued its "Technical Considerations for Additive Manufactured Medical Devices: Guidance for Industry and Food and Drug Administration Staff," along with a statement from FDA Commissioner Scott Gottlieb, M.D. According to Commissioner Gottlieb, the purpose of the new guidelines "will help manufacturers bring their innovations to market more efficiently by providing a transparent process for future submissions and making sure [FDA's] regulatory approach is properly tailored to the unique opportunities and challenges posed by this promising new technology."

To date, the FDA has not promulgated any such guidance for 3D-printed pharmaceuticals, despite more than a dozen pharmaceutical manufacturers formally or informally contacting FDA's Center for Drug Evaluation and Research regarding the use of 3D printing to manufacture drugs.

Regarding potential tort liability, 3D medical printing brings about a plethora of new considerations. Legal questions undoubtedly will include what is a "product," who is the "manufacturer," what is the "marketplace," and who should be liable for a defective 3D-printed medication. Some various liability scenarios include: (1) defective original product used to create the digital design; (2) defective original digital design; (3) defective digital file; (4) corrupted copy of downloaded digital file; (5) defective 3D printer; (6) defective bulk printing material used in 3D printer; (7) human error in implementing the digital design; and (8) human error in using the 3D printer and/or materials.

End users who are injured by 3D-printed medical products may wonder who is liable. In those instances, identifiable entities and presumed "deep pockets" will likely have to combat attempts at expanding their liability, especially in the instance of medical devices and drugs being 3D-printed by consumers, hobbyists or entrepreneurs at home.

Given the novel nature of 3D-printed medical devices and pharmaceuticals, case law involving such products is scarce. The only reported product liability case involving a 3D-printed medical product is Buckley v. Align Technology, Inc., which involved 3D-printed, custom-fitted dental aligners for treating malocclusion (misaligned teeth). No. 5:13-cv-02812-EJD, 2015 WL 5698751 (N.D. Cal. 2015). The *Buckley* plaintiff alleged that the defendant manufacturer of the 3D-printed device "falsely advertised, misled and deceived [consumers including herself] into believing that [the product] could treat their malocclusions," when in fact, the product could not help her type of malocclusion. *Id.* at *1. The defendant moved to dismiss the plaintiff's second amended complaint pursuant to Federal Rule 12(b)(6). *Id.* at **1–2.

Relying on California's learned intermediary doctrine, the court found that because the dental aligns were prescribed solely by the dentist, the defendant manufacturer's duty to warn only ran to the dentist, rather than to ultimate user of the device. *Id.* at *4. Thus, the court reasoned that although the 3D printing manufacturer was involved in customizing its medical device to the plaintiff-patient, the defendant nevertheless functioned as a traditional manufacturer, whose only patient contact was facilitated through the learned intermediary dentist. *Id.* Accordingly, the court dismissed the complaint with prejudice and without leave to amend. *Id.* Notably, *Buckley* involved a relatively straightforward application of 3D printing. As 3D-printed medicine becomes even more personalized, such as via the polypills discussed above, manufacturers undoubtedly will need to have additional communication with their end-users to better understand their unique medical needs. As such, courts may be less inclined to shield manufacturers from liability.

Conclusion

3D-printed pharmaceuticals are sure to become more prevalent in the coming years and offer endless opportunities for medical advancement, cost-savings and personalization. Nevertheless, with new technology comes new potential concerns for manufacturers and their counsel. As discussed herein, uncertainties abound both with the current lack of specific regulations for 3D-printed pharmaceuticals, as well as the paucity of current guidance as to how courts may handle issues of first impression regarding these medicines. Like the technology itself, these evolving areas bear close monitoring by manufacturers and their counsel.

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