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HEALTH LAW VITALS

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Fiduciary Duties of Directors in the Medical Technology Industry

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Theranos Inc., a former biotech company in Silicon Valley, and the source of significant media coverage since 2015, presents a unique case study for members of the boards of directors of corporations in the medical technology industry. According to allegations by the **SEC** and the **DOJ**, Theranos, Elizabeth Holmes (its founder and CEO) and Ramesh "Sunny" Balwani (its COO): (1) defrauded investors, doctors and patients by leading them to believe that Theranos' key product could conduct comprehensive blood tests from small drops of blood (in actuality, Theranos' device produced inaccurate results and could only complete a small number of tests and, to keep this fact from its investors and the general public, Theranos, as it is alleged, conducted the majority of its tests on commercially available and/or modified analyzers manufactured by unrelated third parties), and (2) overstated and made false statements about Theranos' business and financial performance to investors and customers.

In reaction to the above, a question often asked is whether Theranos' directors adequately fulfilled their fiduciary duties to Theranos and its shareholders. The risks for board members in the medical technology industry are particularly high, given the significance of maintaining the confidential nature of the product and associated intellectual property, the complex scientific and clinical expertise required to understand and assess certain claims, and the potential for patient harm as a result of untrue or misleading statements.

While state laws vary, generally, members of a corporation's board of directors owe two core fiduciary duties to the corporation and its shareholders: (1) the duty of care, and (2) the duty of loyalty. The duty of care generally requires that directors use the care that an ordinarily careful and prudent person would use in similar circumstances when making decisions on the corporation's behalf (this could include, for example, taking reasonable efforts to review all relevant

information available and understanding the related material facts). On the other hand, the duty of loyalty generally requires that directors act in good faith for the benefit of the corporation and its shareholders (for example, refraining from self-dealing and usurpation of corporate opportunity). Directors who breach their fiduciary duties could potentially face personal liability.

So what lessons can directors in the medical technology industry take away from Theranos?

1. It is imperative to put in place and maintain governance structures and internal controls to facilitate accuracy in financial statements and marketing claims.[1] According to **Fortune Magazine** and **Forbes**, Theranos' board of directors (which included former Secretaries of State, former Defense Secretaries, former senators and other high level military officers) did not have the proper regulatory and financial expertise to appropriately make decisions on behalf of Theranos' shareholders, or the relevant expertise in the particular industry to bring different viewpoints and identify critical issues.

2. Having a scientific advisory board (or otherwise engaging independent third parties) with knowledge in the relevant industry should be a priority for the board. Corporations in the medical technology industry are encouraged to have scientific advisory boards or engage independent parties so that directors may consult with these experts when appropriate or otherwise have them inspect relevant records (including contracts) to ensure the day-to-day operations are adequately understood.

3. Per the **Wall Street Journal's investigation**, Theranos' board of directors rarely questioned Holmes' and/or Balwani's management – and any member of the board that expressed a dissenting viewpoint or asked challenging questions was reportedly asked to resign. In the course of investing in corporations in the medical technology industry, entrepreneurs, venture capitalists, private equity investors, and their respective advisers, will be encouraged to ensure the corporation is being run and governed for the benefit of all of its investors. Creating a system of transparency that promotes dissenting viewpoints and encourages challenging questions by board members allows the board to thoroughly and properly oversee the management of the corporation.

For more information about fiduciary duties or our **Healthcare Transactions Practice Group**.

[1] *See* Mary Jo White, Chair, SEC, Keynote Address at the SEC-Rock Center on Corporate Governance Silicon Valley Initiative (March 31, 2016) (view the **transcript**).

Telehealth Promises and Pitfalls: Remote Prescribing of Controlled Substances, the SUPPORT Act, and Remaining Risks

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The healthcare industry is in the midst of a historic transformation, as the ongoing proliferation of technological advancements continues to improve the quality of medical care, increasing patient access, and revolutionizing the practice of medicine in the United States. In the context of telemedicine, more specifically in relation to remote prescribing of controlled substances, the ability to capitalize on innovation has, thus far, been stifled in certain respects by the Ryan Haight Online Consumer Protection Act of 2008 ("Haight Act"). However, more recently, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

("SUPPORT Act") was signed into law with the promise to reduce the obstacles imposed by the Haight Act and better equip the medical community to fight the opioid epidemic. While the SUPPORT Act will likely give providers more flexibility in prescribing controlled substances via telemedicine, it is important to understand the regulatory barriers and risks that remain.

The Haight Act and the SUPPORT Act:

In 2008, Congress passed the Haight Act, named after an 18 year old who died after overdosing on prescription painkillers that he obtained online from a physician he had never met.[1] The Haight Act makes it "unambiguous that it is a per se violation of the CSA [(Controlled Substances Act)] for a practitioner to issue a prescription for a controlled substance by means of the internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances."[2] One of the exceptions to the Haight Act allows the DEA to activate a "special registration" for certain providers who: (i) demonstrate a legitimate need for special registration; (ii) are registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located; and (iii) maintain compliance with state and federal laws when delivering, distributing, dispensing and prescribing a controlled substance.[3]

Before providers could utilize the Special Registration exception to prescribe controlled substances over the internet, however, the DEA was required to promulgate regulations, establishing the limited circumstances in which a provider would be issued a special registration and the procedure for obtaining such special registration.[4] The language under the Haight Act did not mandate a deadline for the DEA to enact the Special Registration regulations, and, as a result, such action was never taken. The SUPPORT Act seeks to remedy this issue by requiring the Attorney General to issue the Special Registration regulations by October 24, 2019.[5]

Further, the SUPPORT Act, namely Section 3232 (the Special Registration for Telemedicine Clarification Act of 2018), was enacted to address the growing concern of access to mental health services, with an estimated 111 million Americans living in areas with limited access to mental health professionals.[6] Relatedly, legislators behind the SUPPORT Act believe that authorizing the remote prescribing of controlled substances could add one more tool to fight the opioid epidemic, as certain controlled substances are known to play a vital role in the treatment of opioid addiction, and the rural parts of the country with some of the highest incidence rates of opioid addiction are among the regions with the fewest mental health practitioners.[7] While it is nearly certain that by October 24, 2019, practitioners will have greater freedom to prescribe controlled substances to patients treated via telemedicine, the specific scope and limitations remain to be seen and may be dependent upon more than just the DEA's Special Registration regulations.

Interplay with State Laws:

While compliance programs often focus on the Haight Act in relation to prescribing policies, remote prescribing regulation is largely left to the states. Applicable prescribing restrictions may be found in telemedicine statutes and regulations; state examining board rules and regulations, including, but not limited to, pharmacy practice acts and medical practice acts; and state controlled substances acts. The federal CSA stipulates that state laws on the same subject matter (that would otherwise be within the authority of the state) are not preempted "unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together."[8] In other words, if challenged, state laws that prohibit remote prescribing of controlled substances altogether (or without a prior in-person examination) are likely to be preempted. Also subject to preemption, if challenged, are state laws that expressly authorize remote controlled substance prescribing without requiring the provider to meet, *at least*, the requirements set forth under the DEA's Special Registration regulations (once implemented). However, states that impose additional or different requirements on providers' ability to prescribe

controlled substances online are likely to be upheld, so long as such laws and regulations may consistently stand together. For example:

- Most states prohibit controlled substance prescriptions based solely on the patient's completion of a medical questionnaire online or by telephone
- Numerous states authorize online prescribing of controlled substances if a valid physician-patient relationship has been formed (and some states further list the elements of a valid physician-patient relationship)
- Some states require a provider to obtain separate authorization from the state licensing board before such provider may prescribe controlled substances over the internet
- Many states place additional restrictions, depending on the condition for which the controlled substance is being provided (e.g., acute or chronic pain) or its intended effect (e.g., to cause an abortion)

Accordingly, after the issuance of the Special Registration regulations, providers must still ensure that their prescribing practices comply with state laws and regulations like those listed above, among others, as applicable. Further, it is important to understand that inconsistent state laws will only be subordinated to federal law to the extent related to online prescribing of *controlled substances*. States will retain control over all other prescribing practices. In other words, it may ultimately be the case that, depending on the state laws to which a provider is subject, the provider may prescribe controlled substances in accordance with the Special Registration regulations and other non-conflicting state laws, but such provider may not prescribe *other (non-controlled) prescription drugs* via telemedicine without a prior in-person examination, if at all. Provider practices and other healthcare entities must, therefore, maintain comprehensive compliance policies, incorporating not only the Haight Act (and Special Registration regulations, once effective), but also applicable state laws and regulations, noting, among other things, the different restrictions and requirements based on whether the prescription is for a controlled substance.

Remaining Risks:

In addition to the requirements of the to-be-issued Special Registration regulations and applicable state laws, healthcare providers must account for a number of other potential areas of risk—some of which may be heightened in the telemedicine/remote prescribing context, including, but not limited to, the following:

1. **Payor Coverage/Reimbursement:**

   Although states are increasingly enacting parity rules, whether in relation to Medicaid or commercial payors, and CMS has **recently** expanded the scope of coverage for certain telemedicine practices under the Medicare program and (potentially) **Medicare Advantage** plans, beginning in 2022, there are still serious limitations as to what telehealth practices are covered by a given plan and substantial variation among payors. Accordingly, in addition to the type of prescription drug, the drug's intended effect, and the condition at-issue, among the many other circumstances that may further restrict a provider's ability to prescribe controlled substances via telemedicine under federal and state law, providers must also consider the patient's insurance and the ever-changing conditions of coverage/reimbursement with respect to telemedicine.

2. **Malpractice:**

   Malpractice concerns may be heightened when prescribing controlled substances via telemedicine because, depending on the particular technology used, the provider may not be able to develop as much insight into the patient's condition and other relevant information when conducting telemedical consultations to the same extent as s/he may be able in person. However, most, if not all, states specify that providers are held to the

same standard of care in relation to treatment via telemedicine as that of traditional, in-person treatment. Certain controlled substances may further heighten liability concerns, as providers could face liability for under-prescription, over-prescription, overdoses, and addiction. For example, in 2017, a St. Louis jury awarded $17.6 million to plaintiffs who brought a malpractice suit against a physician for overprescribing pain medication between 2008 and 2012.9 Importantly, in addition to maintaining thorough documentation of patient monitoring and risk assessments, providers seeking to prescribe controlled substances remotely should confirm that their professional liability insurance coverage extends to what many policies describe as "distant care" and that coverage applies in every state in which the provider's patients are located.

3. **Fraud and Abuse:**

It is projected that the global market value of telemedicine, currently at $29.6 billion, will continue to increase at a rate of 19% per year until 2022.[10] Such increased spending and the ever-evolving regulatory scheme governing telehealth and remote prescribing make such practices ripe for heightened fraud and abuse scrutiny. The first false claims case involving telehealth was brought in 2016 in connection with a mental health practice that allegedly submitted false claims to Medicare for certain services provided to patients via telemedicine.[11] The government alleged that the providers improperly submitted claims to Medicare for services rendered over the phone, explaining that, at the time:

> Medicare permit[ted] certain types of "telehealth" services where the patient is in a rural health professional shortage area and where the provider uses an interactive audio and video communications system that permits real-time communication between the provider and the patient. However, the patients treated over the phone by DR. FRY and CPC ASSOCIATES were not located in rural health professional shortage areas and DR. FRY and CPC ASSOCIATES did not use interactive audio and video communications.[12]

Accordingly, it is important to understand the limits of Medicare's coverage and payment policies when providing services via telemedicine. Additionally, providers may be subject to false claims liability in connection with telehealth services provided in contravention of state and/or federal law, such as those described in the preceding sections. Finally, among many others, the practices described below have been identified by the DOJ as particularly suspect:

- Providing free or discounted telehealth equipment or software to individuals who may become patients or consumers of telehealth services
- Providing or offering telehealth-related funding or equipment to organizations that are actual or potential referral sources
- Offering telehealth services to organizations that are potential or actual referral sources and agreeing to refer telehealth patients preferentially to providers within these organizations for non-telehealth services

Conclusion:

Telemedicine's ability to truly reduce access barriers and allow mental health professionals to treat underserved populations suffering from opioid use disorder is dependent, at least in part, on a provider's ability to remotely prescribe controlled substances. We will likely continue to see further state and federal legislation in this space beyond the October 2019 Special Registration regulations mandated by the SUPPORT Act. Due to the potential lack of clarity and uniformity with such additional

legislation, before introducing remote prescribing into provider practices, such providers must develop and implement compliance policies incorporating the applicable laws, regulations, and rules at both the state and federal level and highlighting areas of increased risk.

We will continue to monitor these issues at the state and federal level and will provide updates as needed. In the meantime, any questions may be directed to the Haynes and Boone **Healthcare and Life Sciences Practice Group**.

[1] 21 U.S.C. § 802(54).
[2] 21 U.S.C. § 829(e); DEA, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 FR 15599-15603 (April 6, 2009).
[3] Supra, note 1.
[4] Congressional Research Service, ***The Special Registration for Telemedicine: In Brief***, (December 7, 2018).
[5] *Id.*
[6] Congressional Research Service, ***The Special Registration for Telemedicine: In Brief***, (December 7, 2018).
[7] Medication-assisted treatment (MAT) combines behavioral therapy with one of three Food and Drug Administration (FDA)-approved medications—buprenorphine, methadone, or naltrexone— for the treatment of opioid use disorder (OUD). *See, e.g.*, American Society of Addiction Medicine, *The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* (2015); U.S. Department of Health and Human Services (HHS), *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities* (2013); Substance Abuse and Mental Health Services Administration (SAMHSA), *In Brief, Rural Behavioral Health: Telehealth Challenges and Opportunities* (2016).
[8] 21 U.S.C. § 903.
[9] *Koon v. Walden*, 539 S.W.3d 752 (Mo. App. E.D. 2017).
[10] Reuters, ***Global Telemedicine Market Size, Share, Major Players, Strong Application, Top Region, Industry Investment Analysis and 2022 Forecast Research Study***, (Accessed January 28, 2019).
[11] Press Release, United States Department of Justice, *Danbury Physician and Mental Health Practice Pay $36,000 to Settle False Claims Act Allegations*, (July 27, 2016).
[12] *Id.*

The FDA Expands the Abbreviated 510(k) Pathway (aka, the "Safety and Performance Based Pathway")

Suzanne Trigg , Neil Issar

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Neil Issar

On January 22, FDA Commissioner Scott Gottlieb announced the FDA's latest steps to strengthen the FDA's 510(k) program for premarket review of medical devices.[1] As part of this initiative, the FDA finalized its framework for the Safety and Performance Based Pathway by finalizing a draft guidance formerly known as "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria."

The FDA's final guidance on the Safety and Performance Based Pathway sets forth a framework under which manufacturers of certain, well-understood device types may demonstrate substantial equivalence by showing that their proposed devices meet specific performance criteria, rather than by direct comparison with predicate devices. For eligible device types, FDA has indicated that the Safety and Performance Based Pathway, and use of performance criteria instead of direct comparison, is only appropriate when the FDA has determined that:

- The new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate
- The performance criteria align with the performance of one or more legally marketed devices of the same type as the new device
- The new device meets all the performance criteria[2]

Before manufacturers can utilize the Safety and Performance Based Pathway, the FDA must first

identify the device types to which such expansion of the Abbreviated 510(k) pathway will apply.[3] The FDA has established a new **website** that will, in the future, provide information about the types of devices to which the Safety and Performance Based Pathway will apply. At the time of publication of this article, in part due to delays caused by the recently-ended government shutdown, it is not clear when the FDA will begin to implement the pathway by identifying the first devices types and applicable performance criteria.

Finally, the FDA's recently finalized guidance also provides recommendations for submitters of Safety and Performance Based Pathway 510(k)s.[4] Manufacturers will want to ensure that each element recommended in the FDA's Refusal to Accept Policy for 510(k)s is included in the submission, and if a section is not applicable, that it is designated in the submission as not applicable. The FDA's recently finalized guidance also provides recommendations for specific sections of the submission.

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[1] *See* **FDA Statement** from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on latest steps to strengthen FDA's 510(k) program for premarket review of medical devices.
[2] *See* Part II of the **Final FDA Guidance for Industry and Food and Drug Administration, Safety and Performance Based Pathway**, issued on February 1, 2019.
[3] *See id.*, Part III.A.
[4] *See id.*, Appendix.

Cross Plan Offsetting May Draw ERISA Litigation

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In an opinion issued by the Eighth Circuit on a matter of first-impression, the court in *Peterson v. UnitedHealth Group Inc.* left insurers rushing to revise plan documents to preserve their ability to offset overpayments on one plan by withholding payments on another.[1]

On January 15, 2019, the Eighth Circuit affirmed the partial summary judgment decision of a district court in Minnesota, which held that UnitedHealth Group Inc.'s ("United") interpretation of its plan documents to allow cross-plan offsetting was improper. Cross-plan offsetting is a common insurer practice that recoups overpayments made to providers from one plan by withholding or reducing another plan's subsequent payments to the same provider. Without cross-plan offsetting, insurers such as UnitedHealth stand to lose millions of dollars per year in uncollectible claims overpayments. Read on for a summary of the opinions and an analysis of their impact for healthcare companies in the Eighth and other circuits going forward.

Two healthcare providers brought ERISA claims against United on behalf of several patients alleging that United wrongfully failed to pay them and other providers under its plans.[2] Through a practice known as cross-plan offsetting, United would withhold some or all payments to a healthcare provider on one plan to offset overpayments United believed to have overpaid on other plans to the same provider. Both the district and circuit court opinions noted the fact that the plans alleged to be overpaid were fully insured by United, while the plans from which

payments were withheld were often self-insured by the patients. The plaintiffs argued that this practice unfairly benefitted United and violated ERISA's requirements for employee welfare benefit plans and the actual terms of the United plans.

No Decision on Summary Judgment or Appeal as to Whether ERISA Was Violated

The district court declined to rule on the general permissibility of cross-plan offsetting under ERISA. Instead, the court reviewed United's specific use of cross-plan offsetting under the plans at issue. Where United insured some, but not all, of the plans used in the offsetting arrangement, the district court found this type of offsetting presented "a grave conflict of interest."[3] At a minimum, the court held ERISA would require an administrator to conduct a plan-by-plan analysis of whether cross-plan offsetting was in the best interest of a plan before choosing to engage in the practice.[4] On appeal, the Eight Circuit similarly declined to address whether cross-plan offsetting violated ERISA *per se*. But the court described United's practice as "push[ing] the boundaries of what ERISA permits."[5] United Healthcare has requested an *en banc* rehearing of the panel's decision.

United's Interpretation of Its Plans Was Improper

Before analyzing the ERISA arguments, the district court analyzed United's interpretation of its plan documents that United argued justified its practice of cross-plan offsetting. The court held that the interpretation was improper.[6] United argued that while none of its plans expressly mentioned cross-plan offsetting, generic provisions in its plans "that require United to pay benefits and that grant United discretion to interpret and administer the plans" implicitly allowed United to recover overpayments to self-insured plans from other plans. This authorization allegedly gave United broad discretion to use self-insured plans to recoup overpayments made to other plans.[7] But, the court held that such an interpretation would strip meaning from the overpayment and recovery provisions of the self-insured plans and was overall an unreasonable interpretation.[8] On appeal, the Eighth Circuit agreed, holding that United's proposed interpretation would "be akin to adopting a rule that anything not forbidden by the plan is permissible."[9]

Cross-Plan Offsetting in Other Circuits

Litigation regarding cross-plan offsetting is relatively new, but at least one case in the Fifth Circuit has relied on the arguments in *Peterson* in a similar case against United.[10] In *Omega*, a healthcare provider, Omega Hospital brought ERISA claims against United on behalf of patients whose plans had allegedly been overpaid. The provider argued that United had violated ERISA by recouping overpayments allegedly made to the represented patients by withholding payments on unrelated patient accounts. Significantly, Omega did not attempt to bring its claims on behalf of those unrelated patients. The court held that the provider's argument "may create the inference that 'unrelated patients' are entitled to those benefits recouped through cross-plan offsetting[, but] fail to state a plausible claim that the patients on whose behalf [the provider] brings this lawsuit . . . are entitled to such benefits under ERISA."[11]

The court distinguished *Peterson* and *Omega* by noting that the *Peterson* plaintiffs brought claims on behalf of patients whose plans were used to execute the offsets, while the *Omega* plaintiffs brought claims on behalf of the patients whose plans had allegedly been overpaid. In other words, the *Omega* plaintiffs were attempting to recover on behalf of patients who, "in effect, actually reaped the benefit of United's use of offset."[12] This distinction led the court to reject Omega's reliance on *Peterson* in its dismissal of Omega's claims.

Conclusion

The Eighth Circuit decision is limited to its facts as the court declined to determine whether cross-plan offsetting violates ERISA *per se*. Nevertheless, given the novelty of this issue, both administrators and providers should review plan documents and provider agreements to ensure whether the practice of cross-plan offsetting is a practice that is expressly authorized for any particular beneficiary or plan.

[1] 913 F.3d 769 (8th Cir. 2019).
[2] *Peterson v. UnitedHealth Group Inc.*, 242 F. Supp. 3d 834, 836 (D. Minn. 2017), aff'd, 913 F.3d at 769.
[3] *Id.* at 845.
[4] *Id.*
[5] *Peterson*, 913 F.3d at 777.
[6] *Peterson*, 242 F. Supp. 3d at 842.
[7] *Id.* at 845.
[8] *Id.* at 846.
[9] *Peterson*, 913 F.3d at 776.
[10] *See Omega Hosp., LLC v. United Healthcare Servs., Inc.*, No. 16-cv-00560, 2018 WL 4343411, at *20 (M.D. La. Sept. 11, 2018).
[11] *Id.* at *18.
[12] *Id.* at *18 n.135.

FDA Announces Plan to Increase Oversight of Dietary Supplements

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The FDA's recent **statement** unveiling its goal to implement "one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years" (the "Statement")[1] emphasizes FDA Commissioner Scott Gottlieb's continued focus on enforcement against unlawful activities – including product promotions and advertising – that create substantial public health risk.

The existing framework under which the FDA regulates dietary supplements was shaped, in large part, by the Dietary Supplement Health and Education Act of 1994 (DSHEA).[2] While the growth and development of the dietary supplement industry has stimulated significant health advancements, it has also, according to the FDA, led to an increase in the number of adulterated and misbranded products on the market. These include "those [products] spiked with drug ingredients not declared on their labels, misleading claims, and other risks."[3]

On the same day that the Statement was published, the FDA sent 12 warning letters and five online advisory letters to 17 companies for allegedly making unproven claims that their products can prevent, treat, or cure Alzheimer's disease and other serious illnesses and conditions, including diabetes and cancer.[4] While these letters are the first of the FDA's enforcement efforts under the modernized regulatory scheme, they also reflect a continuation of its ongoing commitment to "protect consumers from Alzheimer's disease health fraud." Specifically, the Agency has issued more than 40 warning letters in the past five years against companies making Alzheimer's disease claims about more than 80 products, collectively.[5] The Statement reiterates that "[d]ietary supplements can, when substantiated, claim a number of potential benefits to consumer health, but they cannot claim to prevent, treat, or cure diseases like Alzheimer's."[6]

As the FDA continues to develop and implement a modernized framework for dietary supplement oversight, industry should expect to see continued, and likely increasing, enforcement against companies making serious medical claims about their products, particularly online and/or via social media platforms. In addition, the FDA's announced plans for the near future include steps to:

- Develop and implement a new rapid-response tool to quickly alert the public when supplements are found to pose a health risk or contain illegal ingredients
- Update the new dietary ingredient (NDI) compliance policy, and amend/issue guidance on the NDI notification process to ensure that it effectively allows the FDA to thoroughly evaluate the safety of NDIs before they are made available to consumers
- Develop new strategies and continue efforts to improve existing internal processes for taking efficient enforcement action when products claiming to be supplements contain unlawful ingredients[7]

- Consider and solicit industry commentary as to whether DSHEA should be amended in accordance with the updated framework (e.g., to establish avenues for dietary supplement exclusivity and/or add a mandatory product listing requirement)

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[1] See FDA *Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight*, U.S. Food and Drug Administration (Feb. 11, 2019).
[2] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).
[3] *FDA Statement*, supra, note 1.
[4] *See id.*; **FDA News Release**, *FDA takes action against 17 companies for illegally selling products claiming to treat Alzheimer's disease*, U.S. Food and Drug Administration (Feb. 11, 2019) [hereinafter FDA News Release].
[5] *FDA News Release*, *supra*, note 5.
[6] *FDA Statement, supra*, note 1.
[7] For example, the FDA issued **guidance** in April 2018 to clarify that dietary supplements containing pure or highly concentrated caffeine in powder or liquid forms are considered unlawful when sold in bulk quantities directly to consumers. Due to the significant public health threat, the guidance took immediate effect. *See* **FDA News Release**, *FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine*, U.S. Food and Drug Administration (April 13, 2018).

Employers May Be Cited for Workplace Violence Incidents as Violation of OSHA's General Duty Standard

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The Occupational Safety and Health Act does not contain a specific standard governing workplace violence. But on March 4, 2019, in *Secretary of Labor v. Integra Health Mgmt., Inc.*,[1] a case of first impression, the Occupational Safety and Health Review Commission held that the Act's general duty standard obligates employers to protect their employees from workplace violence.

Case Summary

In *Integra*, Integra employed "service coordinators" to help its clients, many of whom suffered from chronic medical conditions like mental illness, obtain and maintain medical care. The service coordinators' jobs included face-to-face interaction with the clients in their homes and Integra provided to the coordinators, "in-home" safety training. During an in-home client visit, a service coordinator was fatally stabbed by a mentally ill client. The Secretary of Labor cited Integra for violation of the Act's general duty standard. An administrative law judge affirmed the citation, and the Review Commission agreed.

The general duty standard requires employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."[2] To prove a violation of this standard, the Secretary needs to prove that (1) a condition or activity in the workplace presented a hazard; (2) the employer or its industry recognized the hazard; (3) the hazard was causing or likely to cause death or serious physical harm; and (4) a feasible and effective means existed to materially reduce the hazard.

Integra primarily argued that:

- Violent conduct of the client, a third party, was not a hazard encompassed by the Act
- Hazard that a service coordinator could be physically assaulted during a visit to a client site was not recognized by Integra
- Secretary's proposed methods of abatement would not materially reduce incidence of the alleged hazard

The Commission rejected Integra's argument that the alleged hazard—risk of criminal assault upon

employees by third parties—was beyond the scope of the general duty standard. The Commission interpreted hazard under the Act as one "arising out of the employee's work." It found that there was a "direct nexus" between the work performed by the service coordinators at the client's home and the alleged risk of workplace violence. Thus, the hazard of workplace violence arose out of the employee's work and was within the scope of the Act.

The Commission also rejected Integra's argument that it could not anticipate the violent conduct of the client. Integra had rules and training materials that specifically addressed the possibility of violence by clients. Integra was also aware of safety concerns about the specific client. Thus, the hazard was recognized by Integra. Finally, the Commission found that the Secretary's proposed abatement of additional safety measures was feasible and could have resulted in material reduction in the incidence of the alleged hazard of workplace violence.

Conclusion

Under *Integra*, employers in the healthcare industry could be cited for workplace violence under the Act's general duty standard if that hazard has been recognized. To minimize the potential for such a citation and to be effectively prepared to defend such a citation, it would be prudent for employers to identify and address the risks of violence in the workplace including conducting a review of their safety policies and procedures and the employee training programs. Employers should ensure that the risk of physical assault by patients/third parties at the workplace are adequately addressed in the safety policies and training programs.

While *Integra* applies only to states that do not have their own OSHA plan, in the absence of a specific standard governing workplace violence, such states may follow *Integra* and apply a general duty standard to incidents of workplace violence. In that regard, it should be noted that California's state OSHA plan has a specific standard applicable to workplace violence in healthcare.

[1] OSHRC, No. 13-1124, 2019 WL 1142920.

[2] 29 U.S.C. § 654 (a)(1).

QUICK SHOTS

FDA Sends Warning Letters to Companies Selling CBD products as Public Hearing Date Approaches.	CMS Postpones Billing Rules for Hospitals Operating Outpatient, Provider-Based Departments Until July 2019.	Proposed Legislation (HB 2041) Aims to Require Freestanding Emergency Departments in Texas to Disclose Costs and Insurance Coverage with Patients Before Offering Service.	CMS issues Final Rule, authorizing insurers to provide telehealth benefits in their basic benefits packages for 2020 Medicare Advantage Plans.	2018 was a record year for HIPAA enforcement, with a new all-time high in total collections and the largest individual settlement in HIPAA history.	OIG issues favorable Advisory Opinion regarding medical center proposal to provide free, in-home follow-up care to patients with chronic conditions
Read more	**Read more**	**Read more**	**Read more**	**Read more**	**Read more**

UPCOMING SPEAKING ENGAGEMENTS

Regulatory Issues for Healthcare Employers to Consider

24th Annual Asian Pacific Interest Section (APIS) Conference

Phil Kim and Chris Kang

April 26, 2019

"Sugar" and "Natural" Food Label Claims and Litigation – What's Next?

FDLI Annual Conference: Exploring Advanced Topics in Food and Drug Law

Suzie Trigg

May 2-3, 2019

Labeling Claims – Marketing Ideals vs. Regulation

Texas Food Processors Association (TFPA) Annual Conference

Suzie Trigg

May 15-17, 2019

ICYMI

Timely Notice Critical for Coverage (3/26/2019)

Micah E. Skidmore and Neil Issar

Suzie Trigg in Law360: Claire's Makeup Dust-Up Shows Limits of FDA Oversight (3/11/2019)

2018 False Claims Act Year in Review (1/11/2019)

Stacy L. Brainin, Bill Morrison, Christopher Rogers, Nicole Somerville, Andrew Guthrie, Neil Issar, Phillip L. Kim, Jennifer S. Kreick, Taryn McDonald

It's Still Gray: The 2018 Farm Bill and the Legality of CBD Under Federal Law (1/7/2019)

Suzie Trigg and Kayla J. Cristales

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

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