Introduction

While the long-term litigation effects of the COVID-19 pandemic may not materialize for months - or even years - it is important for tort litigation attorneys and their clients to begin preparing now for potential legal issues that may arise. This bulletin is intended to serve as a non-exhaustive list of tort-focused legal considerations for health care providers, product manufacturers, and their attorneys.
in the new and ever-evolving COVID-19 landscape.

**Issues Facing Medical Facilities and Providers**

Health care providers worldwide are on the front line of the battle to detect and treat cases of the COVID-19 virus. In addition to managing the care of these patients, there are several things hospitals and health care workers can do now to minimize the risk of future litigation related to such care.

1. **Continue to be mindful of HIPAA regulations.** The Department of Health and Human Services Office for Civil Rights recently released a bulletin detailing how covered entities may share patient information in compliance with the Health Insurance Portability and Accountability Act (HIPAA) during an infectious disease outbreak. The most important takeaway from this information is HIPAA privacy protections are not suspended during emergencies such as the coronavirus pandemic. The bulletin outlines circumstances in which a covered entity may disclose patient information for treatment of a different patient, for purposes of public health activities, to family involved in a patient’s care, to prevent serious and imminent threat, and disclosure to the media. The five-page bulletin is a helpful and succinct reminder of covered entities’ responsibility to safeguard patient information. Review this information with your team and contact your Dinsmore attorney with questions.

2. **Stay updated on the latest research and publications on COVID-19.** The Centers for Disease Control and Prevention website contains the most up-to-date information regarding the diagnosis, treatment, and release of COVID-19 patients. As these resources indicate, they are not mandatory requirements or standards providers must follow. Instead, they are important areas of concern for providers (chiefly hospitals) to review in preparation for potentially treating suspected or confirmed cases of COVID-19. Staying abreast of these developments will ensure patients are provided the most appropriate care possible, which will in turn reduce the risk of future litigation.


3. **Be mindful of the applicable legal standard of care.** For medical facilities and providers, the risk of being sued is ever-present, and the aftermath of the coronavirus pandemic will be no different. Potential claims that could later be brought against hospitals and other providers related to their treatment of
COVID-19 include failure to diagnose the virus, failure to adequately treat a patient with COVID-19, and failure to protect against the virus’ spread. The first element of each of these hypothetical causes of action is that the provider must have owed a duty to the plaintiff. Legal liability in a medical negligence suit only arises when the plaintiff proves the defendant medical provider (1) owed a duty of care to the plaintiff (also referred to as the standard of care); (2) breached the duty of care owed; and (3) such breach proximately caused the plaintiff injury. Accordingly, an important step in mitigating the risk of future litigation is understanding the various aspects of the legal standard of care applied to medical providers in infectious/communicable disease situations. These duties can be broken down into two categories:

A. Duties owed to patients

Hospitals, physicians, and other medical care providers and facilities always have the duty to exercise the degree of care and skill a reasonable and prudent hospital or medical provider of the same specialty would exercise under the same or similar circumstances.[1] This remains unchanged in infectious disease situations. Medical providers should continue providing the outstanding care they normally do. Since the COVID-19 pandemic is largely uncharted territory, it is important medical providers stay educated on the latest clinical guidelines for treating suspected and confirmed cases of the virus. Visit the CDC website links above for more information.

B. Duties owed to non-patients

The legal duty of care in medical negligence cases outlined above is generally owed to the patient and no one else. However, in certain circumstances, including infectious disease situations, courts have found that providers owe duties of care to non-patient third parties. The primary factor in determining whether a medical provider owes a legal duty of care to a non-patient third party is foreseeability.[2] In other words, if it is reasonably foreseeable a non-patient third party would be harmed by a physician’s negligent care of her patient, the physician may be held liable to the third party for such negligence. A few examples in the infectious/contagious disease context are below.

- **Bolieu v. Sisters of Providence in Wash.**, 953 P.2d 1233, 1236-37 (Alaska 1998) – Because it was foreseeable that spouses of nursing assistants could be infected by diseases if the hospital did not take reasonable measures to minimize the spread of those diseases to the nursing assistants, or did not warn the nursing assistants to take precautions of avoid infecting their spouses, an Alaska court found the hospital owed a duty of care to the nursing assistants’ spouses.

- **C.W. v. Cooper Health Sys.**, 388 N.J. Super. 42, 906 A.2d 440 (Super. Ct. App. Div. 2006) – When a physician failed to notify a patient of his HIV-positive status and thereafter counsel the patient on how to avoid transmission of the virus, this New Jersey court found the physician owed a duty of care to the infected patient’s sexual partner holding, “If a third person is in that class of persons whose health is likely to be threatened by the patient, and if erroneous advice is given to that patient to the ultimate detriment of the third person, the third person has a cause of action against the physician, because the physician
should recognize that the services rendered to the patient are necessary for the protection of the third person."

- *Doe v. Cochran*, 332 Conn. 325, 210 A.3d 469 (2019) – Holding that physicians owe a duty of care to third parties when diagnosing and treating patients who suffer from sexually transmitted diseases – that duty being to accurately relay the patient’s test results to the patient for the health and safety of the patient and the third-party sexual partner of the patient.

- *Derrick v. Ontario Cmty. Hosp.*, 47 Cal. App. 3d 145 (1975) – There is no common law duty to warn the general public of a discharged patient’s contagious/communicable disease. Any such duty would run afoul of the HIPAA privacy protections and would substantially interfere with the patient-physician relationship. (However, be mindful of all state and federal reporting requirements of the diagnosis, treatment, and release of patients with confirmed COVID-19. This is outside the scope of this bulletin. For further information on these requirements, contact your Dinsmore attorney.)

Of course, the courts do not impose upon medical providers the duty to provide any type of medical care to the harmed third party. In fact, the crux of the legal duty remains the same: Physicians are expected to exercise the degree of care and skill expected of a reasonably competent physician acting under the same or similar circumstances when treating their patients. In these special circumstances, however, foreseeably harmed third parties are allowed a legal cause of action against the negligent physician in the applicable jurisdiction.

Depending on the jurisdiction of your practice, there may be standard-of-care issues and implications unique to infectious disease or public health emergencies such as the COVID-19 pandemic. Consult your Dinsmore attorney for jurisdiction-specific guidance.

**Other potential litigation risks**

Finally, it may be helpful to be aware of potential risks for future litigation that could arise from the COVID-19 pandemic:

- Claims against hospitals or other medical facilities for unavailability of sufficient medical supplies, including inpatient beds, ventilators, facemasks, or COVID-19 testing kits;

- Claims against hospitals or other medical facilities for delay in treatment caused by delay in COVID-19 test administration or delay receiving test results;

- Claims against nurses, physicians, hospitals, or other medical facilities for delay in treatment caused by inappropriate triage;

- Claims against hospitals or labs for inaccurate test results (false positives or false negatives); or

- Claims against hospitals or other medical facilities for understaffed facilities.
If you or your clients have questions about potential liability for these types of claims or risk management issues generally, contact the authors of this bulletin or your Dinsmore attorney. The most important thing health care providers can do to prevent future litigation in these times of uncertainty is to continue providing the same level of excellent care they always do.

**Issues Facing Health Product Manufacturers**

Other types of suits that could arise are those in product liability. Recent headlines have read, “This is the coronavirus math that has experts so worried: Running out of ventilators, hospital beds,”[^3] and “Why Even A Huge Medical Stockpile Will Be Of Limited Use Against COVID-19.”[^4] Manufacturers are working to create products intended to diagnose, treat, and even prevent COVID-19. Laboratories are looking at innovating ways to provide valid and expedited testing. Respirators are being sent to hospitals to help protect patients and health care staff alike. In all of these scenarios, however, the potential for litigation looms.

Product liability claims may arise in state and federal courts relating to COVID-19, although they may take months or even years. Plaintiffs or claimants may bring claims alleging defectively manufactured devices such as respirators. They may claim design defect exists in new testing mechanisms that were authorized under an emergency use authorization (EUA) by the Food and Drug Administration (FDA). Or a failure-to-warn claim may allege a manufacturer should have taken steps to warn its COVID-19 treatment was only minimally effective. In addition to products that test and treat COVID-19, other product liability suits may arise concerning personal protective equipment. For example, in a March 2, 2020 letter, the FDA provided an EUA for all disposable filtering face-piece respirators (FFRs) approved by the National Institute for Occupational Safety and Health (NIOSH), as well as NIOSH-approved FFRs that have passed the manufacturers’ recommended shelf-life, for use in health care settings by health care personnel.^[5]

Possible defendants in these suits include manufacturers, retail suppliers, testing labs – and even clinicians and hospitals. With any product liability or negligence action, certain elements must exist for a claim to be successful, including (1) a duty was owed by the defendant to the plaintiff, (2) that duty was breached, (3) the defendant was the cause of the plaintiff’s resulting injury, and (4) the plaintiff suffered some injury or damage. While negligence actions will be asserted in potential litigation, claims based on strict liability will often be asserted as well. Products claims such as design defects, manufacturing defects, failure to warn, and breaches of express and implied warranties arise in strict liability. Claims in strict product liability will require a plaintiff to prove (1) that the product was inherently defective and (2) that the defect in the product caused the injury or damage. Many of the claims asserted in the wake of COVID-19 litigation in the product liability context will vary from state-to-state. However, strict liability claims are available in every state by statute or otherwise. In defending products claims resulting from the COVID-19 pandemic, many of the same defenses apply that are usually asserted in product liability litigation. Defenses such as contributory and comparative negligence defense, as well as assumption of the risk, will also be available and should be investigated.
Additionally, there may be novel defenses since the Department of Health and Human Services (HHS) declared COVID-19 a public health emergency. Thus, an immunity defense may also be available in certain contexts. This declaration was effective Feb. 4, 2020 but was amended March 10, 2020. The directive was authorized under the Public Readiness and Emergency Preparedness Act (PREP Act). How does the PREP Act protect manufacturers? The PREP Act authorizes the secretary of Health and Human Services to issue a declaration to provide liability immunity to certain individuals and entities who are defined as “covered persons.” Covered persons will be protected against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. In addition to the liability immunity for certain covered persons, the FDA is using its emergency use authorization (EUA) to approve medical devices that diagnose and prevent COVID-19. The EUA allows for expedited review of medical products and a more flexible standard in that process. Thus, it would be difficult for plaintiffs to assert a design or manufacturer defect against the immunity offered to COVID-19 detection, treatment, and prevention product manufacturers by the PREP Act.

It is important that product manufacturers and their attorneys are staying abreast of these developments, which are being issued, edited, and added to with increasing frequency. Although the declaration “consider[s] the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures,” it is not a carte blanche protection for drug, device, or medical technology companies. It is important to operate within the parameters of the declaration and seek guidance from your attorney or the agency if you have questions.

[1] See Lake Cumberland Regional Hospital, LLC v. Adams, 536 S.W.3d 683, 691 (Ky. 2017) (“Hospitals have a duty to make sure patients receive a medically acceptable standard of care, and this duty extends to making sure qualified staff are providing the appropriate medical care.”); K.H. v. Kumar, 122 A.3d 1080, 1095-96 (PA Super 2015) (“A physician who is not a specialist is required to possess and employ in the treatment of a patient the skill and knowledge usually possessed by physicians in the same or similar locality, giving due regard to the advanced state of the profession at the time of the treatment; and in employing the required skill and knowledge he is also required to exercise the care and judgment of a reasonable man. . . A specialist acting within his or her specialty . . . is expected to exercise that degree of skill, learning and care normally possessed and exercised by the average physician who devotes special study and attention to the diagnosis and treatment of diseases within the specialty.”) (internal quotations and citations omitted).

[2] See Doe v. Cochran, 332 Conn. 325 (2019) (extending imposition of liability in certain cases involving an unidentifiable potential victim who will be foreseeably harmed by the physician’s negligence).


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