Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Documents Prepared by Hospitals and other Healthcare Facilities during the Investigation and Evaluation of an Adverse Event Are Privileged under New Jersey's Patient Safety Act

If you are defending a product liability case in New Jersey, don't count on obtaining through discovery documents reflecting a healthcare institution's investigation of an adverse medical event. In *C.A. v. Bentolila*, No. A-32-2012, 2014 N.J. LEXIS 921 (N.J. Sep. 29, 2014), the New Jersey Supreme Court addressed when documents prepared by hospitals and other healthcare facilities during an investigation and evaluation of an adverse medical event are privileged and not subject to discovery in civil lawsuits. The Court's analysis required an interpretation of New Jersey's Patient Safety Act, N.J.S.A. 26:2H-12.23 – 12.25 ("the Act"), which imposes certain obligations on healthcare facilities with respect to the evaluation, self-critical analysis and reporting of adverse events and near-misses, and shields documents created during this self-evaluative process from discovery in litigation. In this case, the Court held that because the document at issue was prepared by the hospital as part of the its self-evaluative process in conformance with the requirements of the Act that existed at the time the document was prepared, the document was privileged and not subject to discovery.

New Jersey's Patient Safety Act

In 2004, the New Jersey legislature passed the Act in an attempt to reduce the number of medical errors that occur in hospitals and other healthcare facilities. The Act obligates hospitals and healthcare facilities to establish a patient safety plan which includes a patient safety committee that is responsible for analyzing and adopting patient safety practices, training hospital staff and evaluating and reporting adverse

Oct
2014

events, preventable events and near-misses. *See N.J.S.A. 26:2H-12-25(b)*. In order to encourage healthcare workers to share information and concerns, and to promote self-critical evaluation by hospital management and staff, the Act provides an absolute privilege to any documents, materials, or information prepared by the hospital or healthcare facility "as part of a process of self-critical analysis" conducted in accordance with the requirements of the Act. *See N.J.S.A. 26:2H-12-25(g)*. Privileged documents under the Act are not subject to discovery and may not be used as evidence during any civil, criminal or administrative proceeding. *Id.*

The Act also directed the Department of Health to promulgate regulations establishing more specific requirements for hospitals and healthcare facilities to follow. The Department of Health finalized its regulations related to hospitals' compliance with the Act in March 2008. *See N.J.A.C. 8:43E-10.1 – 10.9*. The regulations established specific requirements regarding the development of patient safety plans, the make-up, operation and responsibilities of hospitals' patient safety committees, the performance of root cause analyses and reporting of adverse events. In addition, the regulations established more specific criteria regarding the discoverability of documents created in compliance with the Act and its regulations. The regulations specify that such documents are privileged, and not subject to discovery, if they were prepared "exclusively during the process of self-critical analysis … concerning preventable events, near-misses and adverse events …" and that process conformed with the requirements of the Act and its regulations. *N.J.A.C. 8.43E-10.9(b)*.

The Court's Decision

C.A. v. Bentolila involved plaintiffs who asserted medical malpractice claims against The Valley Hospital and several physicians, nurses and respiratory therapists who were involved in the birth and post-natal care of the infant plaintiff in late May 2007. In their suit, plaintiffs alleged that the defendants deviated from the applicable standard of care during and after the delivery which caused the infant to suffer an anoxic brain injury. A few days after the infant plaintiff's birth, the hospital conducted a self-critical analysis of the delivery and the medical treatment provided to the infant plaintiff to determine whether the event needed to be reported to the Department of Health pursuant to the Act. The analysis was led by the hospital's Director of Patient Safety. The Director conducted a round-table discussion with certain members of the hospital's staff and patient safety committee which was memorialized in a memorandum. Plaintiffs requested production of the memorandum but the hospital objected to its production on the grounds that it was privileged and not subject to discovery under the Act. The

alleged malpractice and the preparation of the memorandum at issue occurred after the Act had been issued but before the Department of Health regulations had been promulgated.

The trial court conducted an evidentiary hearing and held that because the hospital created the memorandum as part of the self-evaluative process, and because the hospital's process substantially complied with the requirements of the Act, the memorandum was privileged and not subject to discovery. Plaintiffs appealed. The Appellate Division reversed and held that the memorandum was not privileged because the hospital's self-evaluative process fell short of the Department of Health's regulations, even though those regulations had not been enacted at the time the memorandum at issue was prepared. The hospital sought review by the New Jersey Supreme Court.

The New Jersey Supreme Court reversed the Appellate Division and held that the memorandum at issue was privileged and not subject to discovery. In reaching this holding, the Court pointed out that at the time the memorandum was prepared, the Department of Health regulations had not been enacted. Because the Department of Health did not enact the regulations retroactively, the Court did not analyze whether the memorandum was privileged under N.J.A.C. 8.43E-10.9(b), which requires that the document be prepared "exclusively for self-critical analysis purposes" in accordance with a process that met the Department of Health's regulations.

Rather, the Court addressed whether the memorandum was privileged under N.J.S.A. 26:2H-12-25(g), the provision of the Act that requires the document to be prepared "as part of a process of self-critical analysis" in accordance with the terms of the Act. The Court went on to further explain that at the time the memorandum was prepared, the Act only required hospitals to have safety plans that met four components: (1) a patient safety committee; (2) a process for teams of hospital staff to analyze patient safety practices; (3) a process for teams of hospital staff to analyze adverse events and near-misses; and (4) a process to train personnel about patient safety practices. Because the hospital had demonstrated that the memorandum at issue was prepared "as part of a process of self-critical analysis" that was in accordance with the requirements of the Act, the Court held that the memorandum was privileged and not subject to discovery. The Court further explained that the privilege extended not only to the hospital's decision-making process but also to its "development and collection of information necessary for that determination."

Three judges issued a dissenting opinion. Although the dissent agreed with the majority's decision to limit its analysis to whether the memorandum was prepared as part of a self-critical analysis whose process complied with the Act, and not the Department of Health's subsequent regulations, the dissent disagreed with the majority's conclusion that the hospital's self-evaluative process that led to the preparation of the memorandum complied with the requirements of the Act.

What Does This Case Mean?

Although this decision stems from a medical malpractice case, the Court's decision has potential ramifications for pharmaceutical and medical device manufacturers. More and more product liability cases involving pharmaceutical products and medical devices also contain medical malpractice claims against hospitals and physicians. This is especially true for those products used during surgical and other hospital-based procedures. New Jersey's Patient Safety Act, and the Department of Health's regulations, provide an absolute privilege to any information that is collected and documents that are created exclusively as part of the hospital's self-evaluative process, provided that process complies with the requirements of the Act and the regulations. The decision highlights that New Jersey courts take a broad view of the privilege that is provided by the Act and its regulations. This broad privilege has the potential to limit the information and documents that are discoverable to the parties not only in medical malpractice cases but in product liability cases as well.

We will continue to keep you informed of any new developments in this area.

If you would like additional information, please contact:

Beth S. Rose, Esq.
Chair, Product Liability Practice Group
brose@sillscummis.com | (973) 643-5877

Vincent R. Lodato, Esq.
Associate, Product Liability Practice Group, assisted in the preparation of this Client Alert