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*An Update from the Pharmaceutical
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PRODUCTIVELY Thinking

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GUNVALSON UPDATE: THIRD CIRCUIT VACATES INJUNCTION

In September 2008, we reported on the decision of the United States District Court for the District of New Jersey in the case of Gunvalson v. PTC Therapeutics, Inc., in which Judge William Martini ruled in favor of a terminally-ill plaintiff who sought entry into an experimental drug treatment program over the drug developer's objections. On December 16, 2008, the United States Court of Appeals for the Third Circuit reversed the District Court's decision to issue an injunction allowing the 16-year-old plaintiff (Jacob Gunvalson) entry into a clinical trial. The District Court's decision was widely criticized throughout the pharmaceutical industry because, in effect, the Court was authorizing litigation as a means of gaining entry into clinical trials. In particular, the District Court's decision obligated defendant, PTC Therapeutics ("PTC"), to grant the plaintiff access to an experimental drug called PTC124, which has shown promise as a treatment for Duchenne Muscular Dystrophy ("DMD"), despite plaintiff's previous decision to forego the earlier phase of the trial. Critics viewed the decision as a potential compromise of the tightly monitored parameters of clinical trials. With the Third Circuit's decision to vacate the injunction, however, those concerns are somewhat assuaged.

Despite arguments from PTC that it never promised plaintiff access to PTC124, the District Court previously concluded that there "is a reasonable likelihood that PTC made an enforceable promise to plaintiffs to provide PTC 124 to Jacob." The court found that the "totality of the circumstances" sent signals to plaintiffs that Jacob would receive PTC124 at a later date, causing him to forego participation in the initial phase clinical trial. According to

the court, "it is reasonably likely that plaintiffs' reliance on this promise is the reason that Jacob is not currently enrolled in the expanded clinical trial."

The Third Circuit disagreed with the District Court's determination for several reasons. First, the Third Circuit reasoned that the Gunvalsons did not prove the existence of the "clear and definite promise" needed to support a promissory estoppel claim. Whereas the District Court reasoned that "PTC made an enforceable promise to plaintiffs to provide PTC 124 to Jacob," the Third Circuit concluded these alleged promises "lack[ed] the requisite specificity and clarity required to succeed under the theory of promissory estoppel."

In addition, the Third Circuit concluded that the Gunvalsons did not "reasonably rely" on any promise that PTC may have made. According to plaintiffs, PTC assured them that, if Jacob did not participate in the initial phase of the clinical trial, he would still be eligible to receive PTC124 at a later date. When he then sought to participate in the expanded clinical trials for PTC124, Jacob was rejected due to his failure to participate in the initial phase of the clinical trial. The Third Circuit found that the District Court erred in its analysis "by failing to recognize the Gunvalsons did not enroll Jacob in the Phase 2a trial because Dr. Finkel, the principal investigator for the Philadelphia area clinical trial, ruled Jacob ineligible based on the medical records Mrs. Gunvalson provided him, and not because the Gunvalsons had been promised PTC 124 via some other means." Because of this ruling of ineligibility, the Gunvalsons could not reasonably rely on any subsequent promise from PTC, if any. Although the

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Third Circuit shared Judge Martini's understandable sympathy for the plaintiff, it found no enforceable promise and vacated the injunction set in place by the District Court.

IMPACT ON NEW JERSEY DEFENDANTS

Clinical trials are tightly monitored to ensure safety and research validity. Any deviation during the trial could compromise the study and thwart the efforts of the pharmaceutical company conducting the trial. While it is axiomatic that the allocation of resources to discover an effective treatment to combat deadly illnesses is preferred over the utilization of resources to defend against litigation, it is difficult to fault plaintiffs' efforts to gain entry into the trial. The Third Circuit's decision to vacate the injunction highlights the Court's interest in protecting these trials, and sends a message that litigation may not be the appropriate avenue for gaining entry into a trial.

There is a growing concern that litigation like the Gunvalson case will discourage patients from enrolling in clinical trials and therefore limit a drug company's ability to perform research on potential products. The reason is simple: if a patient's family can sue to get access to an experimental drug before a trial is over, more patients may go to court in lieu of enrolling in a controlled research trial. Additionally, although not explicitly stated, the Third Circuit recognized that punishing PTC for statements it made to the Gunvalson family (statements the Third Circuit found to be vague and not definite promises) would discourage drug companies from openly communicating with patients. The decision temporarily hinders the utilization of litigation as a tactic for gaining entry into clinical trials. Given the fact-specific nature of the decision, however, as well as the significant health issues often at risk, there is little doubt that similar applications will be filed in the future.

Authored by H. Lockwood Miller, III and Stephen V. Ciurczak

Current Mass Torts in New Jersey

<i>Accutane</i>	<i>J. Higbee, Atlantic County</i>
<i>Asbestos</i>	<i>J. McCormick, Middlesex County</i>
<i>Bextra/Celebrex</i>	<i>J. Higbee, Atlantic County</i>
<i>Bristol-Myers Squibb Env't'l</i>	<i>J. Higbee, Atlantic County</i>
<i>Ciba-Geigy</i>	<i>J. McCormick, Middlesex County</i>
<i>Depo-Provera</i>	<i>J. Harris, Bergen County</i>
<i>Fosamax</i>	<i>J. Higbee, Atlantic County</i>
<i>Gadolinium</i>	<i>J. Happs, Middlesex County</i>
<i>HRT</i>	<i>J. Happs, Middlesex County</i>
<i>Mahwah Toxic Dump Site</i>	<i>J. Harris, Bergen County</i>
<i>Ortho Evra</i>	<i>J. Happs, Middlesex County</i>
<i>Risperdal/Seroquel/Zyprexa</i>	<i>J. Happs, Middlesex County</i>
<i>Vioxx</i>	<i>J. Higbee, Atlantic County</i>

The Coughlin Duffy Pharmaceutical and Medical Device Group

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