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“COMPASSIONATE USE” DECISION CARRIES BROAD IMPLICATIONS

On August 21, 2008, in Gunvalson v. PTC Therapeutics, Inc., the United States District Court for the District of New Jersey issued a letter opinion that resonated throughout the pharmaceutical industry. In the written decision from Judge William Martini, the court ruled in favor of a 16-year-old plaintiff, terminally ill with Duchenne Muscular Dystrophy (“DMD”), who sought entry into an experimental drug treatment program despite objections from the drug’s developer.

While there is currently no available treatment or medication for DMD, defendant PTC Therapeutics (“PTC”) is the creator of a drug called PTC124, which has shown promise as a treatment for DMD. The issue before the court was whether PTC induced Jacob Gunvalson to forego entering a clinical trial by promising him eventual access to the drug. 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. While that clinical trial was deemed a success, however, Jacob’s condition deteriorated. 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. Plaintiffs promptly filed suit alleging that PTC induced Jacob to forego his opportunity to participate in the initial clinical trial with false promises of PTC 124 in the future. The plaintiffs sought participation in the expanded trials under the “compassionate use” exception.

The “compassionate use” exception allows drug companies to provide experimental drugs (unapproved by the FDA) to sick persons.

Under this exception, the FDA will allow a drug company to distribute an FDA-unapproved drug if four conditions are met: (1) the drug is for a serious or life-threatening disease; (2) there is no good alternative; (3) the drug is currently under investigation in a clinical trial; and (4) the sponsor is actively pursuing marketing approval. 21 CFR. § 312.34. Judge Martini concluded unequivocally that all four requirements were met in this instance.

The court then turned to whether PTC had some legal obligation to provide Jacob with PTC124. Despite arguments from PTC that it never promised Jacob access to PTC124, the court concluded that there “is a reasonable likelihood that PTC made an enforceable promise to plaintiffs to provide PTC 124 to Jacob.” The court noted the friendship between Jacob’s mother and executives at PTC, finding it reasonably likely that PTC promised to provide Jacob with PTC124 based, in part, on this special relationship. 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 court concluded by pointing to the unique circumstances of this case to justify the unprecedented outcome. Recognizing that drug companies do not have a general obligation to provide experimental treatment to sick people, the court reasoned that the plaintiffs’ reliance on direct promises from the drug company

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mandated entry into the clinical trials. By its own words, the decision should not “in any way suggest that PTC has a general obligation to provide PTC124 –or any experimental drug – to sick persons.” Nevertheless, people seeking to use the courts to gain access to experimental medical treatments may seek to use this opinion for that purpose.

IMPACT ON NEW JERSEY DEFENDANTS

Because drug developers must tightly monitor their clinical trials to ensure safety and research validity, any decision that could potentially compromise those parameters is certain to set off alarms within the industry. And, while the Gunvalson court relies on the unique circumstances of this case to justify its unprecedented decision, the court’s reliance on those facts might have undesired consequences. For example, the court’s use of patient-pharmaceutical company communications to justify its decision could cause drug companies in the future to be much more reluctant to communicate directly with the terminally ill.

Moreover, as a result of this decision, the courts have created an undefined right for patients to access clinical trials through litigation. If this type of decision were to become the norm, it would create a litigation-charged environment likely to muddle clinical trials and result in fewer FDA approved drugs being discovered. While few can begrudge the court’s pragmatic decision to grant a terminally ill teenager access to medication, the use of litigation to achieve the desired result can and should create some pause in the industry. It remains to be seen whether this decision remains a compassionate exception, or whether the court’s decision will encourage similar applications involving other experimental treatments 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>Ciba-Geigy</i>	<i>J. McCormick, Middlesex County</i>
<i>Depo-Provera</i>	<i>J. Harris, Bergen 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>
<i>Zometa/Aredia</i>	<i>J. Higbee, Atlantic County</i>

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