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August 7, 2008

VIA ELECTRONIC FILING & FACSIMILE

Magistrate Judge Mark Falk
Frank R. Lautenberg U.S.P.O. & Courthouse
Room 457
1 Federal Square
Newark, NJ 07102

Re: *Gunvalson v. PTC Therapeutics, Inc.*
Case No. 2:08-cv-03559-WJM-MF

Dear Judge Falk:

My firm, along with Sidley Austin LLP, represents defendant PTC Therapeutics, Inc. ("PTC") in the above-referenced matter. On August 5, 2008, I submitted a letter to Your Honor (which is attached hereto) describing a discovery issue that has arisen concerning our ability to conduct an *ex parte* interview with Dr. Richard Finkel, a physician whose statements the plaintiffs have imputed to PTC in their complaint and preliminary injunction papers. Plaintiffs submitted a response to my letter yesterday.

As an initial point, the only reason PTC is pursuing this issue is because plaintiffs are attempting to attribute Dr. Finkel's alleged statements to PTC. PTC is being placed in the untenable situation whereby plaintiffs are claiming that communications Dr. Finkel may have had with them are privileged, while at the same time also claiming that those same statements are imputed to PTC. This Court should reject plaintiffs' various arguments and allow PTC to conduct an *ex parte* interview with Dr. Finkel to remedy the obvious unfairness caused by plaintiffs' claims that Dr. Finkel's statements to them are privileged but at the same time imputed to PTC.

In their response, plaintiffs spend an inordinate amount of time discussing the history of this issue and distorting my initial letter. There is no need to have a back-and-forth exchange about when calls were made, messages were left, or e-mails sent. The bottom line is that on July 30, Judge Martini

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established the schedule that would govern plaintiffs' motion for a preliminary injunction. At plaintiffs' request, and over PTC's objection, PTC's brief is due on August 11 and the hearing is scheduled for August 19. Despite our repeated efforts to discover plaintiffs' intentions about whether they would authorize an *ex parte* interview of Dr. Finkel, it was not until five days after Judge Martini issued his schedule that plaintiffs' counsel finally informed us that they would not. Once we learned plaintiffs' position, we immediately brought this matter to your attention so that we could prepare our case under Judge Martini's schedule.

The more troubling aspect of plaintiffs' response, however, is their fundamental misunderstanding of the law that applies to this issue. Interestingly, plaintiffs have not established a factual basis for their claim that a physician-patient relationship exists between Jacob Gunvalson and Dr. Finkel and, therefore, a privilege may not even exist. Regardless, plaintiffs wrongly assume that either their version of the *Stempler* procedure or Pennsylvania law necessarily controls the manner in which PTC can interview Dr. Finkel. Plaintiffs' assumption is wrong because federal law controls whether a defendant can conduct an *ex parte* interview. In *Williams v. Rene*, 72 F.3d 1096, 1103 (3d Cir. 1995), the Third Circuit expressed its disagreement with the *Stempler* procedure. Specifically, the Court ruled that "[w]e have reservations about the restrictions imposed in *Stempler* and believe the better approach is expressed in *International Business Mach. Corp. v. Edelstein*, 526 F.2d 37 (2d Cir. 1975). There, the court referred to 'time-honored and decision-honored principles, namely, that counsel for all parties have a right to interview an adverse party's witnesses (the witness willing) in private, without the presence or consent of opposing counsel and without a transcript being made.'" *Id.*

The Third Circuit's ruling in *Williams* is consistent with other federal courts that have held that whether a defendant can conduct an *ex parte* interview with a plaintiff's treating physician is a procedural matter governed by federal law.¹ The Third Circuit's holding in *Williams* makes clear that PTC is entitled to conduct an *ex parte* interview of Dr. Finkel. Plaintiffs' assertions notwithstanding, PTC's intended discussions with Dr. Finkel will relate solely to the claims in this lawsuit. Thus, to the

¹ See, e.g., *Welch v. La. Power & Light Co.*, 466 F.2d 1344, 1345 (5th Cir. 1972) ("[T]he Supreme Court has established a strong presumption that the federal rules govern, rather than state law, in cases involving arguably procedural matters."); *Patton v. Novartis Consumer Health, Inc.*, No. 4:02-cv-0047-DFH-WGH, 2005 U.S. Dist. LEXIS 15453, at *10 (S.D. Ind. July 25, 2005) ("the ground rules for witness interviews are essentially procedural in character and are thus governed by federal law."); *Eve v. Sandoz Pharm. Corp.*, No. IP98-1429-C-Y/S, 2002 WL 32153352, at *2 (S.D. Ind. May 16, 2002) ("[W]hen the issue before the court is not *what* may be discovered, but *how* that discovery may be obtained or (in this case) how trial preparation may be conducted, that issue is a matter of federal procedural law."); *Shots v. CSX Transp., Inc.*, 887 F. Supp. 206, 208 (S.D. Ind. 1995) (holding that the FRCP "leave to the district court the discretion whether to allow *ex parte* conferences"); *Evertson v. Dalkon Shield Claimants Trust*, No. 82-1021-MLB, 1993 U.S. Dist. LEXIS 9670, at *4 (D. Kan. June 2, 1993) ("The method for discovering unprivileged material -- whether by written interrogatories, requests for admissions, depositions, or *ex parte* interviews -- is entirely a matter of procedure governed by the Federal Rules of Civil Procedure"); *Filz v. Mayo Found.*, 136 F.R.D. 165, 175 (D. Minn. 1991) (applying federal law to question whether *ex parte* interviews of treating physicians should be allowed).

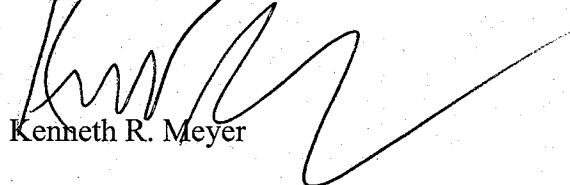
extent that plaintiffs have a physician-patient relationship with Dr. Finkel it has clearly been waived, and PTC is entitled to interview him.

Instead of discussing relevant federal law, plaintiffs take the inconsistent position that either Pennsylvania law or New Jersey law controls this matter. In terms of Pennsylvania law, plaintiffs contend that Pennsylvania has the greatest interest in this issue. However, plaintiffs fail to engage in the appropriate analysis required by New Jersey's choice-of-law rules and do not support their conclusory view that Pennsylvania has the greatest interest. Moreover, plaintiffs' opinion is inconsistent with their filing suit in the District of New Jersey, their insistence that the preliminary injunction hearing be conducted immediately, and the fact that they are basing their claims in this lawsuit on New Jersey law. In view of these circumstances and equitable factors, as well as the aforementioned caselaw holding that federal law controls this issue, plaintiffs have failed to demonstrate that this Court should look to and apply Pennsylvania law.

Plaintiffs also suggest that the New Jersey Supreme Court's ruling in *Stempler v. Speidell*, 100 N.J. 368, 495 A.2d 857 (1985), requires the presence of plaintiffs' counsel during an interview of a treating physician. That is simply inaccurate. The New Jersey Supreme Court held that defense counsel may conduct *ex parte* interviews of a plaintiff's treating physician so long as the physician is willing and defense counsel provides reasonable notice to plaintiff's counsel of the scope of the intended interview. As to the presence of plaintiff's counsel, the Court ruled that a plaintiff could obtain a protective order "if under the circumstances a proposed *ex parte* interview with a specific physician threatens to cause such substantial prejudice to plaintiff as to warrant the supervision of the trial court . . . [which] could take the form of an order requiring the presence of plaintiff's counsel during the interview . . ." *Id.*, 100 N.J. at 383, 495 A.2d at 864-65. While plaintiffs presume that their attorneys have a right to be present when PTC interviews Dr. Finkel, *Stempler* clearly holds otherwise. Moreover, plaintiffs have not demonstrated any prejudice, much less substantial prejudice, that they would suffer if PTC conducts an *ex parte* interview with Dr. Finkel.

Thank you for your consideration of this matter.

Respectfully submitted,



Kenneth R. Meyer

KRM:knh

Enc.

cc: John G. Hutchinson, Esq. (Via Facsimile)
Marc E. Wolin, Esq. (Via Facsimile)
Michael A. Hatch, Esq. (Via Facsimile)

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NEW JERSEY AS A CIVIL TRIAL ATTORNEY
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August 5, 2008

VIA FACSIMILE

Magistrate Judge Mark Falk
Frank R. Lautenberg U.S.P.O. & Courthouse
Room 457
1 Federal Square
Newark, NJ 07102

Re: *Gunvalson v. PTC Therapeutics, Inc.*
Case No. 2:08-cv-03559-WJM-MF

Dear Judge Falk:

My firm, along with Sidley Austin LLP, represents defendant PTC Therapeutics, Inc. ("PTC") in the above-referenced matter. I was advised by Your Honor's Chambers to send this letter outlining a discovery issue that has arisen concerning our ability to speak to Dr. Richard Finkel, a physician whose statements the plaintiffs have imputed to PTC in their complaint and preliminary injunction papers, outside the presence of plaintiffs' counsel.

The Complaint in this matter was filed on July 16, 2008 and served on PTC on July 23. Plaintiffs filed a motion for a preliminary injunction on July 28. On Wednesday, July 30, Judge Martini scheduled the preliminary injunction hearing for August 19, 2008. PTC's opposition brief is due on August 11.

Dr. Richard Finkel was one of the primary investigators for the Phase 2a clinical trials for PTC's experimental drug, PTC124. Those clinical trials, and the reasons why plaintiff Jacob Gunvalson did not seek to be enrolled in them, are squarely at issue in the case. Among other things, plaintiffs assert that Dr. Finkel misled the Gunvalsons by allegedly advising them "it was not worth taking Jacob off Gentamicin," his then-current drug treatment, to receive "only a 28-day dosage of PTC124" as a participant in the Phase 2a trials. (Affidavit of Cheri Gunvalson ¶ 17; see Compl. ¶¶ 22,

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60.) Plaintiffs seek to impute these alleged statements to PTC in connection with their promissory estoppel, fraud, and negligent misrepresentation claims in this case.

On the afternoon of July 30, we spoke with plaintiffs' attorney, Marc Wolin, to advise him that we would immediately require authorizations permitting us (i) to obtain Dr. Finkel's medical records concerning Jacob Gunvalson, and (ii) permitting us to interview Dr. Finkel regarding plaintiffs' allegations in preparation for the upcoming preliminary injunction hearing. We also sought authorization to obtain the medical records of Jacob Gunvalson's pediatrician, Dr. John Parkin, and to obtain the medical records of and speak to Dr. Brenda Wong, another primary investigator for the Phase 2a trials. We were initially interested in speaking to Dr. Wong because it was unclear to us whether or not plaintiffs also were attempting to impute Dr. Wong's statements and actions to PTC. However, upon further review of plaintiffs' motion papers, that does not appear to be the case, and we do not believe it is necessary for us to speak to Dr. Wong directly in advance of the hearing at this time. To the extent that plaintiffs are unwilling to confirm that Dr. Wong's statements are not attributable to PTC, however, we reserve the right to seek the Court's intervention to resolve that issue at a later time.

Following our initial conversation with Mr. Wolin on July 30, we spoke with him again on Thursday, July 31 and Friday, August 1. Mr. Wolin reported that plaintiffs already had signed certain authorization forms prepared by their Minnesota counsel, Michael Hatch. We asked whether those authorizations permitted us to interview Dr. Finkel about the statements and actions alleged in plaintiffs' Complaint and motion papers, but Mr. Wolin was unable to tell us. He said he had no knowledge of the contents of the authorizations Mr. Hatch had prepared. Mr. Wolin also told us that he expected to receive plaintiffs' authorizations by mail, hopefully sometime on Friday, August 1. Mr. Wolin committed to provide the authorizations to us as soon as he received them.

On Friday afternoon, August 1, having heard nothing from Mr. Wolin, I sent him an authorization form for Dr. Finkel in the format that we desired and asked him to respond as soon as possible. As of the afternoon of August 4, Mr. Wolin failed to contact us. Despite our repeated requests, he provided us with no information concerning whether his clients' signed authorizations enabled us to speak to Dr. Finkel. Accordingly, we called Mr. Hatch, who is now admitted in this case, to discuss this issue with him. Mr. Hatch advised us, for the first time since we had made our purpose clear five days earlier, that plaintiffs would not provide authorizations permitting us to speak with Dr. Finkel outside the presence of their counsel. Shortly thereafter, we received signed copies of the release forms Mr. Hatch had prepared, which forms authorize us to speak to Dr. Finkel only in the presence of plaintiffs' attorneys.

Plaintiffs' contention that anything Dr. Finkel said or did in connection with evaluating Jacob Gunvalson for possible participation in PTC's Phase 2a trials could be imputed to PTC is not only erroneous as a matter of law, *see Abney v. Amgen*, 443 F.3d 540, 549 (6th Cir. 2006) (clinical investigators are not agents of drug sponsors), but also constitutes a clear admission that plaintiffs *do*

not consider Dr. Finkel to be Jacob Gunvalson's treating physician. Plaintiffs' claim that Dr. Finkel is PTC, for purposes of their claims in this lawsuit, thus entitles PTC to obtain authorizations allowing us to interview Dr. Finkel privately, if he will agree to do so on a voluntary basis, so that we can determine whether to obtain an affidavit from him, or seek to depose him in connection with PTC's opposition to plaintiffs' preliminary injunction motion.¹

Indeed, even if Dr. Finkel had somehow become Jacob's treating physician by virtue of the clinical trial evaluation, the New Jersey federal and state courts clearly permit defense counsel to conduct *ex parte* interviews of treating physicians where, as here, the plaintiff has waived its privacy protections by putting his medical condition and treatment at issue by filing suit. *See, e.g., Williams v. Rene*, 72 F.3d 1096, 1103 (3d Cir. 1995) (affirming that "counsel for all parties have a right to interview an adverse party's witnesses (the witness willing) in private" – including plaintiff's attending physician – "without the presence or consent of opposing counsel and without a transcript being made," especially where "plaintiff waived the physician-patient privilege with respect to the injuries claimed to have been incurred in the accident") (citation omitted); *Stempler*, 100 N.J. at 381-82, 495 A.2d at 863-64 (holding that *ex parte* "personal interviews" of plaintiff's treating physician by defendant's counsel "are an accepted, informal method of assembling facts and documents in preparation for trial" and their "use should be encouraged" to "reduce the cost and time of trial preparation" by requiring plaintiff's counsel to "provide written authorization to facilitate the conduct of interviews"); *Smith v. Am. Home Prods. Corp. Wyeth-Ayerst Pharm.*, 372 N.J. Super. 105, 855 A.2d 608 (N.J. Super. Ct. Law Div. 2003) (New Jersey law permits defense counsel to conduct informal "personal interviews of the treating physician of a plaintiff . . . outside the presence of plaintiff's counsel").

Of course, should plaintiffs agree that Dr. Finkel's statements cannot in any way be imputed to, or used against PTC, we may have no need to interview Dr. Finkel outside the presence of plaintiffs' counsel. However, if plaintiffs will not make this concession, and continue to take the erroneous

¹ Even if plaintiffs' allegations could be reconciled with a claim that Dr. Finkel was Jacob Gunvalson's physician for purposes of an assertion of privilege – and they cannot – the fact that plaintiffs have placed Dr. Finkel's alleged statements about Jacob's condition and medical advice at issue in the lawsuit unquestionably constitutes a waiver of any applicable privilege or immunity from disclosure. *See, e.g., N.J.S.A. 2A:84A-22.4* ("There is no privilege under this act in an action in which the condition of the patient is an element or factor of the claim of defense of the patient or any party claiming through or under the patient . . ."); *Stigliano v. Connaught Labs., Inc.* 140 N.J. 305, 311-12, 658 A.2d 715, 718 (1995) (where plaintiff "waived the physician-patient privilege" by suing doctor and placing patient's disorder and doctor's advice and treatment at issue, it was "waiver of the privilege in regard to *all* of his knowledge of the physical condition asked about") (citation omitted); *Stempler v. Speidell*, 100 N.J. 368, 373, 495 A.2d 857, 859 (1985) ("instituting suit extinguishes the privilege to the extent that" plaintiff's medical condition and treatment "will be a factor in the litigation").

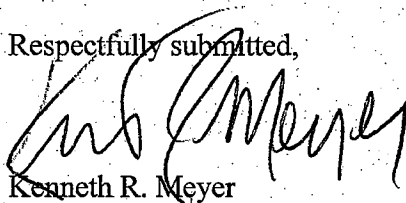
position that one or more of Dr. Finkel's statements constitutes a statement by, or is chargeable to, PTC – thereby plainly admitting that they *do not* believe that Dr. Finkel is Jacob's treating physician – then we respectfully submit that they should be ordered immediately to sign the medical authorization form we have attached to this motion. (See Exhibit A hereto.)

Given the substantial delay caused by plaintiffs' counsel's failure to inform us at the outset that they would not provide us with the medical authorization we made clear we needed, it appears unlikely that we can even obtain the records and testimony that we require in time to prepare and file our opposition brief on August 11, and we respectfully reserve the right to seek adjustments to the current schedule, if necessary.

We will await further direction from Your Honor on this issue.

Thank you for your consideration of this matter.

Respectfully submitted,



Kenneth R. Meyer

KRM:kmh

cc: John G. Hutchinson, Esq. (Via Facsimile)
Marc E. Wolin, Esq. (Via Facsimile)
Michael A. Hatch, Esq. (Via Facsimile)

EXHIBIT A

AUTHORIZATION TO RELEASE MEDICAL INFORMATION

Patient's Name: **Jacob Gunvalson**

Patient's Soc. Sec. No.: **474-23-2274**

Patient's Date of Birth: **October 5, 1991**

Provider's Name: **Dr. Richard S. Finkel**
Address: **Director, Neuromuscular Program**
 Children's' Hospital of Philadelphia
 34th Street and Civic Center Boulevard
 Philadelphia, PA 19104-4399

Regarding: ***Gunvalson, et al. v. PTC Therapeutics, Inc.,***
 08-cv-3559 (WJM) (MF)

We, Jacob Gunvalson, and Cheri Gunvalson as guardian for Jacob Gunvalson, authorize you, Dr. Richard S. Finkel, to disclose a complete copy of Jacob Gunvalson's medical records, as described below, to employees, agents, or representatives of either Porzio, Bromberg & Newman, P.C., 100 Southgate Parkway, Morristown, New Jersey, 07962 or Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019.

We authorize you to release Jacob Gunvalson's medical file and medical records, including, but not limited to, the following:

- billing and insurance information
- biopsies
- consultation reports
- discharge summaries
- entire medical file with the exception of mental health, drug and alcohol treatment records
- genetic testing and counseling documents
- laboratory, pathology, and radiology reports
- medication records
- nurses' notes
- operative reports
- patient consent documents
- patient history and physical exam
- patient questionnaires or patient information sheets
- physician progress notes
- physician's orders

prescriptions
radiographic representations (including, but not limited to, x-rays, MRIs, CT scans or
bone scans)

We understand that if we do not want any of the above information released, we may limit your authorization to release such information by crossing any category of information and initialing it. In addition, we understand that we may identify additional information we do not want you to release in the space below:

We authorize you to disclose these medical records for use in the litigation captioned, *Gunvalson, et al. v. PTC Therapeutics, Inc., 08-cv-3559 (WJM)(MF)*. We understand that Porzio, Bromberg & Newman and/or Sidley Austin LLP may forward these records to a third party during this legal matter, and we authorize this as well. We hereby waive any privilege of any kind whatsoever that could apply to these records.

In addition, we hereby waive any privilege of any kind whatsoever that could apply to your relationship and dealings with Jacob Gunvalson, the Gunvalson family, and representatives of the Gunvalson family, insofar as they relate to the allegations of the above-referenced litigation. This includes, but is not limited to, an express waiver of the patient-physician privilege and any other possibly applicable privilege, law, code, rule, or regulation that could arguably prohibit you from speaking with employees, agents, or representatives of Porzio, Bromberg & Newman, P.C. and/or Sidley Austin LLP about subject matters relevant to those allegations, including, but not limited to, the treatment, examinations, and diagnosis of Jacob Gunvalson, consultations with any member of the Gunvalson family concerning PTC124 clinical trials, Jacob Gunvalson's participation or non-participation in PTC124 clinical trials, Jacob

Gunvalson's treatment with gentamicin, and oral conversations with any member of the Gunvalson family or its representatives about these issues.

We expressly authorize you to discuss with the employees, agents, or representatives of Porzio, Bromberg & Newman, P.C. and/or Sidley Austin LLP any of the above topics. In defending against this lawsuit, PTC is entitled to seek to interview witnesses with relevant information. Your participation in any such interview is entirely voluntary. You have the right to have our attorneys present at the interview.

This Authorization shall remain in effect until the above-referenced litigation is concluded.

We understand that we may revoke, in writing, this Authorization at any time. Our written revocation must be submitted to you at the address indicated above with a copy of the revocation provided simultaneously to **Porzio, Bromberg & Newman, P.C., 100 Southgate Parkway, Morristown, New Jersey, 07962 (Attn: Kenneth R. Meyer)**. We understand that if you have already released information or otherwise acted in reliance upon this Authorization, that any subsequent revocation will not affect the validity of your prior disclosure or other action.

We understand that we have the right to inspect information that you disclose.

A photocopy of this Authorization shall have the same force and effect as an original.

Signature: _____
Jacob Gunvalson

Date: _____

Signed before me this
_____ day of August, 2008

Notary Public

Signature: _____
Cheri Gunvalson,
as Guardian for Jacob Gunvalson

Date: _____

Signed before me this
_____ day of August, 2008

Notary Public

Dated: _____