UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

QT, INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**No. 05 C 6387**
	)	
MAYO CLINIC JACKSONVILLE, MAYO	)	**Judge James B. Moran**
CLINIC ROCHESTER, MAYO FOUNDATION,	)	
MAYO CLINIC COLLEGE OF MEDICINE, AND	)	**Magistrate Judge**
ROBERT L. BRATTON, M.D.	)	**Geraldine Soat Brown**
	)	
Defendants.	)	

MAYO'S MEMORANDUM IN OPPOSITION TO QT'S MOTION TO COMPEL PRODUCTION OF PROTECTED PATIENT HEALTH INFORMATION

QT wants Mayo to produce patient records from the Ionized Bracelet Study without redaction of the patients' identifying information. The patient records contain protected health information from the study. Patient health information is confidential, and Florida state law requires that, if relevant, Mayo produce such health information with identifying information redacted. Under Florida law, QT is not entitled to breach that privilege, especially in pursuit of information that it can obtain without identifying the individual patients. Accordingly, this Court should deny QT's request for unredacted patient records.

FACTS[1]

In early 1999, Dr. Robert Bratton, a family medicine doctor at Mayo Clinic Jacksonville, decided to study the effectiveness of Q-Ray "ionized" bracelets in relieving joint pain. Dr. Bratton contacted QT, Inc. about participating in a clinical study of its bracelet's

[1] As QT's second footnote indicates, the opening of QT's Memorandum is nothing more than unsubstantiated allegations from QT's Complaint without citation to evidence. Mayo contests these allegations, but it is not Mayo's purpose in this Memorandum to refute them.

effectiveness versus a placebo. QT agreed to participate and to provide both the "ionized" bracelets and the placebo control bracelets. (McBride Decl. Ex. 1, 05/14/1999 Park Letter to Bratton.) QT signed a Clinical Research Agreement, in which QT agreed to provide "three hundred and five (305) activated Q-Ray wrist bracelets and three hundred and five (305) unactivated placebo bracelets." (McBride Decl. Ex. 2, 11/03/1999 Clinical Research Agreement 1.) The Mayo Clinic Institutional Review Board ("IRB") approved the double-blind, placebo controlled study, and, after a suspension, reapproved the study. (McBride Decl. Ex. 3, 08/13/1999 IRB Minutes; McBride Decl. Ex. 4, 09/08/2000 IRB-Blue Minutes; McBride Decl. Ex. 5, 10/17/2000 IRB Executive Subcommittee Minutes.) Mayo informed QT that the study had been suspended. QT approved restarting the study and provided a new set of "ionized" and placebo bracelets. (McBride Decl. Ex. 6, 06/01/2000 Park Email to Bratton; McBride Decl. Ex. 7, 10/06/2000 Ciprian Letter to Hall.)

Starting in the Fall of 2000, Mayo enrolled 610 patients in the Ionized Bracelet Study. On enrollment, patients reported the level of any underlying joint or muscle pain in twelve different areas of the body along a scale from 0 (no pain) to 10 (pain as bad as it could be). Mayo gave each patient treatment in the form of an unmarked bracelet that was either a true "ionized" bracelet, or an inactive placebo bracelet. Neither the patient nor the enroller knew what kind of bracelet the patient received. Over the next 28 days, each patient reported the pain level in those same twelve areas of the body six times: day 1, day 3, week 1, week 2, week 3 and week 4. The patients then sent completed forms back to Mayo.

Mayo compiled and analyzed the study results, and Dr. Bratton eventually submitted a manuscript to *Mayo Clinic Proceedings*. *Proceedings* is a peer-reviewed journal that publishes articles on science and medicine from researchers worldwide. *Proceedings* published the results of the Mayo study in a November 2002 article entitled "Effect of 'Ionized' Wrist Bracelets on Musculoskeletal Pain: A Randomized, Double-Blind, Placebo-Controlled Trial." (Compl. Ex. A) The study concluded that the "data showed significant improvement in pain scores in both groups, but no differences were observed between the group wearing the placebo bracelet and the group wearing the ionized bracelet." (Compl. Ex. A 1164). Although the article acknowledged that the study was not designed to test the effectiveness of placebos, the results suggest that patients' subjective perception of pain relief from the bracelet was due to the placebo effect. (Compl. Ex. A 1167.)

From 2000 to 2003, QT was sued three times for consumer fraud and false advertising. The Consumer Justice Center sued QT on December 7, 2000, during Mayo's study (before publication). The *Consumer Justice* suit settled before trial. A class action suit, *Casey v. QT*, was filed in Cook County on January 21, 2003, and the Federal Trade Commission filed suit against QT on May 27, 2003 in federal court in the Northern District of Illinois.

As part of the *Casey* and *FTC* actions, the parties subpoenaed Mayo for Ionized Bracelet Study-related documents and depositions. Mayo resisted the subpoenas, but the United States District Court for the Middle District of Florida ordered Mayo to produce patient records with all identifying information redacted. Mayo produced over 19,000 pages of documents to QT. Since mid-2004, QT has had access to the substance of the patient records.

In 2004, under those same subpoenas, QT deposed three principals involved in the Ionized Bracelet Study: Dr. Bratton (principal investigator), Dr. Peter O'Brien (senior statistician), and Linda Hall (study coordinator). QT's lawyers deposed these Mayo employees over nine days, amounting to over 1700 pages of transcript. QT deposed Dr. Bratton alone for four days, resulting in over 900 pages of transcript.

On October 3, 2005, the *Casey* case went to trial in Cook County Circuit Court as a bench trial before Judge Irwin Solganick. The trial lasted three months. Judge Solganick issued his ruling from the bench immediately upon conclusion of closing arguments. Judge Solganick began by noting that he had "probably spent more time on this case of my own time reviewing testimony, exhibits, briefs submitted by the parties" than "in any other case that I've had in 19 years on the bench." (McBride Decl. Ex. 8, 01/03/2006 *Casey* Trial Tr. 114:15-20.) As QT's lawyers said during the March 7, 2006, Status Conference in this case, Judge Solganick ruled in favor of QT. What QT's lawyers did not say was that after his extensive review of the trial record, Judge Solganick concluded that the Q-Ray bracelet was a "scam:"

> From what I've observed in my experiences in life and what I've observed in cases before me, people who are in pain will try to do almost anything to relieve their pain. With that in mind, I reviewed the evidence in this particular case. And what I really saw in this case was a great scam.
>
> . . . .
>
> And the beauty of that scam was that people were told, well, it doesn't work for everybody. So if it doesn't work for you, well, you are one of the, you know, few percent that the bracelet does not relieve pain for. Beautiful scam.

(*Id.* at 115:6-12, 18-23.) Ultimately, however, Judge Solganick ruled in favor of QT because the plaintiffs' class representatives failed to meet their burden of proof.

> [A]lthough in my mind I believe the actions of Q-Ray were in fact in violation of the [Illinois Consumer Fraud and Deceptive Practices Act]. I don't think it was sufficiently shown by the representatives of the class with regard to the -- what they had viewed, when they had viewed it, how they had viewed it in this particular case or whether or not anything that they had viewed was the basis for their purchase.

(*Id.* at 123:24-124:7.) The *FTC* action is scheduled to begin a bench trial before Magistrate Judge Ian Levin on June 5, 2006.

On November 8, 2005, QT filed this action against Mayo. Mayo filed its Answer on December 7, 2005. The parties held their first conference on January 9, 2006. QT told Mayo that it wanted unredacted patient records from the Ionized Bracelet Study for two reasons: (1) to adequately correlate the different records with each other so that QT could determine which records were associated with a given patient; and (2) to depose individual patients about their participation in the Ionized Bracelet Study. Mayo proposed a new, *ab initio* production of patient records from the study with a more limited set of redactions. (McBride Decl. Ex. 9, 02/21/2006 McBride Letter to Kimbarovsky.) The new production would include, among other things, unredacted document dates, enrollment dates, and a neutral study control number to allow complete correlation of all patient records. Mayo told QT, however, that producing patient records with unredacted identifying information was a violation of the patients' state law privilege of confidentiality in medical records. *Id.*

On March 3, 2006, QT responded to Mayo's proposal, claiming that under federal law it was entitled to completely unredacted patient records for all 610 patients. (McBride Decl. Ex. 10, 03/03/2006 Kimbarovsky Letter to McBride.) Mayo and QT held a telephone conference on March 6, 2006, to meet and confer, but were unable to resolve the redaction issue. Mayo sent QT a list of relevant case law in support of Mayo's position and asked QT for any contrary authority. (McBride Decl. Ex. 11, 03/06/2006 McBride Letter to Kimbarovsky.) QT did not respond. The parties brought the issue of patient record redaction to the attention of the Court during the March 7, 2006, Status Conference. QT's Motion to Compel followed.

ARGUMENT

This Court should not require Mayo to produce unredacted, non-party patient records from the Ionized Bracelet Study. State law regarding medical records confidentiality controls in this diversity action. State law, whether Florida or Illinois, dictates that patient identifying information for non-parties should remain confidential, and that the proper way to protect this confidentiality is to produce otherwise relevant non-party patient records with all identifying information redacted. Moreover, the information QT claims is relevant is better obtained through unprivileged sources. Disclosure of unredacted patient records will have a chilling effect on future researchers' ability to secure willing volunteers for clinical studies.

I. STATE LAW CONTROLS THE DISCOVERABILITY OF PATIENT RECORDS

In diversity actions, state law governs the discoverability of confidential, privileged documents. *Armour Int'l Co. v. Worldwide Cosmetics, Inc.*, 689 F.2d 134, 135 (7th Cir. 1982) (citations omitted) ("The Federal Rules of Evidence provide that on issues governed by state law arising in civil actions privileges of witnesses are determined by state law. . . . This rule applies as well to discovery proceedings."); *Biedrzycki v. Town of Cicero*, No. 04 C 3277, 2005 U.S. Dist. LEXIS 16423, at *19 (N.D. Ill. Aug. 8, 2005) ("[W]hen the case is before a federal court under diversity jurisdiction, state privilege law applies."); Fed. R. Evid. 501, 1101(c).

The confidentiality of the study patient records is a matter of privilege under both Florida and Illinois law. *In re Fink*, 876 F.2d 84, 85 (11th Cir. 1989) (applying Florida privilege law regarding the confidentiality of medical records in diversity medical malpractice suit); *Northwestern Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 925 (7th Cir. 2004) (remarking that federal courts would apply Illinois' "medical-records privilege" in diversity suits).

Apart from Illinois and Florida, other federal courts routinely apply state law to determine the discoverability of records containing patient health information. *See, e.g.*, *Hahnemann Univ. Hosp. v. Edgar*, 74 F.3d 456, 460 (3d Cir. 1996) (noting that confidentiality of health information is a privilege issue properly decided under Pennsylvania state law in federal diversity action); *In re Rezulin Prods. Liab. Litig.*, 178 F. Supp. 2d 412, 413 (S.D.N.Y. 2001) (indicating that "[a]s these are diversity cases, the questions [of health information confidentiality] presented are governed by [Texas] state law," and finding that production of

records with identifying information redacted was consistent with that privilege). This Court, sitting in diversity, should look to state law regarding the confidentiality of the Ionized Bracelet Study's patient records.

II. UNDER BOTH FLORIDA AND ILLINOIS LAW, THE IONIZED BRACELET STUDY PATIENT RECORDS ARE PROTECTED CONFIDENTIAL PATIENT HEALTH INFORMATION THAT MAYO SHOULD PRODUCE IN REDACTED FORM

A. This Court should apply Florida law regarding the confidentiality of the Ionized Bracelet Study patient records

In the event of a conflict of law, this Court applies Illinois' choice-of-law rules in determining what substantive law to apply. *Hinc v. Lime-O-Sol Co.*, 382 F.3d 716, 719 (7th Cir. 2004) ("Federal courts sitting in diversity apply the choice-of-law rules of the forum state to determine the applicable substantive law."). Under Illinois' choice-of-law rules, the law of the state with the "most significant relationship to the occurrence and the parties" will apply. *Jones v. State Farm Mut. Auto. Ins. Co.*, 289 Ill. App. 3d 903, 917 (1997).

Florida has the most significant relationship to the Ionized Bracelet Study. The Mayo Clinic Jacksonville, in Florida, conducted the Ionized Bracelet Study in Florida. Mayo executed the Clinical Research Agreement for the Ionized Bracelet Study in Florida, and the Agreement states that the "Agreement and its effects are subject to and shall be construed and enforced in accordance with the laws of the State of Florida." (McBride Decl. Ex. 2, 11/03/1999 Clinical Research Agreement 4.) The study recruited patients in Florida. Mayo collected and stored the study patient records in Florida. Florida's policy interest in the confidentiality of its citizens' patient health information is so significant that the state elevated the interest to an express constitutional protection. *See Barker v. Barker*, 909 So. 2d 333, 337 (Fla. Dist. Ct. App. 2005).

Illinois, in contrast, lacks a significant relationship to the study and has no meaningful policy interest in Florida citizens' privilege to keep their health information confidential. If the Court finds a conflict between Florida and Illinois law, Florida law should apply. Ultimately, however, there is no conflict of law because both Illinois and Florida law prevent Mayo's production of unredacted non-party patient records from the Ionized Bracelet Study.

B. Florida law dictates that Mayo redact non-party patient records

Florida law contains strong privileges protecting the confidentiality of a person's medical health information. Florida's protection of medical record confidentiality originates in statutory and constitutional provisions. *Barker*, 909 So. 2d at 337 ("A person's medical records implicate the right to privacy guaranteed by our constitution. . . . Court orders compelling discovery of personal medical records constitute state action that may impinge on the constitutional right to privacy."); Fla. Stat. § 456.057 (2005).

Florida courts overwhelmingly rule in favor of protecting the privacy of health information for non-parties, and require that any such health information, if relevant, be redacted of any identifying information. The Eleventh Circuit in *In re Fink*, 876 F.2d 84 (11th Cir. 1989), dealt with a plaintiff seeking the identities of a defendant doctor's other patients who had undergone a procedure similar to the one at issue. Because Florida's law protecting the rights of non-parties is so strong, the Eleventh Circuit granted mandamus on a discovery motion in order to reverse the District Court's order compelling production of unredacted non-party records. *Id.* at 85. The Supreme Court of Florida has ruled that non-party patient confidentiality is, at a minimum, to be protected by redaction of identifying information. *Amente v. Newman*, 653 So. 2d 1030, 1033 (Fla. 1995) (finding that redaction protected non-party confidentiality in instant case, but noting that in "those cases where mere redaction . . . is deemed insufficient . . ., the trial court, in its discretion, may also order the medical records sealed . . . ."). The redaction of identities from relevant non-party patient health information is routine under Florida law. *See, e.g.*, *Cmty. Psychiatric Ctrs. of Florida, Inc. v. Bevelacqua*, 673 So. 2d 948, 951 (Fla. Dist. Ct. App. 1996); *Amisub, Inc. v. Kemper*, 543 So. 2d 470 (Fla. Dist. Ct. App. 1989); *Ventimiglia v. Moffitt*, 502 So. 2d 14 (Fla. Dist. Ct. App. 1986).

QT claims that unredacting patient records to reveal the patient's identity does not implicate privacy concerns because "the data does not involve any private medical information regarding the study participants." (QT Mem. 14.) This is incorrect. QT asks for the complete and unredacted study record containing the patient's identity along with the protected health information. Moreover, the disclosure of non-party patient identities, even when that information is not directly attached to the protected health information as it is in this case, is an invasion of the confidentiality and privacy rights that Florida law protects. *See Haywood v. Samai*, 624 So. 2d 1154 (Fla. Dist. Ct. App. 1993) (finding that a failure to redact from an

appointment book the names and telephone numbers for non-party patients would be an invasion of those patients' privacy).

QT's citation to *Big Sun Healthcare Sys., Inc. v. Prescott*, 582 So. 2d 756 (Fla. Dist. Ct. App. 1991) is inapposite. First, the sign-in sheet at issue in *Big Sun* was merely a list of names. *Id.* at 758. Here, the patient records from the Ionized Bracelet Study contain not only identifying information (names, addresses, phone numbers, clinic numbers), but also protected health information related to the patient's pain and the effectiveness of the study treatment. Second, QT cites to dicta. The *Big Sun* court found any applicable privilege had been waived, and merely noted its uncertainty as to whether the records were privileged to begin with. *Id*.

QT's reliance on *North Broward Hospital District v. Lucas*, 448 So. 2d 622 (Fla. Dist. Ct. App. 1984) is also misplaced. The *North Broward* court quashed a lower court's order to produce unredacted records of non-party patients who were also potential witnesses. *Id.* QT now seeks production of that which the *North Broward* court refused to allow.

C. Illinois law also dictates that Mayo redact non-party patient records

Illinois' law regarding the confidentiality of patient health information is as restrictive as Florida's is, and prevents the production of unredacted patient records from the Ionized Bracelet Study. *See* 735 Ill. Comp. Stat. 5/8-802; *People v. Manos*, 761 N.E.2d 208, 216 (Ill. App. Ct. 2001) ("We hold that plaintiff cannot compel the production of the patient medical records absent a showing that one of the 10 statutory exceptions applies (735 ILCS 5/8-802).");[2] *In re*

[2] The exceptions listed in 735 Ill. Comp. Stat. 5/8-802 do not include any circumstances under which Mayo could produce the study patient records unredacted:
"(1) in trials for homicide when the disclosure relates directly to the fact or immediate circumstances of the homicide, (2) in actions, civil or criminal, against the healthcare practitioner for malpractice (in which instance the patient shall be deemed to have waived all privileges relating to physical or mental condition), (3) with the expressed consent of the patient, or in case of his or her death or disability, of his or her personal representative or other person authorized to sue for personal injury or of the beneficiary of an insurance policy on his or her life, health, or physical condition, (4) in all actions brought by the patient, his or her personal representative, a beneficiary under a policy of insurance, or the executor or administrator of his or her estate wherein the patient's physical or mental condition is an issue (in which instance the patient shall be deemed to have waived all privileges relating to physical or mental condition), (4.1) in all actions brought against the patient, his or her personal representative, a beneficiary under a policy of insurance, or the executor or administrator of his or her estate wherein the patient's physical or mental condition is an issue, (5) upon an issue as to the validity of a document as a will of the patient, (6) in any criminal action where the charge is either first degree murder by abortion, attempted abortion or abortion, (7) in actions, civil or criminal, arising from the filing of a report in compliance with the Abused and Neglected Child Reporting Act [*325 ILCS 5/1* et seq.], (8) to any department, agency,

D.H., 746 N.E.2d 274, 276 (Ill. App. Ct. 2001) (finding that the medical records of non-parties are privileged). Even if this Court were to find that Illinois law, rather than Florida law, applies, the result is the same: Mayo's redactions of identifying information from the Study's patient records would be proper.

D. Mayo is <u>not</u> redacting the names of non-patients who witnessed the informed consent process

QT conflates the issue of witness names with the issue of patient names. As Mayo has told QT, Mayo is not redacting the names of witnesses to informed consent who did not participate in the study. Non-participant witness names will be visible in the produced records. Many of the witnesses to informed consent in the Study, however, were also patients in the study. The law protects those patients' identities for the reasons outlined above.

III. HIPAA DOES NOT PREEMPT MORE STRINGENT STATE LAW

QT spends considerable time discussing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA is not controlling. First, as we show above, state law governs this issue. Second, HIPAA expressly yields to state laws that give greater confidentiality privileges to patients' health information. HIPAA itself, in directing the Secretary of Health and Human Services to enact regulations, notes that such regulations "*shall not supercede* a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are *more stringent* than the requirements, standards, or implementation specifications imposed under the regulation." HIPAA, P.L. 104-191, § 264(c)(2), 110 Stat. 1936, 2033 (1996) (emphasis added). HIPAA's federal regulations codify that HIPAA does not preempt or supercede a state law that grants greater confidentiality and privacy to an individual's patient health information:

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institution or facility which has custody of the patient pursuant to State statute or any court order of commitment, (9) in prosecutions where written results of blood alcohol tests are admissible pursuant to Section 11-501.4 of the Illinois Vehicle Code [*625 ILCS 5/11-501.4*], (10) in prosecutions where written results of blood alcohol tests are admissible under Section 5-11a of the Boat Registration and Safety Act [*625 ILCS 45/5-11a*], or (11) in criminal actions arising from the filing of a report of suspected terrorist offense in compliance with Section 29D-10(p)(7) of the Criminal Code of 1961 [*720 ILCS 5/29D-10*]."

> A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, *except if one or more of the following conditions is met*:
>
> . . .
>
> (b) The provision of State law relates to the privacy of individually identifiable health information and *is more stringent* than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this sub-chapter.

45 C.F.R. § 160.203(b) (2006) (emphasis added).

Florida and Illinois laws are both more stringent than HIPAA in their protections of the confidentiality of individually identifiable patient health information. Neither Florida nor Illinois permit Mayo to produce unredacted patient records from the Ionized Bracelet Study. HIPAA acknowledges that these more stringent state laws control.

IV. QT CAN OBTAIN DISCOVERY WITHOUT VIOLATING PRIVILEGE

QT gives three pages of purported reasons why it needs the unredacted patient records from the Ionized Bracelet Study. The Court should be unmoved. QT can obtain its discovery from less burdensome, unprivileged sources, such as the study investigators and co-authors.

QT claims it needs unredacted patient records "to determine which Forms correlate to which specific Mayo employees." (QT Mem. 8.) This issue is moot because Mayo has already solved QT's correlation problem by agreeing to produce records with a neutral study control number unique to a given patient. QT also wants to know "whether any of the investigators . . . or the published authors of the study, were participants," "whether family members of the investigators were participants in the study," and whether any of the Study patients "knew the study's investigators or coordinators." (QT Mem. 9.) QT can discover this information, if relevant, through interrogatories or depositions of the study principals, without identifying all 610 patients in the Study.[3]

[3] Notably, during its nine days of Mayo depositions, QT did not ask the Mayo deponents about any suspected investigator participation, or investigator family members' participation in the study. QT's conduct undermines the weight the Court should give QT's claim that it now needs unredacted patient records to discover that same information.

QT also seeks information on whether patients enrolled in the first part of the study "were allegedly permitted to participate in the Second Study" or whether Mayo used "survey data from the First Study in tabulating and publishing the results of the Second Study." (QT Mem. 10.) QT can discover this information from the redacted records. The redacted patient records are all dated with document revision dates and patient enrollment dates, allowing QT to identify any alleged enrollments, records, or data from the first study. (McBride Decl. Ex. 9, 02/21/2006 McBride Letter to Kimbarovsky 6-19.) QT can ask the study's investigators and authors any follow-up questions about data collection and analysis. There is no need to disclose privileged patient health information.

QT wants facts related to patients' job titles and departments. (QT Mem. 9 ("whether individuals working in [investigators'] offices or departments participated in the studies;" "If Defendants will argue that certain Mayo employees are exempt from those guidelines [governing use of employees in research], QT is entitled to know identities of the employees to be able to challenge this anticipated defense;" "enable QT to cross-reference [patients' identities] to the list of departments at Mayo to confirm these allegations [that Mayo knew in advance that some employees couldn't comply with study requirements]").) Unredacted patient records will not give QT this information. To the extent it is relevant, QT can obtain job titles and departments through other discovery without actually identifying the individual patients.

The remaining information that QT purports to want is entirely speculative and would require the onerous burden of deposing all 610 study patients. For example, QT claims the "Second Study was flawed, in part, because those persons who participated in both studies were not blinded to the product being tested in the study." (QT Mem. 10.) QT has no basis, and provides no explanation, for alleging that participants were unblinded. QT provided the bracelets for the study, and the "ionized" and placebo bracelets were indistinguishable to the patients. (McBride Decl. Ex. 12, 09/27/2000 Bratton Email to Ciprian.) Therefore, QT appears to be alleging that the investigators improperly unblinded participants. Rather than allow QT to depose all 610 patients, which would be an unreasonable burden, the Court should require QT to take the more reasonable action of deposing the investigators it alleges unblinded the participants. Similarly, QT's desire to learn if patients "discussed the study with one another" or "were routinely working together at Mayo and discussing the study" is speculation and should not be permitted to override patients' confidentiality rights. (QT Mem. 10.)

Because QT can obtain discovery without violating patient privilege, this Court should deny QT's motion. *See Cmty. Psychiatric Ctrs. of Fla., Inc.*, 673 So. 2d at 951 (quashing order to disclose identities of nonparty patients in part because party seeking identities "may be able to obtain the relevant information while maintaining the patients' anonymity").

V. STRONG POLICY GROUNDS SUPPORT MAYO'S REDACTIONS

Mayo's ability to get volunteers for its clinical research will be harmed if it is required to disclose the records and identities of its study patients. Mayo has historically considered the protection of patient confidentiality a core Mayo value. The IRB's Manual for Investigators Conducting Research Involving Humans, in the section on Identification of Subjects in Research Studies, states:

> Protection of the confidential nature of the relationship between patients and physicians has been a fundamental tenet of Mayo Clinic through its history. Every effort has been made to avoid compromising this relationship of trust, which is inherent in medical care of the highest standard.

(McBride Decl. Ex. 13, 1997 IRB Manual for Investigators Conducting Research Involving Humans 105.) The Florida federal court that ruled on the *FTC* subpoenas recognized Mayo's strong interest in preserving patient confidentiality:

> Although the Mayo Clinic is not a federal agency, it is a non-profit organization that produces research results which may benefit overall public health. The Court recognizes the logic of Mayo Clinic's concerns that many patients might decline to participate in studies if they believe their participation or health issues might become public knowledge.

(McBride Decl. Ex. 14, 03/22/2004 Order in *FTC v QT* 3.) If the Court orders Mayo to produce unredacted patient records and QT is allowed to investigate and depose the study patients, it will have a chilling effect on Mayo's ability to secure volunteers for clinical research.

At its core, QT's attempt to get unredacted study records is a fishing expedition. After nine days deposing the principal Mayo employees involved in the study, amounting to over 1700 pages of transcript, QT cannot support its allegations that Mayo was engaged in a broad-based conspiracy to hurt QT. Having failed in its extensive discovery of Mayo employees, QT now wants to depose the patients whose health information forms the basis for the study. The harm

this fishing expedition will do to Mayo's future clinical research outweighs its limited probative value. Thus, the Court should deny QT's motion

VI. IF THE COURT ORDERS MAYO TO PRODUCE UNREDACTED PATIENT RECORDS, FLORIDA LAW REQUIRES NOTICE TO THE PATIENTS AND AN OPPORTUNITY FOR THE PATIENTS TO OBJECT

Florida privilege law not only restricts the circumstances under which patient health information is discoverable, but it also regulates the procedures required before an institution like Mayo may release that health information. Fla. Stat. § 456.057(6) states:

> Except in a medical negligence action or administrative proceeding when a health care practitioner or provider is or reasonably expects to be named as a defendant, information disclosed to a health care practitioner by a patient in the course of the care and treatment of such patient is confidential and may be disclosed only to other health care practitioners and providers involved in the care or treatment of the patient, or if permitted by written authorization from the patient or compelled by subpoena at a deposition, evidentiary hearing, or trial for which proper notice has been given.

Florida courts have recognized that this statute establishes "that outsiders may not subpoena such records from medical providers without prior notice to the patient." *Limbaugh v State*, 887 So. 2d 387, 393 (Fla. Dist. Ct. App. 2004). Before Mayo could produce unredacted patient records, it would have to provide notice of the intended production to all 610 patients and give those patients an opportunity to object.

Providing the required notice to all 610 patients will be highly, and unreasonably, burdensome to Mayo. The burden on Mayo of providing notice will outweigh the speculative, minimal, probative value of the unredacted patient records. Therefore, the Court should deny QT's motion to compel.

However, if this Court decides to order Mayo to produce unredacted patient records, then Mayo respectfully requests that any such Order from the Court recognize the law's requirement of notice and an opportunity to object.

CONCLUSION

For the foregoing reasons, the Court should deny QT's motion to compel.

March 28, 2006

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2006, a copy of the foregoing **MAYO'S MEMORANDUM IN OPPOSITION TO QT'S MOTION TO COMPEL** was filed electronically. Notice to this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular mail. Parties may access this filing through the Court's electronic filing system.

s/J. Scott McBride

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