

Benefits of Ionized Wrist Bracelets
Investigator: R.L. Bratton, M.D.
Statisticians: P.C. O'Brien, Ph.D.
E.J. Atkinson

**Survey
Week 1**

Study number: 7-1089
IRB number: 1086-99 (J)
September 2000

Name: _____
(Last) (First) (M.I.)

Column Item
1-2 07 Survey day
3-6 Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain	←	—	—	—	—	—	—	—	—	→	Pain as Bad as It Could Be										
7-8	Neck	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input checked="" type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
9-10	Shoulders	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
11-12	Elbows	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
13-14	Wrists	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
15-16	Hands	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
17-18	Upper Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input checked="" type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
19-20	Mid Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input checked="" type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
21-22	Lower Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
23-24	Hips	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
25-26	Knees	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input checked="" type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
27-28	Ankles	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
29-30	Feet	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>

Trujillo v. Apple Computer, Inc. et al

Doc. 876 Att. 4

Reminder: "New" pain relievers or anti-inflammatory medications for joint or muscle pain are not allowed to be used during this study.

442A

Benefits of Ionized Wrist Bracelets
Investigator: R.L. Bratton, M.D.
Statisticians: P.C. O'Brien, Ph.D.
E.J. Atkinson

**Survey
Week 2**

Study number: 7-1089
IRB number: 1086-99 (J)
September 2000

Name: _____
(Last) (First) (M.I.)

Column Item
1-2 14 Survey day
3-6 _____ Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain	←	—	—	—	—	—	—	—	—	→	Pain as Bad as It Could Be										
7-8	Neck	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input checked="" type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
9-10	Shoulders	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
11-12	Elbows	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
13-14	Wrists	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
15-16	Hands	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
17-18	Upper Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input checked="" type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
19-20	Mid Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input checked="" type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
21-22	Lower Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
23-24	Hips	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input checked="" type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
25-26	Knees	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input checked="" type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
27-28	Ankles	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
29-30	Feet	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>

REDACTED

Reminder: "New" pain relievers or anti-inflammatory medications for joint or muscle pain are not allowed to be used during this study.

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Investigator: R.L. Bratton, M.D.
Statisticians: P.C. O'Brien, Ph.D.
E.J. Atkinson

**Survey
Week 3**

Study number: 7-1089
IRB number: 1086-99 (J)
September 2000

Name: _____
(Last) (First) (M.I.)

Column Item
1-2 2 1 Survey day
3-6 _____ Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain	←	—	—	—	—	—	—	—	—	→	Pain as Bad as It Could Be										
7-8	Neck	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input checked="" type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
9-10	Shoulders	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
11-12	Elbows	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
13-14	Wrists	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
15-16	Hands	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
17-18	Upper Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input checked="" type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
19-20	Mid Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input checked="" type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
21-22	Lower Back	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
23-24	Hips	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
25-26	Knees	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input checked="" type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
27-28	Ankles	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>
29-30	Feet	00	<input type="checkbox"/>	01	<input type="checkbox"/>	02	<input type="checkbox"/>	03	<input type="checkbox"/>	04	<input type="checkbox"/>	05	<input type="checkbox"/>	06	<input type="checkbox"/>	07	<input type="checkbox"/>	08	<input type="checkbox"/>	09	<input type="checkbox"/>	10	<input type="checkbox"/>

Reminder: "New" pain relievers or anti-inflammatory medications for joint or muscle pain are not allowed to be used during this study.

Benefits of Ionized Wrist Bracelets
Investigator: R.L. Bratton, M.D.
Statisticians: P.C. O'Brien, Ph.D.
E.J. Atkinson

**Survey
Week 4**

Study number: 7-1089
IRB number: 1086-99 (J)
September 2000

Name: _____
(Last) (First) (M.I.)

Column Item
1-2 2 8 Survey day
3-6 _____ Patient number

Please rate your pain involving the following body areas by checking the appropriate number on the scale. Zero being no pain and 10 being the most severe pain.

		No Pain	←	—	—	—	—	—	—	—	—	→	Pain as Bad as It Could Be
7-8	Neck	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input checked="" type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
9-10	Shoulders	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
11-12	Elbows	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
13-14	Wrists	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
15-16	Hands	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
17-18	Upper Back	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input checked="" type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
19-20	Mid Back	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input checked="" type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
21-22	Lower Back	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
23-24	Hips	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
25-26	Knees	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input checked="" type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
27-28	Ankles	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	
29-30	Feet	00 <input type="checkbox"/>	01 <input type="checkbox"/>	02 <input type="checkbox"/>	03 <input type="checkbox"/>	04 <input type="checkbox"/>	05 <input type="checkbox"/>	06 <input type="checkbox"/>	07 <input type="checkbox"/>	08 <input type="checkbox"/>	09 <input type="checkbox"/>	10 <input type="checkbox"/>	

Reminder: "New" pain relievers or anti-inflammatory medications for joint or muscle pain are not allowed to be used during this study.

EXHIBIT 10

UNGARETTI & HARRIS

CHICAGO
3500 Three First National Plaza
Chicago, Illinois 60602.4283
Telephone: 312.977.4400
Fax: 312.977.4405

ROSS E. KIMBAROVSKY
Direct Dial: 312.977.4446
Facsimile: 312.977.9206
ross@uhlaw.com

WASHINGTON
1500 K Street, N. W., Suite 250
Washington, D.C. 20005.1714
Telephone: 202.639.7500
Fax: 202.639.7505

<http://www.uhlaw.com>

March 3, 2006

By E-mail

J. Scott McBride., Esq.
Bartlit Beck Herman Palenchar & Scott LLP
54 West Hubbard Street
Chicago, Illinois 60610

Re: QT v. Mayo/Mayo Study Documents Discovery

Dear Scott:

This responds to your February 21, 2006 letter, concerning the production by Mayo of Mayo clinical trial records related to the Q-Ray® Ionized Bracelet®.

We commend your agreement to produce the study records with fewer redactions than Mayo made in its prior production in the Casey v. QT and FTC v. QT matters and we thank you for forwarding a sample document showing the specific redactions you propose. However, we do not believe that any redactions are necessary. HIPAA specifically provides for a qualified protective order that permits controlled disclosure of medical information. We would be happy to forward appropriate language for your review.

Furthermore, we do not believe that redactions are merited or reasonable. The data you propose to redact, such as for example, the identity of Mayo employees who participated in the studies and identity of witnesses to the Informed Consent forms, goes to the very heart of the allegations against Defendants. Redaction of such data would unfairly prejudice Plaintiff.

We note one other concern with your letter. As you know, Mayo performed two studies, prematurely terminating the first study. We expect to receive (and will request) all hard copy and electronic study records related to both studies.

Please call me at your convenience on March 6 so that we can further discuss this issue in advance of the March 7 status hearing with Judge Moran.

Sincerely,



Ross E. Kimbarovsky

EXHIBIT 11

BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP

www.bartlit-beck.com

CHICAGO OFFICE
COURTHOUSE PLACE
54 WEST HUBBARD STREET
CHICAGO, IL 60610
TELEPHONE: (312) 494-4400
FACSIMILE: (312) 494-4440

March 6, 2006

DENVER OFFICE
1899 WYNKOOP STREET
8TH FLOOR
DENVER, CO 80202
TELEPHONE: (303) 592-3100
FACSIMILE: (303) 592-3140

BY FAX & EMAIL

Ross E. Kimbarovsky
Ungaretti & Harris LLP
3500 Three First National Plaza
Chicago, IL 60602
Fax: (312) 977-9206
Email: rossk@uhlawa.com

WRITER'S DIRECT DIAL:
(312) 494-4436
scott.mcbride@bartlit-beck.com

Re: *QT v Mayo*

Dear Ross:

In our conversation today, I told you that on the issue of a non-party patients' right to privacy, Florida's more stringent privacy laws control over HIPPA. You asked to see some authority.

Please see HIPPA at 45 CFR § 160.203(b) and the following representative cases:

In re Fink, 876 F.2d 84 (11th Cir. 1989)
Amente v. Newman, 653 So. 2d 1030 (Fla. 1995)
Haywood v. Samai, 624 So. 2d 1154 (Fla. Dist. App. Ct. 1993)
Age Inst. of Fla., Inc. v. McGriff, 884 So. 2d 512 (Fla. Dist. Ct. App. 2004)

If you have contrary authority, please disclose it without delay.

Very truly yours,

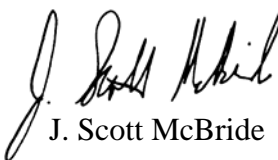

J. Scott McBride

EXHIBIT 12

Bratton, Robert L., M.D.

From: Bratton, Robert L., M.D.
Sent: Wednesday, September 27, 2000 12:22 PM
To: 'Lizz Ciprian'
Cc: Hall, Linda J.
Subject: RE: Q-Ray

Lizz, Please send a sealed letter that notes if the bracelets with the green dots (group A) are activated or placebo and the ones without dots (group B) etc. Put on the outside "sealed research information do not open until end of study" and address to Linda Hall at the same address as before. Thanks

From: Lizz Ciprian[SMTP:lcip@qray.com]
Reply To: Lizz Ciprian
Sent: Wednesday, September 27, 2000 8:34 AM
To: Robert Bratton, MD
Subject: Q-Ray

Dr. Bratton,

Yesterday I shipped the bracelets to you via UPS 3 day service so you should have them by Friday. They were sent to the address mentioned and are in 1 box with 2 inner cartons with the different bracelets. All the bracelets look the same (no marks), what we did was put a round sticker on the green bag of one of the batches they are packed in. The assortments were as you suggested:

100 Small
190 Medium
30 Large
320 pieces

If you have any questions let me know.

Lizz Ciprian
Q-Ray
Tel: 800-262-1180 x15, Fax: 847-228-5195
Internet: www.QRAY.com, Email: lcip@QRAY.com

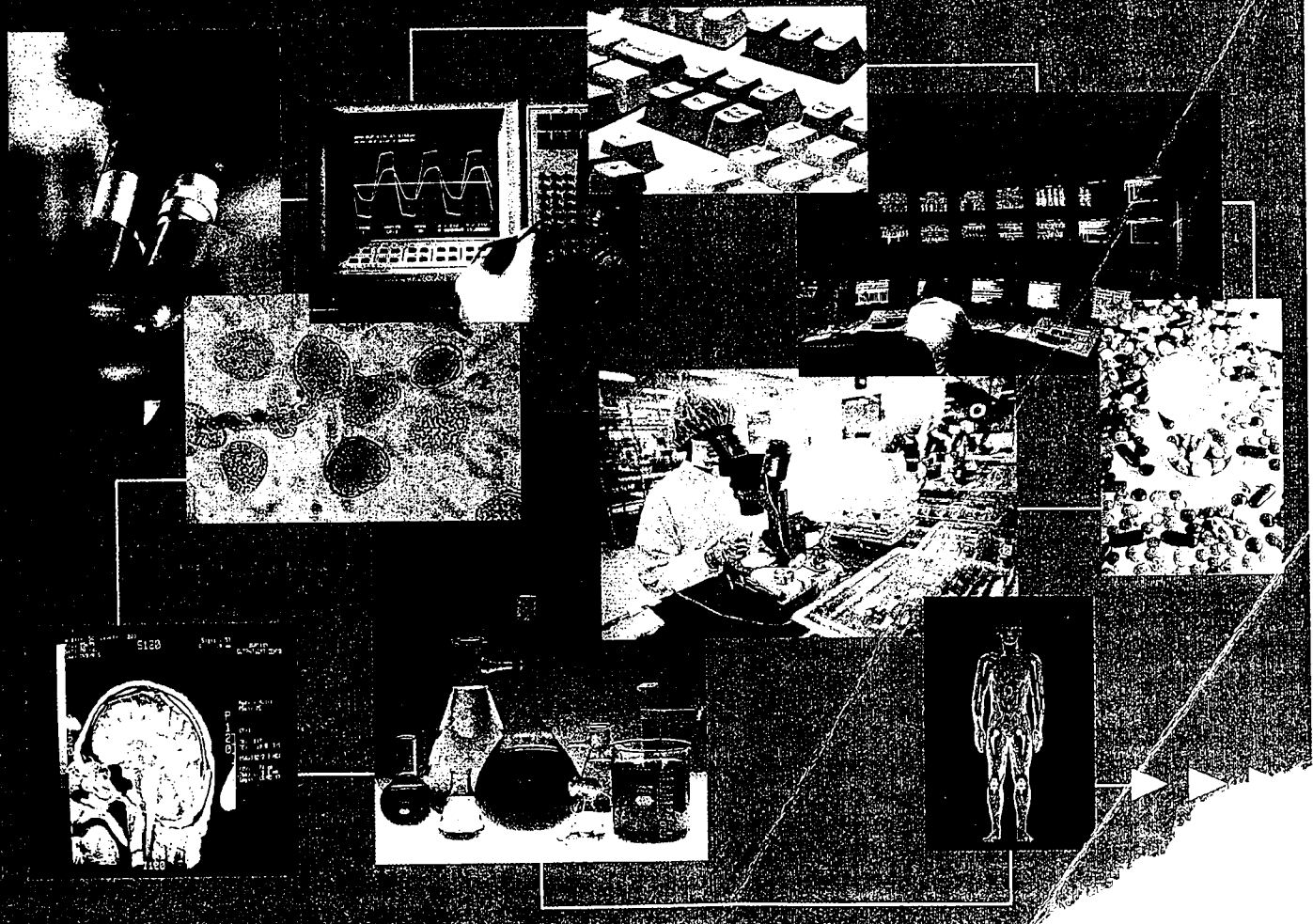
A018347

EXHIBIT 13



Manual for Investigators Conducting Research Involving Humans

Revised and Updated 1997



Identification of Subjects in Research Studies

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.

With the increase in multi-institutional research studies, however, the confidentiality of medical records and the physician-patient relationship has become increasingly difficult to maintain. Such studies often are sponsored and funded by federal agencies. Data banks are frequently structured around the use of patients' names, and refusal of an institution to provide those names may jeopardize participation in a given study.

The Board of Governors recognizes this conflict between patient privacy and the advancement of medical knowledge but is of the opinion that Mayo Clinic is obligated to its patients to adhere fully to the principle of the confidentiality of medical information and thus to set an example that may influence the design of research protocols to avoid the use of patients' names. Toward this end, the Board has approved the following policy:

Patients' names are not to be released for research purposes under existing protocols or new protocols, either with or without permission of the patient. Mayo consultants involved in studies are asked to so advise the individuals who are responsible for collecting data. If the Mayo policy is not acceptable or is considered unworkable with respect to a study, the matter should be discussed at a higher administrative level in the agency supporting the study. Mayo Clinic registration numbers may not be released, however, a unique study identification number devised by the investigator and the initials of patients can be provided when this is essential to the sound analysis of data.

EXHIBIT 14

UNITED STATES DISTRICT COURT,
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

PAM

FEDERAL TRADE COMMISSION,

2004 MAR 22 P 4: 28

Plaintiff,

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

vs.

CASE NO. 3:03-MC-44-J-25TEM

QT, INC., Q-RAY COMPANY,
BIO-METAL, INC., QUE TE PARK
a/k/a Andrew Q. Park, and
JUNG JOO PARK

Defendants.

ORDER

This case came before the Court on March 19, 2004 for a telephonic hearing¹ on the Motion to Quash Subpoenas (Doc. #1) wherein the non-party movants Mayo Foundation ("Mayo"), Mayo Clinic Jacksonville ("Mayo Clinic") and the Mayo Research Team comprised of eleven individuals² requested the Court quash each of twelve subpoenas issued by Defendants in the course of discovery in the underlying case pending in the Northern District of Illinois, Eastern Division. Defendants issued the referenced subpoenas (Doc. #2, Ex. A) to procure numerous documents associated with the research study conducted by Mayo Clinic on the "Q-Ray Bracelet" and to depose the named

¹The non-transcribed recording of the telephonic hearing is hereby incorporated by reference. The parties may contact the Courtroom Deputy of the undersigned if a transcript of the hearing is desired.

²Members of the Mayo Research Team referenced in the Motion to Quash are: Dr. Robert L. Bratton, M.D., Dr. Daniel P. Montero, M.D., Dr. Kevin S. Adams, M.D., Dr. Mark A. Novas, M.D., Dr. Tracy C. McKay, D.O., Linda J. Hall, Dr. Joseph G. Foust, M.D., Dr. Michael B. Mueller, D.O., Dr. Peter C. O'Brien, Ph.D., Dr. Elizabeth J. Atkinson, M.S., and Megan S. Maurer.

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individuals. As expected, Defendants filed an opposition to the instant motion. See Doc. #5, Response in Opposition to Motion to Quash Subpoenas. Plaintiff filed notice with the Court stating it did not intend to take a position regarding the contested subpoenas (Doc. #6). Plaintiff's counsel, Defendants' counsel and Movants' counsel all participated in the telephonic hearing. The Court made several factual inquiries and heard counsel's argument.

Mayo presented three grounds in its Motion to Quash: The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), a research privilege and the burdensome nature of compliance by all those subpoenaed. See Docs. #1 & #2. The Court agrees that HIPAA provides protection of patient identifying information, and in partially denying the Motion to Quash, the Court ordered that all such identifying information be redacted. Defendants did not object to that aspect.

The Court does not find that the Eleventh Circuit has recognized a research privilege *per se*. However, two Eleventh Circuit cases provide some guidance. In *Farnsworth v. Proctor & Gamble Co.*, 758 F.2d 1545 (11th Cir. 1985), the defendant subpoenaed records from the Center for Disease Control ("CDC") concerning information the CDC had gathered from about 300 women in a study of toxic shock syndrome. The CDC provided extensive information, but redacted names and addresses of study participants. The defendant's request to get that information was rejected by the Eleventh Circuit. Although the court noted the "law's basic presumption is that the public is entitled to every person's evidence," it found Rule 26(c), Fed.R.Civ.P., provided courts discretionary authority to fashion appropriate protective order and the CDC's interest in keeping names confidential outweighed the defendant's discovery interests. *Farnsworth*,

758 F.2d at 1546-47. Notably, the court said the decision “does not depend upon a legal privilege.” *Id.* at 1548.

In *Moore v. Armour Pharmaceutical Co.*, 927 F.2d 1194 (11th Cir. 1991), the court upheld the quashing of a plaintiffs’ subpoena to a CDC researcher whose limited time needed on AIDS research outweighed the parties’ interest in deposing a government scientist. Because the CDC is a federal agency, it had statutory authority to limit testimony of its employees. Although again recognizing the strong presumption in favor of full discovery, the court also found the district court’s discretion to deny it in this case was not clearly erroneous. *Id.* at 1197.

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. However, the limited discovery provisions of HIPAA already provide for individual patient confidentiality, and in fact yield a result similar to that reached in *Farnsworth*³ in that the names and addresses of study participants should not be disclosed.

Courts are required to balance the need for the discovery against the burden imposed on the person ordered to produce documents. See *Farnsworth*, 758 F.2d at 1547. The status of the person as a non-party is a factor weighing against disclosure. *American Electric Power Co., Inc., v. U.S.*, 191 F.R.D. 132 (S.D. Ohio 1999). In this case,

³In the case of *In re Fink*, 876 F.2d 84 (11th Cir. 1989), the court also denied discovery of names and addresses of a doctor’s patients who had undergone a particular medical procedure; however, because it was a diversity case, the decision was based on Florida precedent.

Defendants may be facing severe sanctions should they lose. Given the fact that Plaintiff FTC is relying at least in part on the Mayo Clinic study, that Mayo Clinic itself published a summary of the results and that a Mayo Clinic employee provided at least a minor amount of cooperation to the FTC, the Court finds that the need to discover the questionnaires (minus identification redactions) outweighs the burden to produce.

Thus, being fully apprised of the positions of the parties and non-parties, having reviewed and considered the record of this case and the oral argument presented, the Court made the following rulings from the bench, which are repeated here for the sake of clarity. The Motion to Quash Subpoenas (Doc. #1) is **GRANTED in part and DENIED in part**, as set forth below.

1. The parties have identified and agreed there exists approximately four bankers boxes of documents responsive to Defendants' subpoenas. See Doc. #2 at 6; Doc. #5 at 12. Reportedly, three of these boxes contain the study participant questionnaires and the fourth box contains miscellaneous documents, including correspondence and notes about the study. The Court ordered Mayo Clinic to redact all personal identifier information from the questionnaires contained within the three boxes of participant questionnaires and to produce the redacted documents for inspection and copying by Defendants and Plaintiff. Defendants shall be responsible for the costs incurred by the Mayo Clinic in redacting the personal information from the questionnaires. Defendants shall be responsible for the costs incurred in copying the documents for its discovery purposes and Plaintiff shall be responsible for the costs incurred in copying documents for its discovery purposes. The Court reserved ruling on the fourth box of study information pending a more thorough analysis of the privilege log submitted by Movants

(Doc. #2, Ex. G.). Thus, the Motion to Quash as to the Mayo Clinic of Jacksonville was denied as to the research study participant questionnaires, subject to modification noted above.

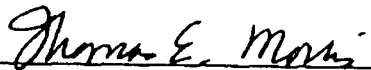
2. The Court **denied** the Motion to Quash as to the subpoenas issued to the Dr. Robert Bratton, M.D. and Ms. Laurie Wingender, R.N. as Manager of the Clinical Studies Unit for Mayo Clinic Jacksonville.⁴ Defendants shall be permitted to depose these individuals on a mutually agreeable date and time. The Court cautioned the parties that deposition inquiry of Dr. Bratton and Ms. Wingender should be limited to the study itself and statistics either as a whole or as sub-groups within the study. No party shall attempt to identify a particular study participant, the method of selection as it pertains to a particular participant, or what the ultimate reporting results were as to a particular participant. The parties may, however, inquire as to whether any individual questionnaires were later "corrected" or altered by anyone conducting the study. The Court **stayed the subpoenaed depositions** of the remaining Mayo Research Team members as likely to be unnecessarily cumulative and duplicative of other discovery. See Fed.R.Civ.P. 26(b)(2).

3. The Court finds the information responsive to Defendants' subpoenas will be confidential and/or proprietary in nature, the public disclosure of which might harm either the parties to this suit or third parties. Additionally, the Court believes entry of a protective order would reasonably forestall new disputes over production of this same

⁴The Court notes the subpoena of Ms. Wingender was not subject to the Motion to Quash as filed. However, all counsel participating on the telephonic hearing expressly agreed the subpoena of Ms. Wingender should be considered by the Court as it went to the same items for record production and to the same inquiries as would be made of Dr. Robert Bratton.

information. Therefore, in accordance with the discretion provided under Fed.R.Civ.P. 45(c), the Court will require all information disclosed under this Order remain confidential among the parties and the movants, their attorneys, attorney support staffs, and/or experts. Should any party or non-party determine further disclosure of this information to be necessary for litigation purposes, the party desiring further disclosure shall first seek consent of opposing counsel. In the absence of agreement to further disclosure, an appropriate motion shall be made to the Court. Upon conclusion of this litigation, all information obtained pursuant to this Order shall be either destroyed by counsel or returned to the providing entity within **thirty (30) days** of final judgment.

DONE AND ORDERED at Jacksonville, Florida this 22d day of March, 2004.



THOMAS E. MORRIS
United States Magistrate Judge

Copies to:
Counsel of Record