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Carol E. Higbee, P.J.Cv.

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In re: ACCUTANE LITIGATION	: SUPERIOR COURT OF NEW JERSEY : LAW DIVISION : ATLANTIC COUNTY : : Civil Action : : : Case No.271 : : **CASE MANAGEMENT ORDER No. 2** :

APPLICABLE TO ALL CASES

THIS COURT, having conducted a Case Management Conference on August 18, 2005, and all parties having been represented by Counsel, and for good cause shown,

IT IS on this 26th day of Sept, 2005,

ORDERED that this Case Management Order ("CMO") No. 2 shall amend prior CMOs to the extent inconsistent therewith, and it is further:

ORDERED as follows and to Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Defendants"):

I. Database Production

A. Defendants shall produce the sales calls database **Voyager,** and its predecessor databases, for Accutane for all of plaintiffs' physicians, and, if known, the office/suite mates of those physicians, or partners in the same practice (i.e., people they work or worked with). However, prior to that production, on or before August 25, 2005, Defendants shall provide the Court a letter brief setting forth the feasibility and burden of producing the entirety of the

Voyager database and any predecessor databases dating back to 1982. **(Transcript of August 18, 2005 Case Management Conference ("Tr."). at 27-28, 31.)**

B. Plaintiffs' request for the production of **DDD** is denied. On or before September 1, 2005, however, Defendants shall provide a certification setting forth the number of Accutane prescriptions it believes have been written for each year beginning with 1982. If the information is unavailable, Defendants shall so certify. **(Tr. at 32.)**

C. Plaintiffs' request for the production of **Sentinel** is denied. On or before September 1, however, Defendants shall provide a certification setting forth whether samples of Accutane were distributed to physicians or, alternatively, that Sentinel and its predecessor systems do/did not contain any information related to Accutane. **(Tr. at 36.)**

D. Plaintiffs have deferred their request for the production of **Convention Express. (Tr. at 39.)**

E. On or before September 1, 2005, Defendants shall make their best efforts to provide further information as to the content of **Pro-Trak-Promotions, Pro-Trak-Field Program and Plandex** as relates to Accutane, in particular to confirm that they do or do not contain anything on Accutane. Defendants shall also report on their position regarding Plaintiffs' request to inspect these databases. No certification is required. **(Tr. at 40-41.)**

F. Defendants shall direct Plaintiffs via email to Defendants' previous correspondence or communication to Plaintiffs' counsel as to whether **IMS** data pertaining to Accutane is retained by Defendants electronically. **(Tr. at 45.)**

G. On or before September 1, 2005, Defendants shall determine whether the company maintains past and present clinical or scientific literature pertaining to Accutane, including (a) where clinical or scientific literature is maintained and whether electronic/in a database; (b) whether clinical or scientific literature has been translated into English; (c) whether

the clinical or scientific literature is summarized or commented on; and (d) how extensive the collection of clinical or scientific literature is on Accutane. **(Tr. at 63-64.)**

II. Master Pleadings

Plaintiffs' Liaison counsel is to follow up with co-Plaintiffs' counsel on the status of the Master Complaint. Defendants may consider utilizing a Master Answer. Should Defendants elect to utilize a Master Answer, the Court will amend the deadline for service of Plaintiffs' Fact Sheets to sixty (60) days from proof of service. Otherwise, should Defendants elect to serve and file a Master Answer, the deadline for service of Plaintiffs' Fact Sheets shall be thirty (30) days after service of the Master Answer. **(Tr. at 70.)**

III. Depositions

A. Plaintiffs have requested the depositions of twenty (20) current and former employees of Defendants regarding Accutane and systemic injuries. Plaintiffs may depose the following witnesses for the number of days indicated below:[1]

Susan Ackerman – 1 day
Alan Bess – 2 days
Katherine Bess – 1 day
John Caminis – 1 day
Margaret Cunningham n/k/a "Goluzzi" (sp) – 2 days
William Cunningham – 2 days
Michael Fox – 2 days
Joseph Hong – 2 days
John Laflore – 2 days
Eileen Leach – 2 days
Louis Manfredi – 2 days
Heather Mayer – 1 day
Ko-Chin Khoo – 2 days
John McLane – 2 days
Urs Niederhauser – 2 days
Michael O'Toole – 1 day
Romericus Stewart – 1 day
Peter Schifferdecker – 2 days
Matt Suchodolski – 1 day

[1] Plaintiffs have requested a one day deposition of Defendants' CEO, George Abercrombie. Defendants' motion for a protective order in connection with that request is pending.

(Tr. at 82.)

B. For Treating Physicians and former employees, the Court will execute Commissions upon receipt from the respective parties. **(Tr. at 94.)**

C. Defendants shall provide a date for the deposition of Joanna Waugh on the topic of her August 17, 2005 certification concerning the reporting of Accutane animal studies to the FDA. **(Tr. at 106.)**

D. Plaintiffs may redepose William Epstein in connection with documents Plaintiffs were precluded from showing him at his August 4, 2005 deposition. Exhibits to be used at the deposition do not have to be produced in advance. Further, Defendants are producing a person with knowledge of the existence of documents related to dosing recommendations by Dr. Gary Peck. **(Tr. at 123.)**

IV. Drug Safety Audits

A. At the July 21, 2005, the Court ordered Defendants to determine whether there was a drug safety audit pertaining to Accutane that was conducted in 1995 to the end of 1998 at the request of the FDA and, if there was such an audit, to advise when responsive documents could be produced. To the extent non-privileged responsive material is identified and was not previously produced, Defendants shall have thirty (30) days to produce it. **(Tr. at 108.)**

V. Correspondence to/from NIH

Defendants shall produce all correspondence with the NIH and/or NIMH related to Accutane by August 30, 2005. In the alternative, by August 29, 2005 Defendants shall provide the Court with a letter brief setting forth the difficulty in meeting such production schedule. **(Tr. at 117.)**

VI. Plaintiffs' Medical Records

At the July 21, 2005 Case Management Conference, the Court ruled that Plaintiffs shall share the cost of scanning those Plaintiffs' records obtained by Defendants pursuant to authorization that Plaintiffs wish to have electronic copies of. The following protocol shall be utilized with respect to the scanning and production of such documents:

1) Defendants will provide a list of records available electronically, with Bates ranges, to Plaintiffs.

2) Upon receipt of the list, Plaintiffs shall advise Defendants in writing what records, if any, they wish to receive.

3) Upon receipt of payment at 7.5 cents per page, Defendants will produce the requested records to Plaintiffs electronically within two weeks.

4) Defendants shall provide an updated list of electronically available records every thirty days thereafter.

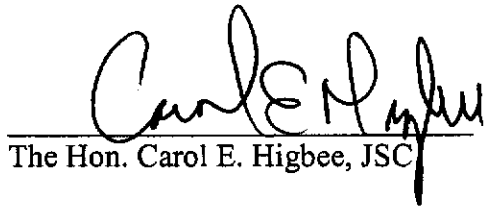
(Tr. at 127 et seq.)

VII. Electronic Discovery Checklists for Plaintiffs

Checklists based upon the parties' agreed protocols for the production of electronic documents and information from Plaintiffs' computers and internet service providers shall be provided to Plaintiffs as appendices to the Plaintiffs' Fact Sheet. **(Tr. at 110.)**

VIII. Case Management Conference

The next Case Management Conference will be held on August 31, 2005 at 1:30 p.m.



The Hon. Carol E. Higbee, JSC