

EXHIBIT

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

Docket No. 6:06-MD-1769-Orl-22DAB

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IN RE: :
SEROQUEL PRODUCTS LIABILITY :
LITIGATION : Orlando, Florida
MDL DOCKET No. 1769 : April 12, 2006
: 2:00 p.m.
ALL CASES :
:
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TRANSCRIPT OF PRETRIAL CONFERENCE
BEFORE THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Plaintiffs: Paul Pennock
Larry M. Roth
Fletch Trammell
Michael E. Pederson
Scott Allen
E. Ashley Cranford
Lezzlie Hornsby
Jonathan Jaffe
Scott Armstrong
Dennis Canty
Richard Freese

Court Reporter: Sandra K. Tremel, RMR/CRR

1 over two months after the initial conference. It took us
2 another month and a half working, trying to work with the
3 defendants to get something that was workable, something
4 that we could review, that we could get through in a
5 reasonable and efficient and effective manner. Not
6 something that was an utter burden that no one could
7 effectively get through in a reasonable period of time.

8 We finally got that in late December. And, yet, when
9 we go through the -- we have been through the IND and NDA
10 almost in its entirety, everything they have given us.
11 There is a wholesale lack of metadata with respect to this
12 IND and NDA. The documents were not produced in
13 chronological order even though we would suggest and we
14 don't know yet because we haven't been allowed any
15 depositions, but we suggest that they're probably
16 maintained in some type of reasonable order by the
17 company.

18 There are a lack of serial numbers, there are
19 numerous documents in this disclosure missing any type of
20 identifying number even though that was the manner in
21 which they were produced. There is no FDA logbook
22 whatsoever, something that's typically found and disclosed
23 in these NDA productions.

24 There is this CANDA safety database. This was an
25 electronic format database that was, we believe, being

1 utilized at the time that this submission was made to the
2 FDA. We have references as early as 1996 that the CANDA
3 database was being utilized. It was the manner in which
4 the defendants would, we believe, produce the safety
5 evaluations and reports to the FDA in an electronic
6 format. We have -- there is nothing in this NDA that we
7 could find that incorporates this CANDA database.

8 Obviously, a central and core aspect of NDA and our review
9 of it.

10 There are -- we know for a fact that internally from
11 the document review we have already done in the so-called
12 custodial files that have been produced that there were
13 reports of diabetes that the company knew about early on.
14 But in the NDA, we can't find those reports that were
15 being made to the FDA. Now, of course, if they weren't
16 reported to the FDA, we will be happy to learn that fact.
17 But we are missing quite a number of reports. And I'm not
18 going to read this into the record. It's from the
19 document that's currently under the confidentiality
20 stipulation. But the bottom line is we know that there
21 should be reports in this NDA that aren't there. And the
22 question, of course, today is where are these reports.

23 Zero telephone contacts with the FDA. We have no
24 internal documentation regarding the FDA-- regarding the
25 NDA and its submission. In other words, memos to one