

July 18, 1990 09:52

To: BEASLEY CHARLES M JR	IVM1
CHAPPELL AMY S	IVM1
FLUDZINSKI LAURA A	IVM1
GOLDSTEIN DAVID J	IVM1
HEILIGENSTEIN JOHN H	IVM1
KOTSANOS JAMES G	IVM1
KRUPA TIMOTHY S	IVM1
MELOY SUSAN M	IVM1
SATTERLEE WINSTON G	IVM1
STREET JAMIE S	IVM1
WHEADON DAVID E	IVM1
cc: MASICA DANIEL N	IVM1

Comments:
FYI to keep you all up-to-date.

----- Forwarded Message -----

July 18, 1990 06:48

To: PERELMAN MEL	RVAX
ZERBE ROBERT L	IVM1
TALBOTT MAX W	IVM1
MASICA DANIEL N	IVM1
AMUNDSON MERLE E	IVM1
REID PHILIP R	IVM1
GOSS REBECCA O	CVAX
cc: THOMPSON LEIGH	RVAX

Paul Leber called yesterday; I contacted him at 6:15 am this morning and half-hour conversation, very very pleasant, with Paul and Tom Laughren.

The call was about suicide. They said this morning's Wall Street Journal article in their mind was "trivial" and the reporter had called them. However, this issue is building and will not go away. They feel some data are required and wanted a study or studies of the issue. Paul suggested several designs:

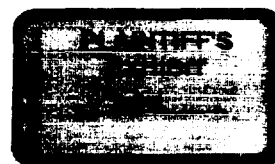
(1) a case control retrospective study, before Teicher, seeing what the frequency is of patients developing the "Teicher" syndrome. Paul felt that the instrument should be developed in concert with Teicher because "only Teicher knows what it was that he is seeing."

(2) cohort study. Paul feels the power is low, but if the incidence is 3.5% even a small study should be able to establish relative rates between fluox and other treatments. Also it should set an upper limit on the incidence of the emergence of suicidal ideation.

(3) best would be a larger blind prospective study, designed with the help of Teicher to detect "his" phenomenon.

Paul said he wasn't commanding any of these particular designs, but wanted to express strongly his feeling that some data are needed. He was very pleasant, but obviously concerned.

He has been awaiting the package of material from us which I promised he would have in his hands this afternoon! He said this may well raise additional questions, to which I agreed, and promised we would work together to resolve them. I urged that we get to scheduling the "seminar" presentation we want to



make on safety.

I then informed him of the suicide expert meeting next Tuesday and told him we would furnish him with detailed reports etc. He was very pleased. But he said: "I agree that the experts on suicide can give for you good testimony on 20/20, Nightline, and 60 minutes, but what we really need are good data." I agreed and committed that Lilly would perform a new study of this issue to be designed in concert with him, with no commitment to design, scope, or timing.

He then said that Temple had asked that we not effect label changes on the suicide issue without clearing them with the FDA first. I think Paul would like this in general, but emphasized Bob's interest specifically on the suicide issue. There wasn't anything else that hinted to more need for label change. I promised we would on suicide NOT use the provision for effecting the change.

Paul also asked for a chronology of all label changes on Prozac, saying he knew that they were being questioned about that and wanted to make sure their chronology agreed with ours. He said he had made a request, he thought, for this through someone else. I told him that I had seen such a chronology prepared by Max in the last week, but did not know it was for him. I promised that the chronology would be in his hands this afternoon. He also asked that we update this periodically--I would suggest, Max, that every time we make any label change we append it to the list and send it to him specifically.

He asked that we FAX nothing to him unless he has agreed to it before hand. He said that "someone has found that mailbox and it makes a second route of information." So he said he was warning people like us NOT to use FAX, unless we had specifically agreed with him to do so. <I think we better start using the Washington office more aggressively to transmit stuff, as this links to the breakin into Paul's computer, etc. I also want to reenergize our periodic discussions about opening an office adjacent to the Parklawn building specifically for the purpose of expediting submissions, dialogue, and meetings.>

Paul said that this reminded him of the [REDACTED] You could just keep it in your medicine chest and then if anything bad happened you had something to blame." This is worrisome considering the terrible pain [REDACTED] has gone through.

Paul is taking a position in talking with outside folks today that Lilly and FDA and working together on the suicide issue and following closely the postmarketing events, but that there are no denominators and the best that can be done is to put a "cap" on the number of events.

PLEASE--I will be happy to carry the two submissions to Paul myself if that would help today. My flight leaves at 10:30 am. If there is ANY problem with getting these to Paul before 4 pm please let me know. My understanding from yesterday is that it will be ready to go at 9 am.

Leigh

THOMPSON LEIGH

RVAX

----- End of forwarded message(s) -----