

---

**From:** Cote, Christine [JANUS]  
**Sent:** Tuesday, February 05, 2002 12:55 PM  
**To:** Gharabawi, Georges [JANUS]; Vergis, Janet [JANUS]; Parish, Irene [JANUS]  
**Cc:** Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeljer, Ronald [JANUS]  
**Subject:** RE: Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

I am able to do the 14th March and will block out the day ,,I am leaving for a big trip on the 28th so unless it was early am and local I would not be able to do 28th

Dr. Christine Cote  
V.P. Medical Affairs  
Janssen Pharmaceutica, Inc.  
Tel: 609-730-3677  
Fax: 609-730-3406

Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that Janssen Pharmaceutica can arrange for proper delivery, and then please delete the message from your inbox. Thank you.

-----Original Message-----

**From:** Gharabawi, Georges [JANUS]  
**Sent:** Tuesday, February 05, 2002 7:42 AM  
**To:** Vergis, Janet [JANUS]; Cote, Christine [JANUS]  
**Cc:** Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeljer, Ronald [JANUS]  
**Subject:** Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

**Subject**

Invitation to a meeting with Prof Biederman and his team at Janssen on March 14 or March 28, 2002 (date pending your approval) to agree on the main deliverables from the Janssen/MGH Center for Child and Adolescent Bipolar Disorders and prioritize the different activities - Your attendance of the 1st hour is needed.

#### Background

Dr Biederman is the pioneer in the area of C&A Bipolar Disorders. He approached Janssen multiple times to propose the creation of a Janssen-MGH center for C&A Bipolar disorders. The rationale of this center is to generate and disseminate data supporting the use of risperidone in this patient population. I met with Dr Biederman in August 2001 and discussed with him the feasibility of this center and agreed that, should Janssen decide to support it, the main focus will be on 2 topics: 1) Diagnostics, including the creation of a screening/diagnostic tool to train clinicians (Pediatricians and General Psychiatrists) on how to diagnose C&A BPD, use of genetics and Neuro-imaging techniques to recognize C&A BPD and the different variants of the disorders and 2) Therapeutics, including short and long-term outcomes of the management of C&A BPD with risperidone including the long-term prophylactic effect on drug abuse. Following a number of internal discussions within the Brand team and with Janet, it was decided to 1) explore the feasibility of involving other J&J companies that would be interested in participating in the center and share the financial support and 2) fund the center pending the submission of a 5-year plan of deliverables including retrospective analyses and prospective exploratory research.

#### Current status

\* In a number of meetings with McNeil and OMP, it was agreed that there was a need for all J&J companies to act as partners and share this research, data generation and dissemination opportunity. Further, it was agreed that the 3 teams should meet and elaborate a plan that would ultimately include research initiatives on combination therapies.

\* A Risperdal Reanalyses, Research and Publication grid was produced by Dr Biederman's team. The grid includes proposed deliverables over the upcoming 5 years starting from 2002. It is planned to produce similar grids for the J&J sister companies over the next 3-6 months.

\* The Risperdal Brand team agreed to fund the center for the year 2002. 500KUS\$ were paid and assigned to the

year 2002.

**Next Steps**

We recently organized a meeting with Dr Biederman including the marketing group from McNeil in order to discuss the next steps. We invited Dr Biederman and his group to an HOV at Janssen Titusville. This meeting will involve, in addition to Dr Biederman's research team, the Risperdal, **REDACTED** teams with the objective of elaborating a full research plan for the years 2002-2007 including a reanalyses and publications plan.

**Proposed agenda**

- Opening address (J&J)
- Background on Child and Adolescent Bipolar Disorders- A clinical and research perspective (Dr Joe Biederman)
- Breakout session:
  - Epidemiology and genetics of C&S BPD
  - Diagnosis: Reanalyses, validation and publication of screening tools
  - Neuro-imaging plans, publication plan
  - Reanalyses of the existing Risperdal data, publication plan
  - Prospective short and long-term studies

Christine and Janet, Your presence, at least at the first part of the meeting is highly desirable and would allow us to continue positioning Janssen as a major partner in the area of C & A psychopharmacology. Further, following your approval of the proposed date, we will extend the invitation to S. Spielberg but will eet with him first.

Sincerely

Georges

Georges Gharabawi M.D.  
Janssen Pharmaceutica Inc.  
Tel (609) 730 3277  
e-mail: ggharaba@janus.jnj.com