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ADOLESCENT DEPRESSION

STUDY 329

1301

Proposal for a Journal Article

Proposed to:

**Ivan Gergel, MD
SmithKline Beecham Pharmaceuticals**

ok direct bill

Proposed by:

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and
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Scientific Therapeutics Information, Inc**

April 3, 1998

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PURPOSE

The purpose of this proposal is to outline the timing, services, and costs associated with writing a manuscript for journal publication that will review the results of a study on "PAXIL in the Treatment of Adolescent Depression," Study 329. Data from Study 329, published literature, and unpublished data to be provided by SmithKline Beecham Pharmaceuticals form the basis of this article.

The article will be developed for a psychiatry journal. A target journal is recommended, however, the decision on which journal to submit the paper to will be determined after review of the study report and after consultation with the primary author and the sponsor.

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DESCRIPTION

The manuscript that is developed will be between 20 and 24 double-spaced typewritten pages and will include figures, tables, and references as appropriate. The manuscript will be designed to conform to the style of the journal selected.

A complete outline of the article will be provided upon review of the data with which we will be working.

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TARGET JOURNAL

There are several potential journals for an article of this nature. The target journal for publication of this manuscript is the *Journal of the American Medical Association*.

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AUTHORS

The primary author of this paper will be Marty Keller, MD. Costs take into consideration that up to three (3) authors will be reviewers on the paper. Additional individuals with associated review and comments will be assessed additional charges.

STI will work with Jim McCafferty of SmithKline Beecham as our primary contact for acquisition of data and coordination of reviews by SmithKline Beecham.

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SERVICES

STI editors will write up to six drafts of the manuscripts with the sixth being the journal submission draft. STI will also work with the sponsor and authors to ensure that the most appropriate journal for publication of the manuscript has been selected.

We will need to discuss journal submission, coordination of the review process, and number of draft(s) with the authors at the start of the review process to minimize untimely delays in the review and commentary process.

STI will develop up to six drafts: Draft I is the initial draft that will be reviewed by the sponsor. Comments on Draft I will be incorporated into Draft II, which will be sent to the primary author and the sponsor for comments. Draft III will incorporate any comments and will be sent to the same reviewers plus up to two (2) additional non-SB authors for review and critique. Draft IV will be sent to all authors and sponsor for comment. Draft V is the pre-journal submission draft and will be sent to all authors and sponsor for final review and approval prior to developing the journal submission package. Draft VI is the journal submission draft prepared for the journal, for which art work will be professionally drawn and the manuscript styled according to the selected journal. Proper referencing and obtaining permissions for use of previously-published data are included. A submission package will be prepared that will be forwarded to the primary author to send to the journal.

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SERVICES (continued)

STI will provide all necessary resources to complete this manuscript including writing, editing, library research and retrieval, copy editing, proofreading, word-processing, art work, and the needed coordination with author(s), sponsor, and journal. Also includes distribution of the final draft to the listed authors as a courtesy.

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TIME AND EVENTS

The manuscript will be completed according to the time and events schedule outlined below. The time from submission to the journal to publication in the journal may take 4 to 8 months.

<u>TIME</u>	<u>EVENT</u>
2nd quarter	Approval to proceed provided
2 months after receipt of study report	Draft I to SB*
3 weeks after receipt of comments	Draft II to primary author and SB
3 weeks after receipt of comments	Draft III to authors and SB
3 weeks after receipt of comments	Draft IV to authors and SB
3 weeks after receipt of comments	Draft V to authors and SB for final approval and signoff for release to journal
3 weeks after receipt of signoff	Draft VI, journal submission package sent to primary author to forward to journal
4-8 months after journal submission	Paper appears in print (estimate)

*We assume that these author and sponsor review periods are limited to no longer than 3 weeks per review.

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COSTS

<u>Editorial Development:</u>	Includes all services as outlined under "Services," including reviews and coordination with up to three non-SB reviewers plus one SB reviewer.	COST:	\$16,750
<u>Honorarium:</u>	Not needed.		
<u>Mailings:</u>	A pass-through cost for overnight mailings and author reminders to return their comments is estimated.	COST (Estimated):	\$500 *
		TOTAL:	<u>\$17,250</u>

Costs exclude: More than 6 drafts; greater than 4 reviewers (SB and non-SB combined), international correspondence; page costs if charged by the publishing journal; costs of journal reprints; copyright royalties, if assessed, in the event the article uses any copyrighted figures or tables belonging to other publishers; working period beyond March 1, 1999; travel expenses for STI editor if needed to visit the sponsor or author (charged at cost plus daily fee for editor time). If any of these are incurred, cost estimates will be provided at the time of the need.

* Pass-through cost.

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PAYMENT SCHEDULE, AUTHORIZATION

Upon initiation of work	\$8,500
Upon submission of Draft III	\$5,125
Upon submission to the journal	<u>\$3,625</u>
TOTAL:	\$17,250

Authorization to proceed for
SmithKline Beecham Pharmaceuticals:

Signature

Print name, title

Date

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Important financial documents attached.

Return immediately to Accounts Payable, FP0825.

To <i>Ivan George</i>	Extension	Mailcode <i>4P4470</i>
From <i>Mindy D.</i>	Extension <i>4346</i>	Date <i>10/2</i>

Company policy requires more information to process the invoice(s) listed below. Please respond to the box(es) checked below. Vendor cannot be paid unless this form and the original invoice are returned to Accounts Payable, FP0825.

Vendor	Invoice	Purchase Order #	Amount
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Scientific Therapeutics *9,8500.00*

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- Please approve the invoiced price.
- Does this invoice complete the PO? yes no
- Has work been completed as invoiced? yes no
- Has material been received as listed on the invoice? yes no
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- This material or service requires a purchase/change order through purchasing department. Please supply.
- Complete departmental cost center/object code required. Please supply subsidiary/subledger if needed.
- Please obtain proper approval, as listed in the chart of accounts.
- Higher approval required. Your approval limit is _____
- Please attach copy of _____
- Please submit original invoice/statement, photocopy not acceptable.
- Invoice differs from PO. Change order needed.
- Invalid PO number. Please advise.
- RUSH - Return Immediately! CASH DISCOUNT INVOLVED/PAST DUE

Full signature required. Initials not accepted by auditors.

Signature <i>[Signature]</i>	Date
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