

PROPOSAL

to the

R.J.Reynolds Tobacco Company

Winston-Salem, N.C.

1. Review EPA Report of May 1990 on ETS
2. Organize and Conduct 2 Workshops

submitted by

Biomedical & Environmental Consults, Inc.

Richland, WA

November 11, 1990

50803 7603

TECHNICAL PROPOSAL

General

- . Biomedical & Environmental Consultants, Inc., hereafter referred to as BEC, proposes that the R.J.Reynolds Tobacco Company, hereafter referred to as RJR, fund, in stages, the projects outlined in this technical proposal. Funding levels for Phase 1 of the projects are outlined in the Business Proposal which, together with the Technical Proposal, comprises the Proposal of BEC to RJR. Funding levels for subsequent project phases will be negotiated between RJR and BEC and added as Amendments to the Business Proposal.
- . The Office of BEC, hereafter referred to as BECO, located at 312 Saint Street, Richland, WA, will organize and administer the projects.
- . BECO will seek a commitment in the form of a signed statement from individuals collaborating on the projects, not to disclose information developed in the course of this work to any third party unrelated to RJR without prior written approval by RJR.
- . BECO will submit to RJR informal written monthly status reports.
- . BEC members collaborating on these projects are independent consultants and not employees of BEC. BECO will exert its best efforts and exercise reasonable care in the exercise of its business but shall not be held liable for acts of commission or omission by its members and other project participants, or any consequences thereof.

Tasks of Phase 1

I. Review and Commissioning Committee

BECO will organize a Review and Commissioning Committee (RCC). The RCC initially will consist of several BEC members. Subsequently, qualified individuals not belonging to BEC may be added. The RCC may comprise up to 12 members.

The tasks of the RCC will be

- . to review, analyze, and develop a written response, through BECO, to the EPA review draft "Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children" (EPA/600/6-90/006A, May 1990). The objective of this review is to examine the scientific validity of data selection, analysis, and interpretation in the EPA report and the conclusions based thereon. BEC proposes to hold a 2-day meeting of RCC members in Week 8 of the contract to discuss findings, to coordinate the response in the form of a report to RJR, and to decide the format of the report to RJR. Organizational and technical tasks relevant to planning the workshops on meta analysis and low-dose extrapolation, to be conducted in Phase 2, will also be discussed.

- . RJR expects receipt of the response within 2 months after the signing of the contract between RJR and BEC.
- . to supervise and administer, through BECO, RJR-authorized and RJR-financed projects and to commission to other committees or entities the performance of certain project tasks when appropriate.
- . to organize and conduct, through BECO, workshops on the following subjects:
 - (1) meta analysis
 - (2) low-dose extrapolation

The workshops will be held in Phase 2.

- . to organize, through BECO, a Meta Analysis Review Committee (MARC). MARC will consist of recognized meta analysis experts recommended by BEC and RJR. It is expected that MARC members will participate in the meta analysis workshop. MARC will critically examine meta analysis issues and submit a report on its findings to the RCC for review. A copy of the report with RCC review comments, if any, will be sent to RJR.

The time table for establishing MARC depends on the availability of recognized meta analysis experts, a factor beyond the control of the RCC and BEC, and on appropriate funding from RJR. Best efforts will be made to establish MARC as expeditiously as possible.

- . to identify RRC members prepared to discuss issues pertinent to ETS risk assessment in regulatory, administrative, or legislative forums. These discussions will take place in Phase 2 or thereafter.

Tasks of Phase 2

I. Meta Analysis Workshop

The RCC, through BECO, will organize and conduct a workshop on meta analysis. The objective of the workshop will be to critically examine advantages and limitations of this technique, and its appropriateness in certain applications. MARC members are expected to attend this workshop. Other recognized experts in this field may also be invited to attend. A report, summarizing the salient points of the workshop discussions, will be prepared and submitted to RJR.

Dates and location of the workshop, number of participants, cost estimates, and other details will be determined at a later date and submitted to RJR in the form of an Amendment to this Proposal.

II. Low-Dose Extrapolation Workshop

The RCC, through BECO, will organize and conduct a workshop on low-dose extrapolation. The objective of the workshop will be to discuss and examine problems with low-dose extrapolation, used to perform risk assessment on environmental tobacco smoke (ETS) and carcinogenesis. In addition to qualified BEC members, other recognized experts may also be invited to attend. A report, summarizing the salient points of the workshop discussions, will be prepared and submitted to RJR.

Dates and location of the workshop, number of participants, cost estimates, and other details will be determined at a later date and submitted to RJR in the form of an Amendment to this Proposal.

The two workshops will be scheduled to allow qualified individuals to participate in both meetings if they so desire.

III. Forum Discussions

After the Week-8 meeting at the Battelle Seattle Conference Center, BEC expects to be in a position to identify RCC members who will be available to discuss issues pertinent to ETS risk assessment in regulatory, administrative, or legislative forums 2-4 days per month throughout 1991.

Schedules, fees, and other details will have to be negotiated directly between the individual RCC members and RJR.

PROPOSED SCHEDULE

Phase 1

Contract Time

Action

I. Response to EPA Report

- Week 1
 - . Execute contract (RJR & BEC)
 - . Send by Federal Express, or similar means, EPA draft and RJR responses to RCC members (RJR)
- Week 2 through 7 . Review and analyze EPA report and prepare written critique (RCC members)
- Week 7 . Submit outline of critique to BECO (RCC members)
- Week 8 . 2-day meeting at Battelle Seattle Conference Center to discuss (1) EPA draft and RCC member responses and (2) organizational and technical tasks relevant to planning the workshops on meta analysis and low-dose extrapolation
- Week 8 + 9 . Fine-tune individual responses by authors and review of final response to RJR (RCC members)
- Week 10 . Submit coordinated RCC response to RJR (BECO)

II. Planning Workshops

- Week 2 through 11 . Provide input and recommendations for mechanisms by which RCC might develop workshops on the subjects of meta analysis and low-dose extrapolation (RCC)
- Week 12 . Submit workshop plans to RJR for review (BECO). The workshops, if authorized and funded by RJR, will be held in Phase 2

III. Forum Discussions

- Not later than Week 8 . Identify RCC members available to discuss issues pertinent to ETS risk assessment in regulatory, administrative, or legislative forums (BEC). The discussions will take place in Phase 2

IV. Establishing MARC

- Week 3 through 12 . Define objectives for MARC; recruit suitable members; organize and establish MARC (BEC)

Phase 2

Contract Time

Action

I. Meta-Analysis Workshop

Month 3 + 4 . Plan, schedule, and organize workshop; invite participants

End of Month 4 . Hold workshop

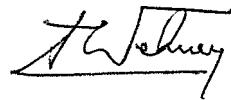
Month 5 + 6 . Prepare report

End of Month 6 . Submit report to RJR

II. Low-Dose Extrapolation Workshop

BEC proposes a schedule similar to that for the meta analysis workshop. Scheduling of the two workshops will be coordinated to allow qualified individuals to participate in both meetings if they so desire.

Details of Phase 2 projects, such as dates and duration of workshops, number of participants, etc., will be provided with a cost estimate as an Amendment to this Proposal when more precise information becomes available.



11/11/90

Dr. Alfred P. Wehner, President
Biomedical & Environmental Consultants, Inc.

BUSINESS PROPOSAL

Biomedical & Environmental Consultants, hereafter referred to as BEC, proposes to conduct work for the R.J.Reynolds Tobacco Company, hereafter referred to as RJR, in Phase 1 of the projects as described in the Technical Proposal, for an estimated total dollar amount not to exceed \$211,887.

A cost breakdown is included as part of this Business Proposal

- . BEC proposes to establish a business account at the Richland branch of the Seattle First National Bank specifically for the RJR projects
- . RJR agrees to maintain, within contract limitations, a balance in that account that is sufficient for BEC to pay anticipated authorized project expenses
- . BEC will submit monthly to RJR an account of expenses
- . If a cost overrun appears to develop, BEC will contact RJR at the earliest indication thereof to discuss appropriate steps to resolve potential problems
- . BEC will submit to RJR Amendments to this Business Proposal before the start of work planned for Phase 2 of the projects
- . In case of cancellation of this Contract by RJR, RJR agrees to pay for financial commitments made by BEC before cancellation in pursuit of its contractual obligations to RJR

BUDGET ESTIMATE

Phase 1

I. Evaluation of EPA Review Draft

(1) This preliminary estimate is based on the following assumptions:

- . \$150/hour = \$1,200/day/person standard consultant fee
- . average of 60 hours/person
- . 10 members in RCC

150 x 60 x 10	\$ 90,000
secretarial services, 40 hours at \$25/hour	\$ 1,000
	\$ 91,000
15% administration and overhead fees	\$ 13,650
Total	\$104,650

This figure will vary if the average number of hours/person spent on this part of the project differs from 60 and if the number of RCC members differs from 10.

(2) Budget for Meeting

The preliminary budget for the meeting is based on the following assumptions:

- . 2-day meeting at Battelle Seattle Conference Center (BSCC)
 - . $\frac{1}{2}$ day traveling to and 1 day traveling from Seattle to home (averaged), i.e., $3\frac{1}{2}$ days/person attending the meeting
 - . \$1,200/person/day standard consultant fee
 - . 10 participants
- \$ 42,000

BSCC's package rate is as follows:

\$45/person/day for conference room; 10 persons for 2 days =	\$ 900
\$90/person/day lodging, incl. breakfast; 3 nights for 10 persons =	\$ 2,700
Travel (incl. roundtrip London-Seattle for one member=\$5,650)	\$ 20,000
	\$ 65,600
15% administration and overhead fees	\$ 9,840
Total	\$ 75,440

This figure will vary with the exact air fares at the time of travel and the number of participants.

II. Planning Workshops

This preliminary budget estimate is based on the following assumptions:

. average of 10 hours/person	
. 10 members in RCC	
. \$150/hour standard consultant fee	\$ 15,000
. 6 hours secretarial time at \$25/hour	\$ 150
	<u>\$ 15,150</u>
15% administrative and overhead fees	\$ 2,272
Total	<u>\$ 17,422</u>

This figure will vary if the number of persons or the number of hours/person spent on this part of the project differs from the assumptions.

III. Forum Discussions

Forum discussions are to be held in Phase 2 or later. Cost estimates for these discussions will, therefore, be submitted at a later time with the Phase 2 budget as an Amendment to this budget.

IV. Establishing MARC

Reviewing field of candidates, recruiting candidates, establishing objectives and procedures, maintaining communications

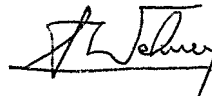
. 80 hours professional time (\$150/hr)	\$ 12,000
. 20 hours secretarial time (\$ 25/hr)	\$ 500
	<u>\$ 12,500</u>
15% administrative and overhead fees	\$ 1,875
Total	<u>\$ 14,375</u>

Grand Total for Phase 1

\$211,887

Phase 2

BEC proposes to submit to RJR cost estimates for the work to be conducted in Phase 2 in the form of an Amendment to this budget when more reliable cost figures become available.



11/11/90

Dr. Alfred P. Wehner, President
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