

Attorney General Consumer and Prescriber Grant Program
Request for Applications
August 31, 2005

**THE MARKETING OF MEDICINES:
DEVELOPMENT, DISSEMINATION AND EVALUATION OF A
CRITICAL SKILLS CURRICULUM FOR PRESCRIBERS**

Attorney General Consumer and Prescriber Education Grant Program
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Background:

On May 13, 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an Assurance of Voluntary Compliance/Discontinuance with the Attorneys General of 50 States and the District of Columbia to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin® that violated state consumer protection laws. Among other things, the settlement provides for a \$21 million Consumer and Prescriber Education grant program to be administered by a Special Committee of state Attorneys General pursuant to an Oregon court order and an Attorney General Memorandum of Understanding.

The Special Committee is comprised of six permanent members: the Attorneys General of Florida, New York, Ohio, Oregon, Texas and Vermont; and two rotating members: currently the Attorneys General of California and North Carolina. The Special Committee has hired the Public Health Trust, a project of the Public Health Institute, based in Oakland, California, to assist in grant administration.

The Attorney General Consumer and Prescriber Education Grant Program will fund programs designed to provide health care professionals and consumers information relating to prescription drugs, the way in which drugs are marketed, and psychiatric conditions and seizure disorders for which Neurontin® is prescribed. Grants will be made in several rounds. The first round will focus on prescriber education. Subsequent rounds will focus on consumer education and on conditions for which Neurontin® is prescribed.

Prescriber Curriculum Development and Dissemination:

Goal:

To improve prescribing practices by: 1) educating health professionals at all levels of training about the drug development and approval process; 2) making health professionals aware of pharmaceutical industry marketing practices and assisting them in developing the knowledge and skills to evaluate those marketing techniques; and 3) providing examples and strategies for evaluating existing sources of drug information, and for accessing unbiased sources of information about drugs.

The purpose of this request for applications is to fund the development, dissemination and evaluation of curricula to provide practicing health professionals¹, and those in training, with the critical skills necessary to evaluate prescription drug information and industry marketing techniques, and to apply this knowledge to their own prescribing practices.

Curriculum development, dissemination and adoption can have a long-term and sustainable impact on prescribing behavior and consumer health and well-being. By teaching health professional students to prescribe objectively and strategically in an evidence-based, cost-

¹The term "Health professionals" includes physicians, pharmacists, nurse practitioners and physicians' assistants.

effective manner, future generations of health practitioners will be better prepared to provide the best possible care for their patients. By offering similar training (or re-training) to clinicians in practice, the quality of patient care can be improved.

Curriculum Development

The curriculum should be targeted to one or more specific audiences at any level (students, residents or licensed health professionals). The curriculum must be designed so that it can be readily adapted for use by other institutions, organizations and learners at all levels, taking into account that approaches might have to be modified for different audiences. The curriculum should incorporate evidence-based educational methods.

Such a curriculum could include the following elements:

- Overview of drug development and marketing in the U.S.
- Roles and responsibilities of the FDA (drug approval, tracking and monitoring)
- Influences on prescriber choice and behavior
 - Pharmaceutical industry marketing practices
 - Pharmaceutical industry's role in medical research and education
 - Direct-to-consumer marketing
 - Research on the effects of marketing practices on clinicians (including students and residents) and patients
- Description of appropriate and cost-effective prescribing behavior
- Strategies for improving prescribing practices
 - Critical evaluation of sources of drug information (industry publications, academic journals, professional publications, pharmaceutical representatives, conferences, etc.)
 - Knowledge of appropriate and inappropriate prescribing for off-label uses

The curriculum should be in a format that incorporates interactive, multi-faceted evidence-based educational methods, and at the same time be highly adaptable and transportable to other institutions or organizations. Examples include web-based tutorials or educational modules that can be imported into noon hour conferences or CME activities. Creative educational interventions are encouraged.

Curriculum Dissemination and Implementation

Methods of dissemination and implementation should be presented, to include the following elements: 1) the targeted audiences, institutions and organizations, including an estimate of the actual number of people in the target audiences, 2) strategies for dissemination, 3) dissemination and implementation goals, and 4) a timeline for completion. The dissemination plan optimally will include submission of the curriculum and/or a report of its impact to a major healthcare journal or online educational portal to optimize its dissemination to a wide audience.

The curriculum could be disseminated to graduate students, residents, and/or practicing health professionals through:

- School course work
- On-line course work
- Lectures
- Continuing education workshops
- Conferences
- Journal articles

Innovative dissemination strategies are encouraged.

Curriculum Evaluation

The goal of curriculum evaluation is to assess outcomes of the educational intervention. Specifically, a plan for evaluation should be presented, including, for example, measures of:

- Changes in knowledge, attitudes and/or future prescribing decisions
- Nature and extent of curriculum adoption
- Actual or self reports of prescribing practices, with any changes attributable to the curriculum noted

Availability of Curriculum

All elements of the curriculum and methods of implementation, dissemination and evaluation (i.e., curriculum and related materials, such as syllabi, power point and slides, course reader, journal articles, pre and post test materials, etc.) must be placed in the public domain and made available for use by the public.

Amount and Project Duration

The total amount requested should not exceed \$400,000, and the project period should not exceed two years. The Special Committee anticipates that five to ten applicants will be funded. The granting entity will be the State of Oregon, which is acting on behalf of the Special Committee.

Eligibility

Eligible applicants include educators at or affiliated with:

- Academic institutions
- Non-profit organizations
- Government agencies

Grant Application Instructions:

One copy of the application should be submitted via electronic mail and received no later than **5pm PDT Friday, October 7, 2005, and** an original and two copies **postmarked October 7, 2005**, should be sent to the address below. Applicants will receive acknowledgement of receipt of an application within one week and notice of a decision within twelve weeks.

Address all correspondence and submit completed applications to:

Attorney General Consumer and Prescriber
Education Grant Program
c/o Grant Administrator
Public Health Trust
180 Grand Avenue, Suite 750
Oakland, CA 94612
E-mail: PHTinfo@phi.org

Format

Applications should be no more than ten pages in length (not including attachments) and should be double-spaced. Please use a 12-point font and one inch margins on all sides of the pages. Each page of the document and attachments should indicate the name of the principal applicant and a page number.

Cover Page and Cover Letter

Please include a cover page in the form attached (see Appendix A), including all required elements. In addition, please include a letter signed by the president, executive director, or dean of your organization/department/school acknowledging awareness and support of the application.

Application Components

Applications must provide all of the following information and must be formatted with sections numbered and subtitled to correspond to the order below:

- 1 Goals and objectives (1 pg)
- 2 Impact and significance (1 pg)
- 3 Methods (5pgs maximum), to include curriculum development, curriculum implementation and dissemination, curriculum evaluation (effectiveness of educational intervention and extent of curriculum dissemination and adoption)
- 4 Anticipated barriers/challenges and the strategies for negotiating each (1 pg)
- 5 Timeline of project (1 pg)
- 6 Bibliography (up to 1 pg)

Attachments

Please provide the following attachments on separate pages labeled to correspond to the order below:

- A Organization description (including mission and summary of accomplishments for the past year; if part of a larger organization, please be specific to your department or program)
- B Itemized project budget (see forms-Appendices B1, B2, & B3)
- C Two letters of reference (one from within the organization, one from outside)
- D Brief biographies (one paragraph, not to exceed 1/3rd of a page) of key project and organizational staff (including a summary of qualifications and responsibilities)
- E List of Board of Directors or Advisors (including board position and organizational affiliation), if applicable
- F Modules of curriculum that applicants have already prepared and used for health professional students and practicing clinicians.
- G If a 501©(3) organization, itemized organizational budget for period not to exceed two years
- H If a 501©(3) organization, a letter of support from your State's Attorney General or other authorized party² (see sample letter-Appendix C)

² Please contact the Grant Administrator for the list of authorized parties and contact information for each state and the District of Columbia.

Selection Criteria:

As required under the Oregon court order, the Special Committee will consider the following factors in reviewing applications:

- (a) the intended purpose of the grant;
- (b) competing requests for grant funding;
- (c) the financial ability of the intended grant recipient to obtain the requested goods, services or funding assistance without grant funds;
- (d) the anticipated public benefit to be served by approving the grant;
- (e) the ability of the Special Committee to audit the use of the grant to ensure that the grant is used solely for purposes authorized hereunder;
- (f) the amount of previous grants, if any, made to a particular grant recipient under the Attorney General Consumer and Prescriber Grant Program and the use of previous grants in accordance with the terms of the Assurance of Voluntary Compliance/Discontinuance and the Oregon court order;
- (g) the ability of the grant recipient to provide the Special Committee with a report regarding the actual results obtained as a result of any grant;
- (h) the academic institution or not-for-profit entity (or its principals if the entity has not existed for three years) has previously successfully operated programs eligible for funding by the Prescriber and Consumer Education Program; and
- (i) the extent to which grant monies are proposed to be used only to fund activities that have not been funded previously or which, but for the receipt of the grant from the Prescriber and Consumer Education Program, would not be fully funded. (If an activity has been previously funded, the grant recipient shall not use its grant from the Prescriber and Consumer Education Program to supplant existing funding and shall only use it to fund shortfalls in existing funding.)

In addition, applications will be judged in competition with others according to the following criteria:

- Eligibility of the applicant
- Proposed impact of the curriculum (short and long-term goals & objectives)
- Presence of innovative teaching interventions, grounded in evidence-based approaches
- Likelihood of achieving the proposed goal(s)
- Amount of funding requested
- Viability of the proposed budget
- Organizational capacity to develop, implement, disseminate and evaluate the curriculum
- Plans for curriculum dissemination
- Rigor of the proposed evaluation plan

- Demonstrated expertise in curriculum development, implementation, dissemination and evaluation
- Letters of reference and support

Applications will be given greater weight if they include any of the following:

- Collaboration with other organizations
- Multiple curricular formats
- More than one target audience
- Geographic scope that includes multiple states

Reporting:

Grantees will be required to submit quarterly progress reports and a final report on the use of the funds and the goals achieved to the Special Committee.

Contact Information:

The Special Committee welcomes phone calls and e-mails from applicants to clarify the application guidelines and procedures. However, staff will not pre-evaluate proposed projects. Calls or e-mails to discuss the details of pending applications or to schedule meetings are strongly discouraged. For questions, please contact:

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W: www.publichealthtrust.org

All decisions made by the Special Committee are final. There is no appeal process.

Attorney General Prescriber and Consumer Education Grant Program

APPLICATION COVER SHEET*(Please type or print clearly.)*Date Applicant Information

Name of Requesting Organization (or Individual)		
Primary Contact	Title	
Address		
City	State	Zip Code
Telephone	Facsimile	E-mail

Proposed Project

Project Title
Brief Summary of Proposed Project <i>(200 words maximum)</i>

Tax Status

<input type="checkbox"/> Tax exempt, charitable organization <i>(Attach copy of IRS determination letter)</i>	<input type="checkbox"/> Government tax-exempt unit
<input type="checkbox"/> Other, please specify: <input type="text"/>	

Proposed Budget & Timetable

Total Project Budget \$	Project Timetable (# of months)
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Signatures

Project Director	Organization Name
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Budget Request Form*

Submitted by (primary contact): _____

Organization: _____

Total Budget Request

Year One

Year Two

1.	Project Staff Salary & Benefits	
2.	Project Staff Travel	
3.	Office Operations <i>(includes expenses for telephones, postage, copying & supplies)</i>	
	a.	
	b.	
	c.	
	d.	
4.	Other Direct Costs <i>(includes expenses for printing, equipment, space rental)</i>	
	a.	
	b.	
	c.	
	d.	
5.	Consultant Fees	
6.	Subcontract(s)	
Total Direct Costs:		\$
7.	Indirect Costs <i>(maximum 10% of total direct costs.)</i>	
TOTAL PROJECT BUDGET:		\$

Line Item Budget*

Submitted by (primary contact): _____

Organization: _____

Total Budget Request

Year One

Year Two

1. Project Staff Salary & Benefits						
	Name	Title	FTE%	Salary	Benefits	Total
a.						
b.						
<i>Total Salary & Benefits:</i>						

2. Project Travel						
	Location	Purpose	Air/Mileage	Hotel	Incidental	Total
a.						
b.						
<i>Total Project Travel:</i>						

3. Office Operations <i>(includes expenses for telephones, postage, copying & supplies)</i>				
	Expense Title	Vendor	Monthly Charge	Total
a.				
b.				
<i>Total Office Operations:</i>				

4. Other Direct Costs <i>(includes expenses for printing, equipment, space rental)</i>				
	Expense Title	Vendor	Monthly Charge	Total
a.				
b.				
<i>Total Other Direct Costs:</i>				

5. Consultants					
	Name	Organization	Activity	Fees	Total
a.					
b.					
<i>Total Consultants:</i>					

6. Subcontract(s)				
	Organization	Contact Person	Activity	Total
a.				
b.				
<i>Total Subcontract(s):</i>				

*Add additional pages as necessary.

Sources of Support*

Submitted by (primary contact): _____

Organization: _____

Total Budget Request

Year One

Year Two

1. Project Staff Salary & Benefits-Other Support						
	Name	Project Name & Description	FTE%	Salary	Benefits	Funding Source
a.			%	\$	\$	
b.			%	\$	\$	

*Add additional pages as necessary.

Sample Letter from Attorney General or other authority

Date

Special Committee
Attorney General Consumer and Prescriber Grant Program
c/o Grant Administrator
Public Health Trust
180 Grand Avenue, Suite 750
Oakland, CA 94612-3766

Dear Special Committee,

I endorse the application by (name of organization) requesting funding under the Attorney General Consumer and Prescriber Grant Program.

Yours truly,

[Printed Name]

[Printed Title]