

Development, Evaluation and Dissemination of a Web-Based Curriculum on Pharmaceutical Marketing

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Abstract

Aims: LCF will develop four self-paced learning modules to enable prescribers to (1) explain the drug development and approval process and FDA review of marketing materials; (2) describe pharmaceutical industry marketing practices; (3) develop the knowledge and skills to recognize pharmaceutical marketing techniques and critically evaluate the information provided; and (4) access balanced sources of information about drugs.

Background: In 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an agreement with the Attorneys General of 50 states to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin[®] that violated consumer protection laws. Among other things, the settlement provided funds for a Consumer and Prescriber Education grant program to be administered by a Special Committee of state Attorneys General. Lovelace Clinic Foundation (LCF) successfully applied for one of these grants as did three other members of the FIMORN.

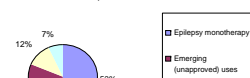
Methods: Planned learning activities will emphasize context of marketing and dissemination of information on pharmaceuticals; critical thinking exercises such as counter-arguing and inoculation for evidence of information and determination of the likelihood of the content being a marketing message; and means of accessing alternative (non-pharmaceutical corporation) sources of information on pharmaceuticals. As part of the evaluation, LCF will review prescribing patterns of attendees before and after the training. A number of collaborations among the various twenty-four awardees have already been initiated. In addition, the AHRQ CERT steering committee is interested in bringing the group of AG awardees within the CERTs together to look for synergy between the proposals and help direct the CERT Education Consortium.

Results: Learning objectives have been drafted for the four modules that LCF will develop, alone and in combination with other awardees, as well as outlines of content and proposed scripts. A face-to-face presentation of the content to a selected group of Lovelace Medical Group prescribers is planned for the spring of 2007 as a pilot. We will assess their achievement of learning objectives and modify content and format as necessary.

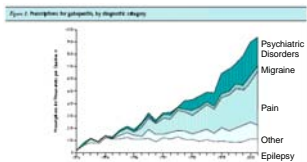
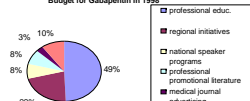
Conclusions: At the conclusion of the project, the curriculum and other activities of all awardees will be available in the public domain through various web page linkages.

Evidence of a Problem

Drift Advertising and Promotion Budget – by Target for Gabapentin in 1998



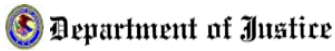
Drift Advertising and Promotion – by Category Budget for Gabapentin in 1998



Off-label uses at the time

Evidence of a Problem

In 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an agreement with the Attorneys General of 50 states to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin[®] that violated consumer protection laws.



WARNER-LAMBERT TO PAY \$430 MILLION TO RESOLVE CRIMINAL & CIVIL HEALTH CARE LIABILITY RELATING TO OFF-LABEL PROMOTION MAY 13, 2004

WASHINGTON, D.C. – Warner-Lambert has agreed to plead guilty and pay more than \$430 million to resolve criminal charges and civil liabilities in connection with its illegal and fraudulent promotion of approved uses for use of its drug products. The drug Neurontin was approved by the Food and Drug Administration in December 1993 solely for adjunctive or supplemental anti-seizure use for epilepsy patients. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called “off-label” uses – any use not specified in an application and approved by FDA. However, Warner-Lambert’s strategic marketing plans, as well as other evidence, show that Neurontin was aggressively marketed to treat a wide array of ailments for which the drug was not approved.

Background

The settlement provided funds for a Consumer and Prescriber Education grant program to be administered by a Special Committee of state Attorneys General.

Lovelace Clinic Foundation (LCF) successfully applied for one of these grants, as did three other members of the FIMORN:

- Harvard Pilgrim Health Care (Steven Simon)
- Kaiser Health Plan of Colorado (David Price)
- Myers Primary Care Institute (Jery Gurwitz)

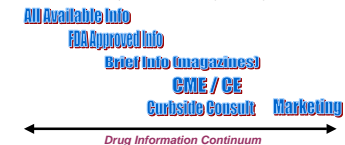
Development of Curriculum

Best value to primary care physicians was deemed to be a curriculum on modifying contributors to suboptimal prescribing practices, such as:

- Lack of rigorous information
- Susceptibility to manipulation
- Overcoming time and workflow barriers

A sub-theme is:

Information about the safety, efficacy & use of drugs is developed by the pharmaceutical industry. It is in the interest of everyone to insist on complete, adequate and balanced information.



- “In God we trust. Everyone else must use data.” W. Edwards Deming
- There is considerable information available on the safety, efficacy and appropriate use of drugs; however, most of it is selected to present only part (usually the most positive part) of the required information, purveyed as information when it really is marketing.
- In addition, pharmaceutical companies have little incentive to develop adequate information on safety and comparative studies. Their obligation is to their shareholders to develop value.
- The role of prescribers and consumers at all levels is to demand that industry develop and present the most useful information and the information presented is complete and accurate.

Development of Curriculum

An Individual can:

• Develop healthy skepticism and skills of resistance to persuasion

Healthy Skepticism Skills:

- Ask questions about what is left out of a message, the untold story
- Assess variety of viewpoints
- Consider content on the basis of accuracy, bias, intent and purpose
- Understand the language of persuasion
- Do not listen passively – passive listening will store message, but not information on the messenger
- Don't be a walking advertisement
- Refuse all gifts – zero dollar limit, including samples

Learn to access balanced information on drugs

Search of Balanced Information

- Primary Emergency Physician Database (PEPD)
- United States Primary Care Physician Database (USPCD)
- Overview (Re-Engagement by Website; October 2006)
- Drugpage 529
- <http://www.pharmaceutical.com/text/ahd/war-drugpage-drugpage-handbook.htm>
- Medical Letter (1/9/04)
- <http://www.medletter.com>
- Prescriber's Letter (3/04/04)
- <http://www.prescribersletter.com>
- Therapeutics Letter (Canada - Free)
- <http://www.tlabb.ca/>
- The Health Effect
- <http://www.cdr.ca/>
- info@csdp.org
- <http://www.industry.com>
- Healthcare Database (2002/03)
- <http://www.hca.com.au/gfrc/wel/0406.htm>
- Consumer Value Best Buy Drug (Free)
- <http://www.crhcbestbuydrug.com>
- Drug Effectiveness Review Project (Free)
- <http://www.pharm.ca/drug/efrc/index.htm>

Assess information presented for balance

Complete Information Checklist

- **authorship:** The presenter or source of the information should be identified, so the consumer can determine author and organizational accountability.
- **sponsorship:** Since every author or presenter receives support for their efforts, support disclosure should be evident to the consumer in order to determine potential bias.
- **conflict of interest:** The presenter may be influenced by financial and non-financial relationships that affect their viewpoint, so the consumer should receive statements about potential conflicts of interest beyond sponsorship.
- **negative effects:** Since every drug has side effects, these should be distinctly displayed.
- **contraindications:** Particularly negative events occur in some patients, so the warning to the consumer about these patients should be very evident.
- **costs:** The cost of prescribing should be available to the consumer, and this information should be expressed in terms that are clinically relevant (cost per course of treatment or per month)
- **comparisons to other class drugs:** Since most drugs compete with other agents in the same or companion drug classes, the presenter should give the consumer comparison information related to drug-to-drug efficacy, cost and negative effects differences, preferably with several competing agents.
- **treatment circumstances:** Drugs are approved for certain treatments and circumstances, and the boundaries of those circumstances should be clear to the consumer.
- **study subjects:** The patients in whom the drug was studied are the ones for whom the evidence applies. Since extrapolating to other patients may risk, the presenter should identify the study population.
- **study limitations:** Treatment circumstances and study patients described for the consumer the best conditions for drug use, but the setting in which the drug was studied, the method of identifying patients and their illnesses may also create gaps in understanding drug efficacy. Noting these limitations for the consumer should be expected.
- **number needed to treat and harm:** These are two particularly useful ways to gauge the impact of treatments, because they take into account disease or outcome probabilities that affect benefit or harm. In essence, they inform the consumer how many patients would need to be treated with a specific drug to accomplish benefit (or harm) in one patient. The presenter should report these figures.

- Opt-out of having individual prescribing information available to sales representatives (Prescription Data Restriction Program)
- Ask the sales representative critical questions rather than allow them to lead the conversation
- Work to improve patient compliance
- Learn to deal with direct-to-consumer advertising motivated requests in ways that do not involve prescribing a requested drug
- Maintain an appearance of propriety
- Ask that companies register all clinical trials and results on a neutral website

Groups can:

- Advocate for changes to e-prescribing and decision support systems
- Develop internal academic detailing
- Leverage the characteristics of a group practice to improve quality of care

Team

A planning committee of content experts, curriculum and accreditation experts, and support staff was assembled:

- **Course Content Expert:**
Eva Lydick, PhD, Lovelace Clinic Foundation
Christie McAuley, MA, New Mexico Media Literacy Project
William Mitchell, MD, Lovelace Health Plan
Louis Morris, PhD, Louis A. Morris & Associates
Elizabeth Rappaport, MD, EBR Consulting
Robert White, MD, Lovelace Clinic Foundation
- **Curriculum Design and Accreditation Oversight by:**
Sarah J. Beaton, PhD, Lovelace Clinic Foundation
Virginia Pruitt-Fedderson, BSN, MSN, CNS, Lovelace Clinic Foundation
April Salisbury, MBA, Lovelace Clinic Foundation
- **Special Thanks to:**
Twila Kunde, MPH, CCRP, Lovelace Clinic Foundation
Billie Nelson, Lovelace Clinic Foundation
Lawrence J. Pesko, MS, PhD, RPH, Lovelace Health System

Timeline

	2 nd Half 2006	1 st Half 2007	2 nd Half 2007	1 st Half 2008	2 nd Half 2008
Contract and assemble planning team and draft learning objectives and educational modules					
Pilot learning modules with a live group of physicians from Lovelace Health System in Albuquerque					
Based on participant evaluation feedback, modify content and make available to the National Center for Farm Worker Health					
The modules will then be developed for online use and placed in the public domain					
As part of the evaluation, LCF will review prescribing patterns of attendees before and after the training					

Evaluation

A face-to-face presentation of the content to a selected group of Lovelace Medical Group prescribers is planned for the spring of 2007 as a pilot. We will assess their achievement of learning objectives and modify content and format as necessary. Prescribing analyses will look at the following in the six months prior to attending the course and in the six months following the course:

- Number of scripts per patient seen
- Scripts for generics versus branded products
- Potential drug-drug interactions
- Drug switches, especially to newer products

Conclusions

At the conclusion of the project, the curriculum materials developed by LCF and by other awardees will be available in the public domain through various web sites (one site will be Federation of State Medical Boards).

This project is sponsored by the Consumer and Prescriber Education grant program, administered by a Special Committee of state Attorneys General.

