Analysis of the Regulatory Environment For Direct-To-Consumer Prescription Drug Ads: a Case Study of Vioxx

Connie Pechmann, University of California, Irvine

This paper will discuss the four categories of prescription drug promotional materials that the FDA does not routinely review: marketing plans, sales representative’s marketing scripts, letters sent in response to physician queries, and marketing research. The paper will present arguments in favor and against FDA review of such materials to help inform decision-making about the FDA’s oversight role. Merck’s promotion campaign for its prescription drug Vioxx will be used as a case example. The case study will identify similarities and differences between the materials that were and were not submitted to the FDA, and assess their consistency with FDA standards.

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SESSION OVERVIEW

Nearly 50 years ago, C.P. Snow described science and literature as “The Two Cultures” of modern society. Research derived from these two cultures involve different theoretical perspectives, methodological tools, and appropriate metrics to evaluate substantive problems. In many ways, this gap has become more pronounced because of the specialization of our research efforts. In the area of health, in general, and communication regarding prescription drugs, in particular, we can see the impact of this separation in the ways researchers approach health concerns and health issues.

The recent call for transformative research by David Mick and others reflects the growing interest in applying marketing and consumer behavior theories and methods to improve consumer welfare. Although this notion of transformative research is new, previous researchers in our field, and in related disciplines, have also called for the analysis of social issues from a wide variety of perspectives. For instance, Mary Goldberg’s SPC Presidential address (1995) was a pointed commentary that consumer researchers were “fiddling while Rome burned;” that is, we were not applying our expertise to improve the human condition. The focus of his argument was the need to apply multiple theories and methods to examine a social issue. Although he did not use the metaphor of building bridges, the spirit of his position was the value in examining a social issue from multiple perspectives.

Two perspectives (or islands) he discussed were upstream (environmental barriers, policy/ regulatory-oriented issues) and downstream (theories of individual decision making, theories of persuasion, marketing-mix variables) approaches to create effective behavioral change programs. Goldberg argued that social issue (or transformative) researchers would benefit from building a bridge across these two (upstream and downstream) approaches.

A second set of methodological islands that influence our approach to health-oriented research is the application of humanistic (e.g., argumentation analysis) and behavioral (e.g., experimental) methods. These two approaches represent different conceptualizations of the value of control in the development of an empirical study.

A third pair of islands reflects the unit of analysis in the research: individual or dyad and the application of static rather than more dynamic models of behavior. Most models of persuasion focus on the individual and apply a static approach; that is, the presentation of a message that is intended to inform the individual and to motivate behavior change or behavior maintenance. An alternative approach is to treat the dyad (e.g., the health professional and the client) as the unit of analysis and examine the dynamic communication process between these two parties.

Our intent for the current proposed session is to describe research that applies these different perspectives to study communication issues associated with prescription drugs. Nakamoto et al. examine issues associated with direct to consumer advertising of prescription drugs by using a humanistic theory and method (argumentation theory) to examine the impact of the structure of DTCA content on the inferences drawn from these ads. This research is an example of Goldberg’s description of “downstream research.” In contrast, Peckmann presents an upstream analysis of DTCA by examining the process used by the FDA to regulate the information contained in a DTCA. Both these papers focus on the consumer as the unit of analysis and approach persuasion as a more static process. Brinberg et al. describe a research project that examines the relationship between pharmacists and their clients by combining observational methods with an experimental study to assess the impact of health messages tailored to the stage of the relationship between the pharmacist and the client.

The proposed session will bring together scholars with different theoretical and methodological perspectives to discuss ways in which these different “research cultures” can be applied to better understand the development of health messages. The session will allow us to illustrate how scholars in the area of transformative research are able to integrate distinct methods to create a more comprehensive investigation of health messages. We expect this session to appeal to researchers involved in the study of social welfare problems and methodologists interested in the application of multiple approaches to study a social problem.

EXTENDED ABSTRACTS

“Argumentation in Direct-to-Consumer Advertising of Pharmaceuticals: Logical Problems and Policy Issues”

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Kent Nakamoto, Virginia Tech
Peter Schulz, Universita della Svizzera Italiana
Anjala Krishen, University of Nevada, Las Vegas

There is an ongoing global debate on the benefits and risks of allowing direct-to-consumer advertising (DTCA)—the promotion of prescription medicines to the general public in the lay media. Currently, DTCA is allowed only in the United States and New Zealand; however, there is strenuous lobbying in many countries to relax national restrictions on DTCA and it can be reached via internet all over the world. Promoters of DTCA argue that pharmaceutical companies have more accurate, balanced, and scientifically based information than any other sources. As such, they are in an unique position to provide people with adequate information on the safe use of medication, as well as to create effective knowledge for evaluating the benefits and risks of drug products, and generally assisting people in managing their health autonomously and appropriately. Opponents of DTCA emphasise the financial gains of the pharmaceutical industries and the fact that DTCA enhances medicalization of normal human experience. Opponents claim that DTCA’s primary aim is to create name and brand recognition with a view to increasing the use of the advertised products.

There is strong evidence that DTCA is effective in increasing sales. In 1999, the 25 top-selling medicines promoted directly to consumers accounted for 40.7% of the overall $17.7 billion increase retail drug spending. The same 25 top-selling drugs had an aggregate one-year sales growth in 1999 of 43.2%. The growth in sales for all other drugs was 13.3%. This coincides with a growth in the number of prescriptions for the 25 DTC-promoted drugs. In 1999 doctors wrote 34.2% more prescriptions than in 1998 for these drugs, while they wrote only 5.1% more prescriptions for all other prescription drugs. In addition, the US General Accounting Office
estimates that 8.5 million consumers annually request and receive from their physician a prescription for a particular drug in response to seeing DTCA.

The above data suggest that DTCA has an impact, and this evidence leads us to enquire into the reasons for this success. The persuasiveness of these ads would not per se be a critical problem. What could point to problems, however, are the data indicating that physicians are ambivalent about the treatment in half the cases in which they prescribe drugs requested as a result of DTCA, and that they prescribe the drug often because of the pressure felt, suggesting that the advertising may be inciting patients to seek and obtain a medication that is neither safer nor more efficacious.

Whatever the corporate motivation for the advertising, our interest in DTCA is the basis for its persuasive impact on consumers. In particular, we want to assess whether these ads present potentially misleading information that can lead to an overestimation of the value of the medicines advertised. We approach this enquiry by exploring the rhetorical strategies used in these ads and the way people process them. More specifically, we make use of argumentation theory as a critical tool for investigating the sources of potentially misleading information.

We report the results of a set of empirical studies examining the recognition by readers of the argumentative structure of pharmaceutical ads. We first provide an analysis of the argumentative structure of the ad and identify the specific dubious arguments it presents, using the framework provided by classical rhetoric and modern argumentation theory. We then report on our studies showing that the dubious arguments are both memorable and credible. We discuss the issue of the persuasiveness of DTCA, showing how readers can make wrong assumptions that, on the one hand, seem to arise independently from the contents of the ads, and on the other hand can promote a fallacious elaboration of the quality of the medicines advertised. The critical policy problem raised by this analysis is that prominent forms of argumentation used in DTCA, in effect, shift the burden of proof for the likely efficacy of the drug for the reader from the advertiser to the reader. Because of the potential deleterious health, as well as economic, effects of inappropriate use of pharmaceuticals, the use of these argumentative strategies could be inappropriate.

"Analysis of the Regulatory Environment for Direct-to-Consumer Prescription Drug Ads: A Case Study of Vioxx"

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The USA is the only country that permits direct-to-consumer (DTC) advertising of prescription drugs, and the practice is controversial even here. The U.S. Food and Drug Administration (FDA) regulates prescription drug advertising and labeling, and the FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) implements those regulations. The FDA Modernization and Accountability Act (1997) authorizes the FDA to collect user fees from pharmaceutical firms. DDMAC also reviews promotional labeling including "brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual material descriptive of a drug and references published" (CFR 202.1.11). DDMAC reviews promotional advertising directed at consumers and/or physicians, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (CFR 202.1.11). DDMAC also reviews promotional advertising directed at consumers and/or physicians by pharmaceutical firms.

In response to demands for reform, the FDA has proposed significant changes for 2007 and beyond. In particular, the FDA has proposed an increase in user fees, so that it can conduct quicker reviews of prescription drug DTC TV ads and can review each ad prior to airing. The industry has agreed to pay higher user fees to obtain this service and has pledged to submit each DTC ad prior to airing. The industry wants the FDA to review its advertising prior to airing, in part to help protect it from law suits involving failure to warn and consumer fraud.

This reform assumes that the FDA has devised an effective method for reviewing prescription drug advertising and labeling, and that it simply lacks resources to conduct the reviews. This paper assesses the validity of that critical assumption and examines whether the FDA’s review of prescription drug advertising and labeling should be expanded in scope, when user fees are increased as expected, to ensure the FDA’s review is thorough and protects the public from false or misleading advertising and labeling. It appears that no prior paper has addressed this issue.

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However, the FDA does not routinely review the following classes of materials that are used in pharmaceutical firms’ promotional campaigns: (a) Marketing plans and strategies, (b) Marketing scripts used by sales representatives when detailing physicians, (c) Direct mail letters sent by firms in response to physicians’ medical queries, and (d) Marketing research about the campaigns (e.g., tracking). The paper will discuss the pros and cons of an FDA review of each class of material. The following specific issues will be addressed:

1. Why doesn’t the FDA currently review these classes of materials, that is, how does the FDA interpret its regulations and how has the agency’s interpretations led to loopholes?
2. Are the nonreviewed and reviewed materials likely to contain the same or different information, that is, are they samples from the same or different populations?
3. Is it feasible for the FDA to review each class of nonreviewed material, and would the benefits outweigh the costs?

The FDA has also proposed new rules that would serve to increase the weight of DDMAC reviews in state and federal law suits. This paper will address those new rules too. Do we want FDA DDMAC reviews to continue to focus on a subset of promotional materials with strong emphasis on DTC TV ads? Will that approach adequately protect public health and safety?

This paper will feature a case study involving the large pharmaceutical firm Merck and its marketing of the prescription
pain reliever Vioxx. Vioxx was sold in the USA from 1999 to 2004. Vioxx was withdrawn from the market based on studies indicating it causes heart attacks. The first study showing a potential heart attack risk for Vioxx appeared in 2000. In September of 2001, the FDA sent Merck a warning letter alleging that aspects of Merck’s promotional campaign for Vioxx were “minimizing” that study’s findings and were “false or misleading” because the firm “misrepresents the safety profile for Vioxx.” The FDA required Merck to send correction letters to health care providers who had attended conferences in which false or misleading promotional messages for Vioxx were disseminated.

The author of the current paper obtained the Vioxx advertising and labeling materials while serving as an expert witness for plaintiffs in Vioxx law suits. This paper will examine promotional materials for Vioxx that were and were not submitted to the FDA’s DDMAC division for review from 2000 to 2003. The review will assess similarities and differences between the materials that were and were not submitted to the FDA and apparent consistencies or inconsistencies with the FDA standards, using the 2001 FDA warning letter and correction letters as standards. After the April 2003 Vioxx label change that included information about Vioxx’s heart attack risk potential, the Vioxx product label will be used as the standard. The aim of this case study is not to draw conclusions about whether Merck’s promotional campaign was or was not misleading or deceptive in terms of conveying information about Vioxx’s heart attack risk potential. Instead, the aim is to describe the contents of the advertising and labeling materials that were and were not submitted to the FDA to address the issue of whether the FDA might in the future want to review some categories of materials it currently does not review on a routine basis.

“Motivating the Pharmacist-Client Relationship: An Integration of Stages of Change to Relationship Development”

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Kim Daniloski, Virginia Tech
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Pharmacists’ role in the health care setting is shifting from product-oriented to patient-oriented, with the goal of understanding and caring for clients. To date, much of the communication between pharmacists and clients has focused on the use and value of prescription drugs to treat various medical conditions. However, the re-professionalization to a more patient-oriented role has created a need for pharmacists to identify areas where they can intervene to enhance the quality of patient care and perform their services with a particular focus on client needs. At the same time, clients need to learn how to use pharmacists as a new source of information. Given the rising complexity and costs of health care, the role of pharmacists as primary health care providers will become essential. As a consequence, research needs to examine strategies to improve the communication between pharmacists and their clients to make the information exchange more patient-oriented and focused on client needs.

Clients’ acceptance of pharmacists’ messages depends on the level of trust clients have in their pharmacists: in other words, acceptance depends on the stage of the pharmacist-client relationship (e.g., developmental stage of the relationship; mature stage of the relationship). The literature does not contain recommendations on strategies that can help pharmacists develop and maintain relationships with their clients.

In the following research, we develop and evaluate a theoretical model that examines the stage of the pharmacist-client relationship and applies the strategies identified in the stage of change model to motivate a change in that relationship. We assess whether these strategies increase trust in the pharmacist and in subsequent interactions with the pharmacist concerning health needs.

We approach our research by integrating observational methods (in-depth interviews with pharmacists, survey methodology) with a field experiment to develop and evaluate our theoretical model.

Data were collected from over 1,000 clients from over 40 pharmacies in the Italian-speaking canton (Ticino) in Switzerland. In the initial phase of this research, we conducted in-depth interviews with pharmacists in Canton Ticino to identify the ways in which they currently interact with their clients and the strategies they use to strengthen that relationship. Based on the information from these interviews, and previous models developed in the relationship marketing literature, we identified three key constructs that influence trust in the pharmacist: perceived expertise of the pharmacist, perceived benefits of the pharmacist-client relationship, and the stage of the pharmacist-client relationship. We viewed the stage of the relationship as both a predictor of trust and as a moderator of the perceived expertise and perceived relational benefits—trust relationship.

All the main effects were significant predictors of trust. More interestingly, the stage of the relationship moderated the relations between the other predictors and trust. Specifically, we found perceived relational benefits and perceived expertise had a stronger effect on trust in the developmental stage of the relationship and neither had a significant impact on trust in the more mature stage of the relationship.

Based on this finding, we hypothesized that stage appropriate messages were more likely to increase client trust. We then conducted a field experiment in which we created two types of messages—one that focused on perceived relational benefits and perceived expertise and a second that focused on a standard message communicated by the pharmacist. We identified 9 pharmacies and randomly assigned them to either the control group (no message), the standard message group, or the experimental message group. We measured trust four months after the client received the message.

Contrasts of the simple main effects at the developing stage of the relationship revealed that the experimental message resulted in significantly higher levels of trust than both the standard message and the control group (t=2.2; p<.05 and t=3.9; p<.01, respectively). The standard message’s impact on trust was also significantly higher than the control group (t=2.2; p<.05). None of the simple effects were significantly different at the mature stage.

In contrast to the papers presented by Nakamoto and Pechmann, the approach used in this study to examine the communication of health information focused on the dynamics/interactions of the pharmacist-client relationship. We will contrast and then discuss some of the implications of using this more dynamic, dyad-oriented approach to the communication of health information.