

ORIGINAL

Before the
U.S. Food and Drug Administration
Rockville, MD

In the Matter of:

Consumer-Directed
Promotion

Docket No. 2003N-0344

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COMMENTS OF THE
COALITION FOR HEALTHCARE COMMUNICATION

Submitted by:

Jack E. Angel
Executive Director
Coalition for Healthcare Communication
January 14, 2004

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INTRODUCTION AND STATEMENT OF INTEREST

The Coalition for Healthcare Communication is pleased to comment on the important matters at issue in the current proceeding regarding Direct-to-Consumer Advertising (DTCA).

The Coalition is a not-for-profit organization. It represents eleven major communications organizations whose members are engaged in medical communications including advertising, publishing, continuing medical education, and the dissemination of information on healthcare products and services. Those organizations are the American Association of Advertising Agencies, Midwest Healthcare Marketing Association, Medical Marketing Association, Healthcare Businesswomen's Association, Healthcare Marketing and Communications Council, Public Relations Society of America, Association of Medical Publications, American Advertising Federation, Association of National Advertisers, American Medical Publishers Association, and American Business Media.

The Coalition's mission is to seek a free flow of medical communications, unencumbered by unnecessary regulation, so that healthcare professionals and patients have open access to essential health information. As an active voice on various issues relating to medical communications, the Coalition consistently seeks to achieve a common goal with FDA, the medical community, policy makers, and the American public to optimize the flow of medical information.

Direct-to-Consumer Advertising is an important ingredient in this mission. An informed public is good public policy. In the health arena, it can promote healthier living, compliance and often save lives. Our membership is dedicated to providing truthful, non-misleading, understandable information to the public at large that they can act on, as appropriate, by having a more informed encounter with their physician.

EXECUTIVE SUMMARY & RECOMMENDATIONS*

The Coalition for Healthcare Communication (CHC or the Coalition) strongly supports efforts on the part of the Food and Drug Administration (FDA) to improve the development and dissemination of important and truthful risk information about prescription drugs to all affected audiences, including the public at large, through all media. In response to FDA's request for comments about the role of DTC advertising in such endeavors, we are pleased to provide several recommendations based on the record, and a two-part commentary on direct-to-consumer advertising. Part 1 is an expert review of the effective use of audience modeling in consumer advertising with comments on the limitations of mass media by Lewis G. Pringle, PhD;

Part 2 is a review of pertinent recent initiatives and developments in the field of health risk communications that we believe are of specific relevance to the current discussions of DTCA regulatory policy.

Over the past several years, FDA has developed significant resources and efforts to ensure that its regulatory policy on DTCA is based on the best available data and research. Implicit in the FDA efforts is the maxim that the American public is best served by fact and data based regulation.

Through FDA's participation as an active member of the Agency for Healthcare Research and Quality's (AHRQ) Centers for Education & Research on Therapeutics (CERTs) program, the CERTs five-part, Risk Communication Workshop series, the development of the CERTs Partnerships to Advance Therapeutics (PATHs) program, its request for public comments concerning experience with DTCA communications, open hearings on the topic, and continued commitment to the development of an appropriate research and education agenda, FDA has

* Note: References for the Executive Summary and Recommendations section will be found at the end of Part 2 of this submission.

established a new standard of public/private cooperation in the conduct of its policy-making affairs.

The FDA, however, cannot adequately assess the success or failure of DTC advertising without a clear specification of the objectives of this advertising. As Dr. Pringle notes, there are fundamental differences between the objectives of “health message design” as used in the public health environment, and the objectives of product-oriented, commercial messages such as DTC advertising.

The primary goal of all DTC advertising is and should be to convince a consumer to discuss a medical condition with his or her doctor. DTC ads are not intended to provide highly detailed information to a consumer about all of a drug product’s benefits and risks. DTC ads are not intended, nor should they attempt, to take the place of a thorough conversation between a patient and doctor about a specific medical condition and the potential benefits and risks of drug treatment or other treatment options. As Dr. Pringle concludes, mass media advertising cannot do these jobs and should not be asked to do so.

There is substantial evidence that DTC advertising presently is successfully meeting its most basic goal – to convince consumers to talk to their doctor about a specific medical condition. In the FDA’s own recent survey of 500 doctors, 80% of those surveyed felt that the ads made patients aware of health problems, while 85% percent felt their patients were more likely to use their prescriptions properly because of the ads. Furthermore, 78% thought these ads led patients to seek treatment for potentially serious conditions. (*Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results*; Washington, DC; Division of Drug Marketing, Advertising and Communication, Food and Drug Administration, January 2003)

A study by *Prevention Magazine* found that DTC advertising led an estimated 24.7 million Americans to ask their doctors about a medical condition that they had not previously discussed. (*Prevention Magazine; National Survey of Consumer Reactions to Direct-to-Consumer Advertising*; Emmaus, PA; Rodale Press, 2001)

In a recent survey of African American physicians conducted by the National Medical Association (NMA), 72% of those responding believed that prescription drug advertising promotes increased communication between doctors and patients. (“To Do No Harm,” *Journal of the National Medical Association*; April 2002)

A major consumer group, the National Consumers League (NCL), also released a highly favorable survey concerning DTC advertising. As Linda Golodner, the NCL President, forcefully stated, the NCL survey demonstrates that: “With DTC ads, large numbers of consumers are made aware of medical conditions and treatments that they may otherwise not know exist.” (*Effectiveness of and Attitudes Towards Medication Advertising: Summary of Survey Findings*; Washington, DC; Prepared for NCL by ORC International, October 2002)

In fact, almost two-thirds of the NCL survey respondents disagreed with the statement that ads for medications should only be in medical magazines for doctors. Golodner also noted that these types of ads often “help destigmatize conditions that may have otherwise gone untreated due to patient embarrassment and limited medical knowledge.” *Ibid.*

While the FDA has made tremendous progress since revising the rules for broadcast DTC advertising in 1997, the Coalition believes that the current rules for print ads, particularly the “brief summary” requirement, deserve careful further consideration.

Advertising is not intended to be an encyclopedia of information about a product. Dr. Pringle cites numerous studies that conclude that all commercial messages have a finite and

limited capacity to convey information. Information overload is a real and serious challenge in advertising for any product or service, including DTC advertising. While print advertising may be able to contain more information than a broadcast ad, even print advertising is subject to information overload. Under the current FDA rules, DTC print ads must contain extremely voluminous, detailed and highly technical information that is generally written for healthcare professionals, not consumers.

Dr. Pringle concludes that vast arrays of information are not necessarily better for the consumer and may actually lead consumers to “tune out” of the entire message.

Current standards for the provision of risk information about prescription drugs are inadequate. As noted by Hoek et al¹, “It is clear from US studies that excessive detail serves only to confuse consumers and inhibits rather than develops their understanding of the promoted brand.”

The work of Schommer et al^{2,3} on the ordering of cognitive effort and information overload that results from the processing of prescription drug information also suggests the need for a flexible approach to the provision of risk information. “[I]nformation processing sequence is important to consider when providing prescription drug information to individuals,” the authors note.

As suggested by the Coalition previously⁴, acknowledged by Schommer et al² and augmented by the comments of Day⁵ at the recent public hearings on DTC, a policy calling for the development of a general warning statement about the seriousness of prescription drug medication suitable for use in all media, coupled with a detailed outline that can be elaborated upon in newspaper, magazine and online media of the most serious potential side effects to

discuss with one's physician, is likely to be the most practical way of solving the regulatory mandate and risk information overload dilemma.

As reported by Day⁵, in her studies, the grade level of readability for side effects information in some cases is six to eight grades higher than for benefits information. Use of the physicians' prescribing information language in newspaper and magazine "brief summaries" therefore, while perhaps satisfying the regulatory mandate for fair balance, is demonstrably inadequate to the task of practically informing patients of the risks of medication in a manner that will not frighten them away from taking valuable medications, or that will enable them to make a reasonably considered judgment about their physician's recommendations.

As Schommer et al concluded³, "More work is needed to understand the delicate balance between individuals' need for information at a level sufficient for decision-making and their need for information at a level that will not overload them as they cognitively process and utilize it."

While the past few years have resulted in the generation of impressive data supporting the value of DTCA, we recognize that as suggested in much of the professional literature and in discussions at the FDA's open meeting of September 2003, significant gaps in evidence still exist. Such evidence is a prerequisite before any fundamental changes in FDA regulatory policy be proposed. Accordingly, the Coalition for Healthcare Communication respectfully requests that:

- 1) FDA maintain its current DTCA policy without the adoption of any major changes, unless such changes are supported by an evidence-based record of need, including data on the likelihood of effectiveness of any specific mandate to achieve its proposed objective, and research on the possibly counter-productive effects of any such mandate and the opportunity for comment by industry and other interested parties before any proposed changes are instituted.
- 2) The FDA carry out a thorough evaluation of the current rules for DTC advertising in print media to determine how those ads can be more effective. As part of such a review of the current print rules, the FDA should request longitudinal studies to examine the impact of alternative risk warnings in all

DTC ads, including a general risk warning, an expanded drug class risk warning and a specific product risk warning – all to include evaluation of each communication for specific “information overload” and actual health outcome data (i.e., prescription fulfillment). Again, no changes should be made in this area without sufficient opportunity for industry comment and input.

- 3) FDA recognize that DTCA is consistent both with First Amendment protections of commercial speech and the advancement of the public health. In the former instance, there is a record that communication mandates have clear limits and possibly counterproductive effects; moreover, no record yet exists on the effectiveness of any specific additional mandate. In the latter instance, special care is needed to develop policies that are likely to actually achieve the intended results – a better informed and motivated patient population; such policies require careful study, continuous monitoring and frequent re-examination and/or revision to achieve optimum effectiveness.
- 4) The FDA should encourage commercial sponsors of DTCA to experiment with alternative methods for disseminating prescription drug risk and benefit information using integrated media plans to optimize such communications for a selected range of U.S. population segments, providing waivers or suspending enforcement of regulations that might otherwise impede such experimentation, and
- 5) FDA initiate its own grants program for appropriate communications research projects providing grants and involving collaboration with the communications industries to help establish standards for effective prescription drug risk communications.

In addition to these specific recommendations, the Coalition also suggests that FDA carefully consider convening a Consensus Conference on Pharmaceutical Communications to examine the current state of the art and to identify areas of potentially fruitful research and collaboration between the public and private sectors, including representatives from appropriate government agencies, the pharmaceutical industry, the communications industries, professional associations, consumer advocates and the public at large. Such an initiative is a next logical step as a result of the extensive presentations and discussion at the September 2003 open meeting. CHC notes that several academic research institutions^{1,2} are involved in the study of issues that are closely related to the policy issues before FDA. In addition to the inclusion of such academic researchers, Coalition members and affiliated organizations such as the Advertising Research

Foundation, the Advertising Council, the Association of National Advertisers, Association of Medical Publishers, and the Medical Advertising Council of the AAAAs would add a significant measure of current, expert, communications industry perspective to the process.

Comment in the Matter of: Consumer Directed Promotion Docket No. 2003N-0344

Part One

Direct-To-Consumer {DTC} Advertising: A Practical Communications Model and
Commentary on Risk Communications

For submission to:

The Food and Drug Administration (FDA)

Prepared by¹

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Professor of Marketing
Yorktown University

Dated:

5 January, 2004

FINAL DRAFT

¹ Supported by a Grant from the Coalition for Healthcare Communication, Greenwich, Ct. 06830

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Yorktown University, Yorktown, Virginia, Professor of Marketing, August, 2002 to Present

Dr. Pringle is a Founding Member of the Faculty at Yorktown University and teaches its Core Courses in Marketing. In addition, Dr. Pringle is Chairman of the Department of Managerial Economics and a Member of the University's Board of Directors.

Miami University, Oxford, Ohio, The Joseph C. Seibert Professor of Marketing, August, 1995 to August, 2001

In 1995, Dr. Pringle accepted a Chaired Professorship at Miami University in Oxford, Ohio. In that capacity, he taught, several times, the Capstone Course in Marketing Strategy as well as several courses in Market Research. In addition to his work in renewing the scholarship role associated with the academic life, Lew served as Chairman of the Marketing Strategy Committee of INFORMS (Institute for Operations Research and the Management Sciences), Chairman of the Search Committee for a new Chaired Professorship at Miami, Chairman of the School's Marketing Strategy Committee, an active member of the Faculty Evaluation Committee and was a member of the Board of the Miami University Performing Arts Association. Dr. Pringle also served six years as member of the Visiting Committee of MIT's Sloan School of Management, as Associate Editor of Marketing Science for 15 years and has published in that journal as well as in such journals as the Journal of Marketing Research and the Harvard Business Review. Even in his retirement from the Seibert Chair at Miami, forced upon him by health considerations, Lew has remained active. In addition to his work on behalf of Yorktown University, he lectures occasionally elsewhere in the U.S., has served as Member of the Board of the INFORMS Marketing College and has recently been named to the Editorial Board of the Journal of Advertising Research. Dr. Pringle is also a Fellow of the Royal Statistical Society and has served as Co-Chair of the Public Information Committee of INFORMS.

L. G. Pringle & Associates and P & W Information Systems, Partner, January, 1992 to August, 1995

In January of 1992, Lew retired from BBDO Worldwide, after twenty three years of service, to form, together with his partners, L. G. Pringle and Associates, Inc. as well as P & W Information Systems, SA., both companies devoted to developing trade, business and investment between Russia and the other new Commonwealth Republics, on the one hand, and Western business organizations, on the other. Fundamental to the business intent of each of these two firms was the establishment of mutually profitable, friendly and lasting business relationships between those involved. The primary objective was to help clients evolve a long term business program, uniting them with suitable Russian interests and capacities, helping them to solve problems and eliminate obstacles in order to achieve mutually profitable, formalized, lasting relationships. To facilitate these efforts, the two firms offered clients consulting advice and services in the areas of trade, investment, joint ventures, participation in current privatization efforts, co-manufacturing, licensing and technology (intellectual property) acquisition. In terms of financial services, direct payment mechanisms, financing, debt exchange, barter and counter-trade transactions were utilized.

BBDO Worldwide, Executive Vice President, Chairman and CEO of BBDO Europe (from April 1986 to August 1990)

In April of 1986, Dr. Pringle assumed responsibility for BBDO's interests in Europe, Africa and the Middle East. At the time, the agency's Capitalized Sales were \$550,000,000. During his four years tenure in this position, those sales tripled to over \$1,600,000,000, while profit grew at about the same rate.

During this period, Pringle served on the Boards of most of BBDO's larger agencies in Europe and completed BBDO's coverage of Western Europe, acquiring agencies in Portugal, Finland, Norway and Ireland, in addition to many additional agencies in those countries in which the company already had representation. He also led the process through which BBDO formed its agency network in the business-to-business area of communications, creating the BBDO Business Communications Network, principally in Europe but also in the US and in Australia. That Network alone, by 1990, contributed about \$300,000,000 in sales to BBDO Worldwide. In addition, Pringle brought BBDO to the Soviet Union, where it became a pioneer in the integration of modern Russia with the rest of the developed world. In the process, Lew developed a number of friendships and professional relationships with very senior Soviet officials, both in the government as well as in the Ministerial system. Pringle regarded his biggest challenge in Europe as the integration of BBDO agencies, market by market, into an organization culturally and professionally committed to serving multinational clients in cross-border marketing and advertising efforts. The experience he gained in this effort, traveling approximately 70% of the time within Europe from his U.K. base, dealing with senior client personnel, typically responsible in their own organizations for their company's interests in Europe

and organizing BBDO's response to better serve the needs of these people, is perhaps the single most important and differentiating aspect of his international career experience.

Executive Vice President, Executive Director, Marketing and Strategy (1984 - 1986)

In 1984, after six years as BBDO Worldwide's Director of Research Services, Dr. Pringle left that position to work with the Chairman/CEO and COO of BBDO Worldwide, to help them formulate a plan for the global future of the company. The task was a highly practical one; to answer the question of what organizational, structural and professional changes were needed in BBDO Worldwide to permit it to optimally address the rapidly evolving needs of its clients on a global scale? The results of his work on this question were presented to a Worldwide Management meeting in September 1985 and those directions were accepted, in all respects.

Senior Vice President, Director of Research Services (1978 - 1984)

Dr. Pringle was Director of Research Services for BBDO Worldwide from 1978 to 1984. During that time, he was elected Senior Vice President and member of the BBDO Worldwide Board of Directors (1978) and Executive Vice President (1981). He managed a department of from 80 to 100 people, with an overall budget approximating \$10,000,000. In terms of professional accomplishments, he thinks of his greatest satisfaction as coming from setting the standards of commitment to BBDO's clients as well as excellence in the work produced; and, in nourishing the culture without which neither can be sustained. Even as Director, he was able to participate personally in the improvement of the company's techniques as well as in the creation of marketing and advertising strategy. BBDO, during this period, had documented credentials as the very best in research and strategy formulation.

Director of Management Information Services and International Research (1976 - 1978)

During this two-year period, Dr. Pringle re-entered the research function at BBDO and was responsible for all research conducted by the agency, on behalf of clients and otherwise, outside the New York Company. In addition, he was responsible for the Marketing Department, Information Center as well as the training of young account executives within the agency.

Management Supervisor and Assistant to the President, International (1974 - 1976)

The President of BBDO's International Company hired Pringle back to BBDO in 1974. During the subsequent two years, he worked as assistant to that man as well as Management Supervisor on the Citibank account. Particularly in the former role, he learned much about international business, in general, as well as about the conduct of business per se.

Assistant Professor, Graduate School of Industrial Administration, Carnegie Mellon University (1973 - 1974)

Because of his prior academic background, Dr. Pringle was long motivated to "test market" Academe and did so for one year at Carnegie Mellon, teaching marketing to Masters Degree candidates and econometrics to PhD's.

Vice President, Director of Management Science (1968 - 1973)

Pringle joined BBDO as an Associate Research Director in 1968, was appointed a Senior Associate Research Director in 1969 and elected a Vice President that same year. In 1971, he was appointed Director of the Management Science Department, a group that he created, numbering about 25 people, of operations research, systems and other analytically oriented people. His academic background, at the time he was originally hired by BBDO, was somewhat unusual for the advertising business. Pringle had an undergraduate degree in Chemistry from Harvard, a Masters in Business from MIT's Sloan School as well as spending another four years at MIT earning a doctorate with specialization in statistics and operations research. At the time he was approached by an executive recruitment firm in 1968, representing BBDO, Pringle was within days of accepting an appointment as Assistant Professor of Finance at UCLA.

Education: **AB, Harvard College, 1959 - 1963**

MS, Sloan School of Management, Massachusetts Institute of Technology, 1963 - 1965

PhD, Sloan School of Management, Massachusetts Institute of Technology, 1965-1969

Personal: **Born 13 February, 1941, three sons, 2 granddaughters, 2 grandsons**

Direct-To-Consumer {DTC} Advertising: A Practical Communications Model and Commentary on Risk Communications

In 1759, Dr. Samuel Johnson said²: “The trade of advertising is now so near to perfection that it is not easy to propose any improvement”. Confirming his endorsement of that view, a century and a half later in 1923, Claude Hopkins, generally regarded as one of the greatest of advertising’s pioneers, said³ “The time has come when advertising, in some hands, has reached the status of science.”

Not wishing to argue with authorities as respected as these and while acknowledging that the views just cited may somewhat overstate the capacity of today’s advertising practitioner to deliver precisely what a Marketing Plan calls for, it is nevertheless fair to state that enough is known about how advertising works to have a high degree of confidence that, in good and faithful hands, advertising will ordinarily accomplish that which can reasonably be expected of it.

Note that I used the phrase “good and faithful hands”. Perhaps more so than in other fields of endeavor, in which the standards of excellence and ability are more uniformly distributed and where calipers appropriate to the task are more readily available to measure the results of the effort expended, this phrase represents a necessary equivocation. The fields of advertising and even marketing are littered with ersatz ‘experts’, each of whom has uncommon confidence in his or her own respective *opinions*. With respect to *most* fields of professional activity, the ordinary onlooker will easily and openly concede a lack of expertise. But, when it comes to advertising, **everyone’s** an expert. As Leo Burnett expressed it, “I’ve learned that any fool can write a bad ad, but it takes a real genius to keep his hands off a good one”. It is, in general, not recognized by the public, nor often even by less able members of the profession, that excellence in advertising really is *not* a chance event, or a fortuitously aligned series of lucky breaks. No, good advertising is learned..... And it is earned.

Claude Hopkins on advertising again⁴: “Thousands of men claim ability to do it. And there is still a wide impression that many men can. As a result, much advertising goes by favor. But the men who know realize that the problems are as many and as important as the problems in building a skyscraper. And many of them lie in the foundations.” It may not be a science yet, but good advertising people generally know what they’re doing. They know what can be done. And, of greater relevance to this commentary, they know what can’t!

² Dr. Samuel Johnson, Weekly Idler, 1759

³ Claude C. Hopkins, Scientific Advertising, Chapter One, 1923

⁴ Claude C. Hopkins, Scientific Advertising, Chapter Five, 1923

Throughout the course of this document, I shall assume that genuine, able and worthy advertising professionals are involved in the advertising to be discussed here.

One of the implications of this restriction is that real professionals in the field of advertising can be expected to insist on particular standards in the execution of their responsibilities. One of these standards, also relevant to the intent of this paper, is the advertising creator's need for certain information prior to beginning the actual creative effort. While it is true that ad professionals and agencies may vary somewhat in the types of information they want, in the ways in which they describe that information and how they articulate the role of each of those elements in their evolving grasp of any marketing challenge which confronts them, *nevertheless the basic elements of information they require are virtually identical – from person to person, from agency to agency, from product category to product category.* Why? Because, ordinarily, really knowing what the advertising *should* be doing is the highest calling of all. As David Ogilvy put it, "What you say in advertising is more important than how you say it." And this, of course, is true of all types of advertising and, I believe, particularly true in the field of public health communication.

An advertising professional wants to know: (a) *who he's going to be talking to/with* and (b) *what, precisely, is the intended advertising supposed to accomplish.* Now, as stated, these two data won't appear to be very much out of the ordinary. In fact, they may seem rather obvious. But, as in much of advertising, appearances can be deceiving. This is one of advertising's most singular points of contrast with other professions. There is an infinity of possible approaches to almost any aspect of its creation. Different approaches to a given objective often appear indistinguishable; the choice between them a matter of near indifference. The putative differences in perceived value among those millions of alternatives may seem, to the casual observer, quite modest⁵. That, however, is a snare and a delusion.

The truth often is that those seemingly modest differences ultimately will have compelling motivational consequences, especially when strung together in series. Take (a) '*who he's going to be talking to/with*', for example. Just the apparently straightforward task of responding to that question alone has millions of alternative executions. The choice of target audience is critically important. If a mistake is made at this point in one's analysis, everything is lost. There is no way to repair the damage.

Let me suggest as examples just a few of the issues: (i) first, on what basis SHOULD a target population be selected? (ii) their number? (iii) their age or other demographic characteristics, (iv) because they already hold certain opinions, (v) because they have prior attitudes we find attractive, (vi) or prior attitudes we wish to change, (vii) because of their behavior in the past, (viii) because they are likely to become ill, (ix) because they buy other pharmaceutical products in great quantity, (x) because they like

⁵ To the cognoscenti, a relatively flat response surface

our brand, (xi) because they *don't* like our brand. And..... many, many more! Each of these viewpoints can be translated into a statement that describes the intended target of our advertising. Which is the right one; the best one?

Next, comes the choice of (b) *what, precisely, is the intended advertising supposed to accomplish?* Note first, an inversion of sorts. This objective isn't stated in terms of what the advertising should say, or look like or even what the copy points should be or in what media should it be placed, etc. etc. Instead, its focus is on what the advertising is expected to accomplish. It is the obligation of Advertising Strategy, then, to (i) define the precise individuals we expect to address with our advertising and (ii) state with explicit and appropriate detail ***what it is we want to have left in the mind of each and every member of that target audience after the advertising has completed its act of communication.***

Now, of what relevance is this discussion to Direct-to-Consumer pharmaceutical advertising? In fact, it is this identification of the purpose of advertising that controls one's view of such issues as:

- (1) what kind of 'advertising content' is *needed* to accomplish the objectives delineated in (b) above.
- (2) to the extent that this desired content (1) is compromised by the need to serve purposes external/additional to those identified in the statement of Advertising Strategy, what will result from such a change in focus? What *are* the costs of adherence to legislation and/or regulatory mandates that require 'compliance' but don't speak to the need for effective communication of the content in (1) above?

Stated more directly, if the objective for DTC advertising is to accomplish the following:

- (i) sensitize and otherwise make members of a defined target population aware that certain physical symptoms may indicate the presence of a particular disease or other condition inconsistent with a state of good health and.....
- (ii) simultaneously, together with achieving the awareness described in (i), give that same target population the clear understanding that medical advances, in particular, medication, may now be available that have the

potential to somehow cure or remediate the condition under discussion and.....

- (iii) that a timely visit with his or her doctor is the **only way** forward both to determine a) whether the treatment described is appropriate and likely to be medically effective for that particular patient as well as b) whether (or not) there may exist significant offsetting risks that the treatment could cause some harm to the patient.

Direct-to-Consumer pharmaceutical advertising then, in this context, has as among its most important charges, alerting potential patients that, for the reasons stated in (i), (ii) and (iii) above, they should go see their doctor. Period.

If that is a correct statement of fact (and I believe it to be so), then any execution of that message should be judged effective predominantly based upon its success in prompting those who **should see** their doctor to actually go do so. That, then, should be the statistic of central public health interest, while the commercial matter of increased prescriptions for the advertised drug becomes a secondary consideration.

Clearly implied by this argument is that the advertising thereby created should **not** be evaluated in terms of the number of words it contains..... or the number of copy points it attempts to communicate. It should also not be evaluated by its ability to communicate a long list of the various types of risk that may or may not be possible sequelae of the treatment at issue. It is well known and will be discussed further shortly, that an advertisement is a fragile thing. It's effectiveness is easily lost by forcing it to attempt too much; by placing upon it excessive and unwise burdens. An ad with too many words will choke the intended target consumer. An ad that attempts to communicate *much* more than one single copy point is likely to fail in the effort. An ad that fritters away its clearly finite ability to do the worthy job already assigned to it as described above, by forcing upon it the accomplishment of duties alien to its fundamental nature, and to do so prior to having a physician determine that the medication is appropriate at all..... is a loss to all involved.

This paper, in summary, intends to make the case that DTC advertising has a truly special, perhaps even noble, life-saving role to play. It can do so best, as long as its real purpose and real capacity is kept foremost in mind.

Prescription drug DTC advertising is not the first to have been asked to do more than it is capable of doing. Nor has this mistake been confined to the realm of pharmaceutical advertising, in general. In

fact, it's a common error, ranging far and wide over the advertising landscape. Most advertising professionals know these mistakes for what they are. As a result, they are easily recognized. The truth is:

- (1) there are some things that advertising cannot do well,
- (2) those things ordinarily need to be done by other means to be effective
- (3) ignoring the truth of (1) and (2) can only damage or destroy all the good of which the advertising, in its unencumbered form, is capable – while achieving little or nothing in return.

YES, garbling-up a message with too many words and (more importantly) concepts will destroy the communication.

YES, describing in excruciating detail the multitude of possible side effects of any given drug therapy will destroy the communication.

All of that is well known and long since established, well beyond any serious discussion to the contrary.

But these facts aren't even the most important ones.

The most important fact is that doing these things is not the proper responsibility of advertising, in the first place. Assigning such objectives to advertising inappropriately removes the pressure to have these worthy goals properly handled in an environment and by the means most appropriate to these tasks. And, in the case at hand, I reference: (i) does the patient actually suffer from the indicated disease, (ii) if yes, is the medication appropriate to the identified task, (iii) is the patient susceptible to certain side effects, (iv) does the patient currently use medication which poses interaction risk of any material sort and (v) having thus deduced answers to (i), (ii), (iii) and (iv), how can those answers best be communicated to the patient? Answer: *only by a healthcare professional whose training, experience, intellect and personal contact with the patient allows him or her to draw those conclusions.* The role for DTC advertising in these five instances is de minimis.

And, if the communication is well handled at this stage, there is little role for DTC advertising with respect to these five issues.

It's my hope that the balance of this paper will serve to support these important observations. Let's begin by establishing that my recommendations are consistent with and, indeed, act to further the objectives of the FDA.

The following five paragraphs summarize, in the FDA's own words, the relevant (to this paper) portions of what it has been tasked to accomplish as well as some of how it sees DTC advertising helping to further that mission.

FDA's Mission Statement

The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Empowering Consumers: Improving Health Through Better Information

Enable consumers to make smarter decisions by getting them better information to weigh the benefits and risks of FDA-regulated products.

Selected Excerpts

The FDA accomplishes this important task in a number of ways. First, the FDA takes steps to ensure that information provided by a product's sponsors is accurate and that it communicates information consumers need to know in order to safely use a product. Second, the FDA itself communicates directly with the public and through healthcare providers concerning risks and benefits of regulated products.

Recent innovations, such as the new label on over-the-counter (OTC) drugs and direct-to-consumer (DTC) advertising, have had positive effects on consumer health decision-making. For example, consumer research conducted in developing the OTC drug label showed that the new label would increase consumers' confidence in their ability to use the information on the label and better enable them to make correct product-use decisions. Yet the FDA also knows that information can at times be confusing to some consumers, and too much information can provide a cacophony of data that can obscure the most important facts. Obviously, scientific accuracy is a key element of effective communication for consumers. Some other factors that affect the value of written medical information include, for example, the vocabulary and grammar used, the size of the typeface, and patient-related factors having to do with the patient's literacy.

Efficient Risk Management: The Most Public Health Bang for Our Regulatory Buck

Use science-based, efficient risk management in all agency regulatory activities, so that the agency's limited resources can provide the most health promotion and protection at the least cost for the public

The FDA's mission has become much more complicated. Public health protection now includes addressing unprecedented challenges and threats to the health of the public -- ones that are more sophisticated and complex than those of the last century.

Direct-to-Consumer (DTC) advertising has become an important source of patient information about prescription drugs. Research demonstrates that these ads can have a positive impact on patient/physician communications. For such advertising to best inform consumers, it must effectively communicate not just the potential benefits of the advertised prescription drug, but also potential risks, such as those associated with drug interactions and the specific health condition of the individual considering taking the drug).

Without doubt, current DTC advertising contributes importantly to the objectives stated above: (i) helping the public to get the accurate, science-based information they need to use medicines to improve their health, (ii) enabling consumers to make smarter decisions by getting them better information with which to weigh the benefits and risks of the available alternatives and (iii) communicating the potential benefits of advertised prescription drugs as well as the fact that there are also potential risks, such as those associated with drug interactions and other side effects, the significance of which can only be judged by a visit with one's doctor.

The FDA knows⁶ that "information can at times be confusing to some consumers, and too much information can provide a cacophony of data that can obscure the most important facts". That general truth, coupled with the very limited ability of mass media advertising to effectively communicate anything other than simple, unambiguous concepts, leads DTC advertisers to conclude that perhaps their most important contribution of all is to urge consumers to raise these vital but necessarily more complex issues of risk with their doctors before using any prescription drug. There, in the confines of a doctor's office, a real exchange of relevant information can take place, in depth, specific to all the facts uniquely associated with a given patient and sensitive to both sides of any medical trade-off which may exist. Directing the focus on matters of risk and risk trade-off to the confines of the doctor-patient relationship, is a very real service, one entirely consistent with the realities of the overall communications paradigm. Mass advertising in :30 spots (or :60s or any realistic time frame) cannot begin to supplant the doctor-patient conversation of which I speak here.

So, urging patients to take proper counsel with their doctor on these matters is a truly significant contribution, by itself, to the American public. But DTC advertising does more. The FDA has documented on its Website some of these contributions (see top of the next page):

⁶ this quote taken from the second paragraph of *Empowering Consumers: Improving Health Through Better Information* on the immediately preceding page. In turn, that excerpt was drawn from one of five initiatives established for FDA by Commissioner Mark McClellan to address five critical challenges facing the agency.

Direct-to-Consumer Advertising

The pharmaceutical industry estimates that in 2001 it spent \$2.7 billion on direct-to-consumer (DTC) ads. In 1999 and 2002, the FDA conducted surveys looking at the impact of DTC ads on the doctor-patient relationship. Considerable research suggests that DTC advertising helps people who have untreated conditions get the treatment they need and encourages consumers to get more involved in understanding their health problems, both of which improve health outcomes:

- **81 percent of consumers had seen a DTC ad in the previous 3 months, and of those consumers who asked their doctors about a particular brand-name drug, 88 percent had the condition the drug treats.**
- **About 30 percent of the patients and half the doctors said that the advertising helped them have better patient-doctor discussions about the patient's health.**
- **About 40 percent of the patients and 45 percent of the doctors felt that the ads encouraged information-seeking about potentially serious medical conditions.**

On the downside, many doctors and others believe that DTC ads may not be giving patients an accurate picture of the risks and benefits of the treatments involved:

- **75 percent of the doctors felt that ads made it seem like the drugs would work for everyone or that patients believed the drug to be more efficacious than it actually is.**

Half the doctors felt that the ads created unnecessary anxieties about health, and more than half felt that they were at least a little pressured to prescribe the specific medication.

Let me try to summarize the Status Quo:

DTC advertising, in all ways but one⁷, is doing all that anyone has ever asked of it. It is sensitizing patients to important aspects of their personal health. It is making many Americans aware that they may be experiencing symptoms known to be associated, in some, with a particular disease and that, depending upon the nature of the particular disease, they need to see their doctor. It is making the right people aware that medical treatment for some diseases is now available and that, depending upon a variety of circumstances idiosyncratic to the individual, may offer the promise of a 'cure' or help or yet another form of remediation. And, it is making as clear as possible that a given medication is *never* appropriate for everyone and, **therefore, as perhaps the most important part of the overall message, there is one and only one best next step: and that is.....a conversation with one's doctor.**

⁷ The data also suggest that it would be helpful to do more work in providing to physicians a clearer rationale for DTC advertising. For example, doctors need to understand that DTC advertising, by its very nature, can never do a good job in explaining risk. And, that, as a result, there will always be some, despite our admonition to the contrary, who will believe the advertising 'promised' it would work for them personally.

**DIRECT-TO-CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS: WHAT IT CAN DO AND
WHAT IT SHOULD NOT BE ASKED TO DO**

The discussion so far now offers the opportunity to establish the two most important points of this paper:

- (1) DTC advertising, professionally created and managed, is performing a wonderfully worthwhile service to the cause of this nation's health. It is doing all that can be realistically asked of it. It is making people aware of the symptoms of disease. It is making them aware of advances in medicine and pharmacology. It is informing them that help is now available in particular instances; help that MAY apply to them, depending upon a whole series of factors peculiar to their circumstance and to that of the indicated health condition. And, it is giving them specific reason to go see their doctor in order to establish – in the only ways that such issues *can* be established – whether or not the new medication/treatment etc. is right for them. It is even reminding them of the vital importance of regularly taking their medication and doing so in the precise manner advised by their physician. For many, then, DTC advertising has value beyond measure.

- (2) But, there is one thing that DTC advertising cannot do. It cannot replace the doctor – patient interaction. Nor should it attempt to do so. Nor can it offer to take on responsibility for certain of the tasks central to the very nature of that doctor-patient interaction. The diagnostic interface between doctor and patient is truly unique. Nothing can serve in its place. And, it's certainly true, beyond dispute, that that 'nothing' includes the information contained in any conceivable :30 commercial. Any attempt to deal with the specifics of side-effects, drug interaction and, quite probably, proscribed patient classes through the use of mass media communication, especially broadcast, will fail. Worse still, it will – depending upon the intensity of the attempt – eviscerate the many positive potentialities described in (1), above. To summarize, it is a mistake to expect DTC advertising to replace the doctor. It cannot provide meaningful, detailed warnings. It cannot be the judge of side-effect risk and drug interaction; nor can it communicate with authority on these topics. In most cases it can't even well serve the cause of eliminating classes of potential users⁸. Mass media advertising cannot do these jobs and it should not be asked to do so.

⁸ although it is my view that this issue does have some potential and could usefully be subjected to appropriate empirical work

DTC advertising should be encouraged to be all that it can be. And, it should not be forced to carry out assignments for which it is singularly ill – equipped.

Nevertheless, because the point continues to be raised by some who seem unprepared to be moved by a mountain of experience, logic and data to the contrary, let's deal here – once again – with the twin issues of information overload and risk communication.

First, information overload.

It is *always* tempting to add another copy point to the commercial. There is probably no more common topic in conversations between ad agency and client than this one. None! And not simply with respect to healthcare advertising either. No. This happens right across the board. Everyone wants to pack their commercial with five times more than that which it can realistically accommodate..... and communicate. What could be so seductively enticing as the thought of adding, for 'free', just one more reason for the wavering consumer to buy your brand. You've already done enough to get their attention. And, you've done it so well that they are even listening to what you have to say – at least at this point. Why not just one tiny little addition? Especially when the request is framed like "if you folks are as good as you've often told me you are, surely its not beyond your ability to simply add that 'it comes in green' too?"

The objective problem, of course, is that there is a cost; a cost that has been recognized by advertising professionals forever and ever. And, by the way, the problem is *not* one of simple diminishing returns to scale. If that were the case, we'd never win the argument. Nor, under those circumstances, would it be appropriate to do so. No. The problem is much more severe. The problem is that, ultimately, the message is lost. Not a diminishing part of it. All of it.

And that's what happens when too much is asked of a DTC commercial. All of it is lost.

Now, clearly, I'd be remiss not to express regret that advertising (mass media advertising) can't actually perform these tasks. The need is great. The last five years or so has witnessed a dramatically renewed focus on Healthcare in this country. Centered around a report⁹ from the Institute of Medicine in the year 2000 entitled "To Err is Human: Building a Safer Health System", attention became riveted on such data as:

⁹ L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., Institute of Medicine, 2000, '*To Err is Human: Building a Safer Health System*', Washington D.C., National Academy Press

Between 44,000 and 98,000 Americans die each year as a result of medical error¹⁰

Only 55% of patients in a recent random sample of adults received recommended care, with little difference found between care recommended for prevention, to address acute episodes or to treat chronic conditions¹¹

The lag between the discovery of more effective forms of treatment and their incorporation into routine patient care averages 17 years¹²

18,000 Americans die each year from heart attacks because they did not receive preventative medications, although they were eligible for them¹³

Medical errors kill more people per year than breast cancer, AIDS or motor vehicle accidents¹⁴

These findings (and others) have acted to bring renewed national resolve to many of the public health issues facing our country. Referring once again to the Institute of Medicine, 2000, report *'To Err is Human: Building a Safer Health System'*, the errors are attributable mainly to "adverse drug events, improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint related injuries or death, falls, burns, pressure ulcers and mistaken patient identities". These are not, clearly, the kinds of tragedies that can be notably mitigated by DTC advertising. In a sense reflecting this fact, the report lays out a comprehensive strategy by which government, healthcare providers, industry and consumers can move to reduce preventable medical errors. The report has established a goal of eliminating 50% of the errors over the next five years and calls upon both regulatory and market-based initiatives to accomplish this objective.

A variety of important initiatives has resulted from this work. In an IOM report of March 2001 entitled "Crossing the Quality Chasm: A New Health System for the 21st Century" a call for the commitment of all healthcare constituencies to a national statement of purpose was identified and proposed. More refined, action-oriented and detailed programs have followed, such as the "Priority Areas for National Action: Transforming Healthcare Quality (2003)" by the National Academy of Sciences. While it would be inappropriate for me to suggest any specific contributions from industry to the furtherance of this cause, I can state that those who are involved in healthcare communications should be playing a more formal and active role at the table. This commentary is largely about what DTC advertising *cannot*

¹⁰ Thomas, E.J., Studdert, D.M., Burstin, H.R., Oray, E.J., Zeena, T., Williams, E.J., Howard, K.M., Weiler, P.C. and Brennan, T., 2000, *'Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado'*, Medical Care 38 (3): 261-71 and Thomas, E.J., Studdert, D.M., Newhouse, J.P., Zbar, B.I.W., Howard, K.M., Williams, E.J. and Brennan, T., *'Costs of Medical Injuries in Utah and Colorado'*, Inquiry 36 (3): 255-64

¹¹ McGlynn, E.A., Asch, S.M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., and Kerr, E.A., 2003, *'The Quality of Healthcare Delivered to Adults in the United States'*, (Comment) New England Journal of Medicine 348 (26): 2635-45

¹² Balas, Egon A., 2001, *'Information Systems Can Prevent Errors and Improve Quality'*, (Comment) Journal of the American Medical Informatics Association 8 (4): 398-9

¹³ Chassin, M.R., 1997, *'Assessing Strategies for Quality Improvement'*, Health Aff. (Millwood) 16 (3): 151-61

¹⁴ Institute of Medicine, 2000; Centers for Disease Control and Prevention; National Center for Health Statistics; Preliminary Data for 1998 and 1999

do. BUT, I have a clear view that – because effective communications is at the heart of so many of the issues confronting American healthcare – representation and involvement of healthcare communications professionals seems to me so obvious that I cannot help but ask why more hasn't been done to make it happen. MOST of the topics that need to be addressed have a significant element of communications inherent in their nature. On many occasions, mass media communication will be unavailing. But.....not necessarily all. Plus, healthcare communications professionals have more arrows in their quiver than mass media alone.

Now, let's return to the subject of information overload.

As implied earlier, in advertising circles it's been clear for decades that the phenomenon of which I speak exists and is controlling. If you want advertising to work for you, you must minimize the number of copy points used in a given commercial.

There was much work done on this subject in the 60's and 70's. And, while there were differences in the findings, the general thrust was consistent. A broadcast message had only a finite and quite limited capacity to convey information. Jack Jacoby did a good bit of the seminal work in this area¹⁵. And¹⁶. And¹⁷. Others included Scammon¹⁸ (1977), Malhotra¹⁹ (1982) and Keller & Staelin²⁰ (1987). Most showed a remarkable decline in the ability of the advertisement to communicate effectively as the number of alternatives (or attributes and/or message elements) increased.

More recently, work on the subject of overload has taken a new tack. In my opinion, because the level of substantiation had generally and long since brought about an acceptance of the broad truth involved (that requiring increasing quantities of information to be communicated by a fixed advertising medium/resource – especially broadcast – soon resulted in overall loss of the ability to communicate at all), focus has moved on to other (related) matters. Now, for example, it is the definition of information itself that earns the spotlight. And, of course, it follows immediately and naturally that Claude Shannon's seminal work at Bell Labs in the 40s is the standard used. Shannon was concerned with the quantification

¹⁵ Jacoby, Jacob, Speller, Donald E., and Kohn, Carol A. 'Brand Choice Behavior as a Function of Information Load', Journal of Marketing Research, 11 (February), 63-69 and 'Brand Choice Behavior as a Function of Information Load – Replication and Extension', Journal of Consumer Research, 1 (June), 33-41

¹⁶ Jacoby, Jacob, Hoyer, Wayne D. 'The Comprehension and Miscomprehension of Print Communications: An Investigation of Mass Media Magazines', Lawrence and Erlbaum Associates, Inc., Paperback. (October 1987)

¹⁷ Hoyer, Wayne D., Srivastava, Rajendra K. and Jacoby, Jacob (1984) 'Sources of Miscomprehension in Television Advertising', Journal of Advertising, 13 (2): 17-26

¹⁸ Scammon, Debra L., (1977), 'Information Load and Consumers', Journal of Consumer Research, 4 (December), 148-55

¹⁹ Malhotra, Naresh K., Jain, Arun K. and Lagakos, Stephen W., (1982), 'The Information Overload Controversy: An Alternative Viewpoint', Journal of Marketing 46 (Spring), 27-37

²⁰ Keller, Kevin L. and Staelin, Richard, (1987) 'Effects of Quality and Quantity of Information on Decision Effectiveness', Journal of Consumer Research, 14 (September), 200-213

of information (ordinarily in bits) in order to assign measure to a string of alphanumeric characters as they were communicated sequentially from a 'source' to a 'receiver'. The amount of 'Shannon Information' contained in such a string was posited to be inversely related to the probability of the occurrence of that string. The underlying theory, obviously, is that if a string is certain (has probability measure 1), it contains no information. Alternatively, if it's very complex and very unlikely, the amount of 'information' thereby transmitted is relatively high. The relationship to Boltzman's entropic measure is more than apparent!

So, armed with Shannon's measure, current market researchers are investigating many of the same issues that were studied twenty and thirty years ago – but with this definitional difference in the fundamental dependent variable. Now, Information (I) is defined to be equal to $c\{\log(N)\}$, with c arbitrary and N, the number of possible outcomes²¹. Lurie²² shows that structural measures of information, such as those from information theory, 'offer a way to more effectively predict information overload'. Alternative model specifications suggest that there may be ways to identify and reduce overload by reorganizing the way in which information is communicated. Thus, the author holds out hope that we can do better but..... at some point, the same fundamental restrictions previously identified still are expected to hold true.

Now let's turn briefly to the corresponding state of play with respect to risk communication. The situation in the prescription drug community is, of course, clearly different. Because of the unique circumstances in the pharmaceutical business and, in particular, the opportunity for the expression of views in the political forums of our country, there is pressure for further research in DTC advertising on subjects which, in the world of consumer product communication, are long since sorted out. The common view is that still more work needs to be done!

As noted by Hoek, Gendall, and Feetham²³ (2001), "[T]he debate about the merits of DTC Advertising has not been informed by robust empirical evidence." One major problem faced by policy makers and regulators is the inter-disciplinary perspective required to resolve health communications issues, which draws not only from the fields of medicine and public health, but also includes the fields of behavioral and cognitive science, psychology of personality, consumer research, cultural health beliefs, risk communication research, and many more.

²¹ see [Appendix A](#)

²² Lurie, Nicholas (not yet published in The Journal of Consumer Research), "Decision Making in Information – Rich Environments: The Role of Information Structure"

²³ Hoek, Janet, Gendall, Philip and Feetham, Pam, "Could Less be More? An Analysis of Direct-to-Consumer Advertising of Prescription Medicines", Marketing Bulletin, 2001, 12, Article 1, at page 1, <http://marketing-bulletin.massey.ac.nz/contents1.asp>

One special problem pointed out by Hoek²⁴ et al. relates to a peculiar regulatory paradox, “the ironic situation of advertisements attempting to convey information in a more socially responsible manner [i.e. clear communication] risking prosecution for failure to comply with the relevant legislation [i.e. “fair balance”].”

“It is clear²⁵ from US studies that excessive detail serves only to confuse consumers and inhibits rather than develops their understanding of the promoted brand. However, it is equally clear from FDA pronouncements that they are unwilling to relax further a regulatory structure considered by some to be excessively liberal....Given this unwillingness to relax the information requirements, researchers need to turn their attention to explaining how the designated information could be more effectively and efficiently communicated to consumers.”

There is also felt to be too little empirical evidence on the cognitive aspects of DTC Advertising. Schommer²⁶ et al. (1998) studied the effect of presenting both promotional and risk-related information in the same broadcast advertisement and concluded that such a communications structure “can lead to problems with the viewer’s rote learning [i.e. short term learning] of each type of information.” Since short-term learning is a precursor to longer-term learning and habit-formation, this study suggests that the inclusion of mixed, benefit-risk information in a single TV commercial could have deleterious effects on the communications objective in “certain groups of consumers, who might be more susceptible to specific rote-learning difficulties after viewing a televised advertisement for a prescription drug”.

The Schommer group additionally noted that consumers’ demographic/psychographic backgrounds, access to information, and health-related knowledge/experience also contribute to their ability to comprehend and the willingness to attend to information given in broadcast advertisements.

Hoek et al. also conducted a pilot study²⁷, among university students, of one TV commercial for a vaccine that affords protection against the Hepatitis A and B viruses. Version A of the commercial contained a final screen containing all of the information necessary to meet the regulatory requirements for DTCA in New Zealand (the only other developed country presently permitting such advertising). Version B was an edited screen containing only the details deemed critical by an expert group.

Of one dozen attributes included in the study, respondents who viewed the edited version of the commercial had higher levels of recall on eleven of twelve factors. The authors suggested, however, “that

²⁴ Hoek, Janet, et al, *ibid*, at page 14

²⁵ Hoek, Janet, et al, *ibid*, at page 8

²⁶ Schommer, Jon C., Doucette, William R., Mehta, Bella H., “*Rote Learning after Exposure to a Direct-to-Consumer Television Advertisement for a Prescription Drug*”, *Clinical Therapeutics*/Vol. 20, No. 3. 1998

²⁷ Hoek, Janet, Gendall, Philip and Feetham, Pam, “*Could Less be More? An Analysis of Direct-to-Consumer Advertising of Prescription Medicines*”, *Marketing Bulletin*, 2001, 12, Article 1

clearly²⁸ the scale and nature of this study limits the conclusions that can be drawn.” Nevertheless, they said: “[R]esults from this study suggest that television commercials containing fewer details about prescription medicines convey at least as much information as those that contain more detail. Ironically, promotion of more responsible DTC advertising may require revision (and reduction) of the information conveyed in broadcast advertisements so that the characteristics of the media are more thoughtfully acknowledged in the regulations.”

FDA’s own studies of DTC communications (Morris²⁹ et al 1980s) and recent positing of a “pharmacokinetic theory” of health communications provide an interesting theoretical basis for discussion of an appropriate benefit-risk content model. One of the outstanding recent reviews on the topic of risk communication may be found in: *Cancer Risk Communication: What We Know and What We Need to Learn*, the report of a major, multi-disciplinary conference sponsored by the National Cancer Institute (1999). As a result of this Conference initiative and the subsequent establishment of a \$40 million “Centers of Excellence in Cancer Communications Research” budget, NCI has set a high, “look before you leap” standard for the design, creation, and evaluation of critical health communications.

“[R]isk communication is inherently uncertain,” concludes an NCI passage on message content, “Determining how best to communicate this uncertainty without undermining the effectiveness of the message is an important outstanding question.” It would be unfortunate if policy makers and regulatory officials at FDA neglected this critical observation as they deliberate how (or whether) further regulation of DTC Advertising is needed at the present time.

BUYER BEHAVIOR MODELING

Now, let’s look first at what DTC advertising can (and does) do so well.

In order to accomplish that objective, please allow me turn to a subject that, at first, may appear to be unrelated to the topic at hand. Buyer Behavior Modeling³⁰ goes back many years, at least to the 1961 work of Robert J. Lavidge and Gary A. Steiner, in which they transformed the original AIDA³¹ model into their theory. They labeled it “Hierarchy of Effects”, based on the view that the effect of advertising

²⁸ Hoek, Janet, et al, *ibid*, at page 13

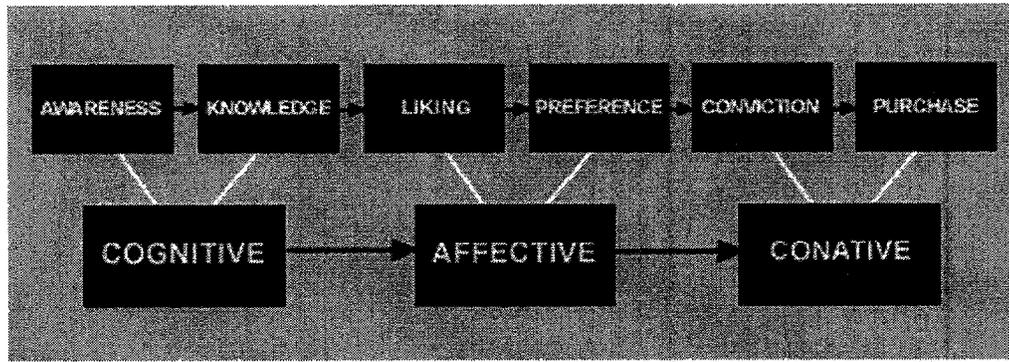
²⁹ Morris, Louis A., Aiken, Kathryn J., “*The Pharmacokinetics of Patient Communications*”, *Drug Information Journal*, Vol. 35, pages 509 – 527, 2001

³⁰ Sometimes also referred to as “Buyer Readiness” or “Buyer Readiness Stage” or, originally, “Hierarchy of Effects” modeling

³¹ AIDA is a mathematical model, from the fifties, based on concepts from psychology that purport to show how people reach decisions. The name AIDA refers to awareness, interest, desire and action, which suggests that when considering making purchases, human thought processes go through those four stages.

was felt by variables *other than* just sales alone. The Lavidge and Steiner model³² posited six (6) steps: awareness, knowledge, liking, preference, conviction and purchase. {Please refer to **FIGURE ONE** below} By “Hierarchy of Effects”, the authors meant that

FIGURE ONE



a target population for a particular brand was to be thought of as partitioned³³ into these six (6) categories or “states” and that the category/”state” chosen for a given individual reflected that individual’s relationship – at that moment in time – with the brand in question. For example, if someone were assigned to ‘liking’, then it could be said of him that he ‘liked’ the brand in question but had not reached a point where he actually preferred that brand above all others. Left out of this partition, of course, is the ‘null state’ or point of origin, which we may think of as the condition: ‘lack of awareness’. Each of the states is largely self-explanatory: (i) unawareness of the existence of the product or service, (ii) awareness of the product or service, (iii) knowledge of what the product has to offer, key aspects of its positioning, (iv) liking, a favorable attitude toward the product, (v) preference, increasing this *affect* until it reaches a point where the product is preferred over all others, (vi) conviction, an intent to purchase coupled with a belief that such an action would be appropriate, a sincerity and urgency of intent and (vii) the actual purchase itself.

Lavidge and Steiner believed that immediate sales shouldn’t be considered as a dominant criterion to measure the effectiveness of advertising because advertising’s effect accrued over a relatively long period of time. The authors further regarded the various steps as “not necessarily equidistant..... Moreover, a potential purchaser sometimes may move up several steps simultaneously”. They also

³² Robert J. Lavidge and Gary A. Steiner, “A Model of Predictive Measurements of Advertising Effectiveness”, *Journal of Marketing* 25 (October 1961)

³³ By ‘partition’ I mean that the population is to be divided into 6 categories in such a way that each individual in the population is assigned to one and only one category. Stated alternatively, every individual is in exactly one box.

believed “that the time taken to move customers to the top of the ladder, which is the purchase, is dependent on their psychological or economic commitment involved in the purchase. For example, the more committed purchases, such as the car purchase, will take consumers longer to go through all seven steps until they actually buy the car while the impulse purchase might occur without consumers going through previous steps”.

But, perhaps the most important innovation offered by the Buyer Behavior modelers was the parallel they drew between the ‘state space’ of behavior³⁴, on the one hand, and a series of marketing communications stages, each of which, in turn, was directly related to the classical psychological model of persuasion. The first two stages, awareness and knowledge, relate to *information and ideas*. The second two steps, liking and preference, have to do with favorable *attitudes or feelings* toward the product and the final two steps, conviction and purchase, relate to *action*, the actual acquisition of the product.

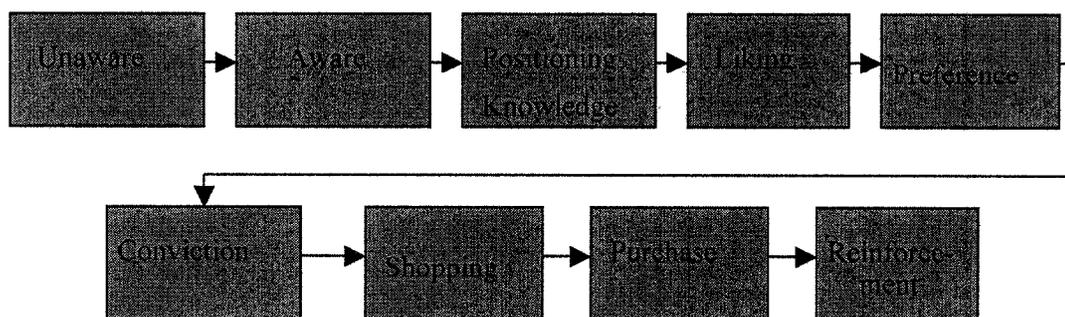
Completing the picture, the first two ‘states’ represent the ‘*cognitive*’ component of this tri-partite psychological model. The communications occurring here involve intellectual, rational, objective data and represent classical learning. The middle two states represent the ‘*affective*’ component of communication, involving ‘*affect*’, feeling, emotion, etc.. And the third and final pair, conviction and purchase represent the ‘*conative*’ or motivational elements of our classic model. Here, we have goal-oriented behavior, an emphasis on action. In sum, the model suggests that as we track brand commitment early in the process, the cognitive/intellectual/rational type of communication will ordinarily dominate the marketing of most goods and services. In the middle, after rational victories have been attained, the field of battle shifts toward *affective* and emotional communication. Then, if and when the potential of the two middle stages has been realized, the communication paradigm shifts one last time. Now, it’s *conative*. Motivational. Action oriented. Serious and compelling.

THE USE OF A BUYER BEHAVIOR MODEL FOR AUTOMOBILES

As already suggested, Buyer Behavior models have been used in a wide variety of environments. In **FIGURE TWO**, at the top of the next page, can be found the schematic that was used to model our work on behalf of a major automobile client. Clearly, the early stages of this modeling effort are indistinguishable from the Lavidge and Steiner model. The last three, however, representing the marketplace in a largely retail context, are quite different. As before, each of these ‘states’ is carefully defined in such a way that the meaning is (nearly!) unambiguous AND that the resulting state space is a partition.

³⁴ In other words the various partitioned states, liking, preference etc.

FIGURE TWO



At this point you might fairly be asking yourself "Why in the world, in a Commentary on issues of vital importance to the Healthcare of all Americans, does Pringle insist on now telling me about his automobile modeling experiences?" The answer is that I have not chosen an automobile example to speak to issues of public health communication without a **very** strong reason for deciding to do so. There **is** a good reason. I simply ask that you bear with me through these next two pages to learn what it is. In fact, the point to be made here may be the single most important point of all that I wish to make in this paper.

Now, please think of the marketplace for automobiles and then consider a marketing experiment in which the population of the target customers for our client's automobile is sampled. Assume further that every sample respondent drawn is assigned – appropriately – to the state that best describes his/her involvement in this marketing effort. For example, let's assume that a particular respondent likes our brand but doesn't prefer it. In that case, s/he is assigned to the 'state' liking. Assume further that the total sample is large enough so that we are able to establish a usable sample of customers in each of the nine 'states'. We are then able to examine, consecutive pair by consecutive pair, the specifics of our overall impact on the market. We can, as an example, ascertain how many people we have made aware and, from them, what proportion have we converted to become "positioning knowledge" state members. We may even begin to learn what it is about some people that makes it easier to convert them, with a view toward concentrating our marketing and communications efforts more intensely on those people who have that set of characteristics.

Suppose, for example, that we were to discover that we had achieved quite good performance, step by step, through the state of 'liking' but somehow failed to convert our 'likers' into 'preferrers'. That – if true – would signal a very serious problem. Why? Because our model, based as it is on historic performance in many other cases, would be telling us that a much higher level of 'preference' should be

flowing from our levels of 'liking'. To NOT observe the expected performance would strongly suggest that we had somehow managed to create 'affect' (liking) on grounds quite irrelevant to those used by our customers in becoming 'preferrers'. That, if true, would be a major marketing disaster since it would have implied that we had unwittingly communicated 'affect' and, quite probably, rational data too which was ultimately unrelated to preference formation and hence, ultimately, to sales.

With these eight (sub) data-bases, in other words, we are able to better understand how to move our customers, step by step, from left to right, further and further toward the 'state' of purchase. For each of the sub-models, we can ordinarily determine from research just exactly what type of message can be brought to our customers in order to maximally impel them through this sequential/hierarchical process. It is, in fact, very rare that a worthy use of advertising will fail to materialize in this context. In the early stages (of the hierarchy), the advertising message will be performance-oriented, rational, objective. As the potential customer moves further through the hierarchy, the advertising will change accordingly. Next, 'affective' messages will predominate. The beauty and power of the car and the way driving it makes you feel. User imagery – how one expects to be regarded by others who see one drive this car etc..

Now, we come to it!

Slowly, gradually at first, a curious and important thing begins to happen. As we move from left to right, further and further along the hierarchy – indeed, as we succeed - the sample sizes grow smaller and smaller. Necessarily! And, it gradually becomes less and less efficient to use mass advertising as our instrument of communication because the target audiences are diminishing in size accordingly **AND** because what we can tell them through mass advertising becomes less and less likely to contain the answers to their increasingly more specific & targeted questions. Gradually, the *kinds* of messages that optimally impel the customer further to the right are becoming more difficult to manage. For one thing, each customer suddenly seems to have different needs. The ability to interact becomes increasingly important. It's no longer sufficient to send out one simple message and have it fit all – no matter *how* compelling it may be on average. The stakes are getting higher. The need for spontaneity and individual attention is growing. The inability of mass communication techniques to deal with all the increasing complexity becomes manifest. And suddenly, at the 'right hand end of the schematic' it's really no longer a world in which mass advertising is very useful. Now, the personal communications elements found in a sales force or a service department become central, or Websites that permit a degree of individualized attention or experts responding to specific individual, complicated questions.

At the *left* end of the schematic, it's all advertising. But, near the *right* end, the persuasive power to complete the transaction is all over. Advertising really can't contribute in the same way any longer. That's what happens with most consumer durables and high-ticket items and, I believe,

that's the way it is with DTC pharmaceutical advertising as well!

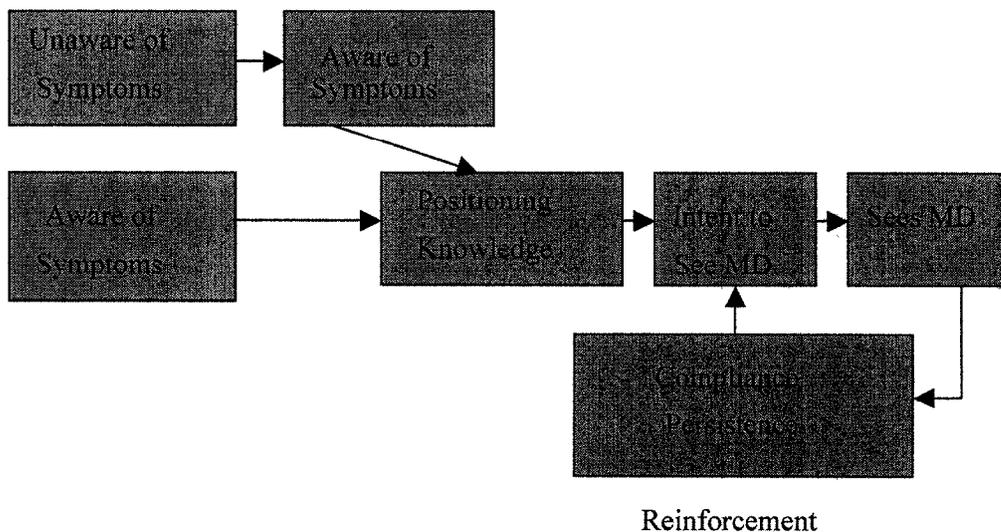
At some point, mass advertising just can't do the required job. We need, therefore, appropriate research to sort these communications issues out before new policy or regulations are issued.

A BUYER BEHAVIOR MODEL FOR DIRECT TO CONSUMER PHARMACEUTICAL ADVERTISING

My efforts to find examples in which this same logic has been applied to a pharmaceutical purchase, based on DTC advertising, have not been rewarded. Despite my best efforts to obtain existing applications, I have been unable to find pharmaceutical modeling work of this sort, even though, as stated, it's long and well-established in packaged goods and other product categories. Clearly, I'm unable to confirm that it has *not* been done. As several people I've contacted for help have told me: there exists a very tight layer of competitive security around many pharmaceutical firms. So, it's possible that this type of work has been done and is just under wraps. In any event, modeling work of precisely this type is needed – whether or not others have actually done so.

Therefore, I should like to *posit* such a model for DTC Pharmaceutical advertising in this commentary. See **FIGURE THREE**

FIGURE THREE
A BUYER BEHAVIORAL MODEL OF DTC PHARMACEUTICAL ADVERTISING



The first point to make is that there are two paths through the schematic, differing only in the fact that on the first of these paths, the target audience is unaware that s/he has the relevant symptoms³⁵. I have maintained the distinction to permit the possible role of DTC advertising as a 'sensitizer' to the symptoms themselves. On that path, therefore, one begins with a target customer 'state' (call it <U>), all the members of which are unaware of any symptoms, at least insofar as they might relate to a given disease. For that type of customer/patient, clearly, the first step is to make them aware that some physical manifestations (of which the patient may not yet be wholly or even partially conscious) represent potential symptoms of disease, in fact a particular disease. It becomes the job of DTC advertising to help make them aware that they have those symptoms. Once that awareness is generated, the member of <U> moves to the next 'state' in which all members are aware that they may (or probably) have the symptoms of some disease and may even know its name. Call this 'state' <A>.

The next 'state' is 'positioning knowledge', denoted here as <PK>. To become a member of this 'state, one must: (i) understand, by name, the general nature of a particular disease, (ii) recognize that a medicine has been created to fight that disease and that, therefore, help MAY be available and (iii) learn the name of that medication. The next 'state' is "Intent to see MD" and is denoted <I>, for intent. To be included in this state, it is necessary for the member to (i) acknowledge that he or she may have the disease and (ii) recognize that the only intelligent next step is to make an appointment with his or her doctor in order to discuss the issue. The next 'state', clearly, is simply the execution of that intent; call it <MD>. A key point is that the schematic doesn't simply end when the patient has seen his or her doctor about the topic(s) raised in the advertising. There remains one final important service for DTC advertising to perform, a service referred to as Reinforcement³⁶ in Figure Three and denoted <R>. As suggested in the Figure, there are two components of <R>. The first of these is 'compliance', which relates to the use of the medications in question in precisely the way determined by the respective physician. The second is 'persistence' which – as the name implies – typically involves reminder copy to help insure recall of instructions, as required, over time.

Viewed in this light, advertising may be seen as having a potentially key role in: (i) moving potential patients from (<U>) to (<A>), (ii) from (<A>) to (<PK>), (iii) from (<PK>) to (<I>), (iv) from (<I>) to

³⁵ for example, Type 2 diabetes is a gradual syndrome with the signs of diabetes developing over years. Although the person may experience excessive urination and thirst, there may be no other apparent diabetic signs. Weight loss and hunger may go unnoticed. For this reason, annual screening for the disease after age 45 is a good idea, especially for anyone who is in a high-risk category. As Type 2 diabetes progresses, some diabetes symptoms may become apparent: fatigue and/or nausea, frequent urination, excessive thirst, weight loss, blurred vision, frequent infections and slow healing of wounds or sores, blood pressure consistently at or above 140/90, HDL cholesterol less than 35 mg/dL or triglycerides greater than 250 mg/dL.

³⁶ with the word 'final' obviously referring only to DTC advertising and in no way intended to exclude certain other marketing efforts like detailing and/or, perhaps, an advertising campaign directed at the relevant class of physicians.

<MD> as well as (v) from (<MD>) to (<R>) In the first of these five cases, the role of advertising is to make the consumer aware/conscious of the symptoms and to urge that consumer to somehow explicitly acknowledge that s/he has (or may have) those symptoms. At this stage, the member of (<A>) may or may not know much at all about the disease of which these symptoms are possible manifestations. In the second of the three cases, moving from (<A>) to (<PK>), the role of advertising is to make clear that, somehow, medical/pharmaceutical remediation of those symptoms is possible! A member of (<PK>) will (i) understand by name the general nature of a particular disease, (ii) recognize that a medicine has been created to fight that disease and (iii) know the name of that medication. In the third stage, the move from (<PK>) to (<I>), the new member of (<I>) will recognize that (i) he or she may have the disease and (ii) recognize that the only intelligent next step is to make an appointment with his or her doctor in order to discuss the issue, the symptoms, the newly created medication etc. Then comes the move from <I> to <MD>, as he or she executes this intent. Lastly, we have what may be regarded as a more or less perpetual feedback loop in which the patient is reminded of his or her responsibilities with respect to the medical course chosen by his or her doctor. In this loop, there is a cycle from (<I>) to (<MD>) to (<R>) to (<I>) to (<MD>) to (<R>) ad infinitum – unless and until the doctor chooses an alternative treatment.

Unlike some of the instances we have discussed earlier, in which advertising was asked to perform a multitude of tasks for which it was singularly ill-equipped, here we have a superb example of the opposite! These are the kind of missions for which mass media advertising was created. Let's recall what we identified earlier as the hallmark of intelligent professional advertising. Two steps.....

- (i) define the precise individuals we expect to address with our advertising

In this case, one could draw on medical data and create the most parsimonious behavioral description of a class of people representing at least 80% of all those who suffer from the indicated disease. In other words, using behavioral variables describe the characteristics of the smallest group of people which nevertheless contains at least 80% of all those who have this disease. Call this the **Target Group <TG>**,

- (ii) state with explicit and appropriate detail *what it is we want to have left in the mind of each and every member of <TG> after the advertising has completed its act of communication.*

- (i) (<U>) to (<A>), sensitize and otherwise make members of (<U>)_aware that certain physical symptoms may indicate the presence of a particular disease or other condition inconsistent with a state of good health and.....

- (ii) (<A>) to (<PK>), simultaneously, together with achieving the awareness described in (i), give members of (<A>) the clear understanding that medical advances and, in particular, medication, may now be available from one's physician that has the potential to somehow cure or remediate the condition under discussion. To become members of (<PK>), each will (i) understand by name the general nature of a particular disease, (ii) recognize that a medication has been created to fight that disease and (iii) know the name of that medication and.....
- (iii) (<PK>) to (<I>), convince members of (<PK>) that a timely visit with his or her doctor is the **only possible way** forward both to determine a) whether the treatment/medication described is appropriate and likely to be medically effective for that particular patient – indeed whether the patient actually has that disease as well as b) whether (or not) there may exist significant offsetting risks³⁷ that the treatment could cause some harm to the patient
- (iv) <I> to <MD>, do it, now!
- (v) (<I>) to (<MD>) to (<R>) to (<I>) to (<MD>) to (<R>)....., continually reinforce the doctor's instructions with respect to the selected medical course by providing information about the correct use of the drug (compliance) as well as reminder copy over time to insure faithful adherence to the regimen prescribed (persistence)

That's it. That is what advertising SHOULD do. It should, in alignment with well known standards of how one creates effective advertising: (i) deliver the messages identified above, (ii) deliver them in language and format that is simple, uncluttered and easy enough for the overwhelming majority of the target to understand and (iii) should avoid distractions and desiderata incongruent with its stated purpose. Loading a commercial message with other materials, words, objectives, constraints, copy points and worthy causes can only result in confusion, obfuscation and, ultimately, failure to satisfy the truly worthy purpose of this kind of advertising.

³⁷ side effects, proscribed classes, interactive effects

WHAT DTC ADVERTISING REALLY CANNOT DO, NO MATTER HOW MUCH WE MIGHT WISH IT COULD

As we've just seen, DTC advertising can do a lot. It has and can (and is!) delivering a truly priceless service to many American families – even as we speak.

But, and as stated earlier in this paper, there is one thing that DTC advertising cannot do. It cannot replace the doctor/patient interface. Why do I focus on that fact? Because none of the three 'risk information types' thought, by some, to be communicable through mass media advertising, has much meaning unless and until informed by an MD's judgment, a judgment based, in turn, on knowing certain facts about a particular patient.

Let's take side effects. No drug is without side effects. Stated alternatively, all drugs have side effects. A zero-risk lifestyle strategy would have us all avoiding all drugs. This is fine, if we 'need' no drugs³⁸. But, what if we do? If that's the case, then our 'need' somehow promises an offsetting 'good'. We're not going to purchase a drug and take a risk with our health without some information that an offsetting positive exists and will become ours. And, now, we have a trade-off. We get a 'good' for taking the drug, yet run the risk of 'bad', for the same reason. How can we decide which is more important; more risky. This is a trade-off and, undoubtedly, without even getting into the relative chemistries involved, very complex. But that's the problem. That's the dilemma with which we (and the FDA) must deal. There are immense scientific and medical complexities involved here. Co-mingled with them are the many problematic aspects involved in assessing personal attitudes toward risk³⁹. Taken simultaneously, this is really not a matter that can be advanced by information provided through mass media advertising.

The same dilemma exists for drug interactions and for proscribed classes of drugs, though in many cases with even *heightened* risks and *bigger* stakes.

Any serious examination of these issues requires expertise well beyond the capabilities of all but the most well informed layperson and, in most cases, it is likely that there is no substitute for extremely rare and specialized expertise. And, in any event, NOT an expertise we're going to obtain from having casually heard part of a 30 second commercial the other night on the Letterman show.

³⁸ it's not entirely clear who's judgment is relevant here. Is it we who decide we need no drugs? Or, perhaps, does it involve others who are helped along by having our best interest at heart. We'll ignore, for the moment, how they are able to make that determination

³⁹ Luce, R. Duncan and Raiffa, Howard, *Games and Decisions*, John Wiley and Sons, 1957, in which the authors describe the state of play, at the time, of both Game and Utility Function Theory, both areas of intellectual endeavor tracing their roots in mathematics back only 25 years (in 1957) to von Neumann (and, less dramatically, to Borel in France). Of particular interest here are the complexities required by those making decisions based on maximized utility and, in particular, the development of a utility based on, inter alia, von Neumann's axioms. Even that brings one only marginally closer to a relevant Healthcare solution because we still require an estimation of an appropriate probability density as well as the resolution of multi-person conflict of interest problems.

So, at just the outset of this discussion, one aspect of any sensible conclusion must be that being exposed, *en passant*, to a commercial for a medication which includes a warning, some kind of contra-indication, a potential negative of some sort,that is NOT a source of information most of us can rely on in what is truly a life and death matter. “No thanks. I think I’ll go see my doctor. He knows me. He knows the rest of my medications. He stays current with the literature and he, I’m convinced, has my best interest at heart.” **NOTHING ONE CAN LEARN FROM A TV COMMERCIAL AT THAT STAGE – NOTHING – CAN IN ANY WAY LEGITIMATELY BE USED TO CONTRADICT WHAT ONE CAN LEARN FROM ONE’S DOCTOR. SO.....NOTHING ELSE MATTERS AT THAT STAGE. SEE YOUR DOCTOR. PERIOD.**

Where and how, we should all ask, does DTC advertising fit into that real life scenario near the right hand extremity of the schematic we’ve just analyzed? The only correct answer is: *it doesn’t*. It’s simply unreasonable on the face of it, mandates and legislation notwithstanding.

Communication of Risk Information

DTC advertising has a truly noble purpose, a purpose that is wholly compatible with its nature. We have just examined that purpose in detail and outlined how it might be implemented.

Communication of risk details (side-effects, proscribed classes, interactive effects) has no place in that message. To summarize, there are three reasons for this:

- (1) Communication of risk details is **not needed** to accomplish the worthy public health objectives of DTC advertising (as those objectives **should** be and as they have been detailed earlier in this paper)
- (2) The regulatory mandate notwithstanding, adequate communication of risk details **is highly unlikely to be accomplished** by DTC advertising
 - i. Attempts to do so necessarily violate basic principles of science, medicine and ethics.
 - ii. Even though mass media advertising may be quite well suited to creating general awareness of the overall risk of Rx communications, it simply is *not* suited to accomplish the stated objective of rendering in its objects the desired levels of detailed and complex understanding.

- iii. Attempts to communicate detailed risk information in DTC advertising despite (1) and (2) not only are highly likely to **result in the failure to do so but also are likely to damage the ability of that same advertising to accomplish its real mission**

Let's now conclude our overall examination of DTC advertising by examining each of these points in somewhat greater detail.

First: "communication of risk details is **not needed** to accomplish the worthy public health objectives of DTC advertising". This one is easy. Please recall that I identified on the second page of this paper that good advertising requires an up-front statement which describes: (a) *who we are going to be talking to/with* and (b) *what, precisely, the intended advertising is supposed to accomplish*. The first of these two requirements is satisfied by:

- (a) drawing on available medical data and creating the 'most parsimonious' behavioral description of a class of people representing at least 80% of all those who suffer from the indicated disease. In other words, the task is to use behavioral variables in a discriminant function framework to find the smallest group which nevertheless includes 80% or more of all those known to have this disease and, having done so, call it the Target Group <TG> and observe that its size is denoted as N_1 . There are certainly many other ways to perform this requirement but none that I prefer nearly so much⁴⁰

And the second by:

- (b) stating with explicit and appropriate detail *what it is we want to have left in the mind of each and every member of <TG> after the advertising has completed its act of communication*. You'll recall that we required only the following⁴¹:

⁴⁰ The end result, then, is to create a Target Group <TG> for advertising purposes which contains at least 80% of those in the country who suffer from the given disease AND in which a random draw of individual x from that <TG> will yield someone having the disease with probability $P\{D | x \in \langle TG \rangle\}$ bounded by $.8\rho N/N_1$ and 1, where, as a hypothetical, illustrative example, that N = population size = 100,000,000, ρ = the proportion of the population which has the disease = .015 and N_1 = 2 million, turns out to be the size of <TG> (i.e. we can't find a way to make N_1 any smaller through the use of behavioral/independent variables, while still including 80% or more of those who have the disease). Then, $\rho N = 1,500,000$ is the total number who have the disease and $.8\rho N = 1,200,000$ is the minimum number of ill in <TG>. From that and a little algebra, it follows that $.8\rho N/N_1 < P\{D | x \in \langle TG \rangle\} < 1$ and if N_1 does turn out to be 2,000,000, then we know that the probability that a random person drawn from <TG> will have the disease must be bounded by (1.2/2) on the low side and 1.0 on the high. Thus, $.6 < P\{D | x \in \langle TG \rangle\} < 1$, and the true probability of diseased individuals in this group is at least .6.

⁴¹ for the record, omitted from this list is the set of tasks I grouped together under the rubric of 'Reinforcement' in Figure Three and denoted <R>. As suggested in that Figure, there are two components of <R>. The first of these is

- i. (<U>) to (<A>), sensitize and otherwise make members of (<U>) aware that certain physical symptoms may indicate the presence of a particular disease or other condition inconsistent with a state of good health and.....
- ii. (<A>) to (<PK>), simultaneously, together with achieving the awareness described in (i), give members of (<A>) the clear understanding that medical advances and, in particular, medication, may now be available from one's physician that has the potential to somehow cure or remediate the condition under discussion. To become members of (<PK>), each will (i) understand by name the general nature of a particular disease, (ii) recognize that a medicine has been created to fight that disease and (iii) know the name of that medication and.....
- iii. (<PK>) to (<I>), convince members of (<PK>) that a timely visit with his or her doctor is the **only possible way** forward both to determine a) whether the treatment/medication described is appropriate and likely to be medically effective for that particular patient as well as b) whether (or not) there may exist significant offsetting risks⁴² that the treatment could cause some harm to the patient

Thus, communication of risk details is **not needed** to accomplish the objectives of DTC advertising. The advertising must make clear only that, as with any medication, there will be risks for some and that only a visit with one's doctor can intelligently assess the likelihood, nature and severity of those risks.

Turning now to the second of the three reasons that communication of risk details (side-effects, proscribed classes, interactive effects) has no place in DTC advertising, recall my assertion that:

Adequate communication of risk details, despite the regulatory mandate, **is highly unlikely to be accomplished** by DTC advertising

'compliance', which relates to the use of the medications in the way determined by a physician and the second is 'persistence' which is intended to help insure recall of instructions, as required, over time. I chose to ignore this section here because it is logically orthogonal to the activities which some see as contending for attention with the communication of risk detail.

⁴² side-effects, proscribed classes, interactive effects

- iv. Attempts to do so necessarily violate basic principles of science, medicine and ethics and
- v. Even though mass media advertising may be quite well suited to creating general awareness of the overall risk of Rx communications, it simply is *not* suited to accomplish the stated objective of rendering in its objects the desired levels of detailed and complex understanding.

Let's concern ourselves here first with the violation of key ethical, scientific and practical principles. Imagine someone ill but unaware of the terrible hold that illness has on her. She is vaguely aware of some minor changes in her body but, of course, has no training to allow her to conclude that real danger exists. Unknown to her, a pharmaceutical company has created a new drug, a drug that is the answer to the prayers she would have made had she known something was wrong. FDA trials confirm the miracle that this drug represents. She is, four times, in front of a television, viewing with ordinary alertness when DTC commercials on behalf of this drug are aired. She ignores all four because she found the commercial confusing and apparently 'not for her'.

This is what real people do. They respond to executional cues that signal them to pay attention – or not. The commercial in question contained scary and confusing language about possible side effects of this medication. It went into great detail about whom this drug was NOT for. The message that a life-saving medication had been designed, created and manufactured specifically for her was lost! As was, in another fifteen months, her life.

This example is hypothetical. But, surely an analogous scenario happens again and again. People are dying, suffering from silent symptoms or needlessly toughing out yet other debilitating effects and will continue to do so because we failed to alert them that medications are available to treat their precise need. Or, because we failed to help them understand that a recent and peculiar set of changes in their body could be significant and should be checked. These omissions are real and they involve life and death situations as well as the perpetuation of chronic disease. Knowing this communications deficiency to be real and failing to act on our knowledge is irresponsible. Worse, it is fundamentally and deeply unethical.

Knowing how people react and then failing to take that knowledge into account in the development of marketing plans and advertising is wrong. A relatively minor example in the non-marketing portion of the world of medicine deals with measurement, in which a particular error is so

common it's earned its own name: *white coat hypertension*⁴³. The same applies to measurements that are delayed in time. Retrospective recall is both biased and unreliable⁴⁴. The key point, though, concerns the actual normative behavior chosen upon learning of this bias and these inaccuracies. It's one thing to enhance available knowledge in such disciplines as the behavioral and cognitive sciences, measurement theory, statistical and research design, sampling, psychometrics, clinical study design and so on. It's quite another to then ignore the obvious implications of the truth they reveal. That is immoral.

There really cannot be a more clear-cut example of this kind of immorality than the failure to recognize and act on known facts from advertising research. And, the facts show that mass media advertising is simply not able to execute the tasks demanded of it by those who insist that side-effects, proscribed classes, and interactive effects be communicated to ordinary citizens in 30 second commercials. My own twenty-five years in advertising, almost ten of them running the biggest and best advertising agency research department in the business, tells me this. Hundreds of conversations with the very best creative minds and thousands of copy tests..... tell me this. Probably 80% of everything that has ever been learned about advertising was learned originally by the pioneering direct response people; foremost among them, John Caples⁴⁵. John was my friend and John taught me this. Scott Armstrong⁴⁶, of The Wharton School, has created an expert system called ESAP that, based on key ratings of commercials, shows which features of an advertisement reduce its effectiveness as well as those that improve it. It is entirely clear to me that the commercials of which I speak could not possibly score well on ESAP. Then, there is the issue of money. The data from packaged goods marketing show that it requires large amounts of money to sell only one simple line, no matter how euphonious, salient and cognitively pleasing it may be. The advertising proposed by the proponents of these 'warnings' is *far* more complicated and *far* less likely to achieve any meaningful levels of even comprehension, let alone recall and playback. On anything like the scale they describe, I promise you; it simply cannot be done. I've built mathematical models⁴⁷ to predict the cumulative awareness (aided and not) of a wide variety of messages and have a very well-founded sense of what is possible and what not. This is not.

The net of this part of the discussion is simple: mass media advertising cannot conceivably be expected to inform lay people responsibly about the details of possible side-effects, proscribed classes of concomitant therapies and interactive effects of a given drug. This job belongs to the physician.

⁴³ referring, obviously, to the well – known tendency for patients to have elevated blood pressure when the reading is taken by 'white coated' medical personnel in clinical situations.

⁴⁴ Shiffman, Saul PhD and Hufford, Michael, PhD, Inividata, Inc., "*The Scientific Principles Underlying Patient Research*", White Paper, 2001

⁴⁵ that's what David Ogilvy said about John, too

⁴⁶ J. Scott Armstrong, "*Expert System for Advertising Persuasiveness: Effectiveness of Strategy, Attention and Persuasion*", Working Paper (rough draft), The Wharton School, University of Pennsylvania, 2001

⁴⁷ the first for Sheraton Hotels, advertising their 800-325-3535 line many years ago

Turning finally now to the third of the three reasons that communication of risk details has no place in DTC advertising, consider the almost ironic fact that attempts to use DTC advertising to communicate risk is likely to cause major damage even to the ability of that advertising to accomplish its real and primary mission. Translated, that means that not only will these attempts fail to provide any detailed understanding of the warnings sought by some advocates, but the many virtues of DTC advertising will be lost in the debris of this failed effort!

A good bit of this effect, in my view, redounds simply from the cost of the time robbed from the main message. But, the whole impact is very much a function too of the executional treatment used. Particularly, if the two types of messages are interlaced, the damage will be greater. As mentioned elsewhere in this paper, a key factor is frequently a series of attention-getting cues that induce the viewer to conclude, somehow, that 'this message is intended for me; I'd better pay attention for a moment'. If that original attempt to arrest the viewer's interest is somehow aborted, the entire message is lost. If the communication results in confusion, that too will destroy any nascent reception. As a result, the very best that can occur is a message the effect of which is diminished (in proportion, by the way, to the square root of the time wasted). In other words, if half a :30 is spent on the various warnings, the delivered message, at best, will be at about 70% of what it could have been. At worst, useless.

Much of what I have written in this commentary is based upon my academic training and my lifetime of experience in advertising. (My curriculum vitae appears at the opening of my commentary.) In executing my responsibilities in the preparation of this paper, I contacted many of my colleagues from the world of advertising research, specifically asking to be pointed in the direction of good work on information overload. Nothing of quality and direct relevance⁴⁸ was forthcoming from this effort. Indeed, I was told several times that the 'sense' was that this matter was so well settled for consumer products advertisers that, in the opinion of the people with whom I spoke, no meaningful research was being conducted on that topic any longer.

In summary, my conclusion is easily expressed. DTC advertising, as it should be executed and as it is described in this paper, is a genuine benefaction by the pharmaceutical industry, a gift of enormous value to the people of this land. Any step taken to limit this advertising by requiring it to serve functions for which it is singularly ill-equipped is a monumental disservice to the health and well-being of Americans. And, a real wasted opportunity.

⁴⁸ One article (about to be published in the Journal of Consumer Research and referenced previously) entitled "Decision Making in Information Rich Environments: The Role of Information Structure" by Nicholas H. Lurie represented good work and was helpful in several respects but still sufficiently far removed from the case of DTC advertising at hand to provide any generalizable answers to the questions raised here

The need for accessible risk information of all the types discussed in this paper is abundantly clear. I have no argument at all with that. The opposition I've expressed to some of the current practice is in no way intended to gainsay this. But, it is of critical importance how (starting with the choice of channel) that information is to be communicated. The task can be done well and should be done well. But, it will not be done well with mass media advertising.

Appendix A

Since this commentary has been all about the communication of information, how to do it and how not, it may be of more than passing interest to consider for a moment what information actually is. Much of what is either ‘wrong’ or of sub-optimal utility in the literature on the subject matter reviewed here redounds to a profound inconsistency and lack of rigor in our collective efforts to achieve inferential power from this jointly created body of work. And that, in turn, at least partially, reflects a rather intellectually cavalier regard for a real understanding of the dependent variable in these models. We count, historically, whatever we are offered. To be sure, when opportunities for contrast and comparison are lost, more than an intellectual loss has been registered – for this is healthcare and the collective wisdom is the only enduring wisdom.

Lurie takes a worthwhile step in the right direction when he describes Information as the joint probability measure of products (P) and attributes (A) by.....

$$I\{\underline{P}, \underline{A}\} = - \sum_i \sum_j \Phi(p_i, a_j) \log \Phi(p_i, a_j).$$

Suppose, to keep things simple, we concern ourselves only with one dimension, Attributes. Now we have $I\{A\} = - \sum_i \Phi(a_i) \log \Phi(a_i)$. Suppose further that we have 16 available computer monitors, 8 of which are small, 4 medium and 4 large, in size. Then, the probability of SMALL is $\frac{1}{2}$, that of medium is $\frac{1}{4}$ and that of large is also $\frac{1}{4}$.

Now, regard ‘information’ as the average # of ‘yes’ or ‘no’ questions you have to ask to find out whether – in drawing at random from these 16 monitors – you have a small, medium or large one. One reasonable approach would be to ask “Is the monitor small?” If you get back a ‘yes’, you are done and you have used one ‘bit’. If you get back a ‘no’, you have to ask another question - for example, “Ok, is it large?” Now, you will get back a ‘no’ if it’s medium and ‘yes’ if it’s large. So, you are done. How did you do on average? Half the time, you asked one question. The other half the time you used two questions. Therefore, on average, you used 1.5 bits of information to get your answer.

How does this square with Shannon’s formulation? Because we are dealing with ‘yes’ and ‘no’, $c = 2$ (the base of the log is two). This is essentially arbitrary and we could formulate the problem to use base 10 or any other base. Using base 2 and staying with the bit as elemental unit, we have.....

$$I\{A\} = - \sum_i \Phi(a_i) \log \Phi(a_i) = -\{ .5 (-1) + .25 (-2) + .25 (-2) \} = -\{ -.5 - .5 - .5 \} = 1.5 \text{ bits,}$$

where the .5, .25 and .25 are the 3 probabilities respectively and the -1, -2 and -2 are the numbers, the log to the base 2 of which are .5, .25 and .25!!!!. If that is unclear, simply note – as an example – that

$$\log_2 .25 = -2, \text{ since } 2^{-2} = 1/(2^2) = \frac{1}{4} = .25$$

Thus, common sense squares with the Shannon formula and now, in current research, provides an operating definition for the previously inchoate term 'information'.

Lurie's use of Shannon's work is natural and, given the state of the literature, entirely appropriate. It should not, however, stop here. A common standard point of reference for healthcare communications research really does need to be developed and agreed upon.

Comment in the Matter of: Consumer Directed Promotion Docket No. 2003N-0344

Part Two

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Aligning Risk Communication Mandates with Practical Communication Challenges

We believe that the evidentiary record to date³ clearly shows that DTCA has been demonstrated to produce significant public health benefits without causing previously hypothesized public health harms. Given the data in the record, it is our contention that the FDA public record strongly supports a decision to continue present DTCA policy of supplying risk information on a medium-by-medium basis, in ways that are limited to avoid information overload or counterproductive rejection of physician's instructions, at the same time alerting patients and the public as to the serious nature of prescription drug medications.

The Coalition further contends that certain new laws designed to protect patient privacy may, in fact, have the unintended consequence of restricting specific risk communications to patients, preventing for example, personalized, tailored communications of significant patient benefit. We believe that FDA is in a unique position to incorporate such concerns into a new, overarching perspective as it considers revisions to its own regulations, as well as to bring such matters to the attention of the Congress to effect beneficial reforms in patient communications.

One of the more far reaching risk communications initiatives of recent times is the AHRQ Certs program.⁴ A recent report⁵ of a gathering of fifty experts at the CERTs Risk Communication Workshop concluded:

- 1) that “*current methods used by governments and industry to the risks of drugs clearly are inadequate,*” and
- 2) that “*the consensus was that a significant investment in research was needed to quantify these issues and to inform policy makers about approaches that could solve the identified problems.*”

One workshop subcommittee has begun development of a general conceptual model that will “*capture the complexity of communicating the risks of drugs and devices After developing a general model, a few case studies . . . will be used to test the accuracy and completeness of the general model. . . . Once a general model of risk communication is developed and adopted, it can be augmented with appropriate data to estimate quantitative and qualitative effects.*”

These initiatives are at their earliest stages. It is the Coalition’s contention that any major changes to existing DTCA or other risk communication guidelines at this time would be extremely premature unless they are couched in terms of “demonstration projects” or “experiments” rather than a regulatory mandate. While initiation of a few risk communication projects has begun, it is the Coalition’s belief that the current evidence-based record remains too insubstantial to support isolated calls from critics for major revisions of FDA’s existing DTCA policy.

In the matter of new DTCA regulation, there is an inherent conflict between FDA’s regulatory mandate to provide *both* risk and benefit information in *each* communication and what is known about the complexity and difficulty of communicating risk information from the social and other sciences. Non-personal communications – including those made through the use

of new, interactive media -- are not without some limitations. Nor should the role of the healthcare professional (HCP) as a “learned intermediary” be overlooked; not only are HCPs an essential factor in the pharmaceutical communications process, but also as a factor in the avoidance of “deception by omission” claims.

It is the Coalition’s further contention that the effectiveness of any risk communication process must be evaluated in its totality, and not in a piecemeal, medium by medium fashion. Effective communication of complex topics to the public through the mass media requires the expert calibration of a mix of media and frequency of exposure that may not be predictable in advance.

Several recent initiatives exist beyond those mentioned above, to inform FDA in its task. For example, in response to the 1998 publication of verbal descriptor guidelines by the European Commission (EC), Berry DC et al (2003)⁶ evaluated the utility of the EC descriptors in a series of seven studies that evaluated hypothetical and real prescription drugs as well as OTC medications, and that included members of the general public, patients, and hospital doctors. The Berry group also reviewed two other recently advocated risk scales, including that of the former UK Government chief medical officer, K. C. Calman. The authors noted that none of the scale recommendations were predicated on empirical evidence.

The conclusions are quite sobering:

“In all studies, it was found that people significantly over-estimated the likelihood of adverse effects occurring . . . This in turn resulted in significantly higher ratings of their perceived risks to health and significantly lower ratings of their likelihood of taking the medicine. . . .

Clearly the biggest challenge for risk communicators and for future research will be to produce a standardized language of risk (and benefit) that is sufficiently flexible to take into account different perspectives, as well as changing circumstances and contexts of illness and its treatment. In the meantime, the EC and other legislative bodies and health professionals should stop advocating the use of particular verbal labels or phrases until there is a much more solid evidence base to support their use.”⁶

In a recent British Medical Journal article, Edwards, A et al (2002)⁷ summarize some of the current literature on risk communication and consumer health informatics, outlining the difficulty in presenting numerical data and uncertainties. “It may be helpful to discuss the frequencies of outcomes but still leave room to explore uncertainties that persist,” the authors write. “Care is required to avoid an overload of information. Most patients, when asked, express a strong desire for information. But people’s ability to assimilate information varies. . . . The importance of the risks to patients also varies. . . . We need to synthesize the current evidence on patients’ preferences for different information formats and assess the effects of various formats. Epidemiological work is required,” they note, “to enable calculation of individualized estimates across a wide range of clinical conditions.” Furthermore, “framing” manipulations of information to achieve professionally determined [i.e. institutional and not patient-oriented] goals should be avoided.

Most recently, Elwyn, G et al (2003)⁸ observe that “few well conducted, randomized controlled trials of interventions to help patients follow their prescriptions have been done.” “The way ahead,” they postulate, is through “*concordance* . . . the process whereby the *patient and doctor reach an agreement* on how a drug will be used, if at all.” (emphasis added)

“The risk communication literature has been useful in providing recommendations for how information about risk might be presented to patients,” writes one respondent to the Elwyn work.⁹ “It has also emphasized that risk communication is a two-way process, that people’s responses to risk rest on qualitative and quantitative aspects of a potential risk outcome, and that the way information is framed affects decisions. . . . Many treatment decisions carry no right or wrong answer because there is uncertainty regarding outcomes.”⁹

Closer to home, the call for research and education about risk communication has led to several major developments¹⁰⁻¹². “The novelty and scope of this initiative,” wrote the National Cancer Institute about its \$40 million “Extraordinary Opportunity in Cancer Communications” project,¹⁰ “reflects the enormous potential of . . . communication to improve health and the NCI’s recognition that effective communications can and should be used to narrow the enormous gap between discovery and the application of discoveries and to reduce health disparities among our citizens. . . . There are increasingly refined theories of information processing, health communication and health behavior, including those that focus on how people represent and process health information, respond to . . . risks and change . . . behaviors. . . . Activated, empowered patients and direct-to-consumer advertising are changing the nature of practitioner-patient communications, and there is an opportunity to examine the impact of these altered relationships. . . .But empirical evidence is critically needed about the efficacy and effectiveness of health communications interventions . . .”¹⁰

It is the hope of the Coalition for Healthcare Communication that this brief review of advertising persuasion models and risk communications might aid FDA decision-makers by providing a helpful perspective on what is known, and what we need to learn about the application of the such models to the communication of risk in furtherance of better patient care.

References:

1. Hoek J, Gendall P, and Feetham P. Could Less Be More? An Analysis of Direct-to-Consumer Advertising of Prescription Medicines. Available at: <http://marketing-bulletin.massey.ac.nz/contents1.asp>. Accessed December 22, 2003.
2. Schommer JC D, WR and Mehta, BH. Rote Learning after Exposure to a Direct-To-Consumer Television Advertisement for a Prescription Drug. *Clinical Therapeutics*. 1998;20(3):617-632.
3. Schommer JC D, WR and Worley MM. Processing prescription drug information under different conditions of presentation. *Patient Education and Counseling*. 2001;43:49-59.
4. Angel J. Paper presented at: Direct-to-consumer Advertising: What works, What doesn't, Where Do We Go From Here; April 17, 1997; New Brunswick, NJ.
5. Day RS. Cognitive Accessibility of Rx Drug Information, Hearing Transcript. *FDA Direct-to-consumer Promotion Public Meeting, September 22nd and 23rd*; 2003:p213-225 and p243-256.
6. (NCI) NCI. National Cancer Institute Funds Four Centers of Excellence in Cancer Communications Research,. Available at: <http://www.cancer.gov/newscenter/pressreleases/CECCR>. Accessed December 29, 2003.
7. US Food and Drug Administration Presentations and Transcripts from Direct-to-Consumer Promotion Public Meeting. Available at: <http://www.fda.gov/cder/ddmac/DTCmeeting2003.html>.
8. Agency for Healthcare Research and Quality (AHRQ). Centers for Education & Research on Therapeutics (CERTs). Available at: <http://www.certs.hhs.gov/>. Accessed December 22, 2003.
9. Campbell WH, Califf RM. Improving communication of drug risks to prevent patient injury: proceedings of a workshop. *Pharmacoepidemiology and Drug Safety* (2003). 2003;12:183-194.
10. Berry DC RD, Knapp P, and Bersellini, E. Patients' Understanding of Risk Associated with Medication Use: Impact of European Commission Guidelines and Other Risk Scales. *Drug Safety*. 2003;26(1):1-11.
11. Edwards A EG, and Mulley A. Explaining risks: turning numerical data into meaningful pictures. *British Medical Journal*. 6 April 2002 2002;324:827-830.
12. Elwyn G EAaBN. "Doing prescribing": how doctors can be more effective. *British Medical Journal* 2003. (11 October) 2003;327:864-867.
13. Leask J. Patient decision making. Is there room for persuasion? *BMJ.com*. 16 April 2002. Available at: <http://bmj.bmjournals.com/cgi/eletters/324/7341/827>. Accessed December 24, 2003.
14. US National Institutes of Health (NIH) Guide, Centers of Excellence in Cancer Communications Research. RFA: CA-03-007. Available at: <http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-03-007.html>. Accessed December 22, 2003, 2003.
15. (NCI) NCI. Cancer Risk Communication: What We Know and What We Need to Learn. *Journal of the National Cancer Institute Monographs*. 1999(No. 25):1-185.
16. National Cancer Institute (NCI). Risk Communication Bibliography Updated September 2003. Available at: <http://dcccps.nci.nih.gov/decc/riskcommbib/>. Accessed November 3, 2003.