On TRACK: Intended and Unintended Consequences of Direct-to-Consumer Drug Marketing

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DTC PHARMACEUTICAL MARKETING

The study by Frosch and colleagues[1] and the accompanying editorial by Kessler and Levy[2] in the last issue of *Annals* stimulated a bevy of insightful comments and debate. Commenting on the editorial, Allen[3] contends that DTC advertising is more effective than doctors at motivating patients. He concludes: "Thanks, Big Pharma, for bringing those people in and for benefiting our public health agenda despite the antagonism of doctors." Likewise, Domino[4] believes "[t]here is tremendous value in DTC advertising; it raises issues that were previously difficult to discuss (depression, erectile dysfunction) and encourages patients to 'ask their doctor' about concerns they may have." Others, however, suggest that this method of motivating the populace to seek prescription drugs does not serve the public good.[5]

Frey,[6] in a link to a previously published article, shares an example of how the "shotgun" approach of marketing to the masses drugs designed for narrow use in specific patients can create a distraction in the examination room, unnecessary prescribing, vague patient symptoms, and a negative effect on the clinician-family relationship. Glaser's experience with patients shows an underrecognized adverse consequence of the current approaches of DTC advertising[7]—the litany of side effects mentioned without contextualization results in patients who could benefit from the drugs avoiding or stopping them because of these poorly articulated concerns. He has observed, for example, that patients who can reduce their risk of cardiac death frequently will not take their cholesterol-lowering statin because they have been scared by the side-effects listed in the ads. Glaser also notes the absence of cost information in DTC ads, and concludes: "Both the issue of cost and side effects lead to a waste of time in primary care consultations."[7]

Lacasse and colleagues[8] summarize and cite their published research showing that ads can be misleading in relation to the balance of scientific evidence on the mechanism and effect of the medication being advertised, finding a "substantial disconnect" between the scientific literature and DTC advertisements.[9] Also citing their published work in this area, Kaphingst and colleagues[10] find that DTC ads present a distorted balance of benefits over risks and do not provide educational content to allow viewers to discern whether the drug might be appropriate for them. Like Step,[11] these authors present several directions for future research in this area.

Scott[12] cites research showing that emotional appeals, such as those that Frosch found are dominant in DTC ads, "function primarily at the unconscious level and are probably considerably more powerful than the overt messages." He notes that if "the ads have their primary effect through this unconscious pathway, it is unlikely that changing regulations for the information content of the ads will be very useful." Finding that less-expensive and equally efficacious generic alternatives are available for 17 of the 24 drugs for which DTC ads were found by Frosch et al, Scott suggests that DTC pharmaceutical ads may be a contributing factor to the skyrocketing costs of US health care. He concludes that only an outright ban on DTC ads by pharmaceutical companies will solve this part of the problem. Mintzes[13] cites additional evidence for the limited educational value and emotional appeals of DTC ads, noting their "emotive images used to sell the idea of a pill as a magic solution."[13] She, too, concludes that an outright ban is the only solution: "It would take political guts and initiative for the US and New Zealand to seriously consider a ban, but if the aim is protection of public health, this is exactly what is needed."[13] In replying to readers' comments about his study, Frosch[14] feels that a ban on DTC advertisements may not be possible.

Kravitz[15] articulates a useful typology of how the benefit-harm ratio of DTC ads plays out for different drugs. His framework considers the prevalence and

severity of the condition to be treated, the effectiveness of the treatment (compared with alternatives), the severity and frequency of side-effects, and the degree to which the condition is over- or undertreated in the population. I have taken the liberty of expanding this typology into a table (Table 1).

If we categorize these factors into the most favorable and unfavorable combinations of drug-related and condition-related features, the balance of risk to benefit for different situations of DTC advertising becomes clearer (Table 2).

The Kravitz framework can be further expanded by taking into account the characteristics of the DTC advertisement, such as the scientific evidence base and balance of presentation for the rational claims, the degree, type, target, and focus of the ad's emotional appeals, the balance of information on risk and benefit and (pharmacological and nonpharmacological) alternative treatment, the potential intended, unintended, and collateral effects of rational and emotional appeals for different target groups and for the broad audiences reached by DTC marketing.

Finally, several comments noted that, unless the house of medicine cleans our own abode, we will not have the moral authority to act to reduce the adverse effects of DTC ads on patients and the public.[16-19] Brody[17] notes that physicians often are quick to decry the biased educational value of DTC ads, but "when the industry feeds us rationalizations about our own behavior, we eagerly lap it up. We nod our heads when industry mouthpieces explain that drug reps provide us with 'education' and 'information.' And that because we are hard-headed scientists, we would never be swayed in our prescribing practices by gifts or blandishments."[17]

Table 1. Effect of Multiple Factors on Harm or Benefit of Direct-to-Consumer (DTC) Ads

Factor	Effect on Ratio of DTC Harm to Benefit
Condition severity	
Serious	↑ potential benefit
Mild	↑ risk of harm
Prevalence of condition	
Rare	↑ risk of harm
Common	↓ risk of harm
Effectiveness of treatment	
High	↑ potential for benefit
Low	↓ potential for benefit
Side effects of treatment	
Severe and/or common	↑ risk of harm
Mild and/or rare	↓ risk of harm
Rate of treatment	
Undertreated	↑ potential for benefit
Not undertreated	↑ risk of harm

Table 2. Effects of Direct-to-Consumer Ads in the Most Favorable and Unfavorable Combinations of Drug and Medical Conditions

	Condition	
Drug Type	Severe, Prevalent, or Undertreated Condition	Mild, Rare, or Overtreated Condition
Effective drug with rare or mild side effects	Likely beneficial	Increased medicalization and cost for a small benefit and rare hazard
Low-effectiveness drug with severe or common side effects	Beneficial for a small subgroup Hazardous for most viewers	Public health hazard

OTHER NOTEWORTHY THREADS OF DISCUSSION

Other interesting threads of discussion enlighten clinician-patient communication, the place of the family in family medicine, continuity of care, clinical guidelines and their development, and innovative residency education.

The study by Epstein and colleagues[20] stimulated an interactive exchange about health care communication, informed both by the literature and deep clinical and educational experience.[21-24] A quotation from Saba[24] epitomizes this discourse:

> We need to think creatively about how to train the "relationship" for more competent communication…. We may not have all the answers about the dose, frequency, therapeutic benefits or adverse side effects of physicians' communications, but we can no longer pretend that they are inconsequential.

Another comment ties the issue of communication with the discussion of DTC advertising:

> Patients entered the exam room, suffering and requesting help; they were accompanied by their explanatory models and influences from popular advertising. Physicians entered with their expertise and desire to help, as well as their own values and beliefs (eg, what constitutes depression and adjustment disorders, how these illnesses should be treated (pharmacologically, psychotherapy, by themselves, or by someone else), how much a physician should give the patient what they want). What emerged in the course of their interaction was a rich, complex dance in which both parties mutually influenced the other.[24]

Responding to a study of communication with adolescent girls,[25] in the November/December 2006 issue of the *Annals*, Karasz notes that "when patients and physicians occupy different cultural worlds, patients may not share the moral premises that underlie many of our primary care interventions … the

manner in which we carry out these [clinical and educational] interventions—the words we use—make a huge difference."[26]

Comments on several different articles from the last issue inform the importance of a family focus for the practice of family medicine and provide perspectives from several different countries. Citing his own US practice-based study, Bloom[27] argues that Coco's sophisticated cost effectiveness analysis of treatment options for acute otitis media[28] "may be missing the locus of infection, the means of diagnosis, and the target of treatment—the family." Bloom decries "losing that family focus, and therefore getting the right answers, but to the wrong questions, and therefore coming to the wrong conclusions." Across the Atlantic Ocean from Bloom, and also citing his published study, Lindbaek[29] also calls for a family focus to the diagnosis and treatment of sore throat, and an Israeli family physician[30] calls for viewing health care utilization within the context of the family unit. The author of a Dutch study of clusters of abdominal pain and headaches in families[31] notes that his study's implication "goes beyond the old message—be aware of family ties. It shows that family influence is especially present in minor complaints and that father's role is specific and more important than presumed."[32]

Guilliford[33]and Starfield[34] engage in a spirited exchange about the meaning and definition of continuity of care that should be required reading for researchers attempting to shed light on this fundamental but challenging area of study. They elucidate the complex relationship between access to care and continuity.

The authors of venous thromboembolism guidelines[35] "offer a few insights into the process of creating guidelines sponsored jointly by two professional organizations."[36] Hull[37] and the authors' reply[36] provide useful updates to the scientific evidence and interpretation of these guidelines. Together, these comments show the challenges of evidence-based medicine: conjoint guideline development is helpful in developing consensus, but the long time frame of the process means that updates may be needed even before the guidelines are finished, vetted, and made public.

Brody's essay "A Headache at the End of the Day"[38] stimulated sharing of clinical wisdom on the use of N of 1 clinical trials of allergy pillow covers to decide whether a patient has a dust allergy.[39] The essay also elicited an analytic appreciation for the sensitivity and wisdom the seasoned clinician author and a typology of patient concerns:

> In my experience, a patient comes to a physician with four underlying questions that must be explicitly addressed before any office visit concludes. He/she want to know (1) 'What do I have?' (2) 'How did I get it?' (3) 'What can I do for it?' and (4) 'When will it be gone?' Even if on occasion we must humbly answer 'I don't know' to one or more of these queries, patients usually leave the office satisfied, if not reassured, by our thoroughness and clinical vigilance.[40]

A Family Medicine Update[41] yielded a gem of experience from the director of an apprentice-style residency program with 2 residents per year. Dr Longenecker's shared experience has implications for the Future of Family Medicine Project's call for a period of active experimentation with innovative practice and educational models[42,43]:

> We can't blame the RRC. The intelligent process described in this essay is much too ponderous and slow-moving, in part because the entities engaged in the process are much too large and bureaucratic. Our program's small size and community-embeddedness, matched with hardship, creativity, and a continuity of faculty over the past 10 years allowed us to adapt within the space of a year to the realities of declining student interest in generalist practice, especially family medicine, and even more, rural practice.... I believe that if family medicine is going to innovate, then mainstream FM must down-size to the level of the community and be more curious about what goes on at the fringe of our specialty, recognizing and rewarding exemplary practice there."[44]

Finally, I wish to commend a student-run journal club for posting their thoughtful analysis of the November/December, 2006 *Annals* Journal Club.[45]

These discussions bring the research published in *Annals* to life and expand the meaning and applicability for diverse stakeholders. Please join the exchange of ideas at http://www.AnnFamMed.org.

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CORRECTIONS

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In the article by Frosch et al, "Creating Demand for Prescription Drugs: a Content Analysis of Television Direct-To-Consumer Advertising" (*Ann Fam Med.* 2007;5[1]:6-13), some authors were given incorrect affiliations. The following author list is matched to the correct affiliations:

Dominick L. Frosch, PhD;[1,2] *Patrick M. Krueger, PhD;*[3,4] *Robert C. Hornik, PhD;*[2,5] *Peter F. Cronholm, MD, MSCE;*[2,6] *and Frances K. Barg, PhD*[6]

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In the article "Describing Primary Care Encounters: The Primary Care Network Survey and the National Ambulatory Medical Care Survey," by Binns and colleagues (*Ann Fam Med.* 2007;5[1]:39-47), the second-to-last sentence in the first full paragraph on page 45 has the word "underreporting" omitted This sentence should read: "Both PRINS and NAMCS survey methods likely result in an underreporting of health behavior counseling compared with direct observation.[25]"

Clarification

Authors wishing to cite the clinical guidelines for management of venous thromboembolism by Snow et al (*Ann Fam Med.* 2007;5[1]74-80) should use the *Annals of Internal Medicine* citation: Snow V, Qaseem A, Barry P, Hornbake ER, Rodnick JE, Tobolic T, et al. Management of venous thromboembolism: a clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians. *Ann Intern Med*. 2007;146(3):204-210.