ARTICLE
Special Theme issue article

Direct-to-Consumer Advertising and the Internet: Implications and Imperatives

Hugh Schulze, president of c|change inc. and

co-author of *Reducing the Stigma of Mental Illness*, Cambridge University Press, 2005

Abstract

In 1996, the U.S. Food and Drug Administration eased restrictions on Direct-to-Consumer (DTC) advertising, opening the way to additional promotion in broadcast media. At the same time, globally, internet usage began expanding at an exponential rate. In this article, we examine what has been learned after a decade of DTC advertising in the U.S. and the ethical implications for communicating about prescription drugs on the Worldwide Web, in an era where government regulation is problematic.

Key Words: marketing, worldwide web, direct-to-consumer, internet, FDA guidelines, DTC, convergence, collaboration

Introduction

In the last half of the last decade of the twentieth century, two developments in the field of communication dramatically changed the field of pharmaceutical marketing: a) in the United States, the Food and Drug Administration (FDA) eased restrictions on the advertising of pharmaceutical products to consumers; and b) globally, the introduction of web browsers such as Explorer and

Figure 1: World Internet Usage and Population Statistics

World Regions	Population (2008 Est.)	Internet Users 12/31/2000	Internet Usage, Latest Data	% Population (Penetration)	Usage % of World	Usage Growth 2000-2008
Africa	955,206,348	4,514,400	51,065,630	5.3%	3.5%	1,031.2%
Asia	3,776,181,949	114,304,000	578,538,257	15.3%	39.5%	406.1%
Europe	800,401,065	105,096,093	384,633,765	48.1%	26.3%	266.0%
Middle East	197,090,443	3,284,800	41,939,200	21.3%	2.9%	1,176.8%
North America	337,167,248	108,096,800	248,241,969	73.6%	17.0%	129.6%
Latin America/ Caribbean	576,091,673	18,068,919	139,009,209	24.1%	9.5%	669.3%
Oceania/ Australia	33,981,562	7,620,480	20,204,331	59.5%	1.4%	165.1%
WORLD TOTAL	6,676,120,288	360,985,492	1,463,632,361	21.9%	100.0%	305.5%

NOTES: (1) Internet Usage and World Population Statistics are for June 30, 2008. (2) Demographic (Population) numbers are based on data from the US Census Bureau. (3) Internet usage information comes from data published by Nielsen//NetRatings, by the International Telecommunications Union, by local NIC, and other reliable sources. (4) Information in this site may be cited, giving the due credit to www.internetworldstats.com. Copyright © 2001-2008, Miniwatts Marketing Group. All rights reserved worldwide.

 (ISSN: 1916-2405)

Netscape gave physicians and the general public alike unprecedented access to information on the Worldwide Web.

While, at present, DTC advertising is limited to the U.S. and New Zealand, three aspects of the global business environment have implications for marketing to both physicians and the general public:

a) FDA Guidelines for advertising products direct-to-consumers on the Internet are the same as those for other broadcast media (i.e., television and radio), thus what can be seen on U.S. television can, in theory, be seen globally on-line through websites such as YouTube.com or Blinkx.com.

b) Internet usage continues to grow at an astonishing rate. Figure 1 shows the usage statistics for the last eight years, though defining statistics by region can be slightly misleading. [(1)]

   For example, while North America shows "penetration," or the percentage of the population accessing the internet, as the highest at 73.6%; in 2008, eight countries had greater access to broadband and cellular networks than the U.S. – with Sweden #1, followed by Iceland, Switzerland, Netherlands, Denmark, Hong Kong, South Korea and Norway respectively.[(2)]

c) Finally, the largest pharmaceutical companies are global companies and while guidelines on marketing to physicians and the general public may vary from country-to-country, these companies operate in a competitive environment in which they actively work to maximize reach and impact of their advertising, as well as amortize costs.

In this paper, we explore ethical implications for both DTC advertising and the internet that have relevance for how pharmaceutical companies market to physicians and the general public, as well as how the dialog is changing between physicians and their patients.

Methodology:

This study relies upon secondary research from medical journals and business publications from both the pharmaceutical and advertising industries. Providing specific numbers – whether that might be viewers of an advertisement or money spent – can be difficult for a number of reasons:

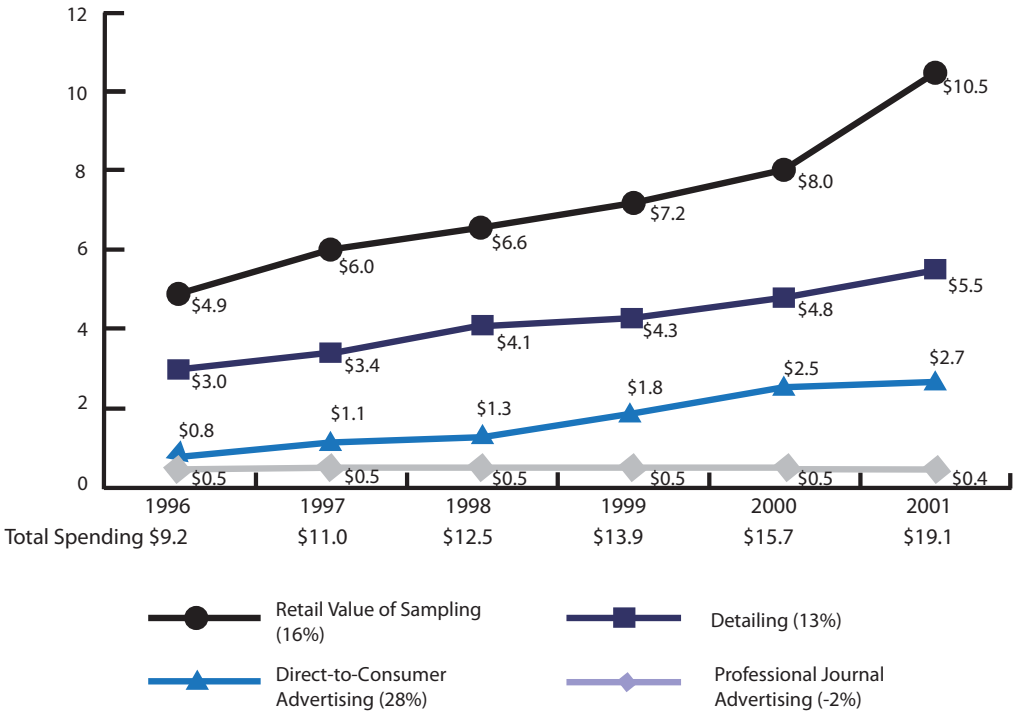
1. Measures vary from medium to medium. Television and radio are what are known as "push" media; that is, they are broadcast at specific times of day, often as part of specific programming which has allowed the industry to monitor performance using methods developed over the last five to six decades. The internet, a medium that has evolved most dramatically in the last 10 years, has become more of a hybrid medium. While content is largely chosen ("pulled") by consumers, advertising through pop-up and banner ads have blurred the line. At present, just as traditional broadcast television and radio are challenged by cable and satellite, marketers are refining better tools to measure advertising effectiveness on the Internet.

2. The definition of "marketing expenditures" can be difficult to define and quantify. A company's report on its marketing mix may capture visits by pharmaceutical sales reps or radio advertising, it may not capture expenditures on event sponsorships or the cost

FIGURE 2: 2006/2007 TOP THERAPEUTIC CLASSES BY US DISPENSED PRESCRIPTION (5)

Rank	Therapeutic Class	2006 Total Scripts (Millions USD)	2007 Total Scripts (Millions USD)	% Increase
1	Anti-Depressants	227.4	232.7	2.3%
2	Lipid Regulators	203.1	220.9	8.1%
3	Codeine & Comb	177.2	186.1	4.8%
4	ACE Inhibitors	154.2	157.9	2.4%
5	Beta Blockers	130.5	132.5	1.5%
6	Proton Pump Inhibitors	101.7	108.4	6.8%
7	Seizure Disorders	94.9	101.8	6.8%
8	Thyroid Hormone, synth.	97.7	101.4	3.7%
9	Calcium Blockers	87.0	87.4	0.5%
10	Benzodiazepines	80.2	82.9	3.3%
	All	3,706.4	3,809.3	2.7%

Figure 3. Trends in Promotional Spending for Prescription Drugs, 1996-2001 ($ in Billions)



NOTE: May not add to totals due to rounding. Percents in parentheses are average annual increases from 1996-2001. Excludes promotional spending for professional meetings and events.

Source: Kaiser Family Foundation and Sonderegger Rsearch Center, *Prescription Drug Trends. A Chartbook Update*. November 2001, using data from IMS Health, Inc. *Integrated Promotional Service*, and Competitive Media Reporting. 1996-2000; 2001 data from IMS Health at www.imshealth.com

for trade show booths at medical conferences and exhibitions. For example, a 2001 report put the annual spending for educational meetings and events for physicians alone at $2.1 billion. [3] In 2009, new guidelines developed by Pharmaceutical Research and Manufacturers of America (PhRMA) will place greater restrictions on how pharmaceutical companies spend marketing dollars and how they report on them. [4]

3. Finally, it should be noted that figures presented in this paper extend across all therapeutic classes. The data presented here have as much relevance for mental health professionals as they do for the general practitioner or cardiac specialist. For example, as Figure 2 below shows, in 2006/2007 anti-depressants and benzodiazapines accounted for nearly 10% of the $3.7 billion (USD) spent for the top ten prescriptions.

Understanding the Marketing Mix – the Trends

In the first five years, following the relaxing of FDA regulations for direct-to-consumer advertising, the expenditures on promotion to both physicians and consumers rose in three out of four areas – with DTCA rising at a rate of roughly 28% annually. (See Figure 3.)

The largest expenditure shown is for sample costs (though it should be noted, these costs reflect retail value).

The second greatest expenditure of the four is in the cost of "detailing" – direct visits of sales representatives to office-based physicians (roughly 86% of the $5.5 billion total) and hospital-based physicians (the remaining 14%). According to the American Medical Association in 2002, pharmaceutical companies employed about 90,000 sales reps – or one for every 4.7 doctors in the United States. [6]

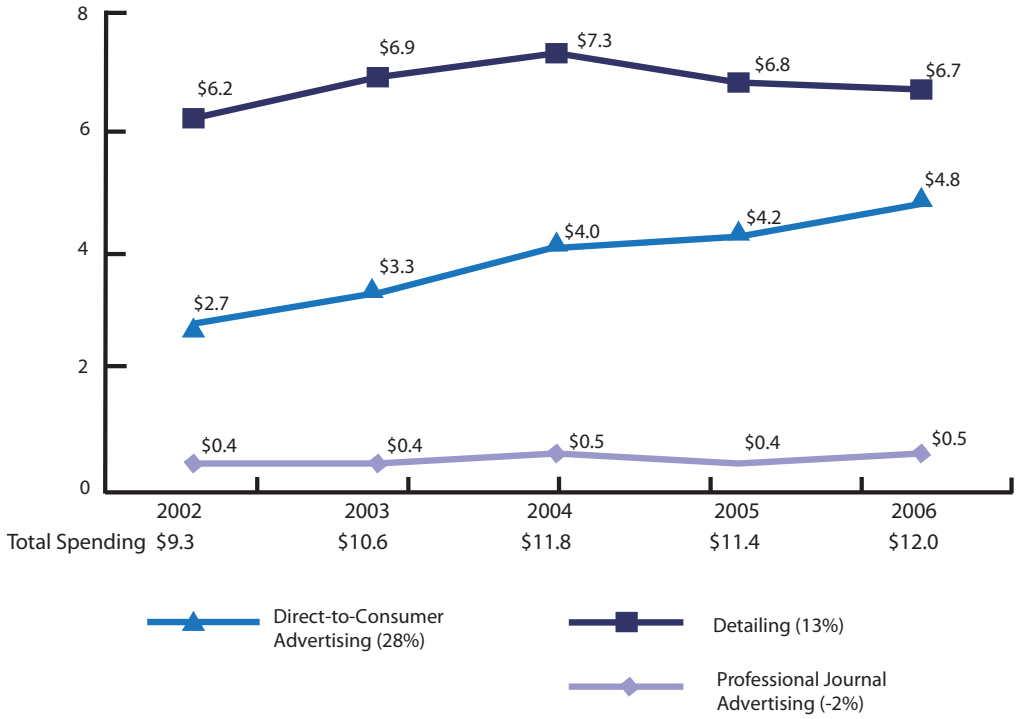
The third shows DTCA rising from $1 billion USD to nearly $3 billion USD in the first five years. Professional journal advertising showed a decrease of 2% in the same five year period.

As Figure 4 shows, these trends continued with detailing to healthcare professionals leveling off and showing a slight decline to $6.3 billion in 2007. While spending on DTCA continues to increase, the rate of growth has fallen dramatically from 28% in the first five years to just 2% from 2006 to 2007.

Examining the Results:

A recent study published in the *British Medical Journal* (Sept. 2008), "the first-ever controlled study of direct-to-consumer advertising (DTCA) of pharmaceuticals", concludes that for two of the three

Figure 4. Total U.S. Promotional Spend by Type, 2006 ($ in Billions)



SOURCE: Data from IMS Health, at www.imshealth.com;

http://www.imshealth.com/imshealth/Global/Content/Document/Top-Line%20Industry%20Data/2006%20Total%20U.S.%20Promotional%20Spend%20by%20Type.pdf

drugs studied, DTC advertising "had no effect whatsoever". In the case of the third product, sales increased 40% after the campaign began, then tapered off with no demonstrable effect after several years.

However, an earlier 2003 study conducted by the Kaiser Family Foundation found:

> "On average, a 10% increase in DTC advertising of drugs within a therapeutic drug class resulted in a 1% increase in sales of the drugs in the case. Applying this result to the 25 largest drug classes in 2000, the study found that every $1 the pharmaceutical industry spent on DTC advertising yielded an additional $4.20 in drug sales."[7]

While these studies may seem contradictory, they do not fully contradict what pharmaceutical marketers have known and how they market their products.

Direct- to-consumer advertising is concentrated among a relatively small number of drugs. As a study by *The New England Journal of Medicine* showed: "the 20 drugs with the highest spending made up 54.4% of total industry spending in 2005." [8] In addition, an estimated 67% of medicines prescribed in the U.S. are generic (i.e., not advertised).[9]

Pharmaceutical companies focus most of their advertising spend on the initial introduction of drugs used to treat chronic conditions. The *New England Journal of Medicine* article cited above noted: "Ten of the top 20 drugs, as ranked by advertising spending, were introduced in 2000 or later. Notably, nearly all (17 of 20) advertising campaigns for the most heavily advertised drugs began within a year after FDA approval of the drug." For pharmaceutical companies the importance of building Awareness during what is called the "launch phase" of a drug's product lifecycle is critical to the long term sales of the product.

A majority of physicians agree that patients exposed to DTC advertising ask more thoughtful questions during their visit and made them more involved in their healthcare. A 2003 study conducted by the Food and Drug Administration (10) found that 92% of physicians could recall a patient who initiated a conversation about a prescription drug they saw advertised; 53% said that it led to a better discussion with the patient. When asked if this created any problems for the interaction with the patient, 82% said No; of the 18% who said Yes – "Time correcting misconceptions" was listed as the #1 problem (41%) with "Drugs not needed/did not have condition" listed as #2.

"The ads can prompt thoughtful discussions between patients and physicians that results in needed treatments being prescribed – often not the treatment mentioned in the ad."(11) This finding from the FDA study, like the three previous observations, present paradoxes and ethical implications.

Four Ethical Implications:

1. **Direct-to-Consumer advertising is concentated among a relatively small number of drugs.** The findings from the *British Medical Journal* in September 2008 have raised questions about direct-to-consumer advertising as well as doubts about the study itself.[12] After ten years of direct-to-consumer advertising in the United States, adherents and opponents appear to be as divided as ever. At the present time, it would appear that pharmaceutical companies have enough sales data pointing to the efficacy of their advertising to continue to spend $5 billion USD on direct-to-consumer advertising. Similarly, the general public appears to support direct-to-consumer advertising. [13] Decoupling discussions of "how much" is being communicated and marketed from "what" is being communicated and marketed will help focus ethical conversations about what physicians know about medications they prescribe and what patients know about the medications they consume.

2. **Pharmaceutical companies focus most of their advertising spend on the initial introduction of drugs used to treat chronic conditions.** In the United States, patents expire after seven years (which is one reason why pharmaceutical companies seek out new indications for their products in hopes of extending the patent for these new indications). A current tension exists between companies looking to build "brand awareness" in the critical time immediately following a launch and the medical reality that a drug recently approved by the FDA is being released to a population much larger than clinical drug trials.

   The case of Vioxx is instructive. Rofecoxib, an inhibitor of cyclooxygenase-2, had been found to have fewer gastrointestinal complications than naproxen, a standard nonsteroidal anti-inflammatory drug. It was approved by the FDA and marketed in May 1999. In November 2000, studies showed that the drug increased the risk of myocardial infarction. As Congressman Henry Waxman later reported: "By the time of rofecoxib's withdrawal from the market in September 2004… more than 100 million prescriptions had been filled in the United States." [14]

   In 2008, following deliberations by the Energy and Commerce Committee in the House of Representatives, the drug companies Merck, Johnson & Johnson, and Pfizer agreed to a six month waiting period on new drug advertising[15]. However, the committee had proposed a *three-year* moratorium after approval. [16] What would be the appropriate amount of time between the approval of a pharmaceutical product by the FDA and promotion of that product? This question needs to be reviewed in light of information accessed by *both* physicians and their patients on-line.

3. **A more informed physician/patient conversation.** A 2003 study published in The *New England Journal of Medicine*[17] found participants from 12 metropolitan areas in the U.S. received only 54.9 percent of recommended care. Only 24 percent of those with diabetes received three or more glycosylated hemoglobin tests over a two-year period. Overall, only 68.0 percent were receiving recommended care for coronary artery disease. In addressing the gap that exists between diagnosis and treatment, authors of this report ask: "What can we do to break through this impasse?" Additional studies have pointed to the possible number of deaths and hospitalizations [18] that might be avoided and the costs that might be saved [19] if there was greater compliance.

   With studies indicating that direct-to-consumer advertising increases the number of questions patients ask – and with the Internet increasing access of patients to therapeutic information – is it time to reassess the physician/patient dialog in light of a more well-informed patient? Results of a 2004 report published in *Medical Care* "suggest that DTCA of antidepressants was associated with an increase in the number of people diagnosed with depression who initiated medication therapy."[20]

   What trade-offs are physicians willing to take between patients who may have an initial exaggerated view of efficacy and the fact that the patient is taking initiative? Is there a possible reduction in the stigma of some illnesses through a broader cultural dialog on certain illnesses – whether that be through advertising on television or bulletin boards on the Internet? Are there ways physicians – perhaps in partnership with pharmaceutical companies – could light a candle and disseminate clearer information, rather than cursing the darkness of ads or websites touting bogus therapies such as dietary supplements?[21]

4. **The paradox of more information.** A 2005 study published in the *Journal of the American Medical Association* found that "DTC-advertisement-driven requests (along with general requests) dramatically boost prescribing." [22] But the authors warn that while the study points to "opportunities for improving care of depression (and perhaps other chronic conditions) by using public media channels to expand patient involvement in care," [23] evidence "supports the hypothesis that DTC advertising may stimulate prescribing more for questionable than clear indications." [24]

   If a rising tide lifts all ships, does an improvement in overall care for those suffering from depression also bring with it the risk of overprescribing? The study found that "the prescription of antidepressants in this context is at the margin of clinical appropriateness." [25]

   That margin may be tested further by "off-label prescriptions." An editorial in *The New England Journal of Medicine* addressed research indicating that "nearly half of all prescriptions in some drug classes may be off-label and more than 70% of off-label uses may have insufficient scientific support." (26) The authors further conclude that:

   "although off-label use of drugs may sometimes represent a reasonable therapeutic choice, the substantial influence that promotion can have on the prescribing practices of physicians, combined with the potential risks to patients and the often greater costs associated with off-label use, in our view justifies the higher level of scrutiny applied to statements made by pharmaceutical manufacturers." [27]

   What would that higher level of scrutiny look like? Is that

the role solely of the FDA? At what point would a physician's judgment and discretion in prescribing to a patient be limited by further limits in off-label use? Are disclaimers enough for busy physicians and their patients? Recently, in November 2008, in a case before the U.S. Supreme Court, Justice Ruth Bader Ginsburg expressed incredulity about the current effectiveness of the FDA in monitoring ongoing warnings for roughly 11,000 prescription drugs. "Is the FDA really monitoring every one of these?"[28]

Oversight and regulation is tested further still when internet marketing is considered as part of the marketing mix. As we shall see, technological advances in user-generated content (sometimes referred to as Web 2.0) provide an opportunity for both physicians and patients to join the conversation.

Adding to the Marketing Mix:

The findings above and their attendant ethical implications are the result of roughly ten years of Direct-to-Consumer advertising in the United States. As indicated earlier, internet usage has grown even faster than DTC advertising, further amplifying ethical issues raised earlier.

As Khee Lee, vertical manager, health at Google puts it: "The dramatic change that's occurred over the last 10 years is that consumers have changed. So the challenge is for consumer marketers to get away from what they've traditionally done and examine their consumers." [29]

Lee and others at Google see both risk-aversion and the relatively new (10-year old) consumer advertising as two reasons pharmaceutical companies have lagged behind other industries in utilizing the web. "[Pharma companies] started off with TV, print, and radio and the needle just never moved because as new brand managers came on board, they didn't change the media mix."[30]

For those with serious reservations about online marketing of pharmaceutical products, this news might not seem as negative as Mr. Lee and his marketing colleagues at Google paint it. But regardless of one's view on direct-to-consumer advertising, one thing is very clear: the internet is changing channels of communication and availability of information far faster than government regulation has – or perhaps can – adapt.

A recent search of brand names for three antidepressants on YouTube garnered thousands of videos ranging from television commercials [31] to parodies of those commercials [32] as well as segments from television news programs [33] to personal videotaped stories. [34]

Among the top 10 results for the searches conducted for each product were videos produced under the brand "illumistream" by FullTurn Media. The company produced two-and-a-half minute videos on: Fluoxetine Hydrochloride (Prozac™) [35], Sertraline Hydrochloride (Zoloft™) [36], and Paroxetine (Paxil™) [37]. It is unclear who funded the creation of the videos, which are titled "Professional Medication Reviews" and presented by a pharmacist from Memorial Sloan-Kettering at the University of Southern California. Each video includes warnings such as a closing title: "The information in this video is intended to supplement not substitute for, the expertise of your physician. Always consult your doctor before using…."

At the time of this writing, statistics for each of these videos showed thousands of views (11,978 for Prozac, 4,733 for Zoloft, 5,077 for Paxil). However, unlike television, radio or print media, the Internet provides feedback mechanisms and dialog for videos like this. In this case, there were but 59 viewer comments for Prozac, 30 for Zoloft, 37 for Paxil. Text comments in the area below the videos range from personal experiences to comments on the video quality itself, as well as comments on comments.

Earlier, we presented data on growth of Internet usage from 2000 to 2008, an increase of 305%. Save for some countries where internet access is limited [38], one-billion-plus visitors to the world wide web have access to all of the materials posted from any country.

Perhaps more astonishing is the growth of on-line video viewing. As technologies and media platforms continue to converge (with web content delivered to cellphones, for example), the current trend is for further exponential growth. Consider that YouTube viewership grew from 58,000 visitors per month in August 2005 to more than 20 million monthly visitors by August 2006.[39] By January 2008, that number had reached 11 billion visitors per month in the U.S. alone.[40] In that same year and a half period, the amount of time spent watching videos online had risen from 73 minutes per month to nearly four hours per month.[41]

Lest the reader think this is a phenomenon among the young, currently, 64% of YouTube watchers are over the age of 35, and nearly a quarter (22%) are over the age of 55 with viewership split almost equally between males (51%) and females (49%).[42]

Consider: those numbers reflect only video viewing – and only video delivered on YouTube!

Add blogs, podcasts, and social networking sites (e.g., Facebook.com and MySpace.com) to the communication mix and one begins to wonder: just how effective is the current government regulation paradigm? The most cursory searches on the internet uncover hundreds, thousands of references to information of all kinds on prescription drugs and therapies. Today, after a drug has been approved by the FDA, current regulations on labeling and advertising seem a bit like posting a traffic cop at the entrance ramp to a highway of information: you may limit a portion of the information making it onto the road, but as the Google marketing executive pointed out earlier: because consumers are driving the demand on the information superhighway, government regulation appears to be less and less relevant.

Time for a New Paradigm?

In the United States, the Food and Drug Administration evolved out of legislation signed into law in 1906. Since that time, print mass media and marketing have been eclipsed by broadcast media of radio, then television. These media in turn are being both augmented and eclipsed by the interactive experience of

the internet – with consumers exercising greater control over the information they access, not only in terms of content, but when and how they access that information.

Executives of pharmaceutical companies who may decry what they see as antiquated or Byzantine guidelines for approval and promotion of their products are themselves faced with challenges to antiquated Darwinian business models focused solely on dominating competitors and gaining new market share.

The most robust, fastest-growing industries are those who have begun to explore business models that rely more heavily on collaboration. A few pharmaceutical companies have begun to embrace this concept of collaboration. In 2007, Novartis released the results of its genomic analysis of Type 2 diabetes on the web. [43] In February 2009, in an effort to address diseases in the poorest countries, GlaxoSmithKline "put any chemicals or processes over which it has intellectual property rights that are relevant to finding drugs for neglected diseases into a 'patent pool', so they can be explored by other researchers." [44]

"Convergence" has been a buzzword in the technology industry for over a decade and we are seeing the results of that convergence with information being delivered across multiple platforms. [45] Collaboration and a convergence of information would help to bridge the clear chasm that exists between the public and private sectors. At present, public health is not well-served by impotent regulators threatening court action against pharmaceutical companies that walk litigious tightropes between the letter and spirit of government laws.

In the opinion of this author, in the coming decade government regulators need to begin thinking more like pharmaceutical companies and pharmaceutical companies must begin thinking more like their much-maligned government regulators. That is, in addition to risk mitigation, government regulators need to spend more time thinking about what information physicians and consumers really need and want (as pharmaceutical marketers do). At the same time pharmaceutical companies need to see themselves as public servants to their customers (as government regulators are charged to do).

Rather than add to the Tower of Babel of websites which threatens to confound the best search engine, what is called for is an amalgamation of information. An opportunity exists for an organization like the World Psychiatric Association – or perhaps a forward thinking company or governmental body – to develop a resource that could:

- Deliver more comprehensive and reliable information to both physicians and patients;
- Provide an improved understanding of the disease states and the variety of treatments available, including non-pharmacological therapies; this improved linkage could:
    - Assist physicians in educating patients, their families and caregivers;
    - Help further educate on complex issues such as comorbidity through a centralized information database;
    - Help reduce the stigma associated with some illnesses.

Ten years of astonishing growth of the internet has made it a resource for patients seeking information on medical conditions and pharmaceutical products. In a survey of searches by drug brand name, conducted by comScore in February 2008 [46], five of the fifteen most searched-for prescription drugs were for treatment of depression – with Chantix™ topping the list at half a million (507,000) searches in that month alone.

Obviously, such a strategy of collaboration between business and government carries with it the possibility for collusion and corruption. Here again, new technologies point a way to opportunities for on-going regulation. Physicians *and* patients represent the other legs of this stool. The most effective resource would include the experience of medical professionals and the general public.

Space does not allow us to outline the pros and cons of these feedback mechanisms and user-generated content. [47] What is clear, however, is that an opportunity exists to take advantage of new media to address existing conflicts between governments and business. The healthcare and pharmaceutical industries have traditionally lagged in the uptake of new operational processes and technologies. (In the United States, the on-going challenge of electronic patient records is just one example.) But just as Google has become a global search engine of choice through a clear, easy-to-use user interface and proprietary search algorithms, a clear opportunity exists for collaboration among government, business, healthcare providers and the general public to apply new technologies for a dynamic, continually-updated resource.

Endnotes:

1. From: http://www.internetworldstats.com/stats.htm.
2. Woyke, Elizabeth "The World's Most Wired Countries," *Forbes* 26 June 2008 (Accessed online on 26 Oct. 2008: http://www.forbes.com/technology/2008/06/25/computers-sweden-wef-tech-bizcountries08-cx_ew_0626wiredcountries.html).
3. Breitstein, J. "Spending Hits a Wall" P*harmaceutical Executive,* 1 Sept. 2002 (Accessed online on 3 Nov. 2008 http://pharmexec.findpharma.com/pharmexec/Current+Issue/Spending-Hits-a-Wall/ArticleStandard/Article/detail/29975?searchString=spending%20hits%20a%20wall).
4. The guidelines can be accessed at: http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf.
5. Source: IMS National Prescription Audio PLUS™; Copyright IMS HEALTH, a healthcare information company.
6. Waxman, H. "The Lessons of Vioxx – Drug Safety and Sales" The *New England Journal of Medicine* Volume 352(2005) 2576-2578.
7. Rosenthal, M., et al. *Demand Effects of Recent Changes in Prescription Drug Promotion* (Summary accessed on October 31, 2008: http://www.kff.org/rxdrugs/6084-index.cfm).

8. Donohue, J. Cevasco, M, Rosenthal, M. "A Decade of Direct-to-Consumer Advertising of Prescription Drugs" *New England Journal of Medicine* 357(2007):673-681.

9. Lakin, M. "Study Casts Doubts on Value of DTC Ads" *Advertising Age*, (Accessed online 26 Oct. 2008 at http://adage.com/print?article_id=130732).

10. Aikin, Kathryn "Direct to Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results" *FDA/Center for Drug Evaluation and Research* (Accessed online 26 Oct. 2008: http://www.fda.gov/cder/ddmac/globalsummit2003).

11. Ibid.

12. "It's very difficult to generalize from a study of three drugs," said Julie Donohue, PhD, assistant professor of health policy and management at the University of Pittsburgh's Graduate School of Public Health. Donohue was the lead author of a review of DTC ads published last year in the New England Journal of Medicine. "Advertising is a tricky business," she added. "There are a lot of factors intervening between the advertiser and the consumer getting the drug. Insurance company and physician preferences are going to affect demand." From American Medical News, Susan J. Landers, Sept. 22/29, 2008 (Accessed on October 26, 2008: http://www.ama-assn.org/amednews/2008/09/22/hlsa0922.htm).

13. Berndt, E. "To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs" *The New England Journal of Medicine* 352(2005):325-328.

14. Waxman, Henry A. "The Lessons of Vioxx – Drug Safety and Sales" The *New England Journal of Medicine* Volume 352(2005):2576-2578.

15. Teinowitz, I. "Drug Companies Agree to Tighter Rules" *Advertising* Age 16 June 2008.

16. U.S. House of Representatives H.R. 6151: *Responsibility in Drug and Device Advertising Act of 2008* (Accessed online October 26, 2008: http://www.govtrack.us/congress/bill.xpd?bill=h110-6151).

17. McGlynn, E., Asch, S., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., Kerr, E., "The Quality of Health Care Delivered to Adults in the United States" The *New England Journal of Medicine* 348(2003):2635–2645.

18. Long, G. et al., "The Impact of Antihypertensive Drugs on the Number and Risk of Death, Stroke and Myocardial Infarction in the United States", NBER Working Paper No. 12096, March 2006.

19. Sokol, M.C. et. al, "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, 43 (2005): 6, 521-530.

20. Donohue, J., et al. "Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines of Depression." *Medical Care*. 42.12(2004): 1176-1185.

21. Drazen, J. "Inappropriate Advertising of Dietary Supplements" The *New England Journal of Medicine* Volume 348: 777-778, February 27, 2003.

22. Kravitz, R. et al. "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial" *Journal of the American Medical Association* 293.16(2005): 1995-2002.

23. Ibid.

24. Ibid.

25. Ibid.

26. Kesselheim, A. and Avorn, J. "Pharmaceutical Promotion to Physicians and First Amendment Rights." The *New England Journal of Medicine*. 358(2008):1727-1732.

27. Ibid.

28. Doyle, M. "Drug companies get sympathetic audience from Supreme Court's conservatives." *Miami Herald* November 3, 2008 (Accessed online 3 Nov. 2008: http://www.miamiherald.com/news/politics/AP/story/754862.html)

29. Monari, Gina-Louise "Pharma finds its voice online" *MedAdNews* (Accessed online on 30 Oct. 2008 at: http://www.pharmalive.com/magazines/medad/view.cfm?articleid=5321&search=1)

30. Ibid.

31. Zoloft™ commercial, (Accessed online on October 30, 2008 at: http://www.youtube.com/watch?v=6vfSFXKlnO0).

32. Zoloft™ ad parody (Accessed online on October 30, 2008 at: http://www.youtube.com/watch?v=oDYwNQz6EJI).

33. ABC Primetime Live – Paxil Addiction Story (Accessed online on 30 Oct. 2008 at: http://www.youtube.com/watch?v=hfQUTHrWnRk).

34. The Paxil Diaries – Episode 1: Preface (Accessed online on 30 Oct. 2008 at: http://www.youtube.com/watch?v=hfQUTHrWnRk).

35. Prozac – A Beginner's Guide, (Accessed online on 30 Oct. 2008 at: http://www.youtube.com/watch?v=3ng4WJ4ZDN4).

36. Zoloft (Sertraline Hydrochloride), (Accessed online on 30 Oct. 2008 at: http://www.youtube.com/watch?v=ngi4Hyzp11k).

37. Paxil (Paroxetine), Accessed online at: http://www.youtube.com/watch?v=MFtAOAsr_jc.

38. Shen, S.K. "China media censors premier's interview" UPIAsia.com October 9, 2008. (Accessed on October 30, 2008 at: http://www.upiasia.com/Politics/2008/10/09/china_

media_censors_premiers_interview/3591/)

39. Ibid.

40. Accessed from www.10minutes.org on October 30, 2008, http://www.10minutes.org/YouTube%20You%20Must%20Know%202008.pdf

41. Ibid

42. Ibid.

43. Pincock, Stephen "Pharma goes open access" *The Scientist* 26 February 2007, http://www.the-scientist.com/news/print/52891.

44. Basely, Sarah "Drug giant GlaxoSmithKline pledges cheap medicine for world's poor" guardian.co.uk 13 February 2009, http://www.guardian.co.uk/business/2009/feb/13/glaxo-smith-kline-cheap-medicine.

45. Take, as just one example, the concept of "three-screen" delivery; companies are working to deliver information across platforms to televisions, computers and mobile devices. What this requires is collaboration, not only between the various device manufacturers, but also satellite, cable and wireless companies that would link up and network these devices, as well as the "content providers" themselves (e.g. media and entertainment companies). New business paradigms are forcing traditional competitors to seek new ways of collaborating and innovating.

46. Newell, J. "HealthNews Dozen – Top 12 Drugs Most Searched on Internet" *HealthNews* 5 Nov. 2008 (Accessed online on 6. Nov. 2008 at: http://www.healthnews.com/disease-illness/healthnews-dozen-top-12-drugs-most-searched-internet-2031.html).

47. For example, one issue is information verification. See: http://www.econtentmag.com/Articles/News/News-Feature/Information-Inaccuracy--Spells-Trouble-for-User-Generated-Websites-53214.htm.

References:

Aikin, Kathryn. "Direct to Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results." FDA/Center for Drug Evaluation and Research (Accessed online October 26, 2008: http://www.fda.gov/cder/ddmac/globalsummit2003)

Berndt, E. "To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs." The *New England Journal of Medicine* Volume 352:325-328 27 Jan. 2005

Breitstein, J. "Spending Hits a Wall" *Pharmaceutical Executive*, 1 Sept. 2002 (Accessed online on 3 Nov. 2008: (http://pharmexec.findpharma.com/pharmexec/Current+Issue/Spending-Hits-a-Wall/ArticleStandard/Article/detail/29975?searchString=spending%20hits%20a%20wall)

Donohue, J., Berndt, E., Rosenthal, M., Epstein, A, Frank R. "Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines of Depression." *Medical Care*. 42.12 (2004): 1176-1185

Donohue, J., Cevasco, M., Rosenthal, M. "A Decade of Direct-to-Consumer Advertising of Prescription Drugs" The *New England Journal of Medicine* 357 (2007):673-681

Doyle, M. "Drug companies get sympathetic audience from Supreme Court's conservatives" *Miami Herald* 3 Nov. 2008. (Accessed online 4 Nov. 2008: http://www.miamiherald.com/news/politics/AP/story/754862.html)

Drazen, J. "Inappropriate Advertising of Dietary Supplements." The *New England Journal of Medicine* 348 (2003): 777-778.

Kesselheim, A. and Avorn, J. "Pharmaceutical Promotion to Physicians and First Amendment Rights." The *New England Journal of Medicine*. Volume 358 (2008): 1727-1732

Kravitz, R. et al. "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial." *Journal of the American Medical Association*. 293.16 (2005): 1995-2002

Lakin, M. "Study Casts Doubts on Value of DTC Ads." *Advertising Age*, 3 Sept. 2008

Long, G. et al. "The Impact of Antihypertensive Drugs on the Number and Risk of Death, Stroke and Myocardial Infarction in the United States", NBER Working Paper No. 12096, March 2006

McGlynn, E., Asch, S., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., Kerr, E. "The Quality of Health Care Delivered to Adults in the United States." The *New England Journal of Medicine* Volume 348(2003): 2635 – 2645.

Monari, Gina-Louise. "Pharma finds its voice online." *MedAdNews* (Accessed online on 30 Oct. 2008 at: http://www.pharmalive.com/magazines/medad/view.cfm?articleid=5321&search=1)

Newell, J. "HealthNews Dozen – Top 12 Drugs Most Searched on Internet." *HealthNews* 5 Nov. 2008 (Accessed online on 6 Nov. 2008 at: http://www.healthnews.com/disease-illness/healthnews-dozen-top-12-drugs-most-searched-internet-2031.html)

Rosenthal, M., Berndt, E., Donohue, J., Epstein, A., Frank, R. Demand Effects of Recent Changes in Prescription Drug Promotion. The Henry J. Kaiser Foundation June 2003.

Shen, S.K. "China media censors premiers interview" *UPIAsia.com* 9 Oct. 2008. (Accessed on 30 Oct. 2008 at: http://www.upiasia.com/Politics/2008/10/09/china_media_censors_premiers_interview/3591/)

Sokol, M.C. et. al. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost." *Medical Care*, 43 (2005): 6, 521-530

Teinowitz, I. "Drug Companies Agree to Tighter Rules." *Advertising Age* 16 June 2008.

Waxman, Henry A. "The Lessons of Vioxx – Drug Safety and Sales." The *New England Journal of Medicine*. 352 (2005):2576-2578.

Woyke, Elizabeth "The World's Most Wired Countries." *Forbes* 26 June 2008 (Accessed online on 26 Oct. 2008: http://www.forbes.com/technology/2008/06/25/computers-sweden-wef-tech-bizcountries08-cx_ew_0626wiredcountries.html)

Acknowledgements: *None*

Competing Interests: *None*

Address for Correspondence:

e-mail: *hschulze@cchangeinc.com*