

# Spin your science into gold<sup>1</sup>: direct to consumer marketing within social media platforms

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**Abstract.** We describe the emerging issues related to warnings with respect to pharmaceutical company use of the internet as a vehicle for direct-to-consumer marketing (DTC) and market research. We describe the various techniques pharmaceutical companies have used to exploit this new communications medium which permits two way exchange of information. The Food and Drug Administration (FDA) has not issued any specific regulations to control internet based misbranding. We describe some examples of the FDA's application of historic regulations to pharmaceutical company use of this new medium and suggest

Keywords: direct-to-consumer, web 2.0, pharmaceutical, social media

## 1. Introduction

Over the past few decades, the FDA has cited the majority of major pharmaceutical companies for exaggerating products benefits and failing to warn about side effects (generally violations of the FDA's requirement that companies provide fair and balanced information).[22,93] We have examined pharmaceutical company use of the internet through direct-to-consumer advertisements on the internet and internet based "social media" (Web 2.0). Kaplan and Haenlein characterize social media as "a group of Internet-based applications that build on the ideological and technological foundations of Web 2.0, and that allow the creation and exchange of user-generated content." [45] We describe many variants of pharmaceutical company internet marketing and use of social media. We also review literature on the efficacy of these campaigns and illegal and unethical uses of these new media.

## 2. Methodology

To identify examples of fraudulent direct to consumer marketing we used 4 major sources of information: scientific literature, gray literature, PubMed and the Food and Drug Administration website. We used to search the scientific literature using key search terms including, internet, social media, *direct to consumer*, *DTC*, and *pharmaceutical direct to consumer*. We used the search engine Google to identify other articles including news articles, government reports, magazine articles, and advocacy group websites.[34] More than ten million results were obtained through these searches and we reviewed the first three hundred. These searches were done in the summer of 2011.

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<sup>1</sup> Marketing slogan from <http://www.phase-five.com/>

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### 3. Results

#### 3.1. Camouflaged Marketing: DTC Marketing in Social Media Platforms

##### 3.1.1 Facebook

One of the largest and most popular social media sites, Facebook, estimates that its more than 500 million active users spend over 700 billion minutes per month on Facebook interacting with its more than 30 billion pieces of content shared each month.[30] Pharmaceutical companies use this interface to promote drug sales.

In July of 2010, the FDA issued a warning letter to Novartis for its Facebook advertising. The FDA sanctioned Novartis for a “Facebook Share” media widget that included information about the efficacy of Tasigna (Novartis’ leukemia drug) but omitted risk information. The FDA noted that the “content inadequately communicates Tasigna’s FDA-approved indication and implies superiority over other products.”[73] Tasigna has a black box warning, the most important warning for a pharmaceutical. This warning stated that “sudden deaths have been reported in patients receiving [Tasigna].”[1] Other serious side effects included thrombocytopenia and neutropenia.[1] However, none of the Novartis web media mentioned or even alluded to these dangers.[1] Further the FDA noted that simply including a link to separate site that includes risk information did not meet the legal requirement that companies need to provide “fair and balanced” information.[1]

Until August 2011, Facebook exempted pharmaceutical companies from the requirement that they maintain a section called a “wall” that allowed anyone to comment on the site.[86] Despite the fact that companies can delete these comments as soon as they are posted they were concerned that “open walls” would lead to the reporting of side effects, promotion of off-label use or inappropriate statements.”[86] As a result many companies removed their Facebook pages.

##### 3.1.2 Youtube

YouTube is one of the most popular video viewing websites on the internet where users can post their own videos and comment on others.[2] A number of pharmaceutical companies have established YouTube channels for marketing purposes, including Abbott,

AstraZeneca, Bayer, Boehringer Ingelheim, Concerta’s ADHD Channel, Excedrin, GlaxoSmithKline, Alergan’s Lap-Band System, Janssen-Cilag’s Living with ADHD Channel, Lilly, Lunesta, Novartis, Pfizer, Sanofi Pasteur, and TevaNeuroHealth.[21] While the issues of advertising ethics and adherence to existing DTC advertisement standards are raised by these promotional outlets, of even greater concern are the *unbranded* (or covertly branded) YouTube channels that a number of pharmaceutical companies have introduced.[21]

In February of 2011, an employee of Warner Chilcott on the sales team for Atelvia posted a Youtube video.[74] The video begins with the sales representative off camera explaining her visit to the physician’s office, the product Atelvia, and makes claims about the drug’s dosing benefits.[74] The video continues and ends with a “spirited conversation” between the sales representative and a staff member in the office.[74] Four months later, the FDA told Warner Chilcott that the video was “misleading” and “fails to present any risks associated with the use of Atelvia.”[74]

In October 2006, Glaxo Smith Kline posted a video directed to sufferers of restless leg syndrome. The video “shows a young man who sets up an elaborate domino run in his home using everyday products -- books, CDs, bars of soap, cereal boxes, waffles, you name it -- to highlight the fact that his father has Restless Legs Syndrome.”[27,84] The video ended with a TV being turned on that read “my dad is one of a million people in the UK who suffer from restless leg syndrome.”[27] As of November 2010 this video had 355,923 hits. GSK is identified as the sponsor of the video but the video was designed to make it appear that it was created by an amateur. This is a disease awareness advertisement and does not mention GSK’s FDA approved treatment Requip; therefore this ad does not violate FDA regulations legal. The success of this video led GSK to subsequently launch its own YouTube channel called GSKvision in August of last year which has received “nearly 9,000 channel views to date”.[84]

##### 3.1.3 Twitter

Twitter, first introduced in 2006, is the newest major social media site gaining popularity and pharmaceutical companies have rapidly adopted this medium to promote drug sales.[18] The site uses 140 character “updates” and allows users to choose to

“follow” other users. Followers automatically receive “tweets” which can include direct hyperlinks to other web sites. At least one online twitter “directory,” which allows Twitter users to list themselves publically, has two pharmaceutical companies listed in the top three of the “pharmaceutical” twitter accounts list.[90]

Novo Nordisk sponsors tweets that are issued under the name of racecar driver Charlie Kimball.[71] Kimball is a paid spokesperson for the Novo Nordisk. Kimball’s product sponsored tweet was the first to name a product company and included a link to a Novo Nordisk website read, “Check out a cool patient resource from Novo Nordisk. I’ve found it really informative and helpful.”[72] The “fair balance” statement which should include safety information is not fully displayed when the linked page is loaded.[71] Pharmaceutical companies call this a DTC “branded Tweet” advertisement.[83] The branded Tweet does not mention drug benefits to maintain its status as a reminder advertisement.[83] Web reminder ads do not have to provide any information on side effects.[77,83] Of course Kimball’s endorsement of Novo Nordisk is a surrogate benefit claim. PhRMA, the organization which represents pharmaceutical companies and which Novo Nordisk is a member, prohibit similar TV advertisements in their guiding principles: “DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.”[69]

In July of 2011, the UK’s Twitter Prescription Medicine Code of Practice Authority (PMCPA) issued the first government complaint related to a twitter advertisement to Bayer UK/Ireland. The PMCPA had previously issued “informal guidance” in April of the same year on online communications which closely follows the code of practice and suggests that “it is highly unlikely that the use of this medium [Twitter] to promote prescription only medicines would meet the requirements of the code.”[60] The PMCPA determined that Bayer’s tweets violated four clauses of the Association of the British Pharmaceutical Industry’s Code of Practice.[7] These clauses include: reduction of confidence in the industry, advertisement of prescription only medicines, information presented to the public that is factual and balanced, and high standards are maintained at all times.[7]

### 3.2 Use of front organizations to increase the credibility of web DTC advertising

People are more likely to believe third party endorsements than identified corporate product advertising.[91] To capitalize on this phenomenon companies have funded patient advocacy groups, disease specific expert panels and physician organizations to promote their drugs.[38,89] Companies have transferred this clandestine marketing technique to the internet which is particularly well suited to support this subterfuge.[91] Pharmaceutical companies have created websites for front organizations (labeled “Astroturf” sites – for fake grassroots) to promote their drugs. These pharmaceutical company-created websites appear to be unbiased sources of information.[19]

Johnson and Johnson received a warning letter from the FDA for their webcast broadcast on the website [www.painawareness.org](http://www.painawareness.org). The website, hosted by the medical communications company Aventine HealthSciences, featured programs and information on pain and pain management.[23] The featured webcast promoted Ultram Johnson and Johnson’s pain medication.[13] The webcast titled “Making Sure Your Relationships Aren’t Pained When You’re In Chronic Pain” featured a physician and gold medalist who the FDA determined “greatly misrepresent what is known about the efficacy of Ultram ER.”[8]

Abbott set up [www.r3i.org](http://www.r3i.org) to promote their fibrate drug for type 2 diabetic patients. The Residual Risk Reduction initiative (R3i) describes itself as:

*a worldwide, academic, multidisciplinary, non-profit, Swiss-law Foundation established by international researchers and clinicians who recognize the importance of the high risk of fatal and non-fatal macro- and micro-vascular complications occurring in patients with atherogenic dyslipidemia who are already receiving the current standards of care.*  
[42]

R3i is devoted to criticizing the results of the ACCORD study which failed to show any benefits of fibrates in diabetes. [32,33] Husten described R3i as “a keystone in the promotional efforts of Abbott to sell more of its fenofibrate drugs (TriCor and TriLipix) and to “spin” the negative ACCORD trial into a positive message for fenofibrate”[42] Information about R3i’s funding and the particulars of its relationship with Abbott are not described on

the website but Abbott and Roche are both listed as 2011 supporters of the R3i foundation.[43]

Abbott also developed an iPhone application Similac StrongMoms Baby that allows patients to track the feeding, changing, sleeping patterns of their baby and connect with “live Feeding Expert[s].”[51] In addition the application “slyly preys on parents' fears to privilege formula over breastfeeding.”[14] A parenting blogger discovered that Abbot pays other mommy bloggers to give positive reviews of its iPhone application for Similac infant formula.[17]

### 3.3 DTC Internet marketing that circumvents the physician intermediary

Physicians stand as the intermediaries between the patient and drug selection and use. However online medical testing allows companies to circumvent the learned intermediary. Internet marketed direct-to-consumer Genetic Testing uses DNA sequencing and genomic profiling to provide individual risk for a particular disease or condition.[36] This system of identifying potential future diseases includes “the sale and use of genetic tests without the involvement of a health care provider.”[34] These tests, which companies directly provide risk profiles for, include but are not limited to fetal sex, lifestyle factors (athletic performance, dermagenetics, smoking cessation), thrombosis risk, chronic diseases (osteoporosis, breast cancer, Alzheimer disease, diabetes, glaucoma) and immune related conditions (HIV and Celiac disease).[34] Critics have expressed concern that absent physician counseling directed testing will confuse or mislead consumers[40] In fact the Government Accountability Office a congressional research service found that test results of four different DTC genetic testing websites were misleading.[50] In several cases the patients were mistakenly told that they had an increased risk of contracting a particular disease.[50] The Federal Trade Commission of the United States issued a statement urging “skepticism” for at home genetic tests.[6]

Many of the companies who market these tests are not covered under the Health Insurance Portability and Accountability Act (HIPAA) meaning that consumers' information can be disclosed or used publically without their consent.[40] Companies provide online repositories for these genetic test results.[65,95,96] Some tests give patients the ability to share the results via the company's social networking tools.[46] 23andMe, a personal genome company, has gone a step further and created

“23andWe” which asks participants to complete survey data that can be combined with other test results for future research.[54] This recent development brings into question the ability to identify individuals and the security of the database.[54] No country has regulations for DTC genetic testing.[15,65,95]

In August 2011, Google acknowledged that it worked with Canadian pharmacies to use web based advertising to circumvent physicians to directly sell drugs to patients in the United States. [61] In a settlement with the United States Department of Justice, Google agreed to pay \$500 million for accepting money from these “rogue” pharmacies and allowing them to advertise despite the fact that they were not registered as official pharmacies.[61]

## 4. Discussion

### 4.1.1 International Perspective

The internet is an international media source and as a result all the US internet based marketing is available in all countries to anyone with an internet connection and vice-versa.[47,87] We examine here how DTC is viewed in similar markets outside the United States.

Currently only the United States and New Zealand allow advertising of prescription drugs directed to patients.[62] Direct to consumer marketing arose in New Zealand primarily because no specific legislation prohibited it. Soon after the treaty was signed, the New Zealand health minister made statements that despite a “huge campaign against me by very powerful and very well heeled pharmaceutical companies” she would support a ban on direct to consumer marketing.[20] If this her ban was implemented, the standards would still allow unbranded material which promoted disease awareness.[20] The New Zealand government held public hearings in 2006; two thirds of the submissions opposed DTC advertising.[85] Despite this opposition, New Zealand has not changed its permissive policies.

Unlike the U.S. and New Zealand, Canada limits DTC advertisements and has done so since 1949.[68] Recent legislation allows two forms of advertisements: reminder ads which include only the brand name with no mention of health claims or product use; and disease-oriented ads, which discuss a specific condition but ambiguous treatment.[63] A

large media company has recently tried to challenge these laws based on “freedom of the press and other media of communications.”[80]

Currently, the European Union restricts all advertising of prescription drugs including television and print advertisements.[3] DTC advertisements are not allowed. An 2002 official vote of the European Parliament showed a large majority (494 to 42) were against DTC advertisements.[63] Nevertheless since 2002, pharmaceutical companies and their supporters have made many proposals to allow DTC advertisements.[24,63] The law currently allows disease-oriented campaigns as long as no brand is mentioned.[29,63] The first television commercial aired nationwide in the United Kingdom in 1999 for the incontinence drug Detrusitol.[29] The advertisement was cleared by the Medicines Control Agency and did not name the company sponsor, Pharmacia and Upjohn, but displayed their logo.[29]

#### 4.2.1 General Evaluation of DTC

Web 2.0 DTC is merely a subset of pharmaceutical marketing; however, as we have shown, it is more likely to be camouflaged, permits companies to directly gather data on patients, and changes rapidly. Internet DTC is difficult to monitor. Many studies have evaluated the impact of “on non-internet” DTC on drug seeking, switching, use and costs. DTC has been shown to increase drug switching and resultant drug costs.[37] Retrospective surveys of physicians and patients have found that most patients believe that ads improved their understanding of diseases and treatments.[31,37] However content analysis research indicates that if patients were influenced they were misled; only 26% of ads provided information on drug risks.[31] Two-thirds of ads omitted information on alternative treatments with fewer side effects (e.g. behavioral changes).[31] Descriptions of drug benefits are often vague and exaggerated.[31] On product web sites, benefits appear on the first page while risk information is often incomplete and several links away.[26,41] Previous research has proposed guidelines for risk information including separate risk and benefit information sections on the website and placing risk and benefit information link on the website.[88]

Consistent with content analysis direct research has found that participants had better recall of drug benefits than risks.[44] There is scarce evidence to conclude that DTC marketing is a valuable educational tool.

## 5. Conclusion

We have reviewed a subset of Pharmaceutical DTC marketing that uses Web 2.0 technologies. The World Health Organization has called DTC advertising “an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way”[66] DTC advertisements are designed to increase sales.[56] The industry acknowledges this through its *DTC Excellence Awards* which only consider “creativity and breakthrough execution of the marketing strategy” - (60%) and “bottom-line results in achieving marketing objectives and growing sales” - (40%) [49] The fact that the awards are based on return on investment (ROI) data means that pharmaceutical companies routinely study and record the impact of DTC on sales. Although they have submitted this information to compete in contests they have never published anything on this topic. The awards do not ask for information related to DTC impact on education of patients or physicians.

The majority of the public does not understand the possible side effects and ultimate purpose of DTC advertising; many believe that the mere presence of DTC advertising indicates that a drug is “perfectly safe.”[16] Increasing numbers of people are utilizing the internet in the hope of obtaining a more complete and accurate drug information source.[48] A survey of people who had seen a doctor within the last three months, revealed that 29% believed “only the safest prescription drugs are allowed to be advertised to the public.”[11] In fact, many drugs are removed due to safety concerns after FDA approval.[52] One study found that English language DTC marketing crossed the US border to Canada and increased sales by 42% in English speaking provinces of Canada compared with French speaking provinces.[53] The drug was later withdrawn from the market due to safety concerns.[53] This study found that direct to consumer marketing had an effect on Canadian prescribers who were affected by advertisements coming from the United States.[53] Bell, Wilkes, and Kravitz raise concerns that DTC advertising may interfere with free, informed choice of health care treatments due to the patient’s “falsely confident views about the extent to which these [advertisements] are regulated.” [94]

FDA has repeatedly cited pharmaceutical companies for illegal Web 2.0 marketing. [10]

Pharmaceutical companies have repeatedly called on the FDA to regulate web based marketing but the FDA has refused to issue any regulations.[25,35] Thus Web 2.0 marketing remains an unregulated threat to public health and the general economy that must be addressed.

In 2005, Senator Bill Frist proposed a moratorium on consumer advertising which he believe led to increased prescription costs. [5] In 2007 the Institute of Medicine of the National Academy of Sciences committee recommended that manufacturers refrain from advertising for the first two years after a drug is approved in order to allow physicians to form their own opinions and safety to be evaluated in the patient population.[82] Even PhRMA, has suggested a moratorium on new drugs to its guiding principles although it does not specify a specific time frame.[69] The impact of DTC on health and health care costs has not been fully researched and remains controversial. Given the magnitude of FDA sanctions it seems clear, that based on current research, the actual and potential side effects of DTC far outweigh any benefits. Pharmaceutical companies who have the best data on the impacts of DTC have failed to publish their results.

Pending publication of reliable and replicated research on all aspects of DTC, the FDA should join the rest of the world and issue a moratorium on all DTC marketing. In the short term, since much web 2.0 marketing is camouflaged, the FDA should require companies engaged in digital marketing to provide the FDA with description and budgets for all web 2.0 marketing.[21]

## Disclosure

DE has testified at the request of people injured by drugs and devices and consults with companies regarding warnings and FDA regulations. ND is employed by DE.

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