



**Presentation By:  
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**FDA Hearing On:**

**Promotion of FDA-Regulated Medical Products Using the Internet and  
Social Media Tools**

**Response to Question 4 on the Use of Links**

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## **Introduction and Credentials**

Ladies and Gentlemen of the Panel,

Thank you very much for the opportunity to speak here today about this important matter for which the FDA is seeking input.

Before I get into the substance of my remarks I'd like to briefly introduce myself and establish my expertise in the use of the Internet and social media in the promotion of FDA-regulated products. In the spirit of full transparency, I must disclose that my work includes providing consulting services to several medical products companies and healthcare organizations. However, the opinions that I am expressing here today are wholly my own and not those of my clients.

I am the founder and currently the chairman of W2 Group, a group of digitally driven marketing services companies that help marketers in their new role as builders of communities and content aggregators. Two W2 Group companies, Racepoint Group and Digital Influence Group, are leaders in social media marketing in both paid and unpaid media and work with several medical products companies.

I have personally been involved with the use of the Internet going back to its earliest days. I helped launch HTML with Sir Tim Berners Lee and AOL with

Steve Case. I founded one of the first interactive marketing agencies and also co-founded the Massachusetts Interactive Media Council, which later became the Massachusetts Innovation and Technology Exchange. MITX is now the largest Internet advocacy association in the world. I have also served as a member of Massachusetts Governor Deval Patrick's Transitional Working Group, which was tasked with providing strategic recommendations for Massachusetts to become the leader in digital governance and digital inclusion. I continue to advise Governor Patrick on technology-related issues.

I have authored two books on the use of social media in business. The first – *Marketing to the Social Web: How Digital Customer Communities Build Your Business* – was published by John Wiley & Sons in 2007. The second – *Sticks & Stones: How Digital Business Reputations Are Created Over Time... And Lost in a Click* – was published by Wiley this past summer. I frequently speak at industry conferences on the topic of social media and business and am delighted to have the opportunity to share my experience and point of view with you here today.

### **Background – Consumer Use of the Internet for Health Information**

There is ample data demonstrating that an increasingly large percentage of Americans are using the Internet as a tool for gathering information on medical conditions, products and services.

According to a June 2009 study by the Pew Internet & American Life Project entitled “The Social Life of Health Information,” 61 percent of American adults look online for health information. That figure is up 15 percentage points from 46 percent in the year 2000. 45 percent of all Internet users now look online for information about prescription or over-the-counter drugs – up from 34 percent in 2002.

When asked about which sources people turn to for information or assistance in dealing with health or medical issues, the Pew research found that:

- 86 percent of all adults ask a health professional, such as a doctor
- 68 percent of all adults ask a friend or family member
- **57 percent – more than half – of all adults use the Internet**
- 54 percent use books or other printed reference material
- 33 percent contact their insurance provider
- 5 percent use other sources

Furthermore, of those people who go online for health information:

- 60 percent said that the information found online affected a decision about how to treat an illness or condition
- 56 percent said it changed their overall approach to maintaining their health or the health of someone they help take care of
- 53 percent said it led them to ask a doctor new questions, or to get a second opinion from another doctor

Conversely, just 3 percent of all adults said that they or someone else they know has been harmed by following medical advice or health information found on the Internet.

Given the data, there is no doubt that the Internet is an important and trusted source of health information for American adults. The usage and percentages are only going to increase with greater Internet broadband penetration of American homes, the possible enactment of healthcare legislation expanding insurance coverage, and the continuing pressure to drive down health-related costs. These three factors combined will lead to greater reliance on the web as the public goes online to understand its treatment options and associated costs. In fact, I believe that the web will ultimately have a greater impact on society and healthcare than television.

### **The Problem**

So what's the problem facing the FDA with respect to Internet advertising and promotion of medical products and the use of online links and social media?

I think that there are two related, major problems.

Problem number one. While people are increasingly turning to the web for health information, companies possessing this information and employing some of the most knowledgeable experts – namely, the pharmaceutical and medical device

manufacturers – are fearful of providing information and of engaging online. The FDA’s failure to distinguish between Internet and print communications – as evidenced most recently by the warnings issued to some pharmaceutical companies in connection with their use of sponsored links – is a major deterrent to manufacturers’ willingness to provide information online. The rigid application of current regulations has caused manufacturers to back away from providing information online and from fully engaging with the social web – rather than risk being singled out by the FDA for violation of regulations designed for print and broadcast media.

Problem number two. As the data I referenced a moment ago indicate, people increasingly trust the web as an information resource. An “If it’s on the web, it must be true” mentality is pervasive. Not to pick on Wikipedia but... people tend to believe everything they read on Wikipedia because it seems like an encyclopedia. Yet, Wikipedia is a community where participants can alter content dynamically and sometimes without citation. The content is not necessarily professionally researched nor validated.

Another example is Google. When people “Google” something they generally rely on whatever information appears at the top of the search results list as the source they go to. Yet, the organic search algorithm that drives links to the top of the list is not based on quality and reliability of content. The search ranking is based on the frequency that the search term has been sourced or referenced.

So, on the one hand we have an adult population that is increasingly using the web, and social media in particular, and trusts the web as a source of health information – whether or not all of that information is accurate and complete. On the other hand, we have a group of companies that possess the desired information and who employ the most knowledgeable experts but that, because of the rigid application of current FDA regulations, are reticent to utilize the full range of the Internet and social media to provide the real-time exchange of information for which these media have been designed and that the public now expects. The result is an information gap of which the average consumer is likely to be unaware.

### **Understanding Online Search**

Nearly one decade into the 21<sup>st</sup> century and 40 years since the birth of the Internet, I think it is time for the FDA to recognize that the web is a fundamentally different communications medium than print and broadcast. Especially with the advent of social media – blogs and micro-blogs such as Twitter, social networks such as Facebook and communities like “PatientsLikeMe” – the web is about interactivity, engagement, and exploration.

The number one application online – and the reason for Google’s meteoric success – is **search**. The Internet provides a quick, easy and inexpensive way for people to get information – anywhere, any time, at their fingertips. The explosion in smart phones such as the iPhone, Blackberry and Droid make that

last statement truer than ever. Online search is by now so ingrained into the fabric of daily life that “Google” has become a verb, not just a noun.

When consumers use Google or any other search engine, they are deliberately looking for links to in-depth information that is related to the keywords that they have entered. Consumers and patients understand that the listing served by the search engine is simply a snapshot to help them determine if the information is relevant to their needs or interests. The expectation is that clicking on a particular link will lead them to more complete information on the topic being searched.

The problem with the current FDA regulations is that they reflect a pre-web communications paradigm in which a passive consumer received information via print and broadcast media. Those regulations don’t take into account the interactivity of the web and the way people search it.

The recent FDA warnings rejected manufacturers’ use of sponsored web links on the grounds that if there is any affirmative statement about the product or the disease it treats on the face of the sponsored link, then the mandatory risk information required by the FDA’s advertising and promotion regulations must appear on the face of the sponsored link itself. According to the FDA, risk information being one-click away is not considered full disclosure and is therefore in violation of its regulations.

This is just not consistent with people's expectations about how web searches work. Sponsored links provide a very limited amount of space for text. It is not possible to include all risk information on the face of the sponsored link, nor do people expect all of that information to appear on the face of the link – especially where the link is bringing people to the manufacturer's web site, where full, compliant risk information is readily available.

### **The Solution**

In my opinion, the FDA should adopt and maintain policies that encourage manufacturers to provide patients and consumers with as much information as possible on all the benefits and risks of a particular drug or device. At the same time, the regulations need to take into account the power of the web as an information sharing platform and as a place where people exchange information, opinions and ideas.

**Transparency** is really the key to freeing up the flow of information from manufacturers to consumers via the Internet. We must ensure that the public understands the source and reliability of health information.

I think that manufacturers will welcome updated guidelines that allow them to provide information and create transparency, especially as it relates to sponsored links and social media. For instance, it should be absolutely clear to consumers that a link is paid or sponsored. Consumers should be made aware that when

they click on a link, they are leaving what could be balanced, unpaid, third-party content and entering a site that is sponsored and that may be designed to promote a medical device or drug. Similarly, participation by manufacturers or by their employees and representatives in social media should be non-anonymous and transparent.

We must not, however, over-regulate the communications revolution of our time. The Internet and social media are meant to give consumers the option to review a diverse range of information. All this must be kept in mind when considering how to regulate in a way that protects patients and allows manufacturers to provide the content for which consumers are searching.

### **Conclusion**

I hope these remarks have been useful to the panel and I would be happy to take any of your questions. Again, thank you for the opportunity to address the questions before us today. Please consider me a resource beyond this public meeting as you consider and take action on these vitally important issues.