KING & SPALDING

Potential Perils of Using New Media in Marketing and Promotion

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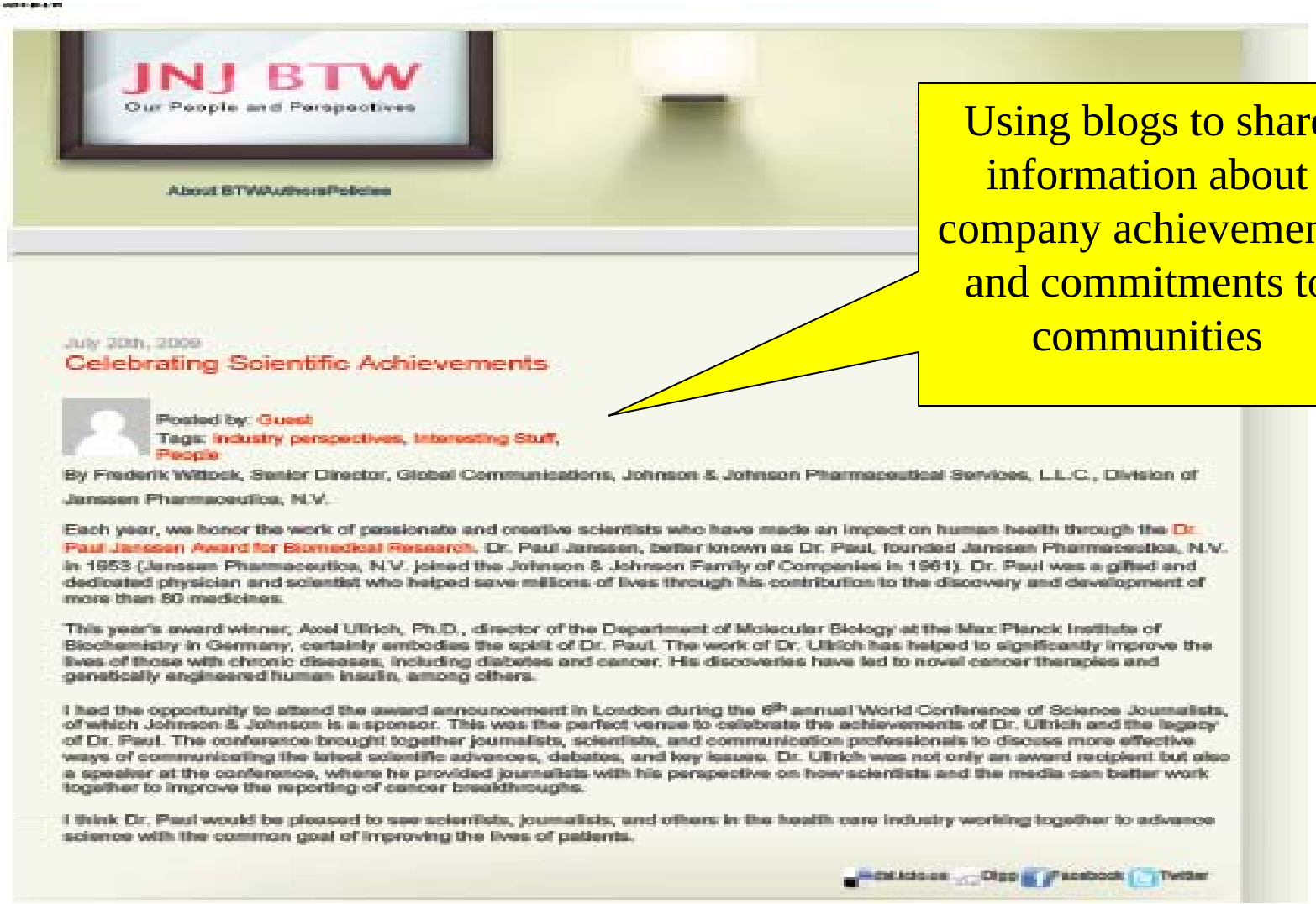
FACEBOOK


Remember Me
facebook
Email
Sign Up
WomenHeart - Strong @Heart is on Facebook
Sign up for Facebook to connect with WomenHeart - Strong @Heart.
Using Facebook to develop online community
STRONG @HEART
WomenHeart - Strong @Heart
Wall
Info
Boxes
Fan Stories
Experts
Fans
6 of 13,955 fans
See All
Erin
Leah
Heather
Betty
Dianne
John
Create a Page for My Business
Report Page
Detailed Info
Mission:
Welcome to the WomenHeart Strong @Heart online community!
Though one in three women in this country has some form of heart disease, women are still not receiving the same in-hospital treatment that men do for heart attacks and as a result, may be more likely to die.
This disparity in care is a big concern. For example, women are 14% less likely than men to be treated with aspirin following a heart attack. Now more than ever, women need to understand their risk factors for heart disease – which include age, a family history, smoking, physical inactivity, high blood pressure, increased LDL cholesterol and diabetes – and advocate for their own heart health.
Bayer Healthcare LLC, the maker's of Bayer® Aspirin and WomenHeart, the nation's only national organization dedicated solely to promoting women's heart health, have teamed up to create this page to provide information, inspiration and hope to the hundreds of thousands of women living with heart disease, their families and friends. By providing you with the tools you need, you can change the course of your health by being smarter, empowered and Strong @Heart.
We'll be providing updates throughout the month of February and beyond to keep you informed of the latest news and information about heart disease and what you can do to protect yourself and your loved ones. Upcoming features will include recent media clips about heart disease, podcasts and interviews with the experts in the field. We hope you'll join our community by becoming a fan and we look forward to seeing you here again soon.

TWITTER

Using Twitter as another communication avenue for company clinical trial and approval news

BLOGS



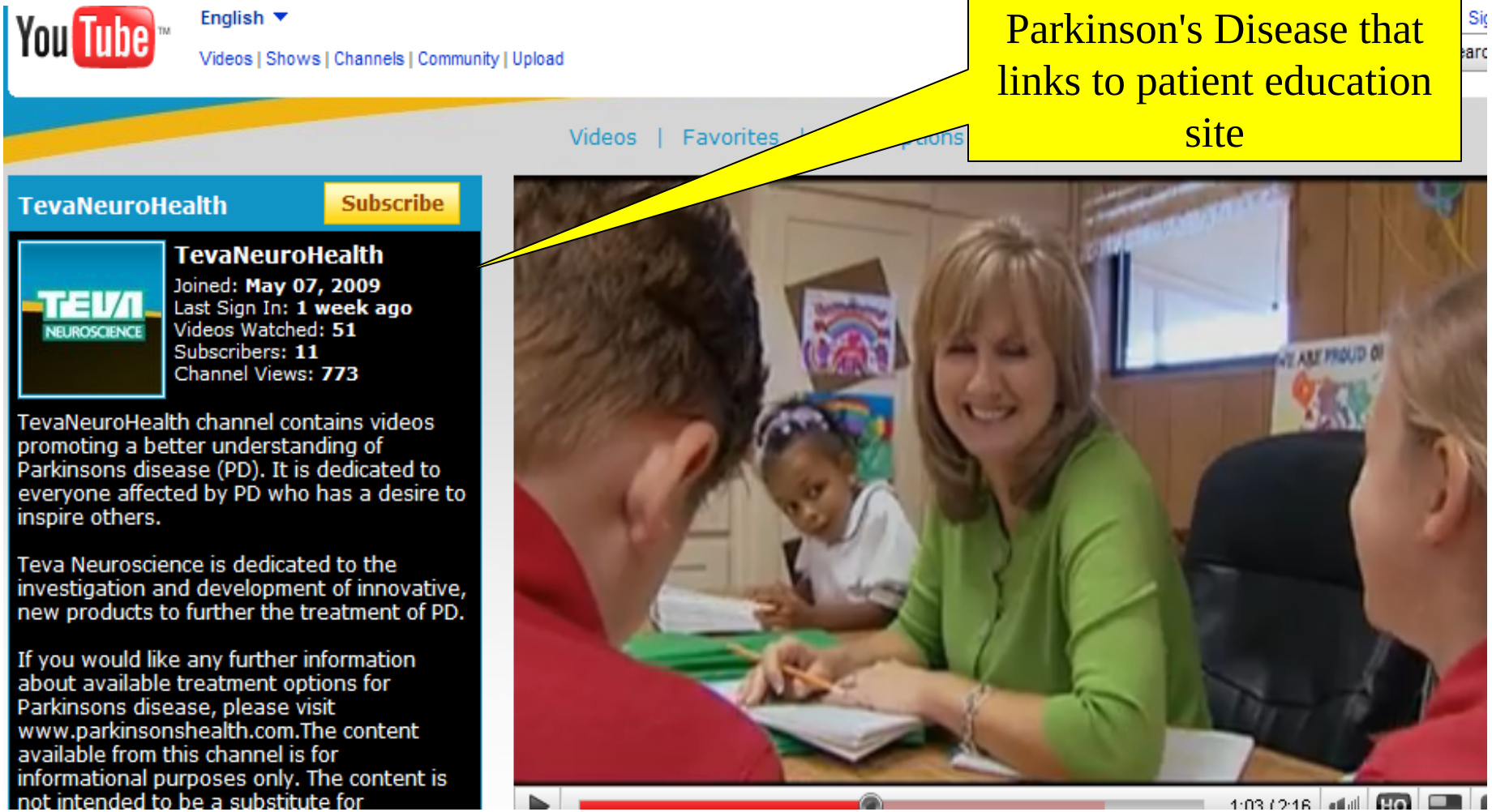
Using blogs to share information about company achievements and commitments to communities

BLOGS

Focuses on corporate and other healthcare related news, chronic diseases, corp. social responsibility, GSK people and musings on healthcare reform

YOU TUBE & WEBCASTS

Online channel about Parkinson's Disease that links to patient education site



POTENTIAL PERIL AREAS OF NEW MEDIA

- Regulatory Compliance
- Kickbacks and False Claims
- Products Liability
- Intellectual Property

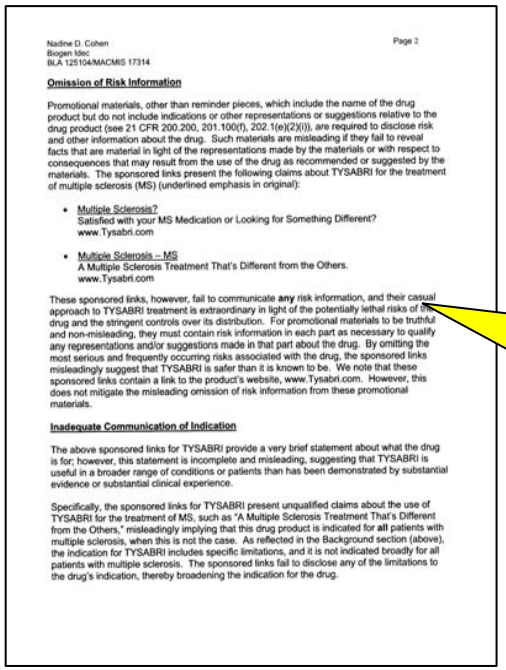
REGULATORY COMPLIANCE

"If drug companies or others working on behalf of drug companies wish to promote [their products] using social media tools, FDA would evaluate the resulting messages as to whether they comply with the applicable laws and regulations. Our laws and regulations don't restrict the channels that prescription drug companies choose to use for disseminating product promotional messages."

- ***FDA Spokesperson Karen Riley, quoted in "Drug Firms Jockey For Space Online," Washington Post (June 16, 2009)***

FAIR BALANCE AND THE INTERNET

FDA affirmatively reviews electronic-based promotional materials and claims -- Even when using a “new” medium such as the internet, promotional messages must provide complete and truthful information about the product.



Nadine D. Cohen
Biogen Idec
BLA 125104/MACMIS 17314

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Omission of Risk Information

Promotional materials, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product (see 21 CFR 200.200, 201.100(f), 202.1(e)(2)(i)), are required to disclose risk and other information about the drug. Such materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. The sponsored links present the following claims about TYSABRI for the treatment of multiple sclerosis (MS) (underlined emphasis in original):

- Multiple Sclerosis?
  Satisfied with your MS Medication or Looking for Something Different?
  www.Tysabri.com
- Multiple Sclerosis – MS
  A Multiple Sclerosis Treatment That's Different from the Others.
  www.Tysabri.com

These sponsored links, however, fail to communicate **any** risk information, and their casual approach to TYSABRI treatment is extraordinary in light of the potentially lethal risks of the drug and the stringent controls over its distribution. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any representations and/or suggestions made in that part about the drug. By omitting the most serious and frequently occurring risks associated with the drug, the sponsored links misleadingly suggest that TYSABRI is safer than it is known to be. We note that these sponsored links contain a link to the product's website, www.Tysabri.com. However, this does not mitigate the misleading omission of risk information from these promotional materials.

Inadequate Communication of Indication

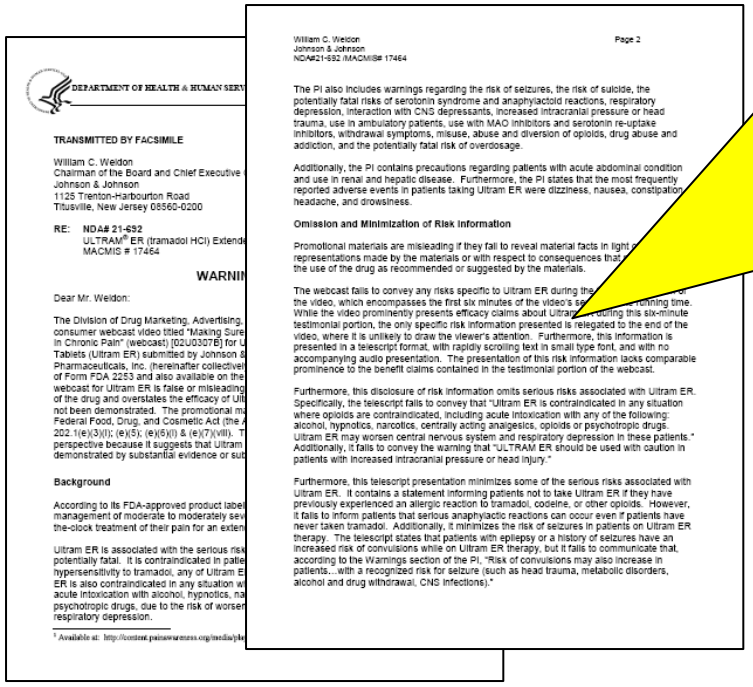
The above sponsored links for TYSABRI provide a very brief statement about what the drug is for; however, this statement is incomplete and misleading, suggesting that TYSABRI is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience.

Specifically, the sponsored links for TYSABRI present unqualified claims about the use of TYSABRI for the treatment of MS, such as "A Multiple Sclerosis Treatment That's Different from the Others," misleadingly implying that this drug product is indicated for **all** patients with multiple sclerosis, when this is not the case. As reflected in the Background section (above), the indication for TYSABRI includes specific limitations, and it is not indicated broadly for all patients with multiple sclerosis. The sponsored links fail to disclose any of the limitations to the drug's indication, thereby broadening the indication for the drug.

“The above sponsored links for TYSABRI provide a very brief statement about what the drug is for; however, this statement is incomplete and misleading, <u>suggesting that TYSABRI is useful in a broader range of conditions or patients than has been demonstrated</u> by substantial evidence or substantial clinical experience.”

FAIR BALANCE AND THE INTERNET
J&J Warning Letter, May 12, 2009

- In webcasts, risk information must have comparable prominence to benefit information.



DEPARTMENT OF HEALTH & HUMAN SERV

TRANSMITTED BY FACSIMILE

William C. Weldon
Chairman of the Board and Chief Executive
Johnson & Johnson
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560-0200

RE: NDA# 21-692
ULTRAM® ER (tramadol HCl) Extend
MACMIS # 17464

WARNI

Dear Mr. Weldon:

The Division of Drug Marketing, Advertising,
consumer webcast video titled "Making Sure
In Chronic Pain" (webcast) [02U0307B] for U
Tablets (Ultram ER) submitted by Johnson &
Pharmaceuticals, Inc. (hereinafter collectivel
of Form FDA 2253 and also available on the
webcast for Ultram ER is false or misleading
of the drug and overstates the efficacy of Ult
not been demonstrated. The promotional m
Federal Food, Drug, and Cosmetic Act (the A
202.1(e)(3)(i); (e)(5); (e)(6)(i) & (e)(7)(viii). T
perspective because it suggests that Ultram
demonstrated by substantial evidence or sub

Background

According to its FDA-approved product label
management of moderate to moderately sev
the-clock treatment of their pain for an exten

Ultram ER is associated with the serious risk
potentially fatal. It is contraindicated in patie
hypersensitivity to tramadol, any of Ultram E
ER is also contraindicated in any situation w
acute intoxication with alcohol, hypnotics, na
psychotropic drugs, due to the risk of worsen
respiratory depression.

[1] Available at: http://content.painawareness.org/media/pk

William C. Weldon
Johnson & Johnson
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The PI also includes warnings regarding the risk of seizures, the risk of suicide, the potentially fatal risks of serotonin syndrome and anaphylactoid reactions, respiratory depression, interaction with CNS depressants, increased intracranial pressure or head trauma, use in ambulatory patients, use with MAO inhibitors and serotonin re-uptake inhibitors, withdrawal symptoms, misuse, abuse and diversion of opioids, drug abuse and addiction, and the potentially fatal risk of overdosage.

Additionally, the PI contains precautions regarding patients with acute abdominal condition and use in renal and hepatic disease. Furthermore, the PI states that the most frequently reported adverse events in patients taking Ultram ER were dizziness, nausea, constipation, headache, and drowsiness.

Omission and Minimization of Risk Information

Promotional materials are misleading if they fail to reveal material facts in light of representations made by the materials or with respect to consequences that the use of the drug as recommended or suggested by the materials.

The webcast fails to convey any risks specific to Ultram ER during the video, which encompasses the first six minutes of the video's seven-minute running time. While the video prominently presents efficacy claims about Ultram ER during this six-minute testimonial portion, the only specific risk information presented is relegated to the end of the video, where it is unlikely to draw the viewer's attention. Furthermore, this information is presented in a telescript format, with rapidly scrolling text in small type font, and with no accompanying audio presentation. The presentation of this risk information lacks comparable prominence to the benefit claims contained in the testimonial portion of the webcast.

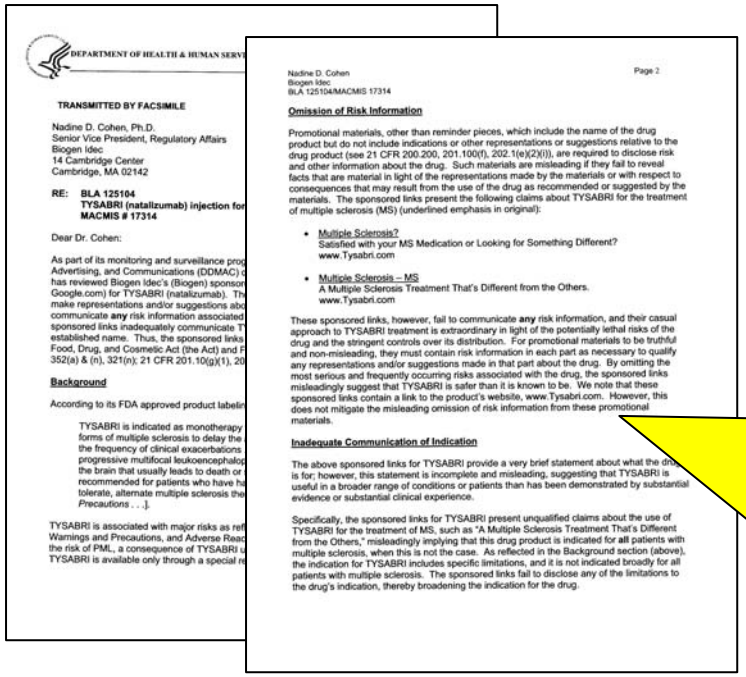
Furthermore, this disclosure of risk information omits serious risks associated with Ultram ER. Specifically, the telescript fails to convey that "Ultram ER is contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. Ultram ER may worsen central nervous system and respiratory depression in these patients." Additionally, it fails to convey the warning that "ULTRAM ER should be used with caution in patients with increased intracranial pressure or head injury."

Furthermore, this telescript presentation minimizes some of the serious risks associated with Ultram ER. It contains a statement informing patients not to take Ultram ER if they have previously experienced an allergic reaction to tramadol, codeine, or other opioids. However, it fails to inform patients that serious anaphylactic reactions can occur even if patients have never taken tramadol. Additionally, it minimizes the risk of seizures in patients on Ultram ER therapy. The telescript states that patients with epilepsy or a history of seizures have an increased risk of convulsions while on Ultram ER therapy, but it fails to communicate that, according to the Warnings section of the PI, "Risk of convulsions may also increase in patients...with a recognized risk for seizure (such as head trauma, metabolic disorders, alcohol and drug withdrawal, CNS infections)."

"The webcast fails to convey any risks specific to Ultram ER during the testimonial portion of the video, which encompasses the first six minutes of the video's seven-minute running time. While the video prominently presents efficacy claims about Ultram ER during this six-minute testimonial portion, **the only specific risk information presented is relegated to the end of the video, where it is unlikely to draw the viewer's attention**. Furthermore, this information is presented in telescript format, with rapidly scrolling text in small type font, and with no accompanying audio presentation. The presentation of this risk information lacks comparable prominence to the benefit claims contained in the testimonial portion of the webcast." (emphasis added)

FAIR BALANCE AND THE INTERNET

- In April, 2009, FDA sent Untitled Letters to approximately 14 pharma companies stating that the use of sponsored links on internet search engines such as Google.com are misleading because they do not include product risk information.



DEPARTMENT OF HEALTH & HUMAN SERV

TRANSMITTED BY FACSIMILE

Nadine D. Cohen, Ph.D.
Senior Vice President, Regulatory Affairs
Biogen Idec
14 Cambridge Center
Cambridge, MA 02142

RE: BLA 125104
TYSABRI (natalizumab) injection for
MACMIS # 17314

Dear Dr. Cohen:

As part of its monitoring and surveillance prog
Advertising, and Communications (DDMAC) c
has reviewed Biogen Idec's (Biogen) sponsor
Google.com) for TYSABRI (natalizumab). Th
make representations and/or suggestions abo
communicate **any** risk information associated
sponsored links inadequately communicate T
established name. Thus, the sponsored links
Food, Drug, and Cosmetic Act (the Act) and F
352(a) & (n), 321(n); 21 CFR 201.10(g)(1), 20

Background

According to its FDA approved product labelin

> TYSABRI is indicated as monotherapy
> forms of multiple sclerosis to delay the
> the frequency of clinical exacerbations
> progressive multifocal leukoencephalop
> the brain that usually leads to death or
> recommended for patients who have h
> tolerate, alternate multiple sclerosis the
> *Precautions . . .*].

TYSABRI is associated with major risks as ref
Warnings and Precautions, and Adverse Reac
the risk of PML, a consequence of TYSABRI u
TYSABRI is available only through a special r

Nadine D. Cohen
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"The sponsored links, however, **fail to communicate any risk information**, and their casual approach to TYSABRI treatment is extraordinary in light of the potentially lethal risks of the drug and the stringent controls over its distribution . . . By omitting the most serious and frequently occurring risks associated with the drug, the sponsored links misleadingly suggest that TYSABRI is safer than it is known to be. We note that theses sponsored links contain a link to the product's website. . . However, this does not mitigate the misleading omission of risk information from these promotional materials."

THIRD PARTY USE OF INFORMATION

- FDA has informally recognized that some content about a company's products may be on the web without the company's knowledge or permission (anyone can post content to You Tube).
- A company will only be responsible for content that it *created or put together.*
- The key from an enforcement perspective is to determine the *company's involvement* in the message - key considerations include:
  - Did the company or a third party working on the company's behalf (*e.g.*, ad agency) create the piece?
  - Did the company have control over any part of the activity, including prompting others to comment about the drug?

THIRD PARTY USE - ALTERING CONTENT

- FDA also understands that a 3rd party (*e.g.,* the media) may alter the content originally created and approved by the company, for example, by showing only the benefit information and not including risk information in a news segment.
- Drug companies should protect themselves from enforcement with respect to unauthorized alterations or use by submitting promotional materials as proof of what the company intended to release into the public domain.

March 2009 Podcast with Dr. Jean-Ah Kang, Special Assistant to Tom Abrams at DDMAC in charge of Web 2.0 policy development available at:
http://www.eyeonfda.com/eye_on_fda/2009/03/a-conversation-with-fdaddmac-about-pharma-social-media-and-web-20.html

UPCOMING OPPORTUNITY TO REQUEST FDA GUIDANCE

- Public meeting scheduled for November 12-13, 2009.
- Written comments may be submitted through February 28, 2010.

- **Topics of FDA interest include --**
  - Scope of responsibility and accountability
  - Manner of fulfilling regulatory requirements
  - Parameters for linking between sites
  - Adverse event reporting

POTENTIAL PERIL AREAS OF NEW MEDIA

- Regulatory Compliance
- Kickbacks and False Claims
- Products Liability
- Intellectual Property

ANTI-KICKBACK STATUTE

- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) makes it a criminal offense to:
  - knowingly and willfully
  - offer, pay, solicit or receive
  - any remuneration (in cash or in kind -- cash, services, anything of value)
  - to induce (or in exchange for)
  - the purchasing, ordering, or recommending of any good or service reimbursable by any federal health care program
- Intent-based, but requisite intent may be inferred from the circumstances.
- Exposure if one purpose -- not even primary purpose -- is to induce.

ANTI-KICKBACK STATUTE

- Almost anything of value provided to a prescriber or referral source can implicate the broad scope of the statute:
  - Work done by the company for which the physician gets sole credit (*e.g.*, ghostwriting)
  - Public relations work, such as press releases
  - Free publicity
  - Web hosting

FALSE CLAIMS ACT

- False Claims Act (FCA) (31 U.S.C. §§ 3729-33) makes it unlawful (civil) to:
  - knowingly (which can be shown by reckless disregard for the truth)
  - present a false claim for payment, or
  - use a false record or statement to get a claim paid or approved, or
  - cause a third party to do either of the above

- "Knowledge" = actual knowledge, reckless disregard, deliberate ignorance.
  - Must prove only by preponderance of the evidence

FALSE CLAIMS ACT

- **Under "implied certification" theory, violations of regulatory requirements may be adequate predicate for FCA violation.**
  - Example: A US District Court recently allowed qui tam plaintiff to proceed on theory that GMP violations could form the basis of an FCA suit in the context of a Defense Department contract for the production of anthrax vaccine. (BioPort)
- **Prosecutors (and some courts) have held that kickback violations also result in FCA liability.**
  - Theory: Government would not reimburse for goods/services that are the subject of the kickback, companies therefore "cause" false claim to be submitted.

FALSE CLAIMS ACT

- Private citizens ("relators") may bring an action under the FCA by filing a ***qui tam*** complaint, which is filed under seal and served on the Attorney General.
- Government required to investigate and make decision on whether to "intervene"; if so, government takes over investigation.
- If government does not intervene, private *qui tam* relator may pursue the action on his/her own (though government may still participate in the case).
- Successful *qui tam* relators can receive:
  - Up to 25% of eventual recovery in cases where government intervenes
  - 30% where relator pursues case on his/her own
- Vast majority of major health care fraud cases in past 10 years involved *qui tam* complaint.
- DOJ and HHS OIG officials have said there are many *qui tam* complaints against pharmaceutical manufacturers in the pipeline.

ENFORCEMENT

- Justice Department Announces Largest Health Care Fraud Settlement in its History:
  - Pfizer pays $2.3 billion for alleged fraudulent marketing.
  - Criminal fine of $1.195 billion.
  - $1 billion to resolve allegations under the civil False Claims Act regarding alleged illegal promotion of four drugs that resulted in false claims to be submitted to government health care programs for uses that were not medically accepted indications and thus not covered.
  - Whistleblower lawsuits filed three different federal districts (KY, MA and PA) triggered the investigation.
  - Key allegation: Promoting the drug using ghostwritten journal articles that never disclosed the company's role.

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QUESTIONS?