FDA's Internet Ad Warnings: Implications for Social Media

National Pharma AudioConference

Meredith Manning

Partner

May 20, 2009

HOGAN & HARTSON

FDA's Enforcement History

HOGAN & HARTSON

- In 2001, Washington Legal Foundation petitioned FDA to treat internet communications as advertising, as opposed to labeling
  - This would allow internet ads to contain a brief summary of risks rather than adequate directions for use and the full prescribing information
- FDA demurred, indicating that it would assess internet communications on a case by case basis
- For years, the agency said virtually nothing more
  - Informal statements by DDMAC indicated that industry could "choose" between promotional labeling and advertising rules
- Industry largely adopted its own conventions for presenting risk information
  - Included links to the full prescribing information (under a "one click" away theory)
  - Important Safety Information at the bottom of internet pages

FDA's 2008 Letters

HOGAN & HARTSON

- The Adderall Letter
  - **In September 2008, FDA sent enforcement letters to the manufacturers of drugs approved for ADHD**
  - **Among those was a letter to Shire that objected to a video "testimonial" by a celebrity posted to YouTube**
  - **DDMAC's objections to the video mirrored its objections about the Adderall webpage –**
    - **broadens the drug's indication, overstates effectiveness, omitts safety information**
  - **DDMAC added that the video had not been submitted to FDA on first use**
  - **On balance, the Adderall letter was not about the YouTube video, but made clear that the video would be treated the same as a print testimonial**

FDA's 2008 Letters

HOGAN & HARTSON

- The Diovan NOV
  - In August 2008, Novartis received a NOV regarding Diovan banner ads
  - The letters objected to numerous banner ads because the ads included risk information *only* through a link to the full PI and patient package insert
  - Diovan is a Black Box product but FDA did not make this distinction in its letters
  - FDA objected to effectiveness claims in the banner ads without presentation of any risk information

April 2 “Sponsored Links” Letters

HOGAN & HARTSON

- The April “sponsored link” letters made the same allegations regarding the use of sponsored links as the Diovan letter
- The links are sponsored by companies, thus they are considered advertising or promotional labeling by FDA
- The links included a brand name plus a claim, thus they triggered the requirement for risk information
- But, the ads only provided risk information through a link
- The letters appear selective – many companies did not get letters
  - FDA has not indicated the factors it used in determining which sponsored links are acceptable vs. those that are not
  - Does this mean that “vanity” URLs are acceptable?

Metatags

HOGAN & HARTSON

- It is clear that DDMAC believes that metatags may broaden an indication
  - FDA has objected to metatags in the context of unapproved new drugs, particularly supplements
  - H&H has seen DDMAC correspondence regarding companies' uses of metatags to drive traffic to an internet site
- This position also indicates DDMAC is unwilling to expand the principles behind the print rules to the internet
  - The metatag position does not recognize that consumers/patients may want internet searching to be both easy and broad in scope
  - Does this represent FDA's tendency toward paternalism?

Questions About Social Media

HOGAN & HARTSON

- Because of this trend, seems clear that a manufacturer will be held responsible for its own conduct on a social media site
  - Must follow the print rules, e.g. the Reprints Guidance, the unsolicited request policy
- But, there are major questions surrounding responsibility for third-party posts or activities
  - The *Craigslist* principle (website hosts are exempt from standards applying to media publishers under the Fair Housing Act) should apply to third party conduct
- Manufacturers will have to make difficult decisions about sponsoring blogs, chat rooms, and interactive for a
  - Does monitoring sites help or hurt?
  - How will FDA apply the “intended use” rules governing the actions of third parties to these sites?

HOGAN & HARTSON

For more information on
Hogan & Hartson, please visit us at

www.hhlaw.com