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The Global Impact of the Internet on the Pharmaceutical Industry

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The Encyclopaedia Britannica Story

- ◆ Leader in its field - content
- ◆ Direct sales force
- ◆ A new technology: CD-Rom
- ◆ A new competitor



The Britannica Lessons For Pharma

- ◆ Market leaders - Most Vulnerable
- ◆ Corporate Culture - Obscures Vision
- ◆ Legacy Assets - Cannibalization Dilemma
- ◆ Not a Zero Sum Game



Pharma on the Web

- ◆ The pharmaceutical industry has been a relatively slow adopter of the Internet.
- ◆ Lessons learned from the eHealth sector shakeout.
- ◆ From “Who Wants to be a Millionaire?” to “Survivor.”

You have to be in e-commerce in every element of your business, in all your supply chain, in all your information flow, in all your communications, in all your customer interactions. This is not some activity outside the business – this is business.”

-Jack Welch
CEO of GE



The Internet and Pharma

- ◆ Research
- ◆ The Consumer
- ◆ The Physician



The Internet and Pharma

- ◆ Supply Chain Management
- ◆ Alliances/Licensing/Biotech
- ◆ End to End Impact



The Shifting Focus Of Pharma

- ◆ Broader and more effective marketing is a means of sustaining revenues in a time of slowed new product development.
- ◆ The Internet is the new frontier in marketing for pharma.
- ◆ E-commerce takes on new meaning for pharma:
 - ❖ Can't sell pills directly to consumers
 - ❖ Pharma on the Internet focuses upon facilitating or influencing the process of getting pills to consumers



Pharma Dollars on The Web

- ◆ In 1999, despite a record \$1.9 billion spent on advertising, less than 1% was spent on Web sites.
- ◆ 90% of pharma companies plan to increase Internet spending.
- ◆ 20% intend to double Internet spending.

- Source: Jupiter Communications



Physician Sites

- ◆ Branded information-centric sites for healthcare professionals
- ◆ Non-branded information-centric sites that focus on disease state, treatment guidelines and breaking category news
- ◆ E-detailing and e-CME
- ◆ Speaker support centers



Physician Sites

- ◆ Micropublishing opportunities.
- ◆ Promotional websites for physicians' offices.



Consumer Sites

- ◆ Consumer sites typically focus upon either:
 - ❖ Trial (visiting physician to discuss condition and ask for Rx)
 - ❖ Compliance (completing full course of treatment)
 - ❖ Persistence (Refilling scripts)



Stakeholder Sites

- ◆ Influencing stakeholders like MCOs, PBMs and pharmacies to obtain favorable position on formularies.

- ◆ Non-branded or “softly branded” disease state sites that:
 - ❖ Can be “private labeled” by MCOs
 - ❖ Used to increase member educational services and interactive tools as trackers or diaries
 - ❖ Contribute outcomes and satisfaction data



How Are Consumers Responding?

- ◆ 28% of consumers would fill prescriptions online.
- ◆ 40% consider pharmaceutical sponsorship a reason for doubting the credibility of healthcare information.
- ◆ 49% of users viewing product information online will ask for the product by name when they visit doctors (at a marketing cost of only \$14 per request).

- Source: Cyber Dialogue



Privacy Issues -- Overview

- ◆ A maze of contradictory and competing laws, both within and outside the U.S., may apply to sites that collect personal data about users:
 - ❖ Electronic Funds Transfer Act.
 - ❖ Fair Credit Reporting Act.



Privacy Issues -- Overview

- ❖ European Union Privacy Directive.
- ❖ The Children's Online Privacy Protection Act.
- ❖ FDA electronic submission regulations.
- ❖ Health Insurance Portability and Accountability Act of 1996 (HIPAA).



Pharma and Online Privacy

- ◆ The pharma industry has invested in and sponsored many leading eHealth sites.
- ◆ Pharma is often driving the collection of online user data.



Privacy Policies

- ◆ A web site privacy policy should not be a generic document -- it must reflect your actual privacy practices.
- ◆ Deceptive or incomplete privacy policies may violate state consumer protection or false advertising laws.
- ◆ Possibility of FTC scrutiny.



Common Privacy Policy Mistakes

- ◆ Failure to disclose use of cookies.
- ◆ “Puffing” regarding level of security protections -
- there’s no such thing as “100% secure.”
- ◆ Failure to address Children’s Online Privacy Protection Act (when applicable).



Common Privacy Policy Mistakes

- ◆ Clearly and accurately describe use of aggregate or de-identified data.
- ◆ Consent to policy updates through continued use of site.
- ◆ Display the policy prominently in order to enhance enforceability (*Ticketmaster v. Tickets.com*)



New Theories of Liability

- ◆ Failure to comply with a site's posted privacy policy may violate state unfair and deceptive acts and practices statutes, as enforced by state Attorneys General.
- ◆ Possibility of negligence action for security breaches, including acting as a host for hacker attacks.
- ◆ A class action lawsuit has even been filed in Texas seeking to apply the Texas anti-stalking law to Yahoo's use of cookies.



Fraud and Abuse in Cyberspace

- ◆ Example: pharmacy advertises on a medical information site and the pharmacy pays based upon number of click-throughs or prescriptions filled.
- ◆ Potential violation of federal anti-kickback statute if payments are being made to induce the referral of goods or services (like some pharmaceuticals) reimbursed by Medicare or Medicaid.
- ◆ Office of Inspector General has not pursued fraud and abuse on the Internet -- yet.



E - Health Ethics Initiatives

- ◆ Health on the Net Foundation's Code of Conduct for Medical Websites
- ◆ Hi-Ethics Alliance Principles
- ◆ Internet Healthcare Coalition's draft "International e-Health Code of Ethics"



E - Health Ethical Issues

- ◆ Disclosure of financial relationships.
- ◆ Distinguishing content from advertising.
- ◆ Utilizing credible sources of medical information and providing authoritative attribution of sources.



Online Prescribing

- ◆ Problem first came to attention with online sales of Viagra to U.S. residents before drug was approved for use in this country.
- ◆ California Attorney General and State Osteopathic Board shut down website of Dr. James DeYarman of San Diego for prescribing Propecia without a good faith examination.
- ◆ FDA and Kansas, Illinois and Missouri state regulators (among others) have taken action against online prescribing of Viagra, Meridia, Xenical and Celebrex.



Online Prescribing

- ◆ Medical Board of California establishes committee to review online prescribing.
- ◆ AMA is establishing Internet prescribing guidelines.
- ◆ National Association of Pharmacy Boards has begun a “Good Housekeeping Seal of Approval”-type program certifying online pharmacies.



FTC Enforcement

- ◆ FTC's Bureau of Consumer Protection, is targeting fraud, violations of consumer privacy and deceptive marketing practices on the Web.
- ◆ FTC's "surf days."
- ◆ Areas of focus: online pharmacies and healthcare products making deceptive claims.



Pharma Sites And Napster?

- ◆ The Association of American Physicians and Surgeons has filed a “friend of the court” brief supporting Napster’s appeal of a preliminary injunction.
- ◆ AAPS brief suggests that the same reasoning that suggests Napster should be shut down could cause Yahoo to be prevented from providing search results with links to sites endorsing off-label uses or criticizing pharma products (e.g., Ritalin).



FDA and The Internet

- ◆ FDA regulates web sites by applying the same rules as apply to other professional activity.
- ◆ When technological differences raise new issues, FDA handles case by case.
- ◆ FDA has not clarified whether the Internet is “labeling” or “advertising.”



Pharma Risk Areas

- ◆ Lack of fair balance
 - ❖ Banner ads need risk information

- ◆ Unsubstantiated claims
 - ❖ URL addresses can constitute a claim (e.g., 100% Cure.com)



Foreign vs. U.S. Approval

- ◆ Information on a company's web site may be lawful in foreign jurisdictions but not in the U.S.
- ◆ FDA's position is that a company's web site must conform to the U.S. clearance or approval status if it is accessible from this country.



Foreign vs. U.S. Approval

- ◆ Web site should clearly indicate U.S. regulatory status of products.
- ◆ Disclaimers alone are not enough.
- ◆ Site must use separate links for U.S. versus foreign visitors regarding products with unapproved or investigational U.S. uses.
 - ◆ VISX Warning Letter (January 12, 2000)



Links and Off-Label Information

- ◆ What if a site links to other areas of Internet discussing off-label information?

- ◆ Examples:
 - ❖ Other sites with links to journal articles
 - ❖ Message boards
 - ❖ Chat rooms



Links And Off-Label Information

- ◆ FDA's position: a firm is responsible for information it links to in the same way that it is responsible for other information.
- ◆ If link would be permissible offline, it is permissible online and vice versa.



Links and Off-Label Information

- ◆ What if content of linked site changes?
- ◆ Most likely, FDA would look at the nature of the site and attempt to determine if the company had a promotional interest in linking to it:
 - ❖ Example: trade association web site might be OK
 - ❖ Example: chat room known to include discussion of off-label use might not be acceptable
 - ❖ No publicly available warning letters so far.



Corporate Review Policy

- ◆ FDA holds firms responsible for their web sites in the same manner as for other promotional materials.
- ◆ It is advisable to have a policy of regulatory review for all material before publishing.