

Federal Regulation of eHealth

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Healthcare Online

Do we really have a problem?

- Three samples (not random)
- Online medicine
 - AskDrWeil.com
- Online pharmacies
 - ThePillbox.com
- Online clinical trials
 - Burzynski Research Institute

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Prescribing Pharmacies on the Net



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Will create Rx online



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Network of physicians for referrals



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Conflict of interest issue?



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Online Docs: Holding out as expert



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Responding to specific cases



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Offering specific advice



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Conflicts and disclosures



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Blurring of Content and Commerce



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Online Clinical Trials



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Assume a consumer... start with Excite



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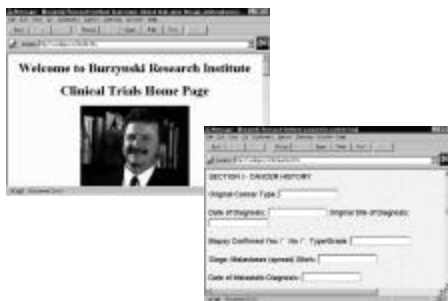
First clinical trial listed for "brain cancer"



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Online enrollment - fees!



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Federal Agencies and Laws

- Department of Health and Human Services
 - Payment - HCFA
 - Pharmaceuticals, devices, biotech - FDA
- Federal Trade Commission
 - Advertising
 - Other than advertising for an Rx product
- OSHA
 - Healthcare workplace
- HIPAA
 - HHS authority to set regulations for privacy of health information

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Healthcare Online

The Wrong Idea?

- **FDA:** "the Internet raises some new and important and very different issues regarding the regulation of promotion"
- **FTC:** "Consumers spend millions of dollars on unproven, deceptively marketed products on the Web."

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Scope of FDA Regulation

Prescription Drugs and Devices

- Traditional promotion
 - Journal advertising
 - Detailing pieces (slides, brochures, pens, mugs)
 - Radio/TV/telephone
- Industry-sponsored activities
 - Continuing medical education
 - Newsletters/house organs/books
 - "Scientific" events (speaker's bureaus, grand rounds, etc.)

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Important Concepts

"Off-Label Use"

- Off-label use: not approved by FDA
 - Physician may prescribe if product is FDA approved
 - No direct promotion through labeling or advertising
- Exceptions
 - CME (if it meets test for independence)
 - Unsolicited request
 - FDA reform law
 - Peer-reviewed article or medical text and
 - Supplemental application will be filed (usually) and
 - Other conditions are met

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The FDA and Metaphysics

The Devil's in the Details...



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration

WARNING LETTER VIA FEDERAL EXPRESS

DEAR DR. XXXXXXX:

The Food and Drug Administration (FDA) has learned through the product labeling accompanying the "XYZ" pregnancy test kit that your firm claims a performance characteristic of, "virtually 100% accurate." . . . [CDRH] has reviewed your premarket notification records and determined this device was not cleared under section 510(k) with a "virtually 100%" claimed performance characteristic. The XYZ device was cleared for a labeled performance characteristic of "greater than 99% accurate."

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1996 FDA Public Meeting

Major Issue Areas for Rx Activities Online

- Presentation of product information
- Direct-to-consumer promotion
- Links between web sites
- Investigational product information
- Chatrooms and newsgroups
- International issues

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HHS - HCFA and HIPAA

Health Care Financing Administration

- Government payer system
- History of fraud and abuse
- Special laws that affect business relationships
 - Antikickback provisions
 - Prohibit any remuneration that influences reimbursement
 - Similar state laws

HIPAA

- Gave HHS regulatory authority in healthcare privacy
- Proposed regulations (2 year delayed effectiveness)

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History of the Draft HIPAA Regulation

- State Laws
 - Patchwork approach (specific record types)
- Legislative efforts
 - Previous bills failed
- EU Directive
 - General approach to individual privacy
 - "Chain of Trust" approach
- HIPAA "exploding authority"
 - Congress had to act before August 1999, or HHS was granted authority to regulate

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HIPAA Coverage

45 CFR 160.103

- Health plans
 - Special transition provisions for "small" plans
- Health care clearinghouses
 - "a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements."
- Health care providers
 - Who transmit health info electronically
 - In connection with a covered transaction

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What does the regulation say? 45 CFR 164.506

- A covered entity may not use or disclose
- an individual's protected health information
- except as otherwise permitted or required by this part
- or as required to comply with applicable requirements of this subchapter

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Uses requiring authorization 45 CFR 164.508

- Authorization required for any use not related to treatment, payment, or health care operations, including but not limited to:
 - Marketing to individuals
 - Disclosure by sale, rental, or barter
 - Disclosure to non-healthcare divisions of entity
 - Disclosure to employers
 - Disclosure for fund-raising purposes
- Special authorization required
 - For use of psychotherapy notes by other than creator
 - For use of research info not related to treatment

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Federal Trade Commission

Regulatory Initiatives in Healthcare

- Regulation of advertising
 - NOT for Rx products (FDA)
 - "Jogging in a Jar"
- Consumer protection
 - FC backup of privacy policies, self-regulation
 - Education - e.g., "Dot Com disclosures"
 - Proposed general privacy legislation
- FTC gets it!
 - The most active federal agency in Internet enforcement and education
 - BUT they are not healthcare focused

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Jurisdiction - A Meta-Problem Online

Local law on a world-wide web

- Web sites available anywhere in the world
 - Except a few countries that attempt to repress
- Web sites often intend their audience to be worldwide
- Default language of the web is currently English
- No one pays attention until there's an issue
 - Canada: Nazi sites on CompuServe
 - Germany: Kiddie porn
 - *Sports Illustrated* in Iran?

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Jurisdiction: Definition

Definitions (derived from Black's 5th ed)

- Subject matter jurisdiction
 - The authority by which courts take cognizance of and decide cases
 - Class of case (e.g., tax)
 - Proper parties (e.g., actual defendant)
 - Powers of court (e.g., geographic region)
- Personal jurisdiction
 - Power which a court has over a person or entity
 - May also have a geographic basis

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Example of Jurisdiction Issue

Direct-to-Consumer Promotion of Rx Drugs

- In the US: No prohibition, but content is regulated
 - Print ads for a decade
 - Web sites for two years
 - Broadcast ads for a year
- Outside the US: A criminal offense
 - No print, broadcast, or web promotion allowed
 - Some exceptions based on different systems
- Cultural approach to patient care differs
 - And payment is usually through national government

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Eli Lilly Approach



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Jurisdiction Issue - Whose Laws Apply?

Range of Practices for Self-Definition

- Open site (no regional checks)
- Self-selection
 - Stateless vs. cookie
 - Intermediate disclaimer page
- Password-protected site
 - Identifying codes (ZIP)
 - Physician verification (DTC issue)
 - Other technologies
- Physical location/language
 - Country specific

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Jurisdiction

Open issues

- Does the Internet require development of new legal systems to handle jurisdictional problems?
- Or is the Internet just the latest in a series of "global village" developments?
- We are just seeing the first real problems
 - Commercial Internet = US dominates for now
 - But e-commerce developments will change that

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Does Enforcement Work?

Can laws create quality health care information online?

- The government regulates professional health care:
 - Products: FDA and FTC
 - Practice/Licensing: OSHA, States
 - Reimbursement/insurance: HCFA, States
 - And self-regulatory organizations/accreditors
- But what about nonprofessionals?
 - Consumers
 - Unregulated practitioners

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Why Government Can't Do It All

The "Focus on the Fringes" Approach at FTC

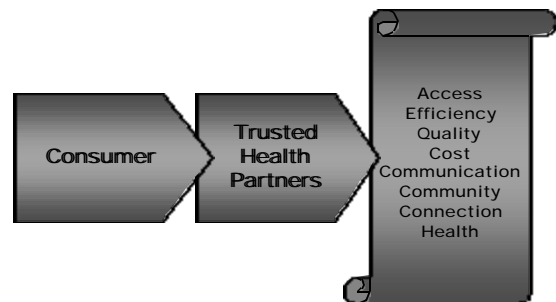
- "Our law enforcement efforts will continue to focus on deceptive and unproven claims. But limited resources cannot keep up with the proliferation of web sites promoting fraudulent products. Consumers must be provided with reliable resources so that they can use the Internet to find the support and health care information they need"

- FTC Press Release, June 24, 1999

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Reintermediation: Building Trust



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Resources Online

Health Care Information Quality

- Educational/Tools
 - Internet Healthcare Coalition (www.ihealthcoalition.org)
 - HITI (<http://hitiweb.mittek.org/>)
- Codes of Conduct
 - Hi-Ethics (www.hi-ethics.org)
 - eHealth Ethics (IHC-led effort)
 - Health on the Net (www.hon.ch)
- Rating sites/systems
 - Healthfinder (www.healthfinder.gov)
 - MedPICS (www.medpics.org)

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Resources Online

Federal Regulation and Laws

- FDA (www.fda.gov)
 - Links to HHS and GPO for Fed Regs
- FTC (www.ftc.gov)
- Healthfinder.gov (HHS educational site)
- www.RAInfo.com
 - Index to international regulatory sites
- Findlaw.com
- Thomas: legislation (<http://thomas.loc.gov/>)

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Q & A Period

Follow-up Questions:
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