HIPAA Compliance Strategies for Pharmaceutical Manufacturers, PBMs and Pharmacies

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HIPAA Colloquium Harvard MA; August 22, 2002

Agenda

- Privacy ~ Definitions and Context
- HIPAA ~ Pharmaceutical Companies
- HIPAA ~ Online Marketing
- HIPAA ~ R&D
- Privacy ~ Current PHA Approach

Right of Privacy

 The claim of individuals to determine for themselves when, how and to what extent information about them is communicated.

- 1. What kind of Information
- 2. How we use it
- 3. Who we are sharing it with

PII, PHI

Personal identifiable information (PII)
means any confidential or sensitive
information that can be related back to
an individual.

 Personal identifiable health information (PHI) means information about an individual's health.

PII

- 1. Name
- 2. Address
- 3. E-Mail Address
- 4. Social Security Number
- 5. Password (if used to access the site)
- 6. Bank Account Information
- 7. Credit Card Information
- 8. Any combination of Data that could be used to identify a consumer, such as the consumer's birth date, zip code and gender.

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Mapping

Identification of Regulations and Legal Pitfalls and Tracking of Information Flow:

- Regions
- Customers
- Channels
- Technology

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Points of Access

- Pharmaceutical Company Employees
- Third Party Developers/Contractors
- Third Party Hosting Company
- Subcontractors of Third Party Hosting Company
- Third Party Transmission Company
- Third Party Service Provider
- Other Points of Access or Links

Regulatory/Legal Environment Privacy & Security

- Federal Regulations
- State laws
- Attorney General's actions
- Litigation
- EU Safe Harbor
- Canada.....

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HIPAA

HIPAA (Health Insurance Portability and Accountability Act)

- Requires (DHHS) to develop standards and requirements for maintenance and transmission of health information that identifies individual patients.
- Protect the security and confidentiality of electronic and other health information.

Covered Entities

- Health Plans
- Healthcare Clearinghouse
- Healthcare Providers

Business Associate

- Access of Protected Information through or from Covered Entity
- Either acts on behalf of or acts as part of an Organized Health Care Arrangement

For The Pharmaceutical Industry The Rule May Affect:

- HR
- (online) Marketing
- Reimbursement Programs
- Disease management programs
- Pharmacy benefits programs

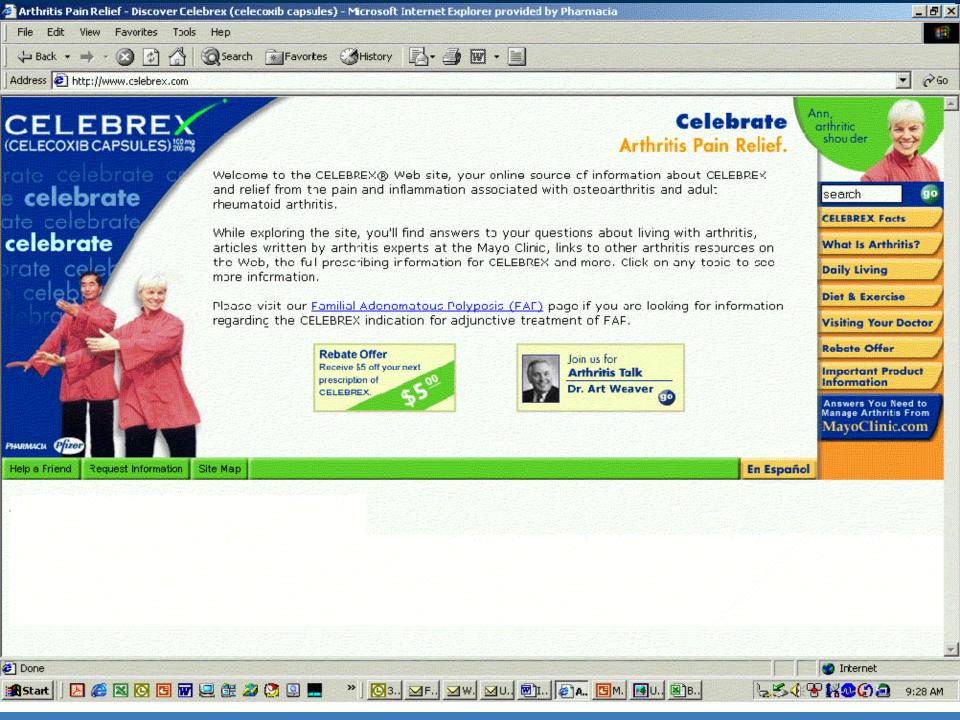
For The Pharmaceutical Industry The Rule May Affect:

R&D

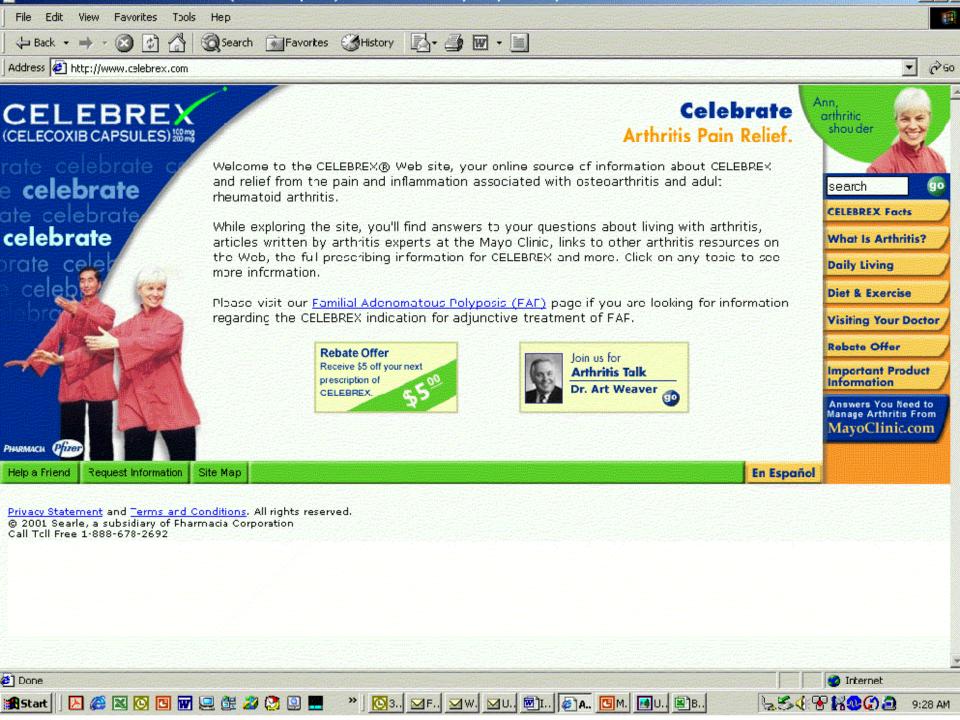
- **DNA** ?
- Clinical trials?
- Drug safety monitoring
- Biostatistical analysis
- Outcomes or economics studies ?

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Privacy Statement



Privacy Statement

The Privacy of your personal information is important to Pharmaca. To better protect your privacy, we provide you with our Privacy Pclicy so that you will understand both our commitment to you and to your privacy. This Privacy Policy describes what information we may collect about you; how we use your information; how we protect it; and what choices you have on how that information is used. At Pharmacia, we understand that health is a very personal, private subject, and we want you to feel as comfortable as possible visiting our various Web sites and using their respectives services.

Pharmacia is a licensee of the <u>TRUSTE Privacy Program</u>. This statement discloses the privacy practices for this Pharmacia site. When you visit a Web s ted displaying the <u>TRUCTE trustmank</u>, you will be informed of the following: What personally identifiable information of yours is collected; What organization is collecting the information; how the information is used, What whom the information may be shared; What choices are available regarding collection, use and distribution of the information; What knd of security procedures are in place to protect the loss, misuse or alteration of information under our control; and, How you can correct any inaccuracies in the information.

If you have questions or concerns regarding this statement, you should first contact privacy.officer@pharmacia.com. If you do not receive acknowledgement of your inquiry or your inquiry is not satisfactorily addressed, you should then contact TRUSTo through the TRUSTe Watchdog Dispute Resolution Process. TRUSTe will then serve as a liaison with the Wab site to resolve users concerns.



Pharmacia aso complies with the standards set by <u>Health on the Net [HON]</u>, as is indicated by the presence of the seal.

As our privacy policies change in significant ways, we will make every effort to notify you of the changes. Minor changes to the policy may occur that will not affect our use of individually identifiable health information. When the privacy policies change in a way that significantly affects the way we handle personal information, we will not use the information we have previously gathered without obtaining your consent. We will post privacy policy changes on our Web sites in a timely manner.

The "ollowing Articles make up our Privacy Policy. We hope that reading them gives you a clear idea of how we manage information regarding you. For immediate access to a particular topic, click on the title of that topic.

- I. Personal Information We Collect
- II. Use of Your Information
- III. How Pharmacia Handles Privacy Internally
- IV. Your Privacy Choices
- V. Updating Your Personal Information and Contacting Pharmacia



Privacy Statement

Ann, arthritic



search

CELEBREX Facts

What Is Arthritis?

Daily Living

Diet & Exercise

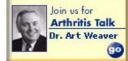
Visiting Your Doctor

Rebate Offer

Important Product Information

Answers You Need to Manage Arthritis From MayoClinic.com

Home



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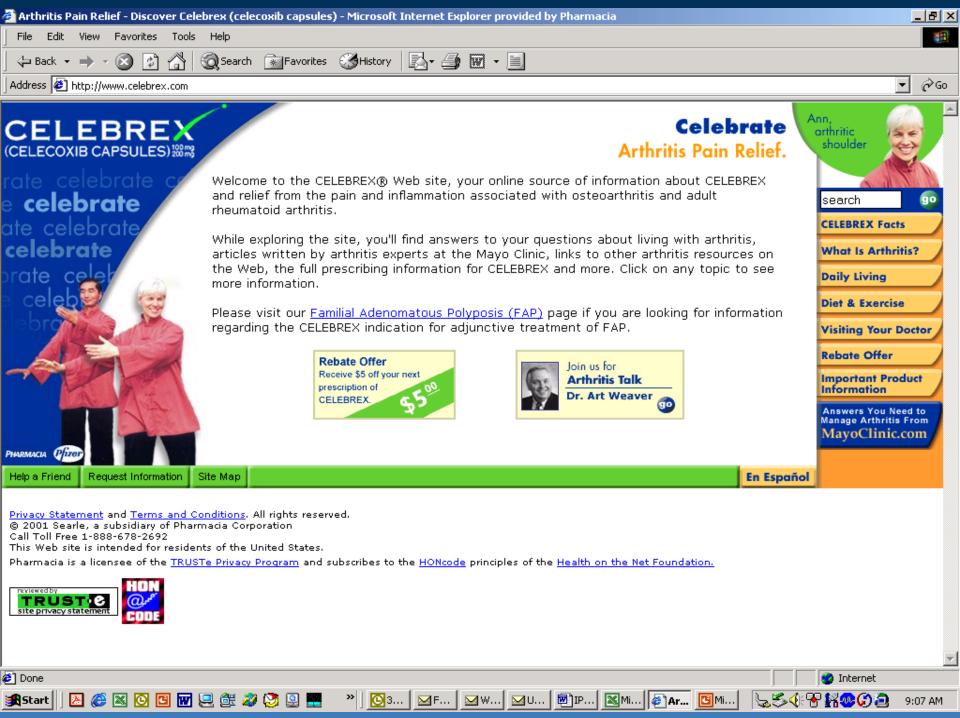


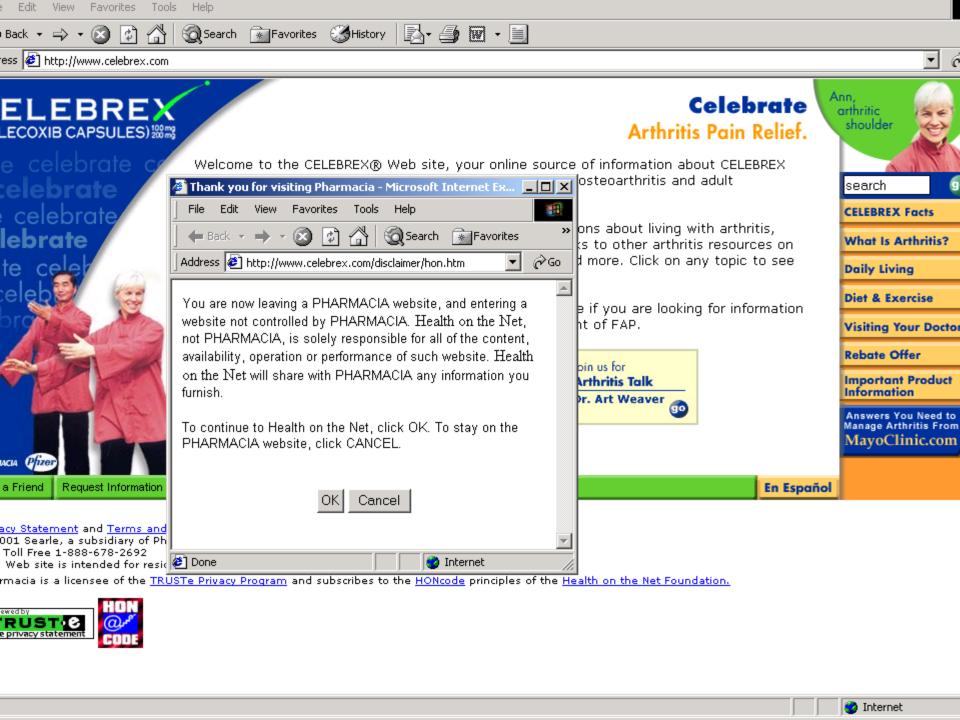
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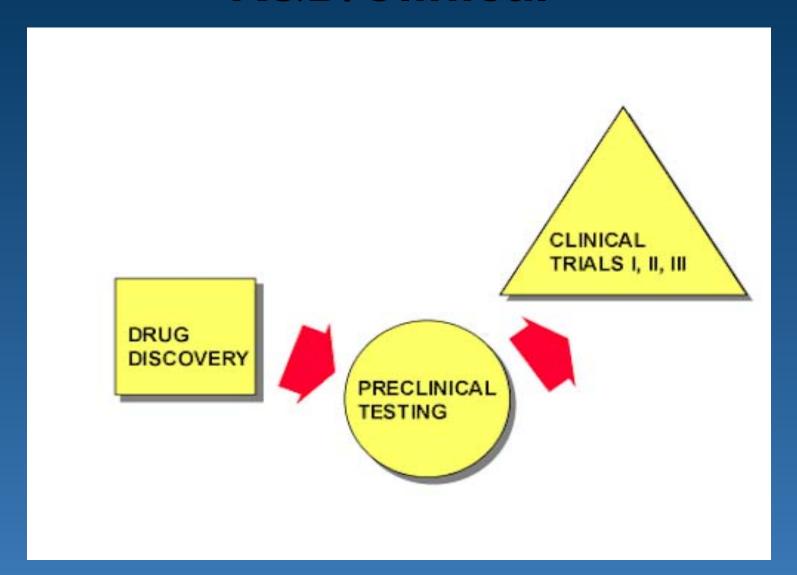
HIPAA April 14, 2003

- Uses and disclosures of Protected Information
- Consent, Authorization and Opportunity to Agree Requirements
- Organizational Requirements
 - Privacy Officer
 - Training
 - Safeguards
 - Enforcement Program
 - Policy and Procedure Standards

Agenda

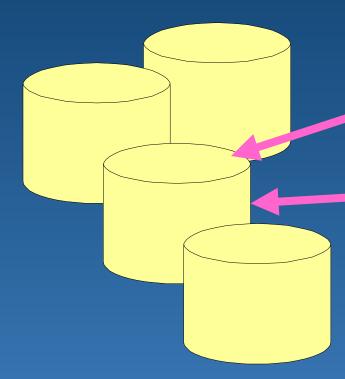
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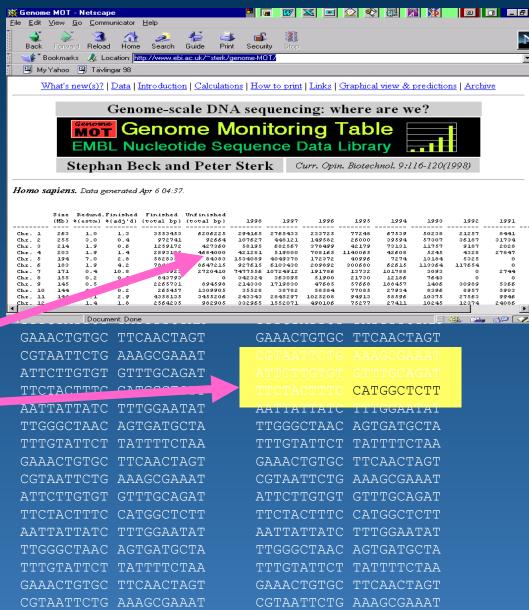
R&D/Clinical



Human Genome Project

FINDING TARGETS





- Who is covered?
 - Healthcare providers who transmit health information in electronic transactions: including researchers who provide treatment to research participants
 - Health Plans
 - Healthcare Clearinghouse

- What is covered ?
 - Protected Health Information
 - Decedents Health Information
 - Transmitted or maintained in any form or medium
 - For Research that involves treatment
 - For Records research History of Patient Data

- The Privacy Rule permits covered entities to use and disclose PHI for research conducted:
 - With individual authorization, or
 - Without individual authorization under limited circumstances

 Patient authorization elements under NPRM (public comments, expected Final Aug '02):

- The information
- Who may use or disclose the information
- Who may receive the information
- Purpose of the use or disclosure
- Expiration date or event
- Right to revoke authorization

- Use and disclosure of PHI Without Individual Authorization * (current Final Rule):
 - 1. Obtain documentation that an IRB or privacy board has determined specified criteria were satisfied
 - 2. Obtain representation that the use or disclosure is necessary to prepare a research protocol or for similar purposes preparatory to research

^{*} DHHS Office for Human Research Protections, May 2002

- Use and disclosure of PHI Without Individual Authorization * (current Final Rule):
 - 3. Obtain representation that the use or disclosure is solely for research on decedents' PHI
 - 4. Only use or disclose "indirect identifiers" for research, public health, or health care operations

AND

Require a data use agreement from recipient agreeing to use only for purpose provided and not to re-identify or contact individual

DHHS Office for Human Research Protections, May 2002

The Privacy Rule does not override the Common Rule of FDA's human subjects regulations

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Pharmacia Approach

- 1/ Mapping
- 2/ 'Data Privacy Agreement'
- 3/ Implementation
- 4/ Certifications
- 5/ Privacy Officer

1. Mapping

Identify Regulations and Legal Pitfalls for

- Regions
- Customers
- Channels
- Technology

2. Data Privacy Agreement for each Business Trust Partner

- Permitted uses and disclosures of Protected Information
- Appropriate safeguards of records
- Report any unauthorized disclosures to entity
- PHI available for inspection, amendment, accounting
- Books and records available for inspection by DHHS
- Destroy/Return PHI at termination of contract

3. Implementation

- Implement Privacy/Security rules:
 - Front-end: informed Consent,
 Statement, Terms and conditions...
 - Back-end: Security, Business Partners...

4. Certification

- Internet Healthcare Coalition "e-Health Code of Ethics"
- Health Internet Ethics Alliance "HI-Ethics"
- Health on the Net Foundation Code of Conduct "HON code"
- Other (TRUSTe, BBB, PWC, URAC...)

5. Privacy Officer

"The PO has the responsibility for the creation, implementation and maintenance of the company's privacy compliance related activities"

Thank you!

JeanPaul.Hepp@Pharmacia.com