

Trends and Developments in Privacy, Identity Theft & Information Protection Impacting Pharma Privacy Symposium at Harvard August 22, 2007

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Agenda - Trends & Developments

1. Pharmaceutical and Life Sciences Companies – Rebuilding Trust
2. State of the State – Moving from FTC’s Lilly to Global Programs
3. Commercial and Clinical – Old Approaches to New Problems
4. New Focus Based on Identity Theft/Security Breaches
5. Closing Thoughts
 - Questions

Pharmaceutical & Life Sciences Companies – Rebuilding Trust



Pharmaceutical Industry Trends Impacting Compliance

- **Fundamental Change #1 – End of the Blockbuster.** The expiration of many US patents for certain pharma blockbusters marks the beginning of more competitive environment where increased importance will be placed on portfolio management strategies, increased R&D trials and partnerships, alliances and consolidations.
- **Fundamental Change #2 – Focus on Safety; Likelihood & Cost of Approval.** Given a host of new challenges and safety concerns, the productivity of R&D research is diminishing, compliance efforts are increasing and the cost of a new drug is escalating to \$1-1.7 Billion.
- **Fundamental Change #3 – Need to Build Trust.** Over \$3 billion has been recovered from sales, marketing and pricing settlements and GMP enforcement actions and has made it critical for pharma to rebuild trust and focus on integrity driven performance across the entire value chain.

State of the State – Moving from FTC's Lilly to Global Programs





- **For Release:** January 18, 2002
- **Eli Lilly Settles FTC Charges Concerning Security Breach**
- ***Company Disclosed E-mail Addresses of 669 Subscribers to its Prozac Reminder Service***
- Eli Lilly and Company (Lilly) has agreed to settle Federal Trade Commission charges regarding the unauthorized disclosure of sensitive personal information collected from consumers through its Prozac.com Web site. As part of the settlement, Lilly will take appropriate security measures to protect consumers' privacy.
- "Even the unintentional release of sensitive medical information is a serious breach of consumers' trust," said J. Howard Beales, III, Director of the FTC's Bureau of Consumer Protection. "Companies that obtain sensitive information in exchange for a promise to keep it confidential must take appropriate steps to ensure the security of that information."

Data Protection - Key Board and Management Issue

Board and Management Issue: Controls over the Privacy and Security of sensitive data has received increased attention over the past 18-24 months.

- Attention has been driven by the business impacts of failure – on both long-term relationships and value – and has elevated privacy and information risk management to board and senior executive business issues.

Maturity of Industry in Privacy: Following the FTC's enforcement decree with Eli Lilly, the industry built privacy programs and matured significantly. Retail industry now in the hot seat. Focus on data protection rather than truthfulness of privacy policy.

Drivers: Based on our experience, the following factors are driving this increased attention.

- Numerous New Laws & Regulations Across Industry Bounds and Increased Regulator Focus on Data Protection Controls
- Highly Visible Press Coverage over Identity Theft
- Globalization of Business, Outsourcing and International Compliance

Trend in Pharmaceutical Industry to Certify Safe Harbor

Organization	Date	Type of Data Certified
Abbott Laboratories	02/07/2007	Human Resources Data
Alcon Laboratories, Inc.	09/12/2006	Human Resources Data
Amersham Health Inc. (part of GE)	04/11/2003	Commercial, Clinical and Human Resources On-Line, Off-Line & Manually Processed Data
AstraZeneca Pharmaceuticals LP	12/18/2006	Human Resources Data
Baxter International, Inc.	06/21/2002	Commercial & Human Resources On-Line and Manually Processed Data
Eli Lilly and Company	08/18/2004	On-Line, Off-Line, Human Resources, Manually Processed
Ethicon Endo-Surgery Inc. (a J&J co.)	11/19/2004	Human Resources & Clinical Operations Data
Johnson & Johnson Pharmaceutical Research & Development	11/09/2004	Data processed in support of clinical operations
LifeScan, Inc. (a J&J company)	11/15/2004	Human Resources Data
Merck & Co., Inc.	11/05/2001	On-Line, Off-Line, Manually Processed, Human Resources
Novartis Pharmaceuticals Corp.	09/25/2006	On-Line, Off-Line, Manually Processed Data
Schering-Plough Corporation	05/01/2006	Human Resources Data
Pfizer Inc.	12/31/2004	Human Resources Data
Proctor & Gamble Co. & US affiliates	06/29/2001	Human Resources, Consumer, Research, Shareholder
Wyeth & US subsidiaries & divisions	06/29/2001	Employee Data

Commercial and Clinical – Old Approaches to New Problems



Commercial and Clinical – New Wrinkles on Old Problems

• Commercial:

- **New Focus on Health Care Providers.** Compliance with AMA Opt out, state laws around the use of prescriber data, support for pharmaceutical manufacturer state reporting requirements relating to prescriber compensation.
- **Integrated, Multi-Channel and Interactive Marketing Efforts & Databases.** New approaches to build loyalty and relationships involve complexity, technology and heightened risk. Attention to cross-brand marketing ability.
- **New focus on health care providers.** Compliance with AMA Opt out, state laws around the use of prescriber data, support for pharmaceutical manufacturer state reporting requirements relating to prescriber compensation.
- **Focus on Vendor Oversight.** Increasingly integrated into efforts to streamline procurement and enhance compliance and cost savings.

• Clinical:

- **International Regulator Focus.** Focusing on all forms of data for consumers and investigators. Unifying practices as part of overall global harmonization of clinical compliance policies and requirements.
- **Alternative and Other Uses.** Protecting the value of research and trial data, especially at the advent of electronic medical records.
- **Focus on Clinical Data Management.** New clinical trial management systems, electronic data capture, bar scanning bracelets and other technologies have privacy implications.

New Focus Based on Identity Theft/Security Breaches

- Data Element Inventories & Data Classification Schemes

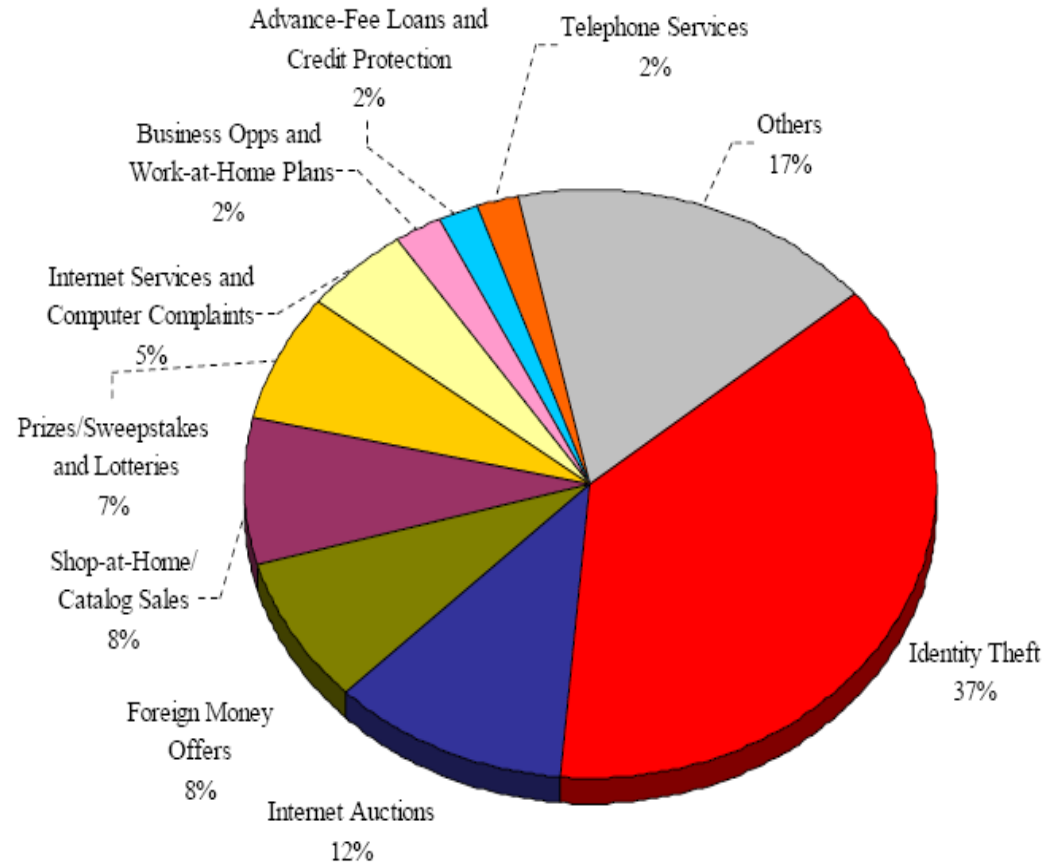
Breaches & Costs

Gartner projected that by 2006, 20-30% of Global 1000 will suffer exposure due to privacy mismanagement, and costs to recover from privacy mistakes will range from \$5 - \$20 million each.



Identity Theft Has Become a Major Concern

- Number one complaint to FTC
- Impacts 4.6% of US per year
- 2006 survey, companies reported ID Theft:
 - 10% globally
 - 9% in US
 - 19% in India
- \$50+ billion in losses
- 68.2% obtained off-line versus 11.6% obtained online
- 50+% conducted by employees and contractors
 - Part-time & temporary workers three times more likely to commit



Impact. Higher theft risks: SSN, Driver's License Number, Credit Card Number, Health Insurance ID Number

Pharma's Have Been Subject to Public Disclosures

- **Several Pharma and Device Companies Incidents:** Areas include lost/stolen laptops, back-up tape issues, peer-to-peer networks, marketing and fulfillment, call centers, web sites, clinical and investigator data, vendors, HR area and more.
- **New SSN Laws:** Many new US state laws restrict the use of Social Security Numbers as a key identifier in access controls for consumers, employees and web sites, in mailing, faxes and other marketing materials, on pay stubs.
- **Data Element Approach:** Pharma and device companies have started protecting data at the data element level, not the system and application level.

Closing Thoughts



Closing Thoughts

- **Privacy Viewed as Compliance and Legal Function.** Privacy was initially viewed as a compliance obligation. Increasingly integrated into business processes.
- **Privacy Is a Proxy for Trust.** There is a lot at stake, and privacy can be part of the solution to build trust.

Questions?



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