



# Pharma Privacy Update for Compliance Professionals: 10 Things You Need to Know Now about Privacy

November 4, 2014

Pharma Congress Forum Mini Summit V

# Presenters

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Global Leader, Commercial Privacy Practice; Co-Leader,  
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# Agenda

- ▶ Business Trends in Pharma/Life Science and Device Impacting Privacy
- ▶ Privacy Feud – Top New Technologies, New Risks, Top Safeguards (Spotlight on 10 Key Areas)
- ▶ Questions



## Business Trends in Pharma/Life Science and Device Impacting Privacy

# Business Trends in Pharma/Life Science and Device Impacting Privacy

- ▶ **Globalization.** Pharma and life sciences trend around globalization and the borderless need to access and use data for commercial operations, trials, IT development and service center and human resources to drive business, recruit trial subjects and cost savings.
- ▶ **Analytics.** Desire to leverage big data analytics to inform commercial and clinical strategies, population health and compound effectiveness.
- ▶ **New Engagement Technologies.** Reduction in old school detailing for increasing use of new electronic communication channels (web, mobile, social , online behavioral advertising, QR and others) with Health care professionals (HCPs) and patients.
- ▶ **Cloud.** Increasing data consolidation for efficiency or relocation to cloud or third parties for hosting, analytics and other.
- ▶ **More Vendors and Business Associates Needed to Enable and Support.** New business partners, business associates and independent contracts needed to deliver and host new healthcare delivery methods and new technologies.
- ▶ **New Cyber Threats Attacking Healthcare.** Many pharma, medical device and business associates have been the target of cyber attacks and incidents. Dramatic increase in knowledgeable insider and cyber risks seeking intellectual property and individual information.
- ▶ **New Laws and Enforcements.** More than 200 laws in more than 150 countries with privacy and data protections laws.

**Key Trend.** The combination of new technology risk (and comparably lower spending on cybersecurity than other industries) and valuable intellectual property and personal information makes pharma/device companies increasingly attractive target.

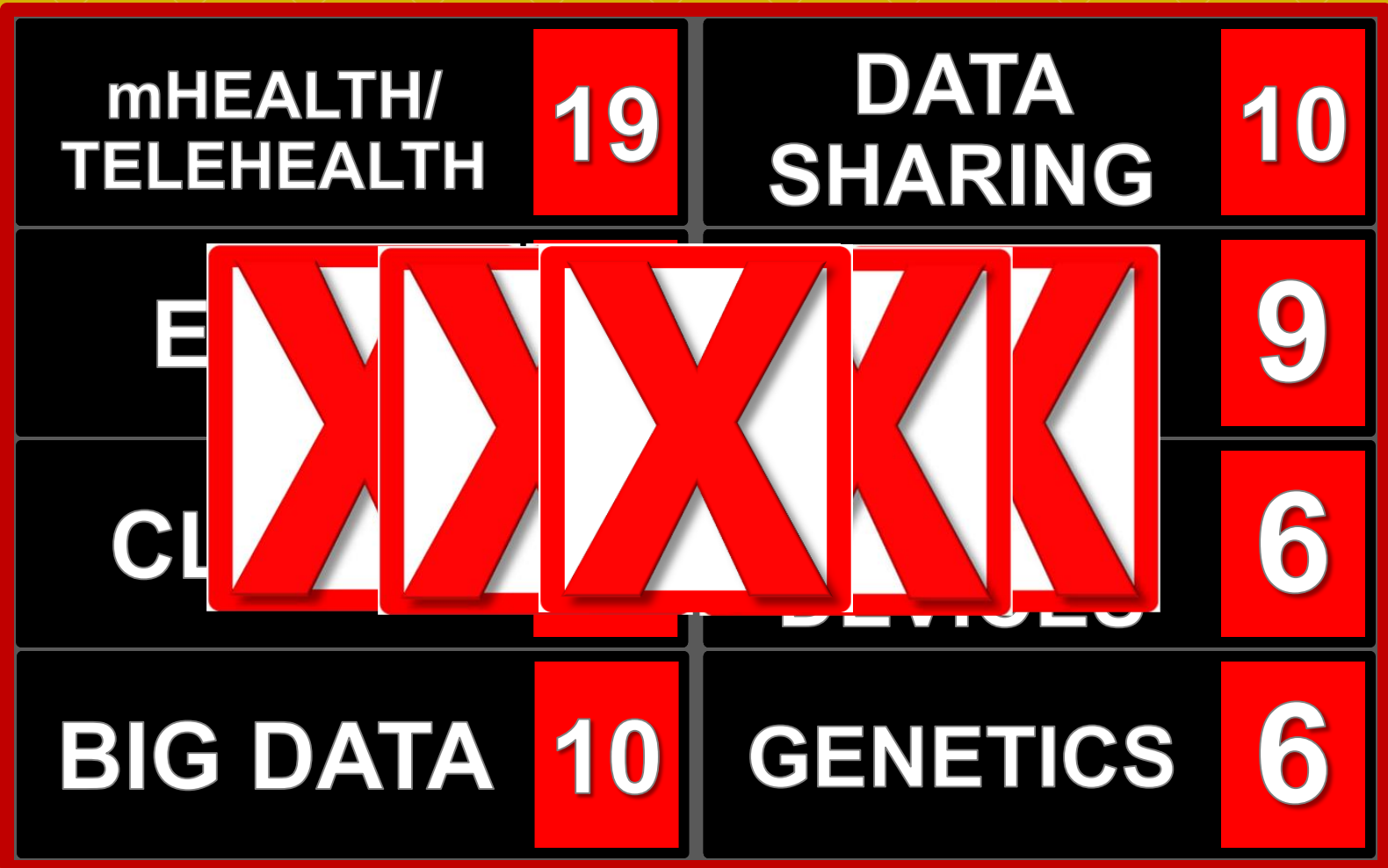


## Privacy Feud – Top New Technologies, New Risks, Top Safeguards (Spotlight on 10 Key Areas)



**PRIVACY**  
**FEUD**

Q1 - What new technological advance in healthcare do you see as posing the greatest threat to privacy and security that is not being addressed?



- 1
- 2
- 3



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<b>mHEALTH/ TELEHEALTH</b>	<b>19</b>	<b>DATA SHARING</b>	<b>10</b>
<b>EHRs</b>	<b>13</b>	<b>APPS</b>	<b>9</b>
<b>CLOUD</b>	<b>11</b>	<b>MEDICAL DEVICES</b>	<b>6</b>
<b>BIG DATA</b>	<b>10</b>	<b>GENETICS</b>	<b>6</b>

# Technological Advances Biggest Threat to Privacy & Security

## Spotlight

### Technological advances:

- ▶ mHealth, Tele-health
- ▶ EHRs
- ▶ Cloud
- ▶ Data sharing/amount of data
- ▶ Big data / new analytics
- ▶ Mobile App security
- ▶ Medical devices
- ▶ Genetics/personalized medicine

- New technical abilities and proliferation driving new analytics
- Commercial move to Global CRM, social media, online behavioral advertising
- Clinical use for trial recruitment, registries
- Privacy implications:
  - Consent
  - Trans-border transfer of data
  - De-identification standards

Agatha

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- Ability to access shared computing resources from any location or device via an interface
- Driven by cost savings
- Privacy implications:
  - Trans-border transfer of data
  - Who secures?
  - Audits rights?
  - Retention and destruction

Debbie

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- mHealth and Telepresence used in clinical trials and to drive commercial engagement
- Privacy Implications:
  - FDA regulation of mobile apps
  - FTC has mobile security cases and state cases on privacy policy

Jim

# Technological Advances Biggest Threat to Privacy & Security

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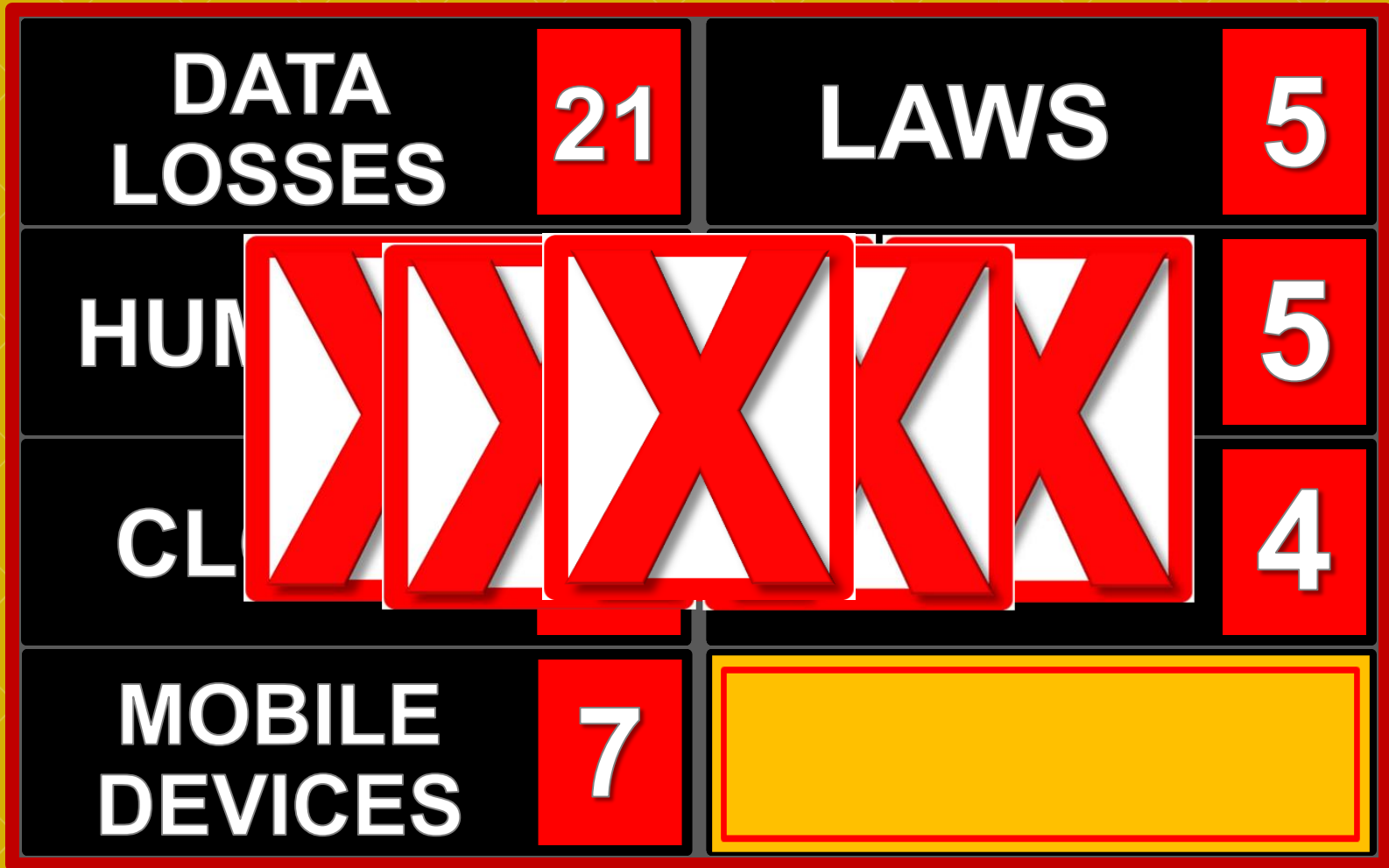
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- Medical devices that are internet addressable are vulnerable
- Privacy Implications:
  - FDA regulation of medical devices
  - New cybersecurity assessments mandatory

Debbie

Q2 - Today, what risk to privacy and security of health information do you feel least prepared to manage or is your biggest challenge?



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<b>DATA LOSSES</b>	<b>21</b>	<b>LAWS</b>	<b>5</b>
<b>HUMANS</b>	<b>19</b>	<b>VENDORS</b>	<b>5</b>
<b>CLOUD</b>	<b>11</b>	<b>ACCESS</b>	<b>4</b>
<b>MOBILE DEVICES</b>	<b>7</b>		

# Risks Least Prepared to Handle

## Spotlight

- ▶ Data losses
- ▶ Humans
- ▶ Cloud
- ▶ Mobile devices
- ▶ Vendor management
- ▶ Laws
- ▶ Access monitoring/controls

- Many new privacy laws globally and many new types of laws
- Privacy implications:
  - EU update
  - Cookies
  - Breach notification
  - Data transfer (and drive for Safe Harbor and BCRs)
- Ancillary laws with privacy impact (e.g., tax, FCPA, eDiscovery, Physician Payment Transparency Acts/Trial Reporting Requirements)

Agatha / Debbie



# Risks Least Prepared to Handle

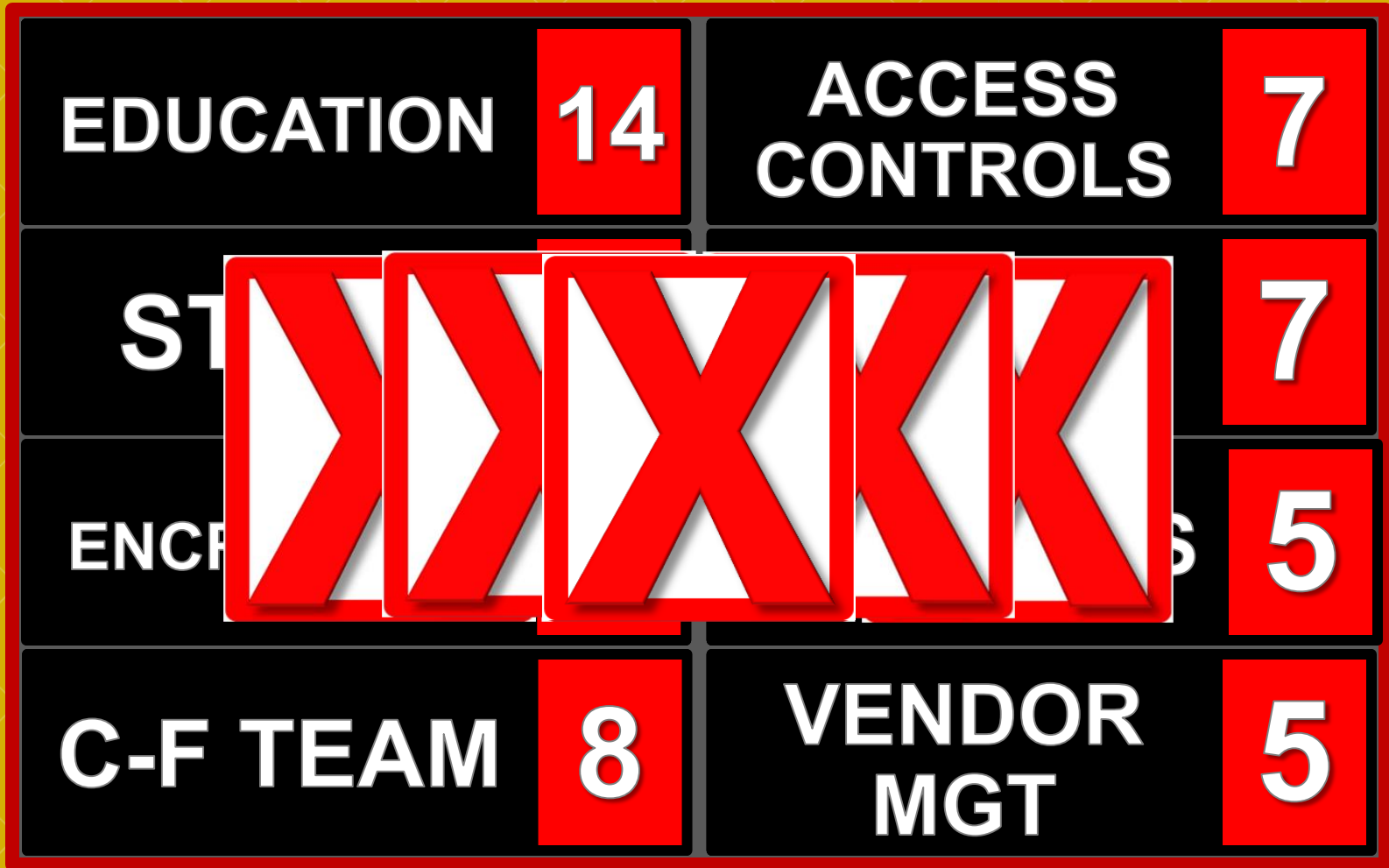
## Spotlight

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- Proliferation of cyber attacks on pharma/life science and device
  - 90+% report breaches, all 3 leading device companies
  - 70+% of incidents discovered by third party (often FBI)
- 30+% have cyber/breach insurance
- SEC - Risk Assessment and Disclosure Requirements for Publicly Companies
- NIST - Framework Used in Class Actions and Contracts Potentially as a “De Facto Standard

Jim

Q3 - If you had a magic wand (and money were no object), what resource or tool would be a must-have for your privacy program?



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<b>EDUCATION</b>	<b>14</b>	<b>ACCESS CONTROLS</b>	<b>7</b>
<b>STAFF</b>	<b>14</b>	<b>AUDIT</b>	<b>7</b>
<b>ENCRYPTION</b>	<b>13</b>	<b>DATA LOSS</b>	<b>5</b>
<b>C-F TEAM</b>	<b>8</b>	<b>VENDOR MGT</b>	<b>5</b>

# Most Desired Tools

## Spotlight

- ▶ Education
- ▶ Personnel
- ▶ Encryption
- ▶ Cross-Functional team/InfoSec
- ▶ Audit
- ▶ Access controls
- ▶ Vendor management
- ▶ Data loss prevention

- Employee lack of awareness may be largest risk and most difficult to resolve
- Privacy Implications:
  - Drive culture with integrated privacy and security efforts
  - New technologies, laws, marketing, analytics covered
  - New types of training
    - Phishing
    - Pre-text phone calls
    - Cybersecurity wargame simulations

Debbie

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- Issues – proliferation of vendor uses and risks
  - 34% of breaches / 51% of individuals impacted
- Vendor employee risks and theft
- Privacy Implications
  - New HIPAA and state laws
  - New contract Provisions
    - Encryption
    - Limits on access
    - Responsibility for breach costs / notices
  - Trend to assess more types and more vendors

Agatha

Questions?

## Copies of the Presentation

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