Where's the App for That?
Mobile Medical Apps, Cybersecurity and the Regulatory and Litigation Landscape

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Today's Presentation

The Topics

- FDA
- FTC
- Start with Security
- State Attorney Generals
- Consumer Class Actions
- Takeaways

Mobile Medical Applications:

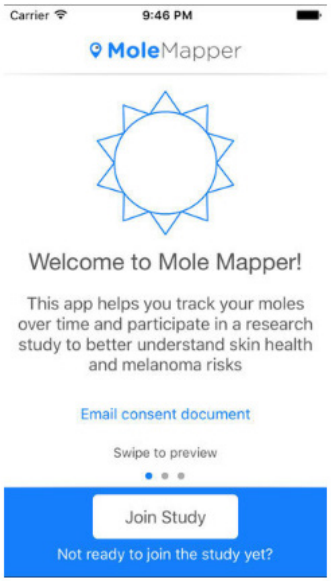
Convergence of Privacy and Patient Safety

Johns Hopkins researchers to use Apple Watch data to study epilepsy

EpiWatch app will help researchers better understand epilepsy, develop new methods for monitoring, managing the disorder

Jania Matthews / **October 15**

Epilepsy.com Launches New iPhone App to Help People With Epilepsy Manage Seizures, Symptoms and Treatment



Sage Bionetworks Launches Mole Mapper iPhone-app Enabled Research Study to Better Understand Melanoma

Patient-centered app-based study to quantitatively track moles and help detect early signs of malignant melanoma -- the deadliest form of skin cancer

OCTOBER 20, 2015 BY CHARLES MOORE

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Data Breach: Health Information

- The average cost of a data breach is estimated to be $3.8 million
  - Healthcare records have the highest cost per stolen record at an average of $363.
- PHI is worth up to 20 times more on black markets than financial information

Crowded Regulatory Field

Federal Trade Commission
Protecting America's Consumers

REGULATORY EXPOSURES

ONC

FDA

DEPARTMENT OF COMMERCE
UNITED STATES OF AMERICA

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OIG

DEPARTMENT OF JUSTICE
QUI PRO DOMINA JUSTITIA SEQUITUR

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
Office for Civil Rights

NIST
National Institute of Standards and Technology

National Association of Attorneys General

FCC

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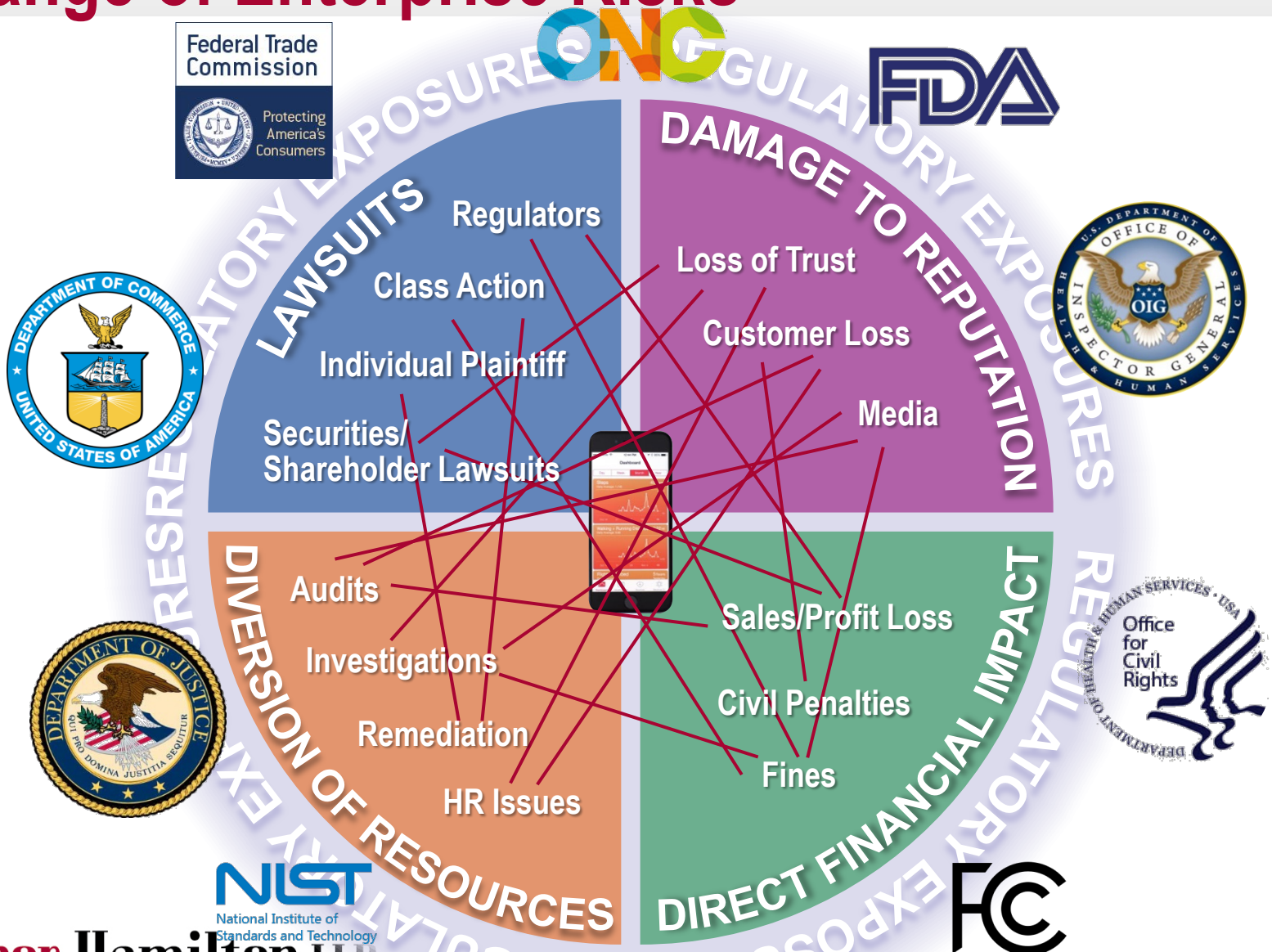
Range of Enterprise Risks



Questions to Ask Yourself

- What is the function and use of the device?
- Is it a non-mobile device with the same function already regulated?
- Who are your customers? Covered Entities? Business Associates?
- Is the consumer controlling decisions about data collection, use, and transmission?
- What PII/PHI do you absolutely need to operate?
- Which business areas/practice segments interact directly with those customers or their data?
- What standards are established and/or are developing in your industry regarding data privacy and security?
- Who has oversight over the laws and regulations that apply to your industry and company?

Food and Drug Administration Regulation and Enforcement

What is a Medical Device?

A medical device is defined as:

- An instrument, apparatus, implement, machine, contrivance, or other similar or related article, including a component part or accessory, that is intended:
  - For use in the diagnosis of disease or other conditions;
  - For use in the cure, mitigation, treatment, or prevention of disease; or
  - To affect the structure or any function of the body

Source: 21 U.S.C. §321(h)

If a Medical Device…

FDA Regulatory Requirements include:

- Establishment Registration and Medical Device Listing
- Investigational Devices Exemption (IDE) requirements
- Labeling Requirements
- Premarket submission for approval or clearance (based on classification)
- Quality System Regulation
- Medical Device Reporting
- Correcting Problems

If a Medical Device…

FDA Regulatory Requirements include:

- Risk based classification based on controls necessary to provide reasonable assurances of safety and efficacy
  - Class I (low to moderate risk): general controls
  - Class II (moderate to high risk): general and Special controls
  - Class III (high risk): general controls and Premarket Approval

February 9, 2015, FDA Guidance on Mobile Medical Applications

- What is the force of a “Guidance”?
- FDA intends to regulate mobile medical software that poses a threat to public safety
- The key regulatory factor is the **intended use** of the mobile health application
- Mobile medical Apps will be subject to the same standards FDA applies to traditional medical devices

Glooko glucose monitoring logbook app and cable, © 2015 Glooko, Inc.

Intended Use Driving Classification

Will FDA regulate a **flashlight app**?

- If the app is advertised as a flashlight, FDA unlikely to regulate
- But if the app is advertised as an alternative to an ophthalmoscope (the light doctors flash in your eye), it may be subject to FDA regulation

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Source: February 9, 2015, FDA Guidance on Mobile Medical Applications

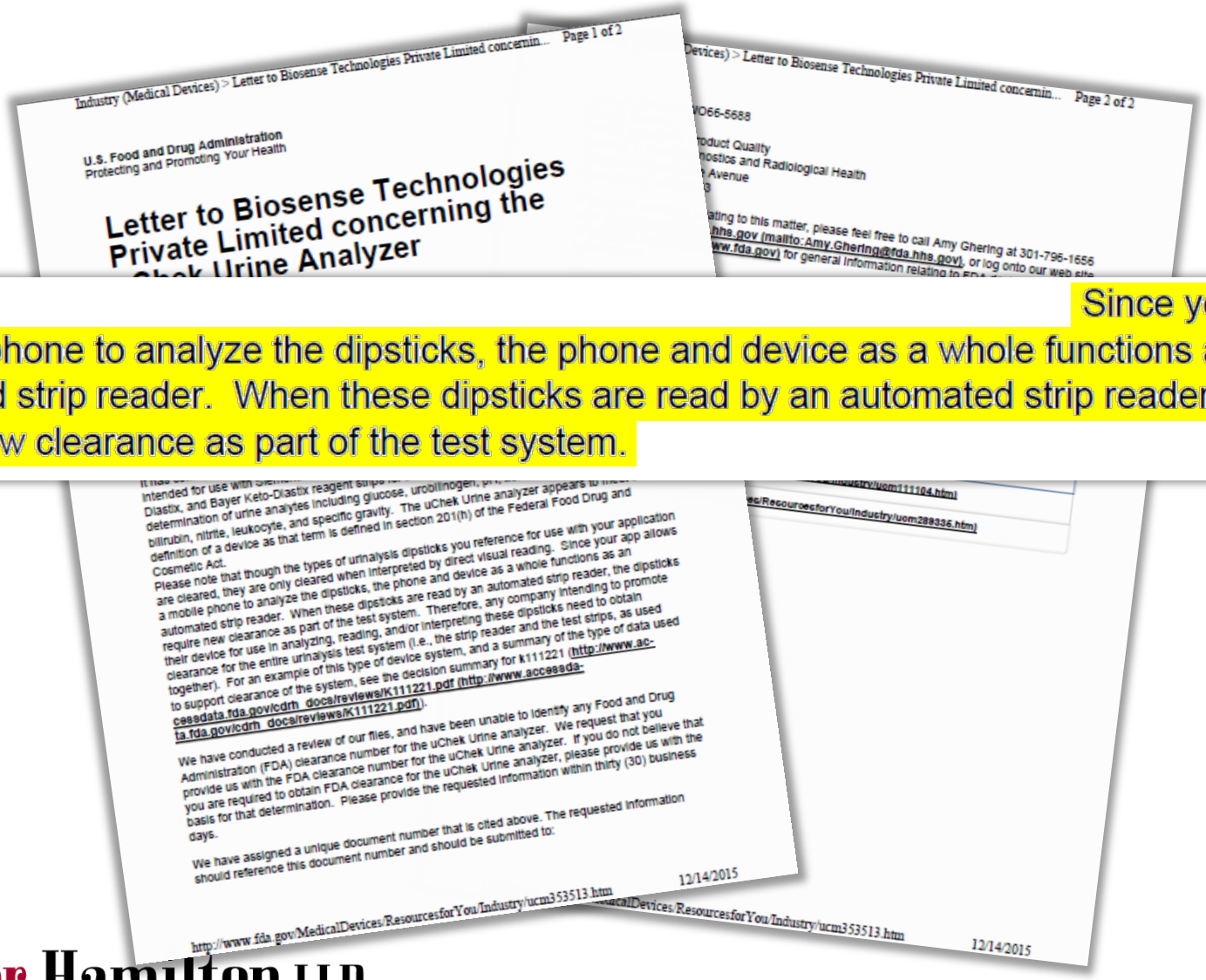
Example of an FDA-Regulated Accessory

uChek app allowed users to analyze their urinalysis dipsticks using the camera on their mobile phone

- Dipstick is a cleared Medical Device approved only for direct visual reading
- App now enables a mobile phone to analyze the dipstick

Source: May 2013 Letter from FDA Offices of in Vitro Diagnostics and Radiological Health to Biosense

Approved Device Analyzed by App Requires New FDA Clearance



Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader. When these dipsticks are read by an automated strip reader, the dipsticks require new clearance as part of the test system.

Industry (Medical Devices) > Letter to Biosense Technologies Private Limited concernin... Page 1 of 2

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Letter to Biosense Technologies Private Limited concerning the Chek Urine Analyzer

Devices) > Letter to Biosense Technologies Private Limited concernin... Page 2 of 2

...066-5688

...oduct Quality
...nostics and Radiological Health
...Avenue

...ating to this matter, please feel free to call Amy Ghering at 301-796-1656
...hhs.gov (mailto:Amy.Ghering@fda.hhs.gov), or log onto our web site
...ww.fda.gov) for general information relating to FDA

...ec/ResourcesforYou/Industry/ucm111104.htm)

...ec/ResourcesforYou/Industry/ucm289336.htm)

intended for use with ...
Diastix, and Bayer Keto-Diastix reagent strips ...
determination of urine analytes including glucose, urobilinogen, ...
bilirubin, nitrite, leukocyte, and specific gravity. The uChek Urine analyzer appears to ...
definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act.

Please note that though the types of urinalysis dipsticks you reference for use with your application are cleared, they are only cleared when interpreted by direct visual reading. Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader. When these dipsticks are read by an automated strip reader, the dipsticks require new clearance as part of the test system. Therefore, any company intending to promote their device for use in analyzing, reading, and/or interpreting these dipsticks need to obtain clearance for the entire urinalysis test system (i.e., the strip reader and the test strips, as used together). For an example of this type of device system, and a summary of the type of data used to support clearance of the system, see the decision summary for k111221 (http://www.accessdata.fda.gov/cdrh_docs/reviews/K111221.pdf (http://www.accessdata.fda.gov/cdrh_docs/reviews/K111221.pdf)).

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance number for the uChek Urine analyzer. We request that you provide us with the FDA clearance number for the uChek Urine analyzer. If you do not believe that you are required to obtain FDA clearance for the uChek Urine analyzer, please provide us with the basis for that determination. Please provide the requested information within thirty (30) business days.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm 12/14/2015

...alDevices/ResourcesforYou/Industry/ucm353513.htm 12/14/2015

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Source: May 2013 Letter from FDA Offices of in Vitro Diagnostics and Radiological Health to Biosense

FDA Will Regulate:

- Extending medical device **to control** the device for use in active patient monitoring
- Acting as an **accessory** to a medical device
- Using attachments, screens, sensors to **transform** mobile platform into a medical device
- Performing **patient-specific** analysis
- Assisting with diagnosis or **patient-specific** treatment recommendations

Source: February 9, 2015, FDA Guidance on Mobile Medical Applications

FDA Does Not Intend to Regulate:

- Providing patients with tools to organize/track health information
- Helping patients document or communicate medical information to providers or access Medical Records
- Performing **simple** calculations used in clinical practice
- Enabling individuals to interact with EHRs and PHRs

Source: February 9, 2015, FDA Guidance on Mobile Medical Applications

FDA Does Not Intend to Regulate:

- Examples
  - Fitness Coach from iTunes
  - Apps for patients to log data they collect (*e.g.*, blood pressure) and report to provider
  - BMI calculators; delivery date estimators
  - Web portals to access own records
- Beyond the FDA, other regulators (and regulations) may apply:
  - FTC
  - HIPAA/HITECH with transmission of PHI
  - FCC
  - State Consumer Protection Laws

Source: February 9, 2015, FDA Guidance on Mobile Medical Applications

Understanding Risk

Influenced by:
- General acceptance
- Pervasiveness
- Complexity
- Extent of Reliance

Low Risk ← → **High Risk**

BMI Calculator

Radiation dose calculator

Trending algorithm for determining next clinical action

Medical image analyzer for disease/anomaly detection

Medication Reminder

Cancer treatment recommendation

Drug-drug interaction/ allergy verification

Complex analyzer for untrained user

FDA and Cybersecurity

- **Premarket Cybersecurity**

  - On October 2, 2014, the FDA released regarding the management of cybersecurity risks in the design and development of interconnected medical devices.

  - Recommend thorough risk analysis and use of controls to:
    - Limit access to trusted users
    - Ensure trusted content; and
    - Detect, respond, and recover

  - Recommend submission of cybersecurity control information in premarket submissions.

Source: July 28, 2015 "Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"

FDA and Cybersecurity

- **Postmarket Cybersecurity**
  - On January 15, 2016, the FDA announced draft guidance identifying steps manufacturers should take to identify and address postmarket cybersecurity vulnerabilities that pose a risk to patient safety and public health.
  - FDA recommends adoption of risk management program to monitor, identify, detect, assess, and mitigate vulnerabilities arising postmarket.
  - "Uncontrolled" risks (posing an unacceptable risk that the clinical performance of a device could be compromised) may result in reporting obligations.

Cybersecurity Risk Management Program

- Monitor cybersecurity information sources to identify and detect vulnerabilities and risks
- Detect, assess and understand the presence and impact of a vulnerability
- Establish and communicate processes for handling vulnerabilities
- Develop mitigation strategies to protect against, respond to and recover from risks
- Adopt a vulnerability disclosure policy and practice
- Develop preventive measures to mitigate and address risks early and prior to exploitation

FDA and Cybersecurity

- July 2015 FDA Safety Alert regarding Hospira Symbiq Infusion System
  - FDA urged facilities to transition away from these devices because external hackers could control the device and change the dosage the pump delivers remotely

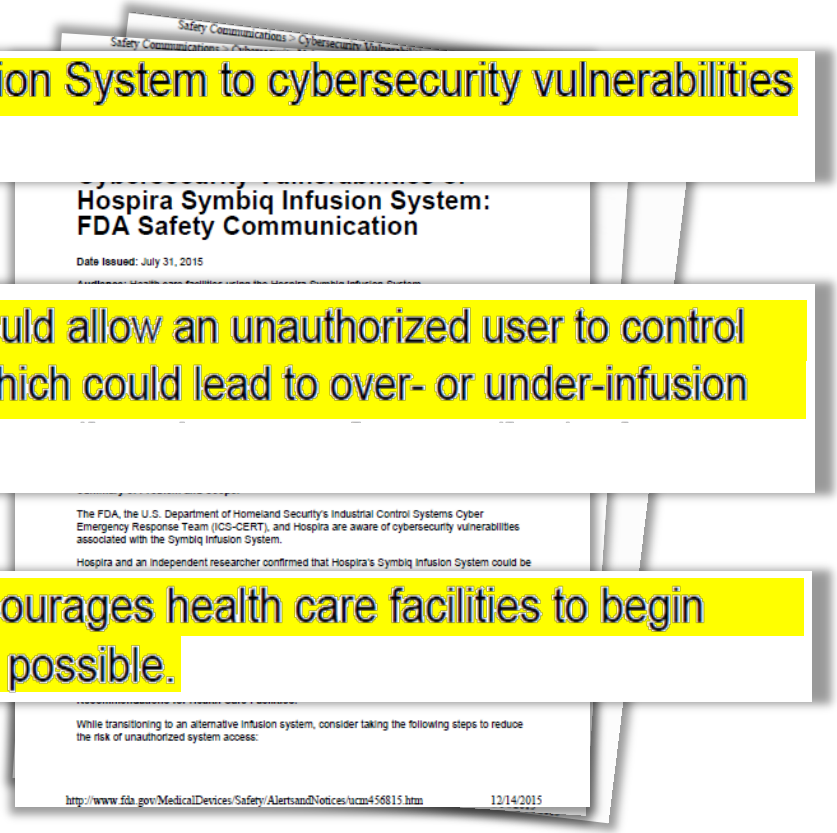
Source: July 31, 2015 FDA Letter to Hospira regarding "Cybersecurity Vulnerabilities of Hospira Symbiq Infusion System: FDA Safety Communication"

FDA and Cybersecurity: FDA Safety Alert

The FDA is alerting users of the Hospira Symbiq Infusion System to cybersecurity vulnerabilities with this infusion pump.

accessed remotely through a hospital's network. This could allow an unauthorized user to control the device and change the dosage the pump delivers, which could lead to over- or under-infusion of critical patient therapies. The FDA and Hospira

the FDA strongly encourages health care facilities to begin transitioning to alternative infusion systems as soon as possible.


Safety Communications > Cybersecurity

Hospira Symbiq Infusion System: FDA Safety Communication

Date Issued: July 31, 2015

The FDA, the U.S. Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team (ICS-CERT), and Hospira are aware of cybersecurity vulnerabilities associated with the Symbiq Infusion System.

Hospira and an independent researcher confirmed that Hospira's Symbiq Infusion System could be

While transitioning to an alternative infusion system, consider taking the following steps to reduce the risk of unauthorized system access:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm456815.htm 12/14/2015

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Source: July 31, 2015 FDA Letter to Hospira regarding "Cybersecurity Vulnerabilities of Hospira Symbiq Infusion System: FDA Safety Communication"

U.S. Department of Health and Human Services Regulation and Enforcement

2016 OIG Work Plan

Auditing and Enforcement

- Calls for increased scrutiny into data security capabilities of "networked medical devices" that are connected to electronic medical records (EMRs)
- Plans to examine whether FDA's oversight is sufficient to keep electronic protected health information (ePHI) contained within medical devices safe

Source: Office of Inspector General Work Plan – Fiscal Year 2016

Mobile Health Applications and HIPAA

- On October 5, 2015 the U.S. Department of Health and Human Services Office for Civil Rights (OCR) released an online platform for mobile application developers and others to submit questions and comments to anonymously to OCR on HIPAA compliance issues.

- OCR posted health application use scenarios in in February, 2016 to help provide clarity as to the application of HIPAA to use of mobile applications in certain situations.

Federal Trade Commission Enforcement

Topics

- The FTC's Interest in Mobile Medical Devices and Apps
- Select FTC Enforcement

FTC Interest

- The FTC sees itself as the super-regulator, best equipped to protect consumers
  - Safety and advertising
  - Competition and economic impact
  - Privacy-by-design/Internet of Things
- FTC is empowered under, FTC Act § 5, which penalizes "unfair or deceptive acts or practices in or affecting commerce."

Source: 15 U.S.C. § 45

FTC Enforcement

- *FTC v. Wyndam*
- *FTC v. LabMD*

FTC v. Wyndham

FTC Enforcement

- Action arose from three (3) separate hacking incidents in 2008 and 2009
  - 619,000 customer records (names, addresses, credit cards) compromised
  - $10.6 million in losses
- FTC alleged, among other things, that Wyndham
  - failed to maintain reasonable security measures to monitor unauthorized computer access;
  - failed to conduct security investigations; and
  - failed to reasonably limit third-party access to company networks and computers.
- FTC brought an enforcement action under both the unfairness and deceptive prongs of Section 5

FTC v. Wyndham

FTC Enforcement

- Wyndham moved to dismiss at District Court level
  - Wyndham only challenged FTC's unfairness authority under Section 5. Wyndham claimed
    - Data security practices are not included in the definition of "unfair and deceptive" practices under Section 5
    - Section 5 violated principles of fair notice and due process because FTC fails to notify companies of rules, regulations and guidelines governing data security
- District of New Jersey denied motion to dismiss but certified the unfairness claim for appeal

FTC v. Wyndham

FTC Enforcement

- Third Circuit affirmed trial court and found FTC has authority to pursue enforcement action. The Court found
  - Unfairness does not require unfair conduct or unethical behavior and can occur even if company is victimized by criminal conduct
  - FTC does not have to publish rules and regulations for fair notice
  - FTC enforcement actions with other companies were sufficient to provide Wyndham with notice of acceptable cybersecurity standards
  - FTC's authority to police cyber-breaches is solidified
- Wyndham recently settled with the FTC
  - Settlement looks fairly similar but has enhanced monitoring provisions

FTC v. LabMD

FTC Enforcement

- LabMD is a privately held company that operated as a medical services provider, performing tests for patients at the request of doctors
- As part of its business, LabMD stored electronic billing records and medical records on an office computer
- In May 2008, a third party contacted LabMD and told LabMD that some of these files was available through LimeWire, a peer-to-peer sharing system

FTC v. LabMD

FTC Enforcement

- After being notified, LabMD determined that LimeWire had been installed on its billing computer, which LabMD promptly removed
- LabMD also searched and monitored LimeWire for several months for any evidence of the leaked files but found no evidence beyond the third party
- Nevertheless, the FTC brought an enforcement action against LabMD under the unfairness prong of Section 5

Comparison of Allegations

FTC Enforcement

FTC v. Wyndham

- failed to maintain reasonable security measures to monitor unauthorized computer access;
- failed to conduct security investigations; and
- failed to reasonably limit third-party access to company networks and computers

FTC v. LabMD

- did not employ readily available measures to prevent or detect unauthorized access to personal information on its computer networks; and
- did not develop, implement, or maintain a comprehensive information security program to protect consumers' personal information

FTC v. LabMD

FTC Enforcement

- Holding: No evidence that any consumer suffered any actual harm from alleged failure to employ “reasonable” data security
- There was no also evidence of a high likelihood of future harm

LESSONS LEARNED

- It matters how you react to an alleged data breach
- In the event of a data breach, use independent judgment to perform thorough investigations
- Monitor computer systems to determine if unauthorized software has been installed
- Breach does not necessarily mean liability

Federal Trade Commission

Protecting America's Consumers

START WITH SECURITY

FTC Start with Security

Visit http://bit.ly/1YhdEiK to download materials and listen to a recent Pepper/Bloomberg BNA webinar that addresses compliance and best practices under the FTC's 'Start with Security' initiative.

Start with Security

The FTC provided guidance from lessons learned from 50+ data security related enforcement actions

1. Start with security
2. Control access to data sensibly
3. Require secure passwords and authentication
4. Store sensitive personal information securely and protect it during transmission
5. Segment your network and monitor who is trying to get in and out
6. Secure remote access to your network
7. Apply sound security practices when developing new products
8. Make sure your service providers implement reasonable security standards
9. Put procedures in place to keep your security current and address vulnerabilities that may arise
10. Secure paper, physical media, and devices

National Association of Attorneys General

State Attorneys General Regulation and Enforcement

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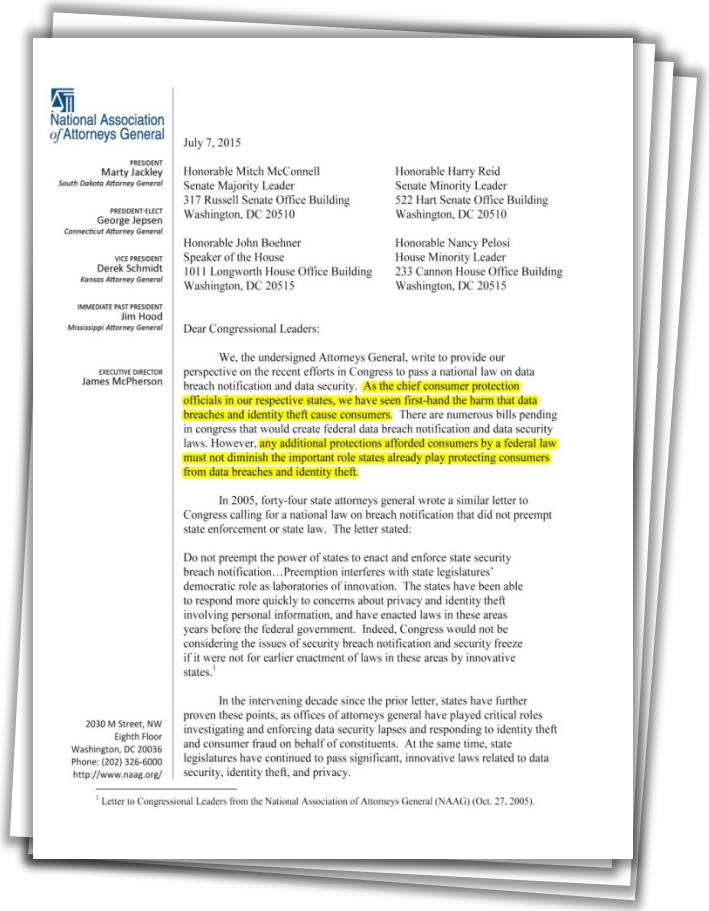
State AGs: Intense Interest

Letter to Congressional Leaders from the National Association of Attorneys General (Oct. 27, 2015)



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July 7, 2015

Honorable Mitch McConnell
Senate Majority Leader
317 Russell Senate Office Building
Washington, DC 20510

Honorable Harry Reid
Senate Minority Leader
522 Hart Senate Office Building
Washington, DC 20510

Honorable John Boehner
Speaker of the House
1011 Longworth House Office Building
Washington, DC 20515

Honorable Nancy Pelosi
House Minority Leader
233 Cannon House Office Building
Washington, DC 20515

Dear Congressional Leaders:

We, the undersigned Attorneys General, write to provide our perspective on the recent efforts in Congress to pass a national law on data breach notification and data security. As the chief consumer protection officials in our respective states, we have seen first-hand the harm that data breaches and identity theft cause consumers. There are numerous bills pending in congress that would create federal data breach notification and data security laws. However, any additional protections afforded consumers by a federal law must not diminish the important role states already play protecting consumers from data breaches and identity theft.

In 2005, forty-four state attorneys general wrote a similar letter to Congress calling for a national law on breach notification that did not preempt state enforcement or state law. The letter stated:

Do not preempt the power of states to enact and enforce state security breach notification…Preemption interferes with state legislatures' democratic role as laboratories of innovation. The states have been able to respond more quickly to concerns about privacy and identity theft involving personal information, and have enacted laws in these areas years before the federal government. Indeed, Congress would not be considering the issues of security breach notification and security freeze if it were not for earlier enactment of laws in these areas by innovative states.[1]

In the intervening decade since the prior letter, states have further proven these points, as offices of attorneys general have played critical roles investigating and enforcing data security lapses and responding to identity theft and consumer fraud on behalf of constituents. At the same time, state legislatures have continued to pass significant, innovative laws related to data security, identity theft, and privacy.

2030 M Street, NW
Eighth Floor
Washington, DC 20036
Phone: (202) 326-6000
http://www.naag.org/

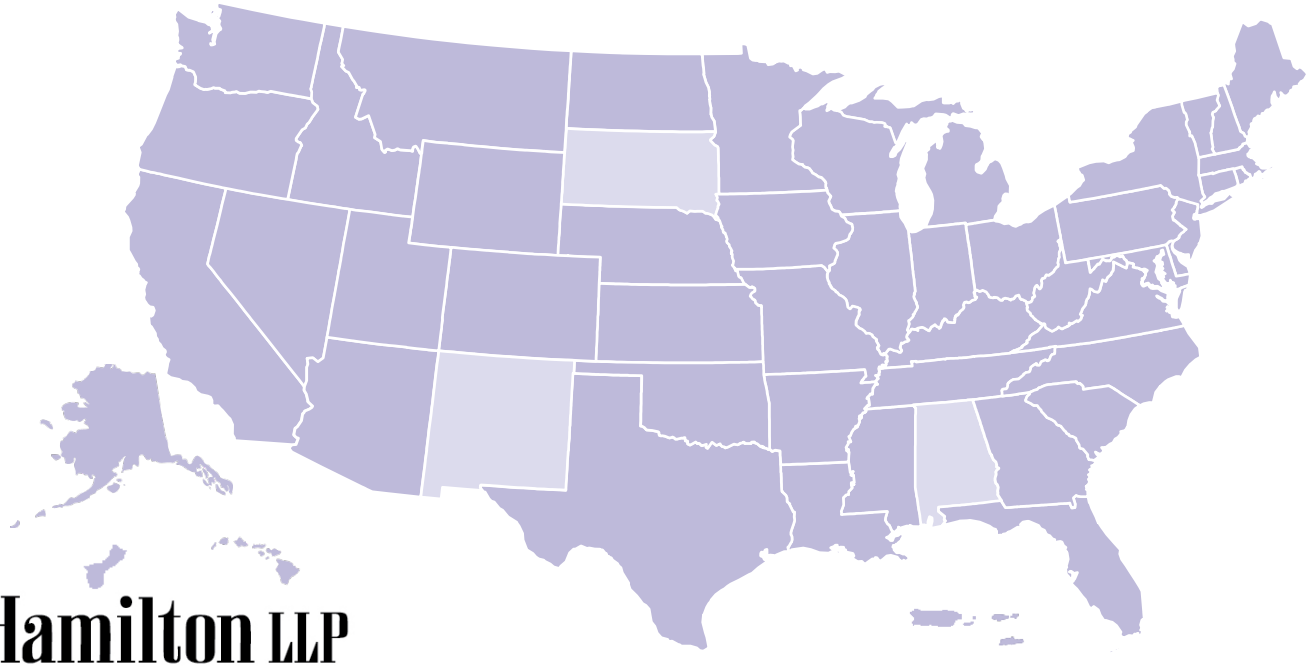
[1] Letter to Congressional Leaders from the National Association of Attorneys General (NAAG) (Oct. 27, 2005).

- **Data Breaches and Identity Theft Cause Significant Harm to Consumers**
- **States Play an Important Role Responding to Data Breaches and Identify Theft**
- **Federal Law Should Not Preempt State Law**
- **Data Security Vulnerabilities Are Too Common**

State AGs

Data Breach Notification Laws

- 47 states have enacted data breach notification laws
  - All require prompt notification of breach to consumers
  - Some require companies to adopt reasonable data security practices
- Provide for additional liability and impose civil penalties



State AGs

Enforcement Mechanisms

- What does a typical consent decree look like?
  - Penalties and fines dependent on the extent of the breach
  - Creation of new policies and procedures to ensure future compliance
  - Free identify theft protection/mitigation services
  - Mandatory audits and reporting back to State AGs
  - Creation of security based roles, including Chief Privacy Officer
  - Mandatory employee training on data security practices
  - Updates to technological infrastructure

State AGs

Consumer Protection

- Violating Data Breach Disclosure Laws can be a violation of Unfair Trade Practices Act
- State consumer protection laws based on Section 5 of FTC:
  - "Capable of misleading"
  - "Violates public policy"
  - "Unfair"
  - "Concealing or omitting a material fact in selling product"
  - Misrepresenting "characteristics or benefits…"
- Injunctive relief, restitution, civil penalties, disgorgement
- No proof of harm to collect civil penalties

State AGs

California Attorney General 2016 Data Breach Report

- California AG emphasized the legal responsibility of entities that collect personal information to implement and maintain reasonable security measures.

- Stated failure to implement relevant information security controls from Center for Internet Security's Critical Security Controls constitutes a lack of reasonable security.

- Demonstrates AG emphasis on industry standard processes to help ensure appropriate information security. For manufacturers, this means standardized framework for assessing and addressing potential vulnerabilities and secure application development.

Consumer Class Actions

Consumer Class Actions

- In addition to the state and federal government authorities, mobile medical app providers are also at risk for class action suits brought by private litigants
  - Sutter Health Class Action
  - Nike FuelBand Class Action

Sutter Health

Consumer Class Actions

- An unencrypted (but password-protected) laptop was stolen
- Plaintiffs sought statutory damages of $1000 per patient for over 4 million patients, totaling over $4 billion in nominal damages
- A purported class plaintiff claimed that Sutter Health violated California's Confidentiality of Medical Information Act (CMIA)
- The trial court denied Sutter Health's motion to dismiss, and Sutter Health appealed

Sutter Health

Consumer Class Actions

- The Court of Appeal vacated the decision and ordered the case dismissed because there was no evidence that patient information had been accessed or viewed by an unauthorized person

LESSONS LEARNED

- State statutory law has the potential to expose recipients of health information to large damages awards
- Even if ultimately successful, opposing class actions brought on state statutory grounds can be costly
- Securing physical media/devices is equally as important as securing electronic access to information

Nike FuelBand

Consumer Class Actions

- Purported class plaintiff brought action in California state court claiming Nike and Apple falsely advertised that the Nike Plus FuelBand electronic wristband accurately records each calorie burned by its wearer during physical activity
- Case settled for $15 check (or $25 Nike gift card) per consumer and $2.4 million in attorneys' fees all paid by Nike

LESSONS LEARNED

- Be careful what you advertise your product does
- When working with collaborators, hold collaborators to your standards and/or seek indemnification

Questions to Ask Yourself

- What is the function and use of the device?
- Is it a non-mobile device with the same function already regulated?
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Final Thoughts and Questions