

REGULATION OF HEALTH DATA TRACKERS

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HEALTH (FITNESS) DATA TRACKING

- Includes emerging market of wearables, “connected” fitness devices, apps.
- 13.4 Million fitness trackers sold in 2015 (almost doubled from 2014).
- Fitness tracking built into latest Apple iPhone hardware, software; as well as other mobile platforms
- Health app downloads projected to grow to to 248,000,000 by 2017
- This is something that people want.

WEARABLES

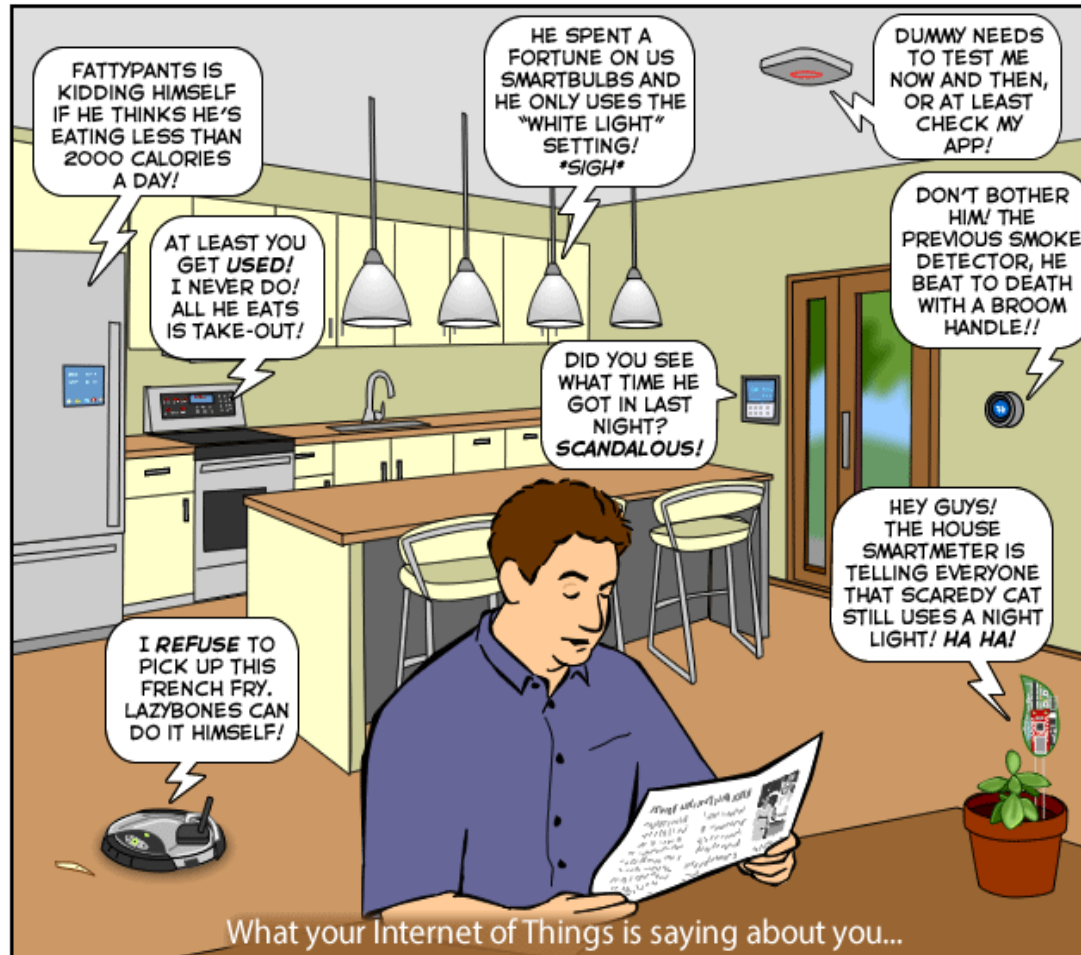
Any device that collects personal fitness or activity data and has the potential to aggregate those data to a central database and/or “share” data via consumers’ “preferences”



THE INTERNET OF THINGS

The Joy of Tech™

by Nitrozac & Snaggy



WHAT IS BEING COLLECTED?

- Activity Tracking
- Nutritional Information
- Basic Vital Signs
 - Heartrate / Pulse
- Sleep Duration and Quality
- Basic imaging with device cameras
- The list will grow and the data will improve in quality and automation.



YES, IT EVEN TRACKS THAT.

Christian college says mandatory Fitbits won't track sex

Oral Roberts U's code of conduct forbids premarital relations.



Steve Dent , @stevetdent
02.04.16 in [Sex](#)

33

Comments

Shares



Pornhub wants to help you get fit

No prizes for guessing the method.



Daniel Cooper , @danielwcooper
05.18.16 in [Sex](#)

Comments

Shares

WHAT CAN THE DATA TELL US?

- Individually
 - Baseline assessment of fitness data
 - Tracking changes over time
 - Incentives to improve health markers
 - Pairing with other social media (Facebook, etc.)
 - Goal-setting, either by individuals, across social media groups, or by the app or service itself

WHAT CAN THE DATA TELL US?

- Aggregated (“Big Data”)
- In many ways, this is the promise of health data tracking
- Sheer size of the data sets may enable “data mining” of basic health data that would be impossible or impracticable in a clinical setting
- Power of Big Data predictive analytics applied to basic health information in a way it cannot with EMR information.
- Individually- generated data may be combined with other consumer data currently held by data brokers

PRIVACY



PRIVACY CONCERNS

- Are data identifiable?
- What are the limits on use of data?
- What are the limits on disclosure of data?
- Can individually innocuous data points be aggregated to provide accurate, intrusively predictive results?
- Can my data be accessed by others?
 - Employer or potential or past employer?
 - Insurers?
 - Government/ Law Enforcement?

VALUING PRIVACY?

The Joy of Tech™ by Nitrozac & Snaggy

Currently...

nest Learning Thermostat
70°
nest Smoke Detector
BUDGET!
Smoke Detector for your home!
WITH EAR PIERCING ALARM!
FIRE AND SMOKE PROTECTION!
THERMOSTAT
All manual functions for most heating and cooling systems. Built in thermometer.

\$130.00 **\$250.00** **Clearance!** **\$9.95 each!**

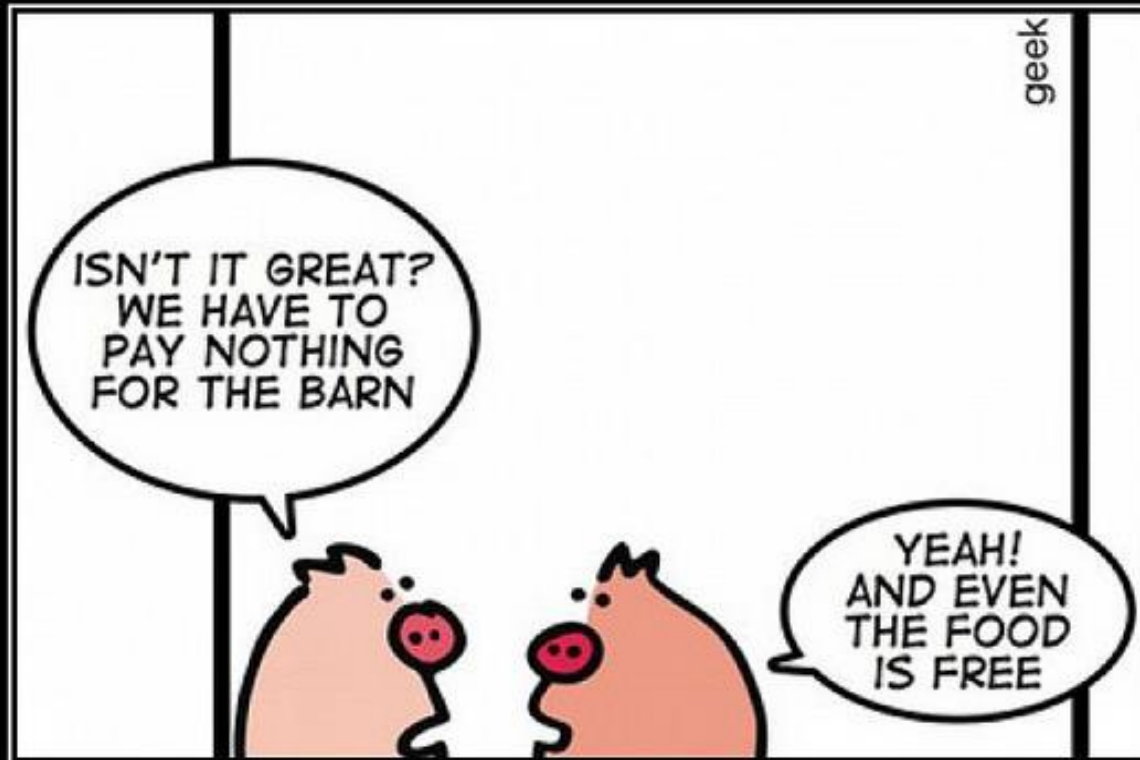
Coming soon...

nest Learning Thermostat
subsidized by **Google**
70°
nest Smoke Detector
BUDGET!
Smoke Detector for your home!
WITH EAR PIERCING ALARM!
FIRE AND SMOKE PROTECTION!
THERMOSTAT
All manual functions for most heating and cooling systems. Built in thermometer.

BOTH for \$9.99! **or FREE with G+ commitment!** **Old school! NOT-connected to Google! TOTAL PRIVACY!** **\$299.00 each!** **Get 'em while you can!**



"It's free, but they sell your information."



FACEBOOK AND YOU

If you're not paying for it, you're not the customer. You're the product

CURRENT “REGULATION”

- HIPAA / HITECH Act
 - Data collected outside a healthcare relationship not covered
- FDA Medical Device Regulation
 - FDA choosing to exercise regulatory discretion
- Electronic Communications Privacy Act
 - “Tracking Device” exemption
- Private Law (Contract)
 - “Clickwrap” contracts written by and in favor of manufacturers

US DATA PROTECTION

- Currently, these data exist in largely unregulated space
- Government starting to become aware of and articulate need for concern about data protection
- Including health data, and including consumer-generated, non-EMR data
- However, data collection and mining may be protected speech
 - (Sorrell v. IMS Health – no state ban on mining and sale of pharmacy records describing MD prescription practices)

MAY 2014 WHITE HOUSE BIG DATA REPORT

- Asymmetry of power between those who hold the data and those who supply it
- Few opportunities to control the collection, use and re-use of information in individual data profiles
- De-identification is limited; re-identification technology rapidly evolving
- Lines blurring between personal data and health care data
- Notice and Consent-based regulation inadequate to regulate Big Data practices

CONSUMER PRIVACY BILL OF RIGHTS

- Individual control over collection and use
- Transparency in privacy
- and security
- Respect for context in collection, use and disclosure
- Security in handling of data
- Access and Accuracy
- Focused Collection: reasonable limits on data collection
- Accountability

MAY 2014 FTC DATA BROKERS REPORT

- Survey of Nine leading data brokers
- Focusing on activities not regulated by FCRA
- Report acknowledges the benefits of data collection and processing, but notes that
 - Consumers may not know how (or even that) their data are being collected and used
 - Consumers may not be able to access their data once aggregated
 - Data held may not be accurate or timely

DATA BROKERS REPORT

- FTC recommendations:
 - Consumer Access to broker data on them
 - Opt-Out Rights to data collection
 - Disclosure of data usage and processing (names and sources of data)
 - Requiring firms interacting with individuals to notify that they share data with data brokers and provide opt-out
 - Require opt-in (affirmative consent) for some sensitive data types, such as health (not sure how health information defined)

FAIR CREDIT REPORTING ACT

- Foundation of US consumer protection law
 - Privacy
 - Accuracy
 - Availability
-
- Note congruences between the FRCA goals and the set of FTC recommendations.
 - Note tension between “Privacy” and “Availability”

REG FF

- Currently, FRCA-regulated entities are prohibited from using “medical information.”
- 232.1(b): A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit, except as provided in this section.

THE GOOD NEWS

- **232.1(5): Medical information** means:
 - (i) Information or data, whether oral or recorded, in any form or medium, **created by or derived from** a health care provider **or the consumer**, that relates to:
 - (A) The past, present, or future physical, mental, or behavioral health or condition of an individual;
- (emphasis added)

THE BAD NEWS?

232.1(5)(ii) [“Medical Information”] does not include:

- (A) The age or gender of a consumer;
- (B) Demographic information about the consumer, including a consumer’s residence address or e-mail address;
- (C) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition ..., including the existence or value of any insurance policy; or
- (D) Information that does not identify a specific consumer.

MORE BAD NEWS?

- 232.2(a) A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

LIMITS OF FCRA

- Contains some protections which are broader than those in other legal contexts
- Not able to assure quality of data in many fields of concern (insurance, employment, etc)
- Premised on the existence of big data in the field and the value of those data in making economic decisions

HEALTH DATA AND FINANCIAL DATA

- Some existing regulation of health data is modeled on regulation of financial data.
 - HITECH Act data breach reporting modeled on state laws re: financial information (credit card/banking)
- Health data breaches are now inevitable
- No right to have one's health data offline
- What does this mean for personal fitness/activity data collected and shared voluntarily by individuals?
- Is health data just another form of consumer data, or is it qualitatively different because of the risks posed by disclosure?

QUESTIONS GOING FORWARD

- Should I be able to “opt out” of data aggregation?
- Should I have to “opt in” to data aggregation?
- Is there a “moral duty” to participate in some way if I want the benefits?
- Is the proper analogy the credit reporting system?
- Should there be “hard” limits on data collection, retention or sale?
- What are the principles that should govern regulation of the market in these data?

REG PRINCIPLES

Financial Info	Health Info
Consistency	Flexibility
Completeness (Utility)	Data Minimization
Notice and Control (Accuracy)	Notice and Control
Acceptable/Ethical Use	
Availability	Security
	Consent?

TO BE CONTINUED...

- Balancing consumer protection with the potential benefits of this data collection will be difficult
- Existing law is inadequate; old analogies may not provide the correct balance of risk:reward.

