Trustworthy Medical Device Software

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http://secure-medicine.org/

Public Meeting: Recommendations Proposed in Institute of Medicine Report: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years," September 16, 2011

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- Received support on medical security from NSF, HHS, IOM
- Patent pending technology:
  - Low-power flash memory
  - Zero-power security
- This presentation is based on both my own research and the research of others. None of the opinions, findings, or conclusions necessarily reflect the views of my past or present employers.
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Why Trustworthy Software?

- Recommendation: FDA should **develop procedures that ensure the safety and effectiveness of software** used in devices, software used as devices, and software used as a tool in producing devices.

- Yes, and here are reasons why.

How Much SW in Medical Devices?

- 1983-1997
  - 6% of all recalls attributed to software
- 1999-2005
  - **Almost doubled**: 11.3% of all recalls attributed to software
  - 49% of all recalled devices relied on software (up from 24%)
- 1991-2000
  - **Doubled**: # of pacemakers and ICDs recalled because of SW
- 2006
  - Milestone: Over half of medical devices now involve software
- 2002-2010
  - 537+ recalls of SW-based devices affecting 1,527,311+ devices

[Sources: Bliznakov et al. 2006, Faris 2006, Maisel et al. 2002, Wallace & Kuhn 2001]

Why Is Software Different?

- Cannot be tested thoroughly

(radiation therapy)

``'...there is **not enough time** ... **to check** the behavior of a complicated device to **every** possible, conceivable kind of **input**,' said Dr. Williamson...."

[Walt Bogdanich, NY Times, 1/26/2010]

[Source: Parnas 1985, Pfleeger et al. 2001]

Substantial Equivalence

- "One of the interesting classes is radiation equipment...Even the software, which I wonder where they got the first **predicate for software**."

-David Feigal
Fmr. Director, FDA Center for Devices and Radiological Health (CDRH)
[Institute of Medicine Meeting 2, June 2010:
Public Health Effectiveness of the FDA 510(k) Clearance Process]

Horse technology was shown safe and effective. The horse-car is substantially equivalent.

510(k) Substantial Equivalence: What are appropriate predicates for medical device software ?

[http://www.epicfail.com/2009/11/23/horse-and-buggy-fail/]

Predicates: software ≠ hardware

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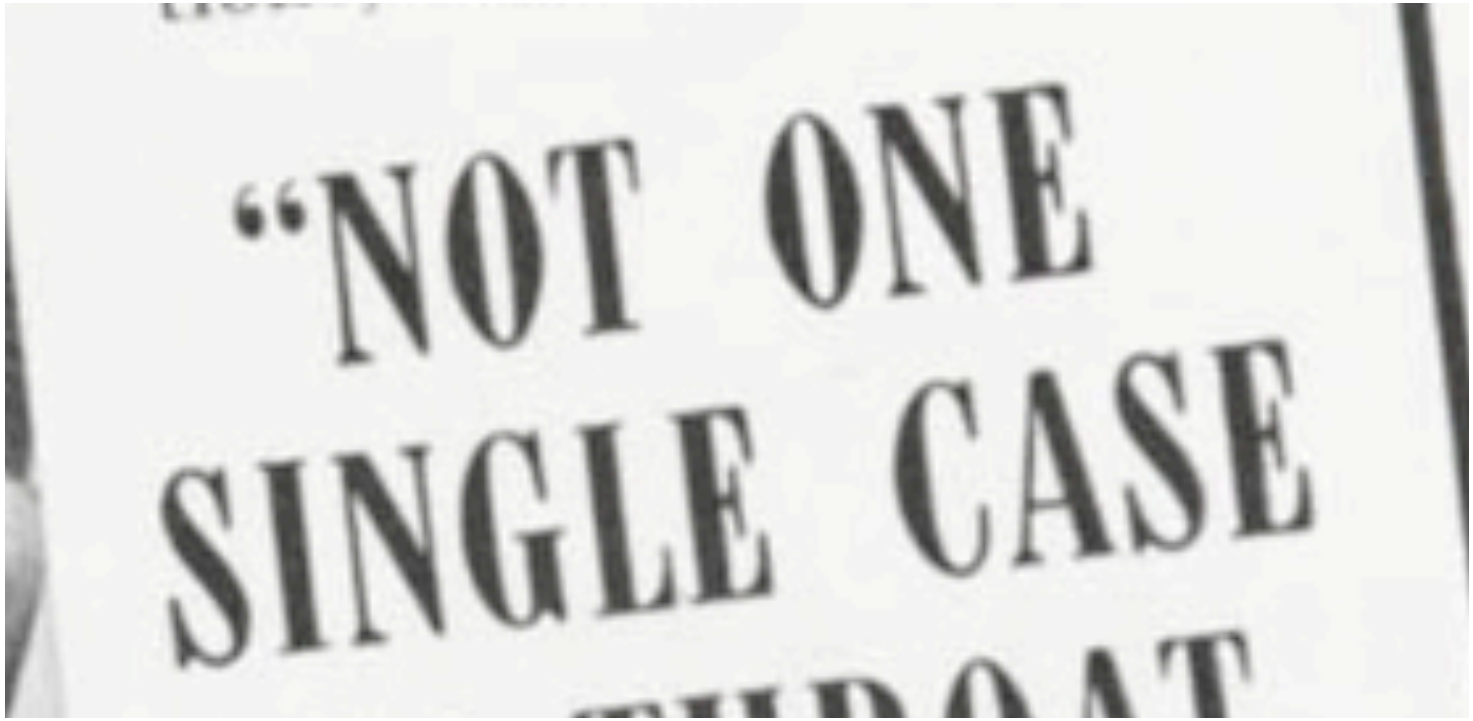
How to attract hackers to medical devices:

- Increase software complexity
- Add radio communication
- Trust the Internet for clinical decision making

[http://www.surfersam.com/funny-pictures/hackers.jpg]

Information Assurance or Bliss?



http://tobacco.stanford.edu/

Information Assurance or Bliss?

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[B. Feder, "A Heart Device Is Found Vulnerable to Hacker Attacks" NY Times, March 12, 2008]

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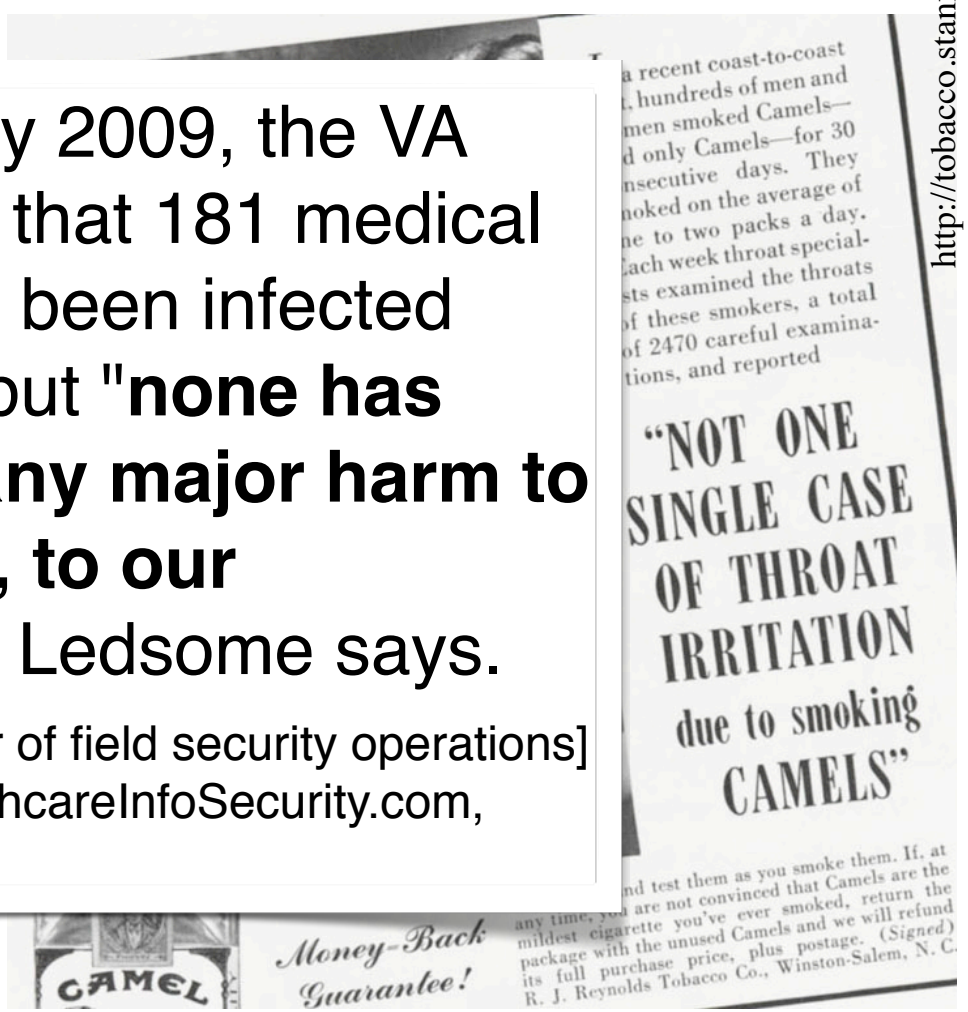
[VA's acting director of field security operations] [H. Anderson, HealthcareInfoSecurity.com, June 21,2011]



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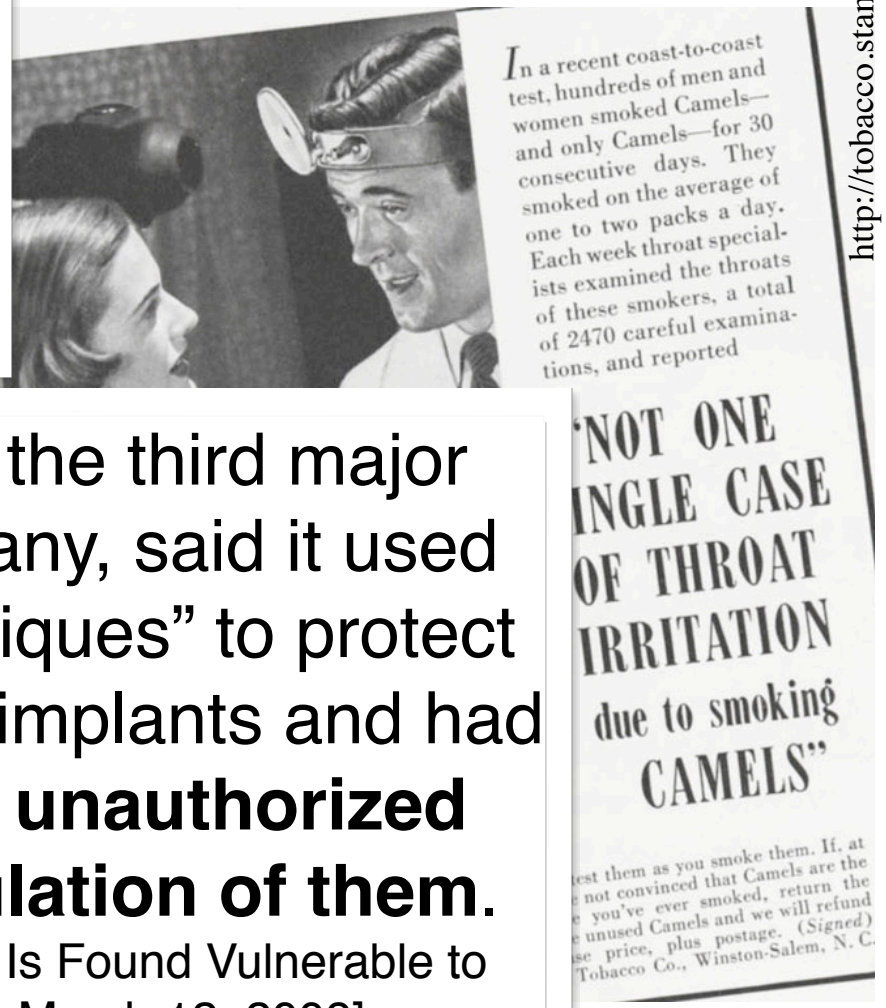

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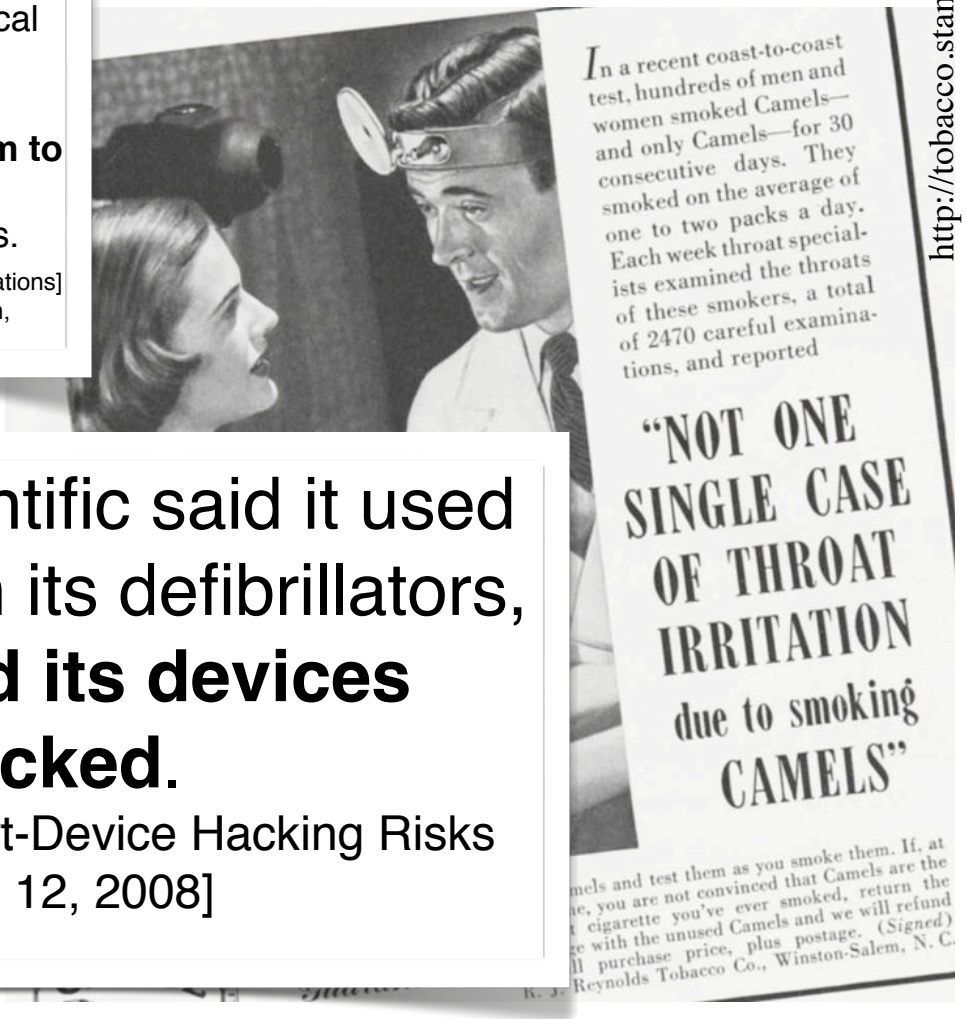

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Boston Scientific said it used encryption in its defibrillators, and **doubted its devices could be hacked**.

[K. Winstein, "Heart-Device Hacking Risks Seen" WSJ, March 12, 2008]

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←Ways Forward ↗ for software?

[http://en.wikipedia.org/wiki/Washington_State_Route_510]

Trustworthy Medical Device SW

- Software:
  - breeds overconfidence,
  - is not thoroughly testable, but
  - is flooding into medical devices
- Manufacturers could mitigate risks with known technology
  - Avoid hardware as a predicate for software
  - Adopt modern software engineering & systems engineering tech.
  - Create more meaningful specification of requirements
  - Better analyze human factors
  - Develop safety net for security and privacy
- Need: Better surveillance of SW, clearer responsibility

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