Connected Medical Devices and the Healthcare System

Dean Chen, Director of Product Management

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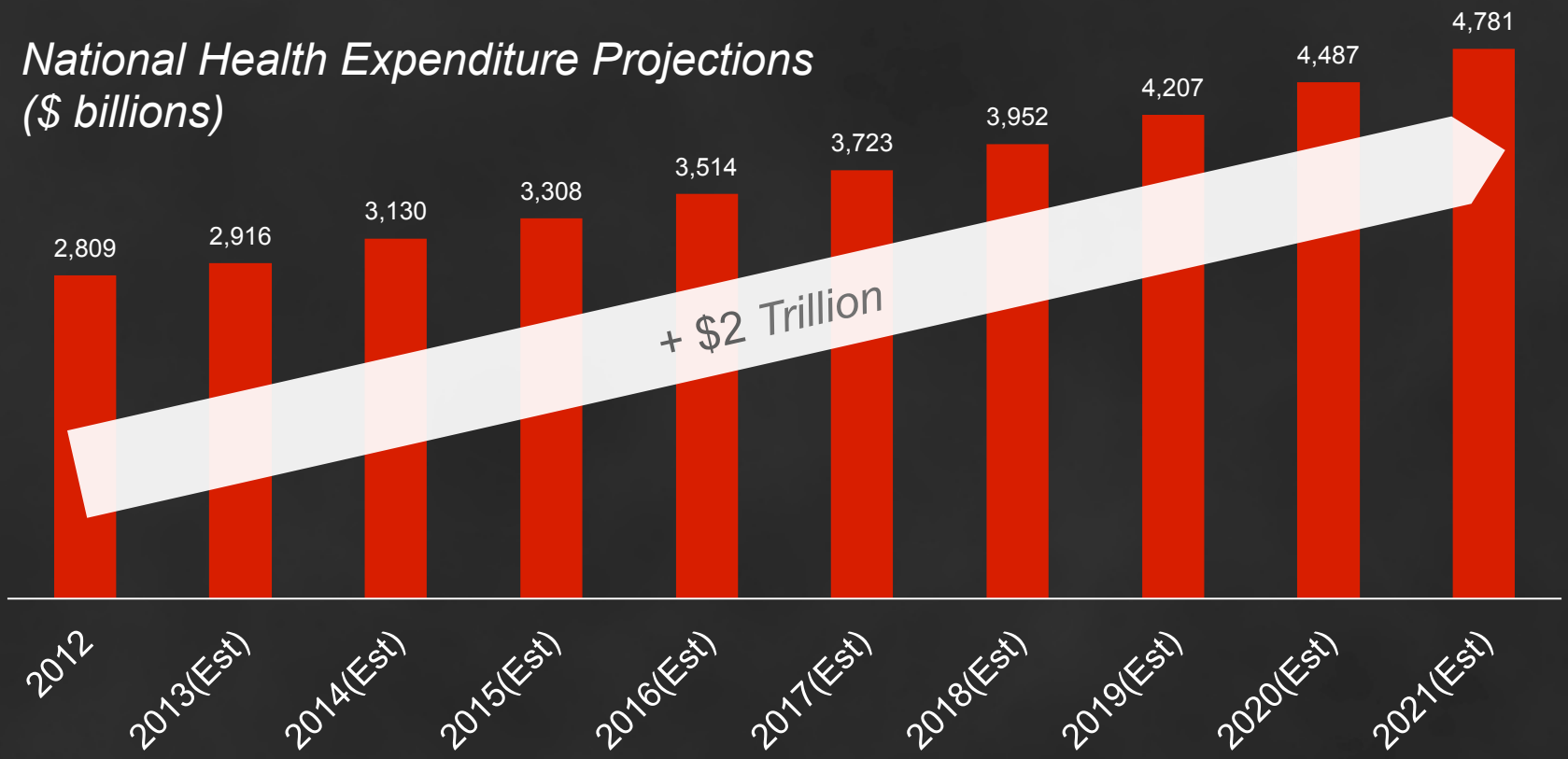
Healthcare Costs Are on an Unsustainable Trajectory



Source: U.S. Department of Health and Human Services

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Hospital Consolidation Driving Price Pressure on Device Manufacturers


THE WALL STREET JOURNAL.

U.S. EDITION ▾ Wednesday, March 18, 2009

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TOP STORIES IN BUSINESS

1 of 12 E-Book Ruling Puts Crimp in Apple

2 of 12 Humble Roots Fed Smithfield Deal

3 of 12 Cigarette Bans to Hit Europe

Wal-Mart Scraps D.C. Sto Plans

March 18, 2009

Medical Device Makers Face Health-Care Reform Pressures

Year	2007	2008	2009	2010	2011	2012 First 6 months
Number of Hospital Mergers and Acquisitions	60	60	50	76	90	47

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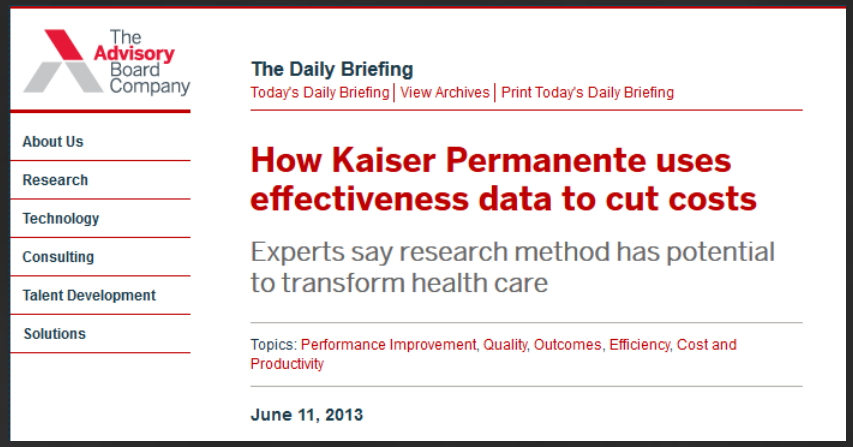
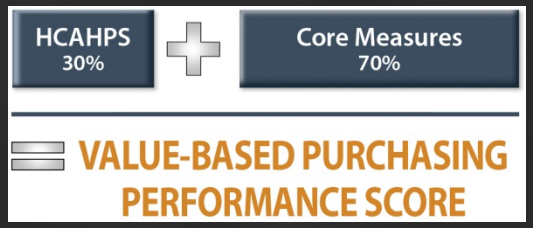
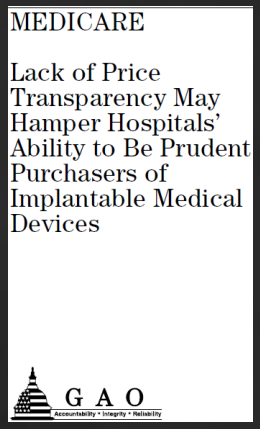
Device Value Will Be Critically Assessed by Enterprise Purchasers

- UDID integration with EHR/ clinical information systems will enable hospitals to assess device effectiveness *outside* of clinical trials.
- Clinically superior devices receive preferential treatment; parity devices will compete on *price*.







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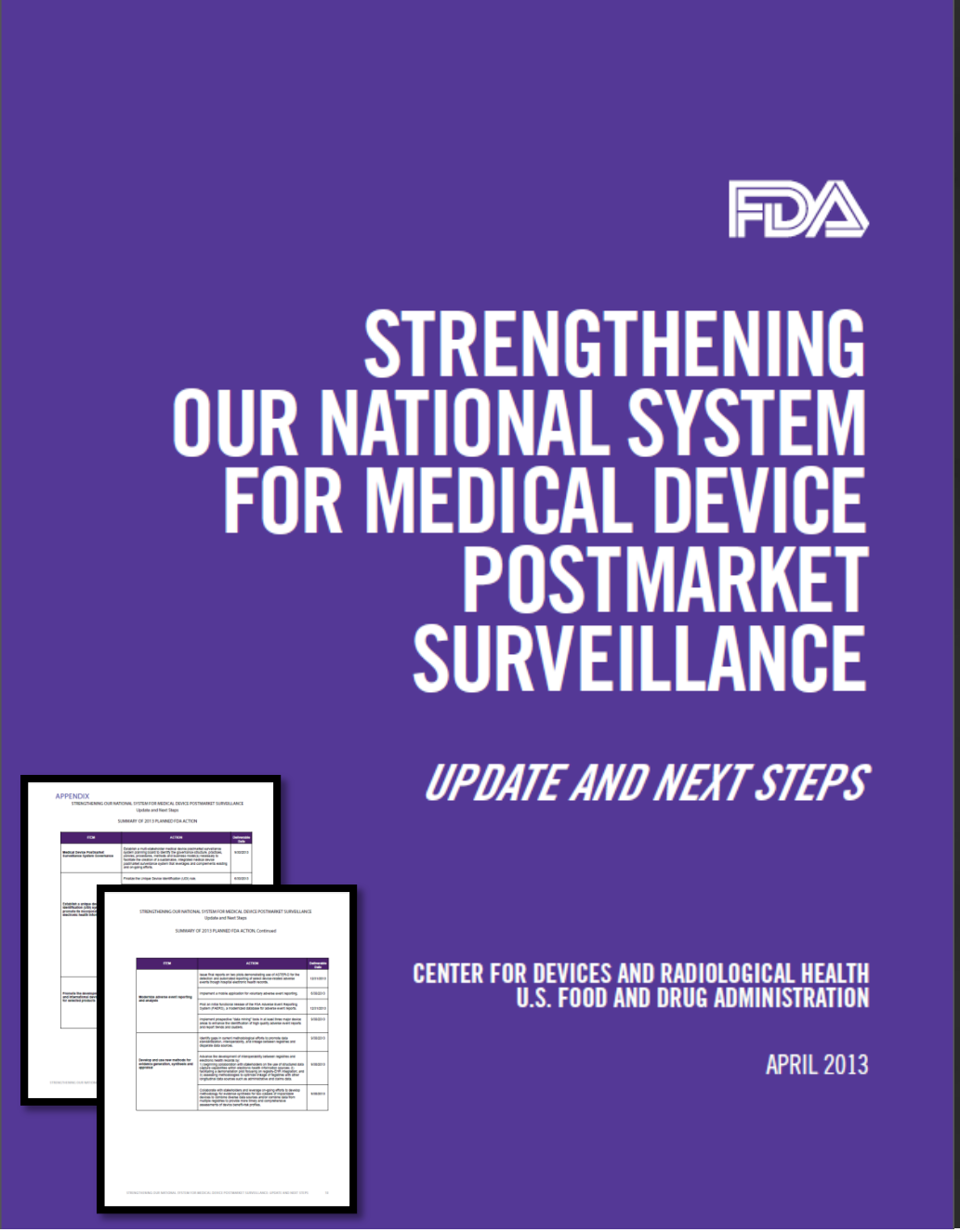

FDA Oversight Increasing

- Establish a multi-stakeholder **Medical-Device Postmarket Surveillance System Planning Board.**
- Establish a **unique device identification (UDI) system** and promote its incorporation into electronic health information.
- Promote the development of **national and international device registries** for selected products.
- Modernize **adverse event reporting and analysis.**
- Develop and use new methods for **evidence generation, synthesis, and appraisal**.

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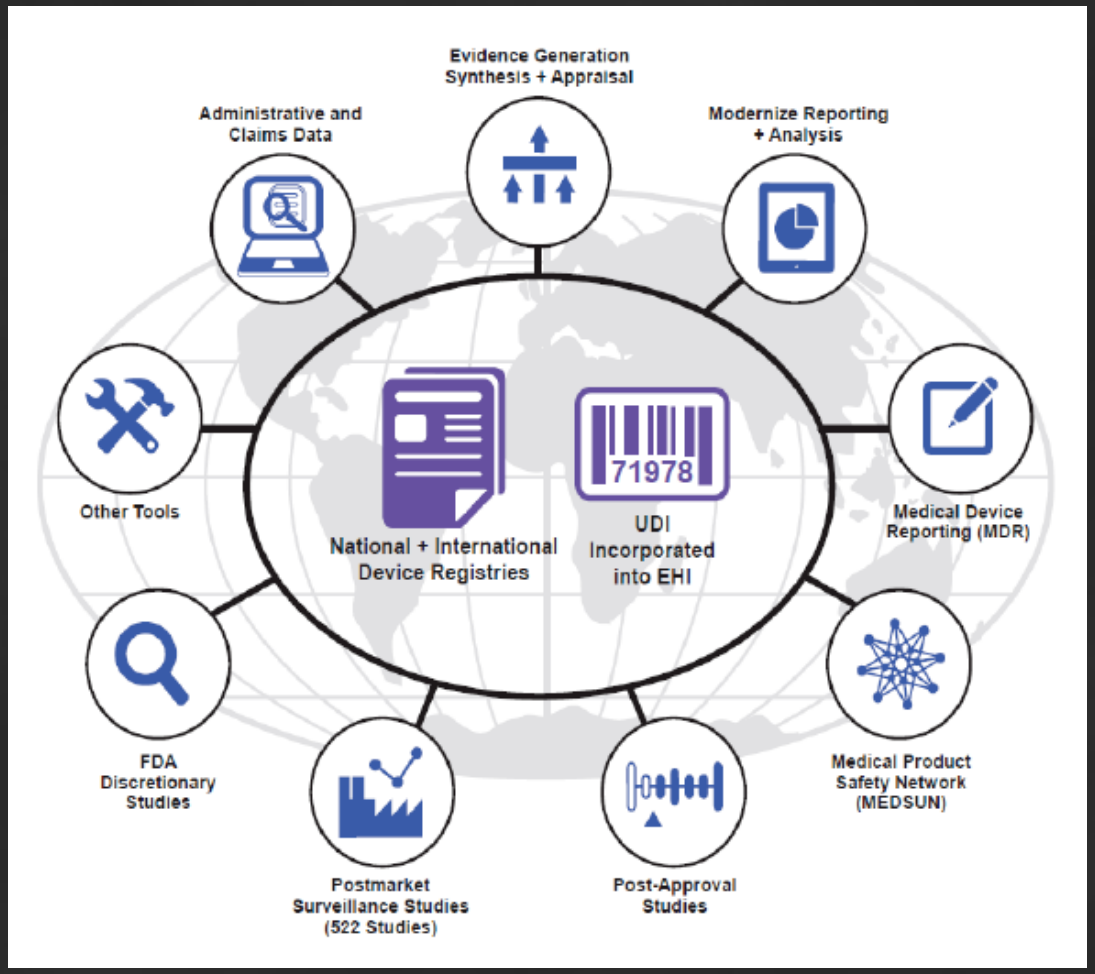
FDA Building an Integrated Device Surveillance System



- Can manufacturers differentiate their products in a world of comparative effectiveness research?
- How will CDRH structure and conduct data fusion across disparate data systems?
- When does CMS enter the picture?

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What Does It All Mean?

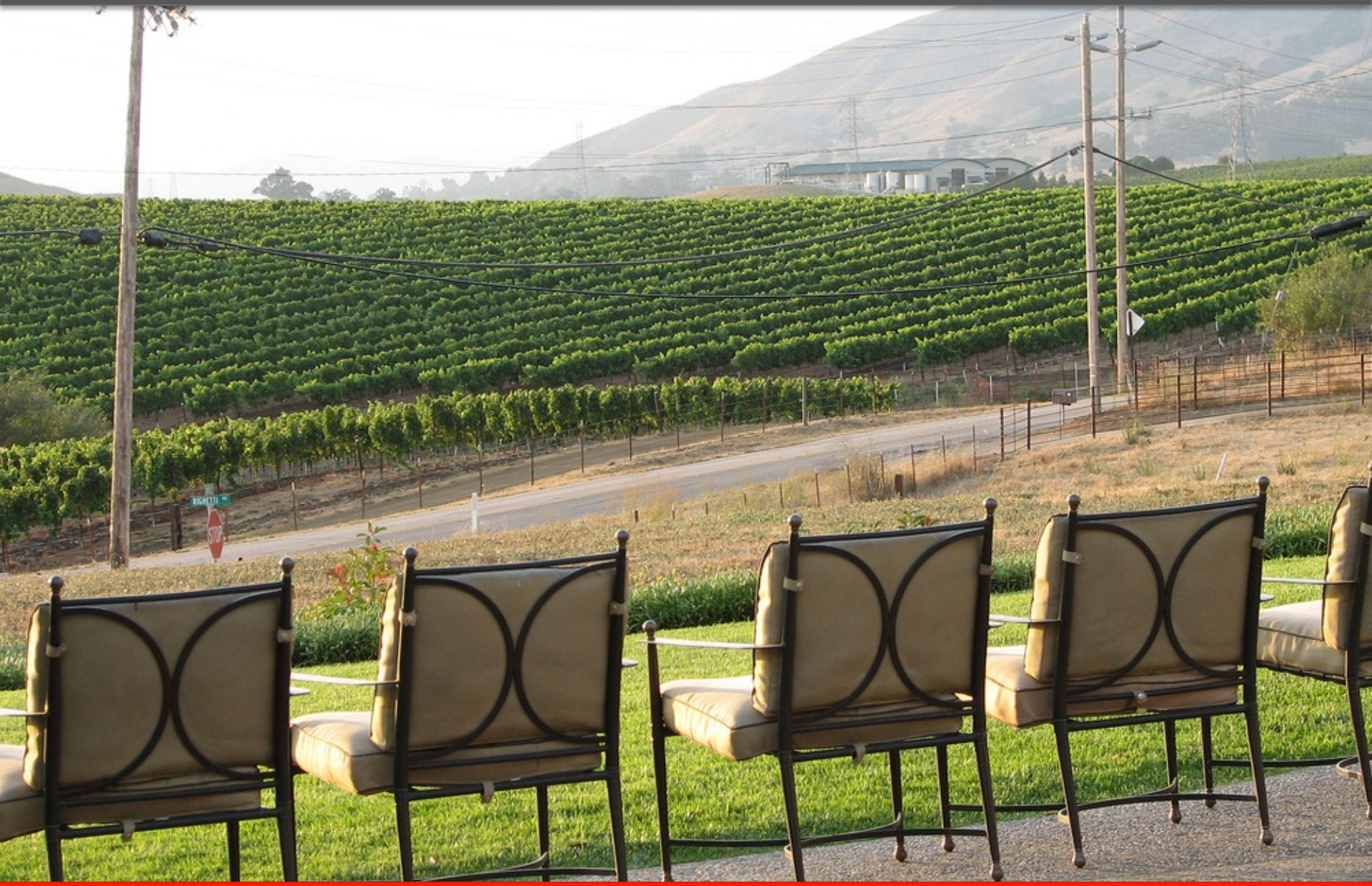
- Medtech VC investment was down 17% in 2013.
  - *40%* decline from 2007
- The pipeline for “bolt-on” tech acquisitions is thinning.
  - Unlikely to be a good strategy in any case, going forward
- Established industry players must adapt business models to continue growth in the coming decade.
  - Delivering value-added platforms and services to the healthcare system
  - Streamlining development and support operations with common technology

What hasn’t changed?

We’re still here to help patients get better.

Modern Medicine: A Case Study

Mark retires after a long career.

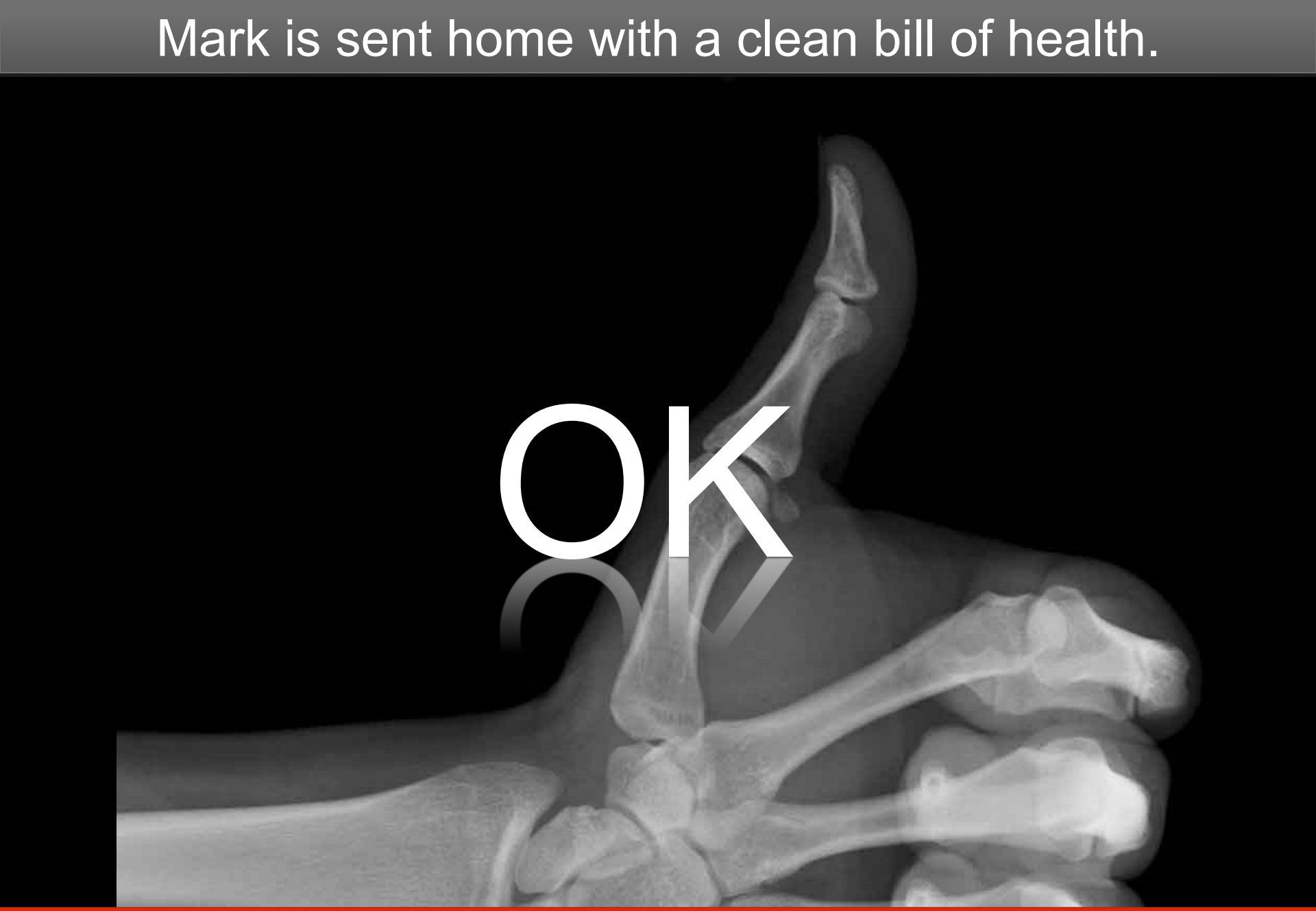


After a bottle of wine, his right eye vision dims.

Mark mentions this at his next physical.

His doctor does a brief exam and finds nothing.

Mark is sent home with a clean bill of health.



But he’s in the early stages of heart failure.

Back to bad eating habits.

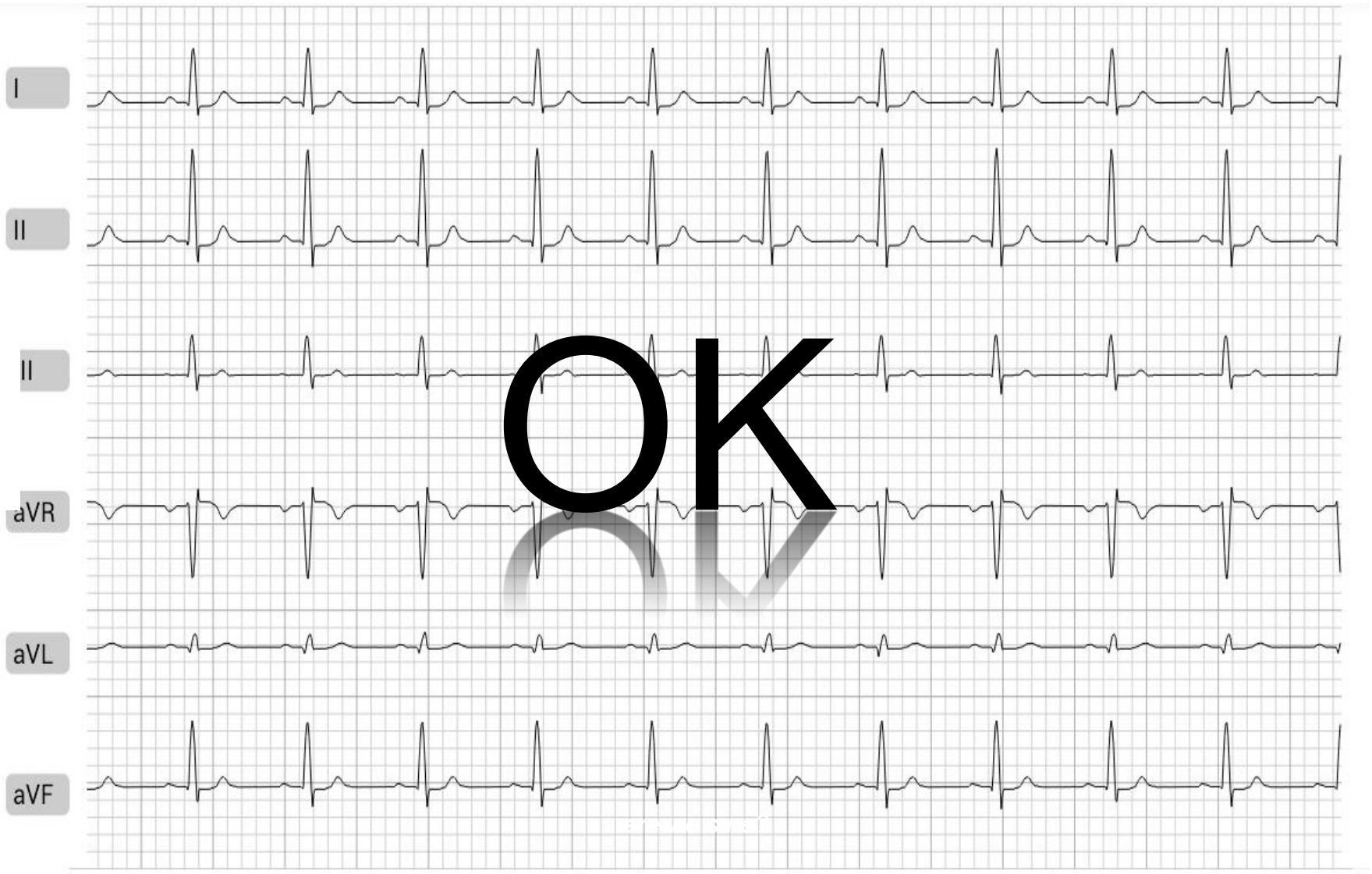
His condition worsens over the next 5 years.

Mark's SAINTS win the Superbowl.

Heart rate up, his cardiac stress is the highest it's been in 5 years.

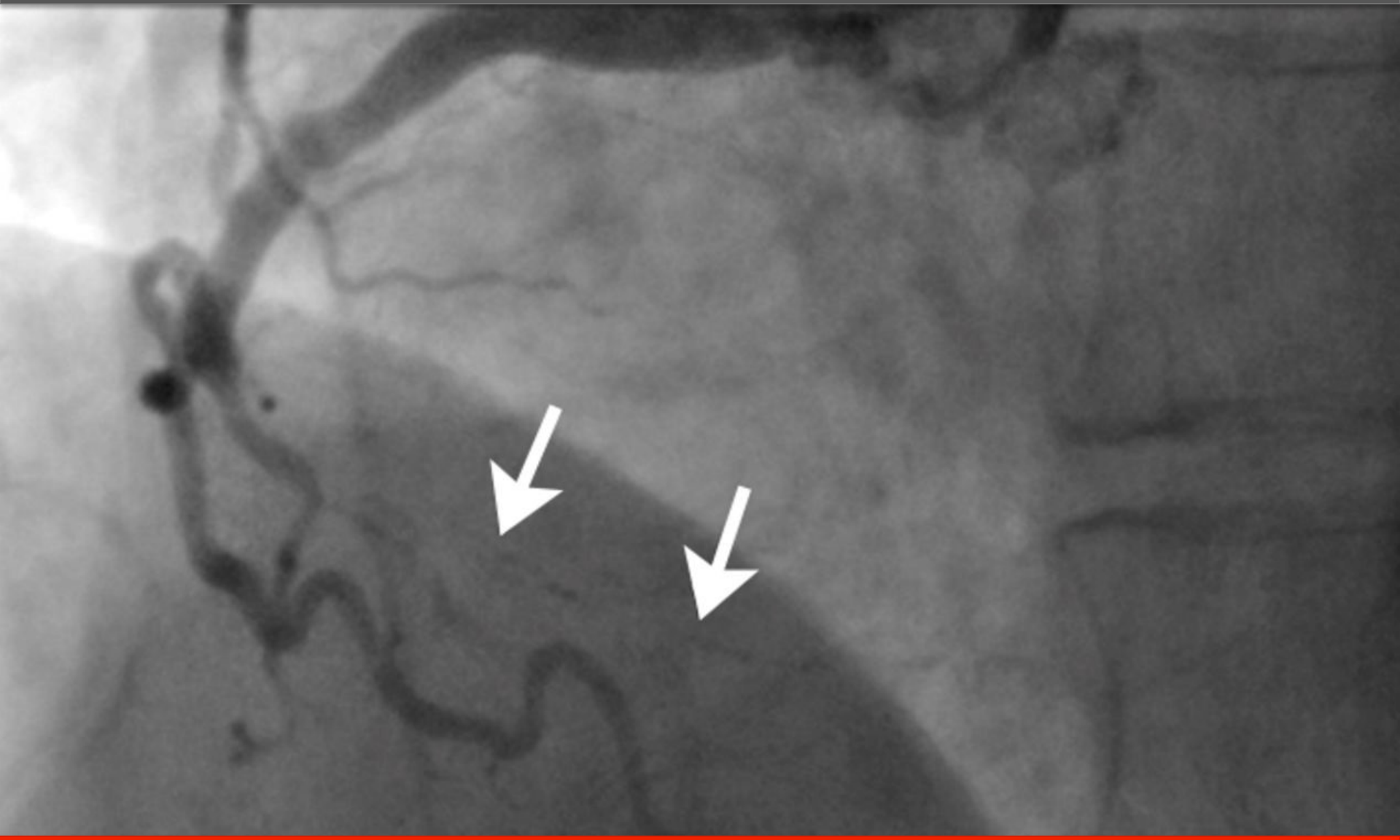
Mark faints and goes to the emergency room.

A normal ECG at the ER—the stress was episodic.



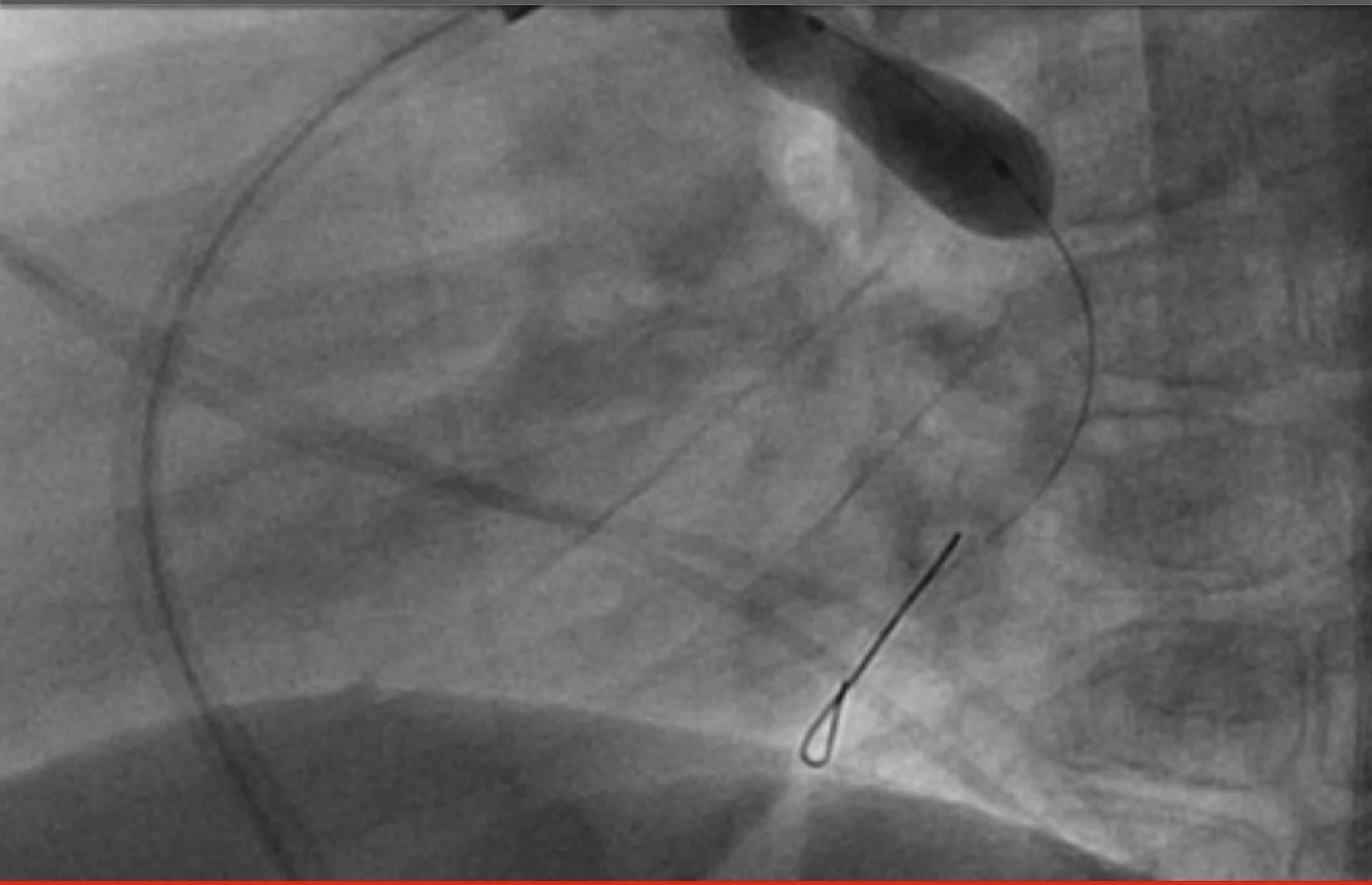
But his heart is near the breaking point.

The ER refers Mark to a cardiologist, who orders a precautionary screen for arterial occlusion.



The screen is positive, but this isn’t the real problem.

Mark undergoes cardiac revascularization.



Cost to the healthcare system: $30,000

Mark feels a lot better, and takes up hiking.

But the damage to his heart remains.

Mark summits Mt. Tam.

His heart stops.

Medevac is inbound, but there's no clear landing zone.

Mark dies during evacuation to the trailhead.

Wrongful death lawsuit commences.

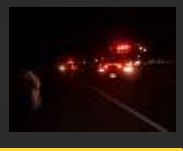
The hospital settles for $8 million.

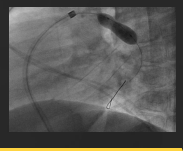
What Went Wrong?


Poor Habits


Checkup


Worsened Health


Relapse

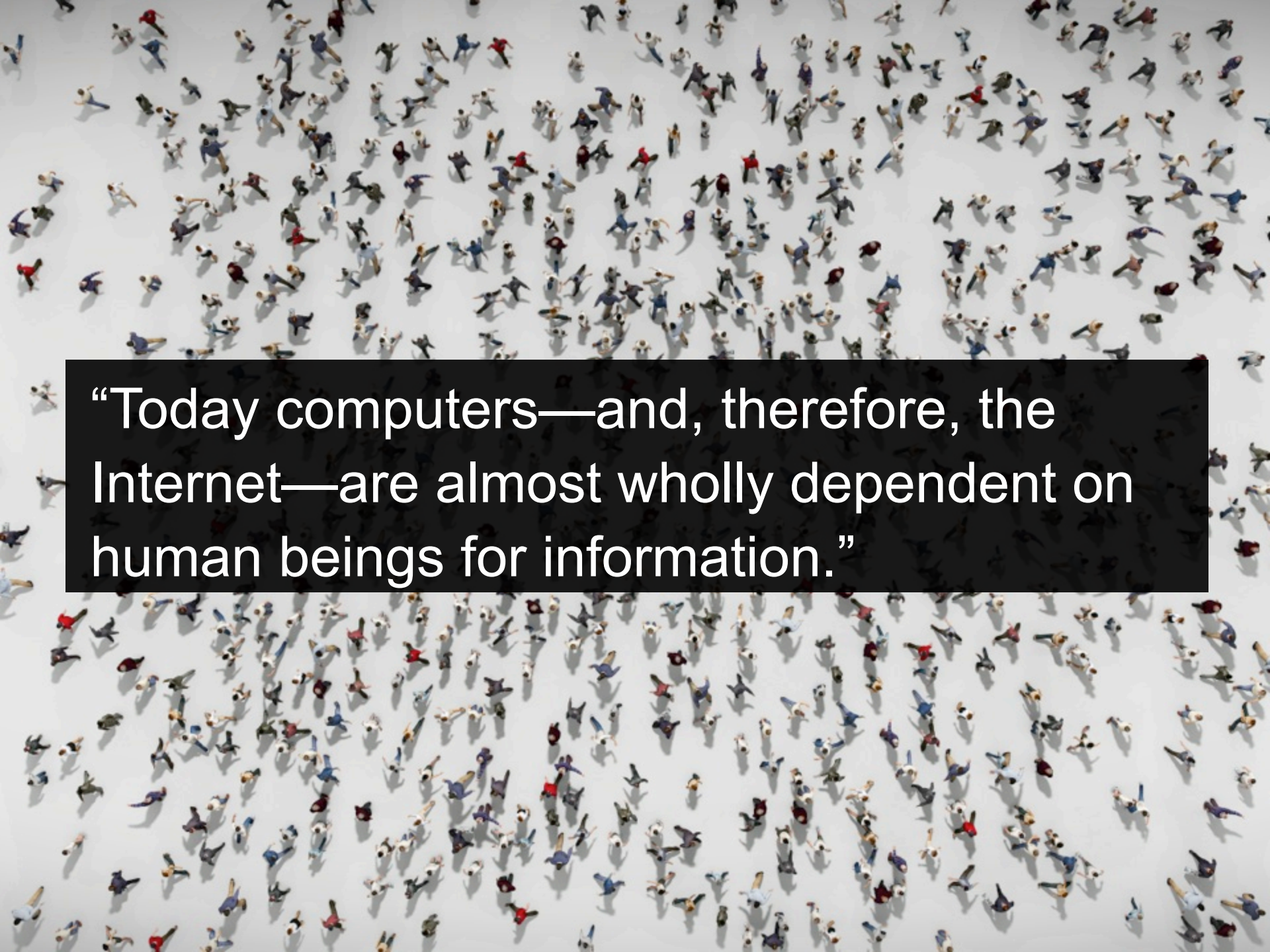

Wrong Diagnosis


Worsened Health


Death


Lawsuit

- No objective data at the initial visit
- Minimal information sharing across time or place of patient interaction
- Stale data at the second visit
- Lack of remote monitoring capability after the initial intervention


“Today computers—and, therefore, the Internet—are almost wholly dependent on human beings for information.”

How Mark's Case Could Have Gone Differently

- **Quantitative data collection (ECG) with low-cost devices at the initial symptom presentation**
  - Generate real data to check clinician "gut instinct."
- **Long-term at-home monitoring with a connected, intelligent device after discharge from the hospital**
  - Develop a full picture of the condition outside of the doctor visit.
- **Seamless transfer of information between care sites and caregivers**
  - "Connect the dots" so the right signals get to the right people.
- **Robust analytics to identify signals of early-stage heart failure**
  - Limit reliance on humans for repetitive, standardized tasks.
- **Intensive follow-up by clinicians, augmented by machine-generated alerts**
  - Intervene at the right time and limit unnecessary cost.

Science Fiction?

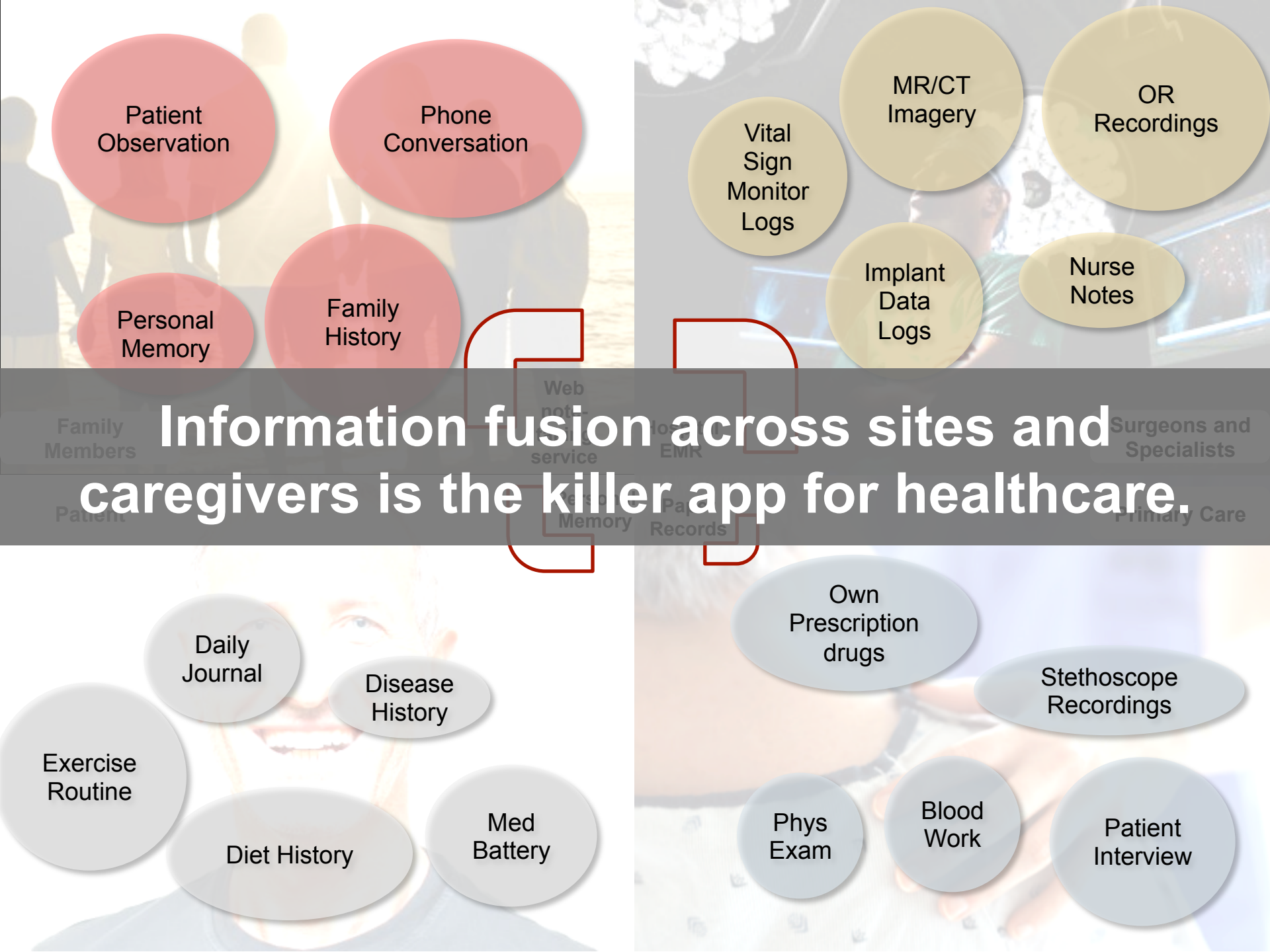
Home ECG Sensor.

ECG Remote Monitoring System

iPhone ECG Readout App

Data-Logging Implantable Defibrillator

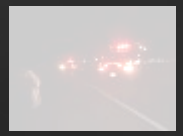
Products Available Today

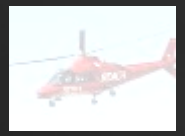


Information fusion across sites and caregivers is the killer app for healthcare.

An Alternate Universe



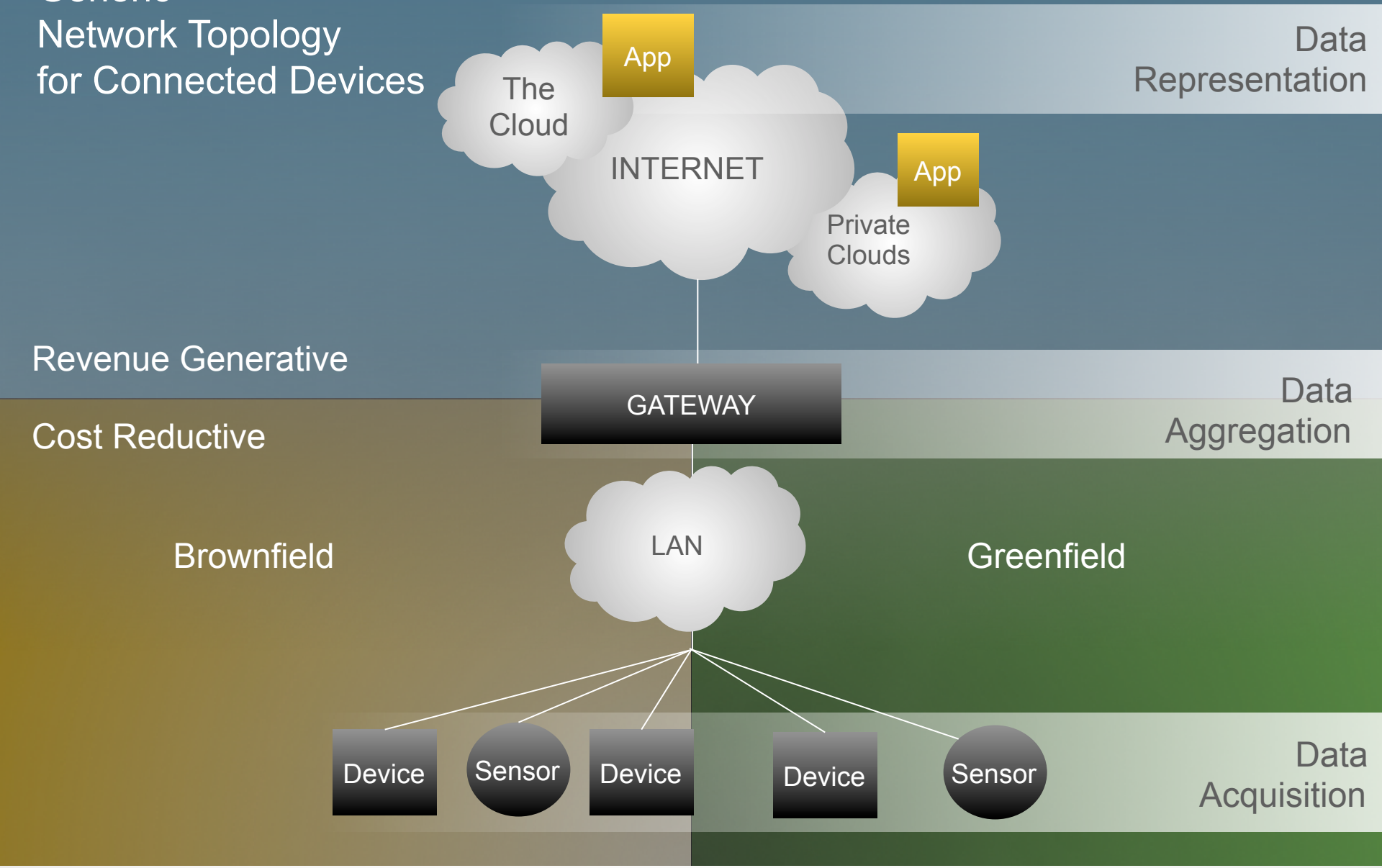

Poor Habits → Checkup → Worsened Health → Relapse → Wrong Diagnosis → Worsened Health → Death → Lawsuit





Objective Monitoring → Machine-Flagged V Fib Risk → PCP/Specialist Live Data Review → Confirmed Diagnosis → Defibrillator Implantation **LIFE SAVED** → Data Loop Back to Machine Learning Algorithms

Generic Network Topology for Connected Devices



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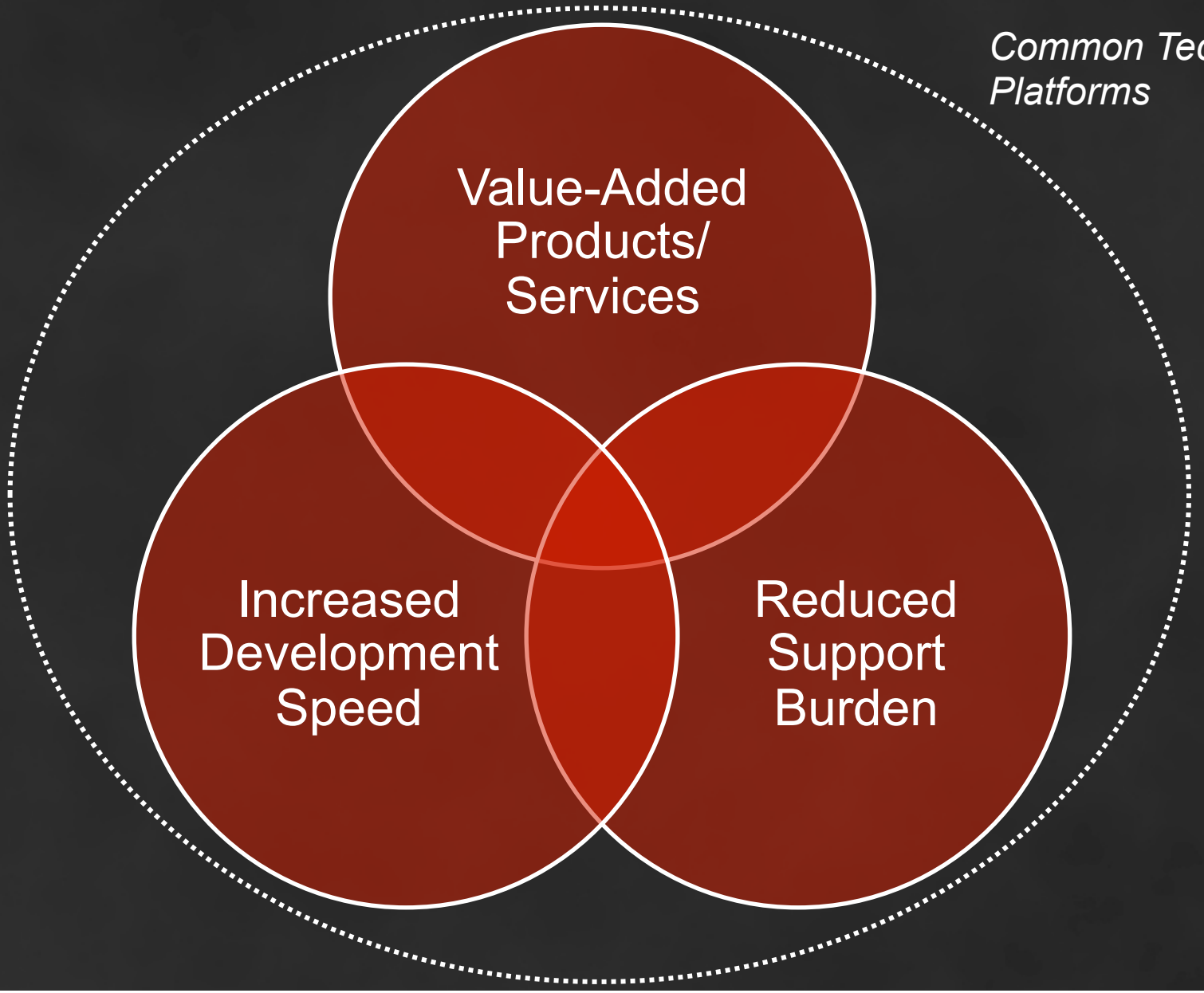

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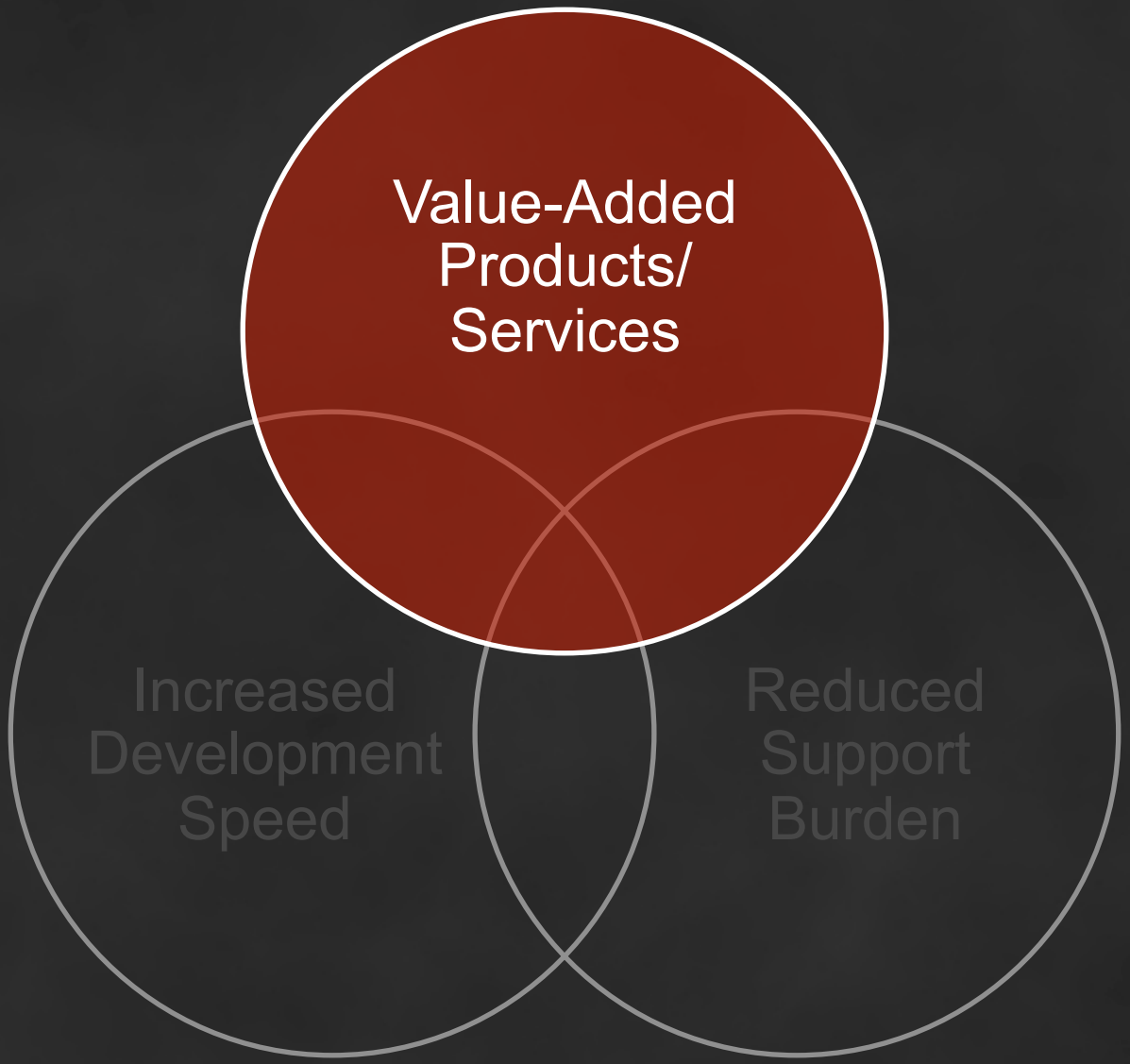

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Presentation


Diagnosis

Medication


Re-diagnosis


Procedural Intervention


Recovery

Medication Adjustment


Device Adjustment


Followup

- Device manufacturers play a **limited role** in the care continuum.
- Competition and heavy R&D have delivered **excellent products.**
- **Cost is king** in this rapidly maturing market.

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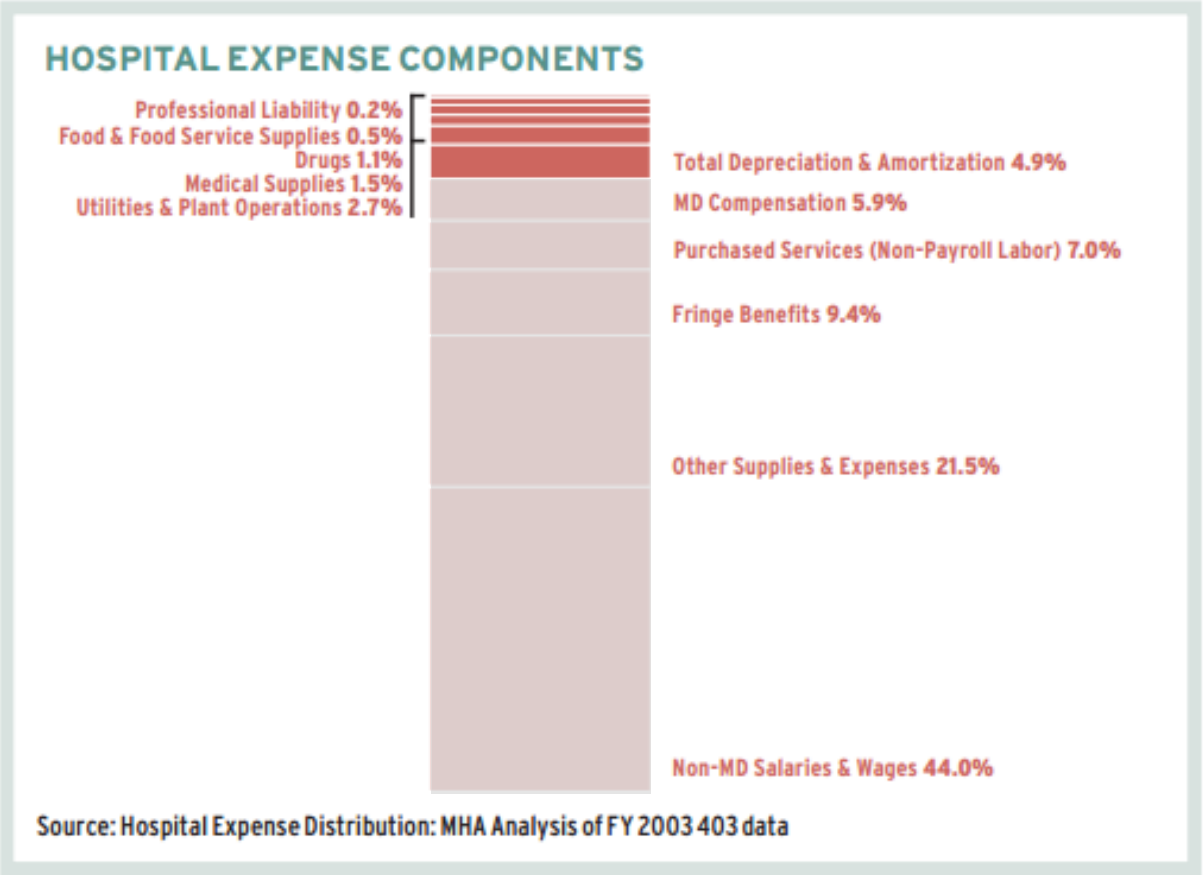
Massive Opportunity to Deliver Value Beyond Price Reduction

The bar chart to the right shows the **categories of hospital expenses** in fiscal year 2008 and what percent of total expenses each represents for all hospitals in Massachusetts.



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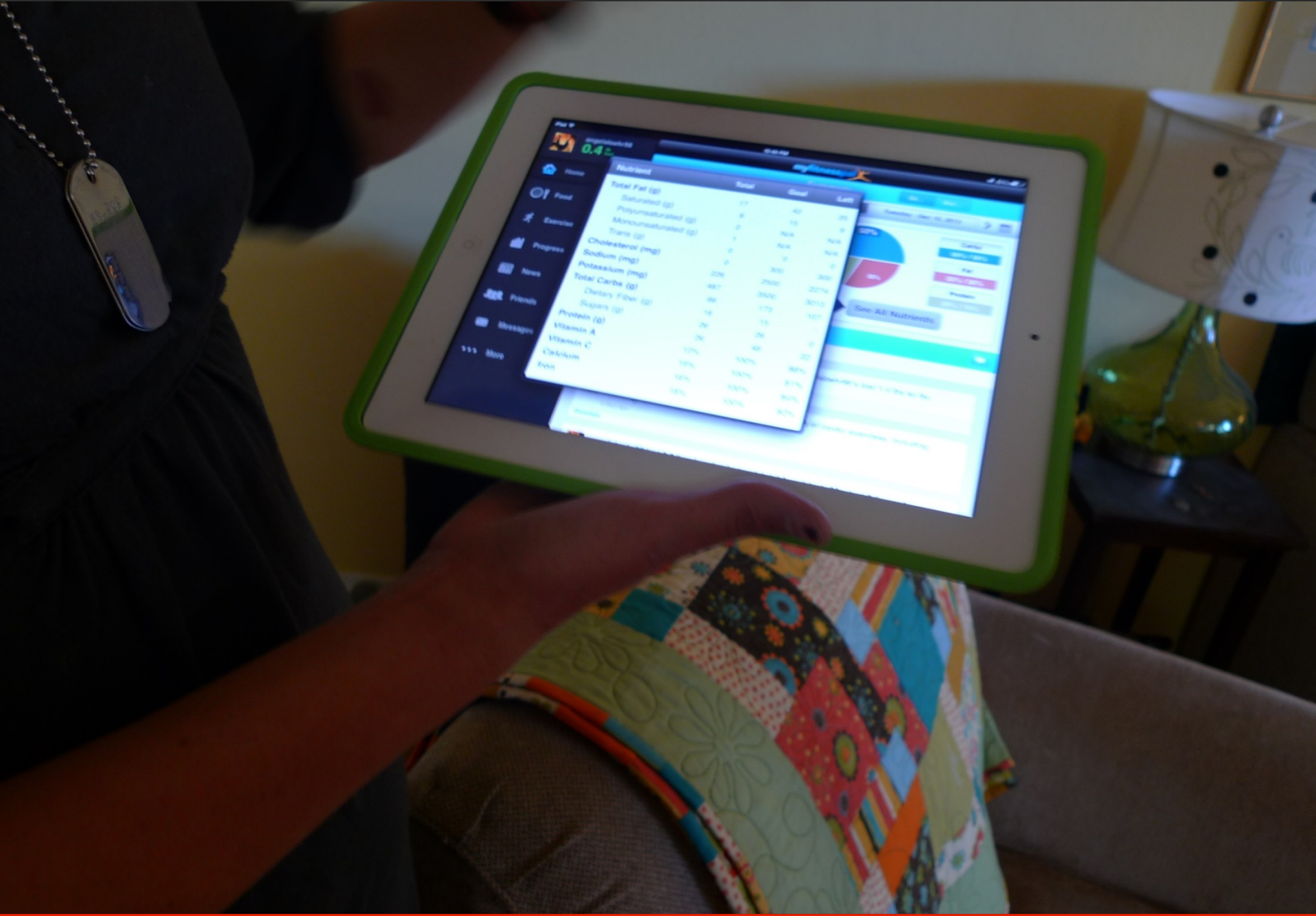
Hospitals are already connecting devices

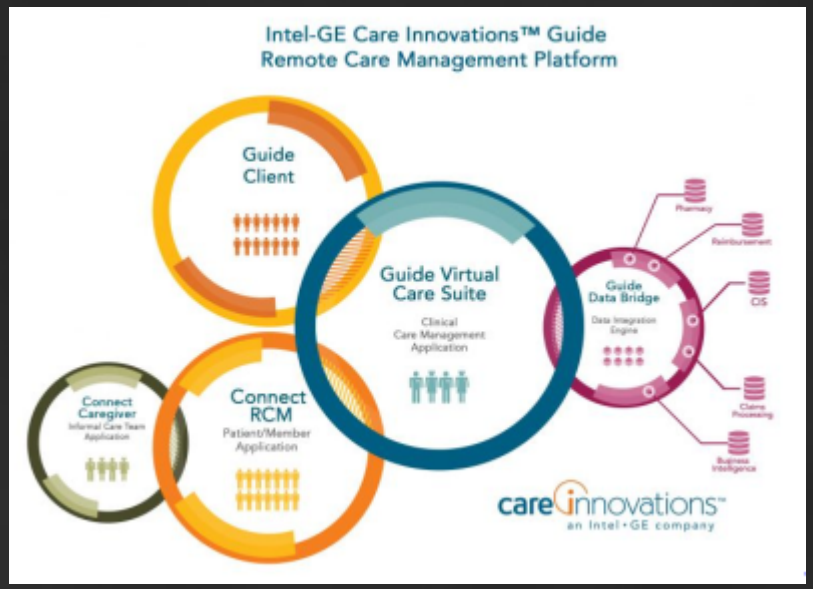
… as are medical device manufacturers.

The next wave is sensor integration



… and consumer-acceptable technology.

Device Manufacturers Beginning to Expand Service Offerings



DealB%k WITH FOUNDER ANDREW ROSS SORKIN

DaVita to Acquire HealthCare Partners for $4.4 Billion

By MARK SCOTT

THE WALL STREET JOURNAL.

HEALTH

Medtronic Expands Into Disease Management

Acquisition of Cardiocom Fits With New Law's Push to Reduce Hospital Readmissions

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- Information fusion requires **alliance development.**
- The technology **environment is heterogeneous.**
- Device data aggregation **infrastructure can be developed in parallel** with partnerships.

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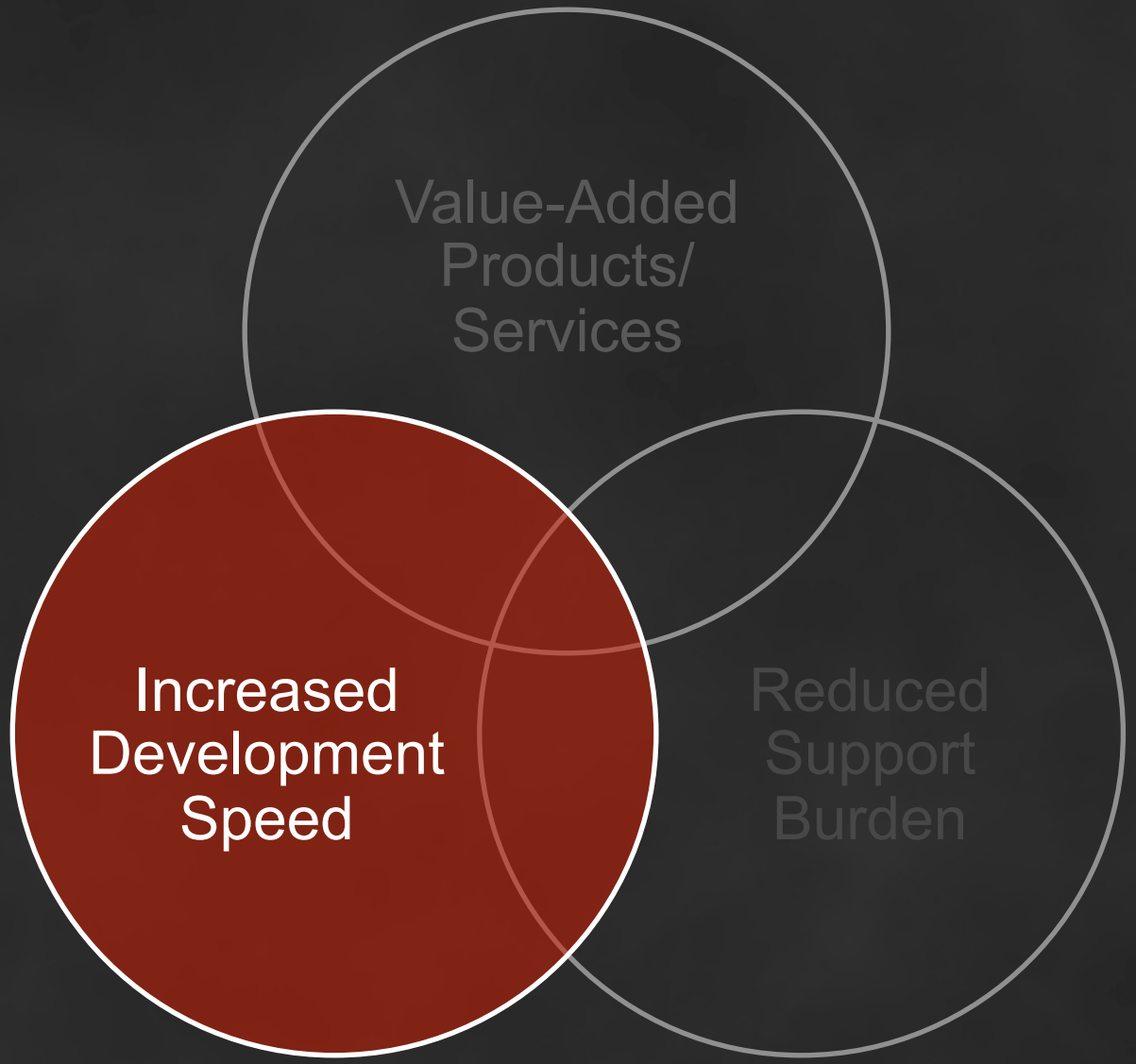

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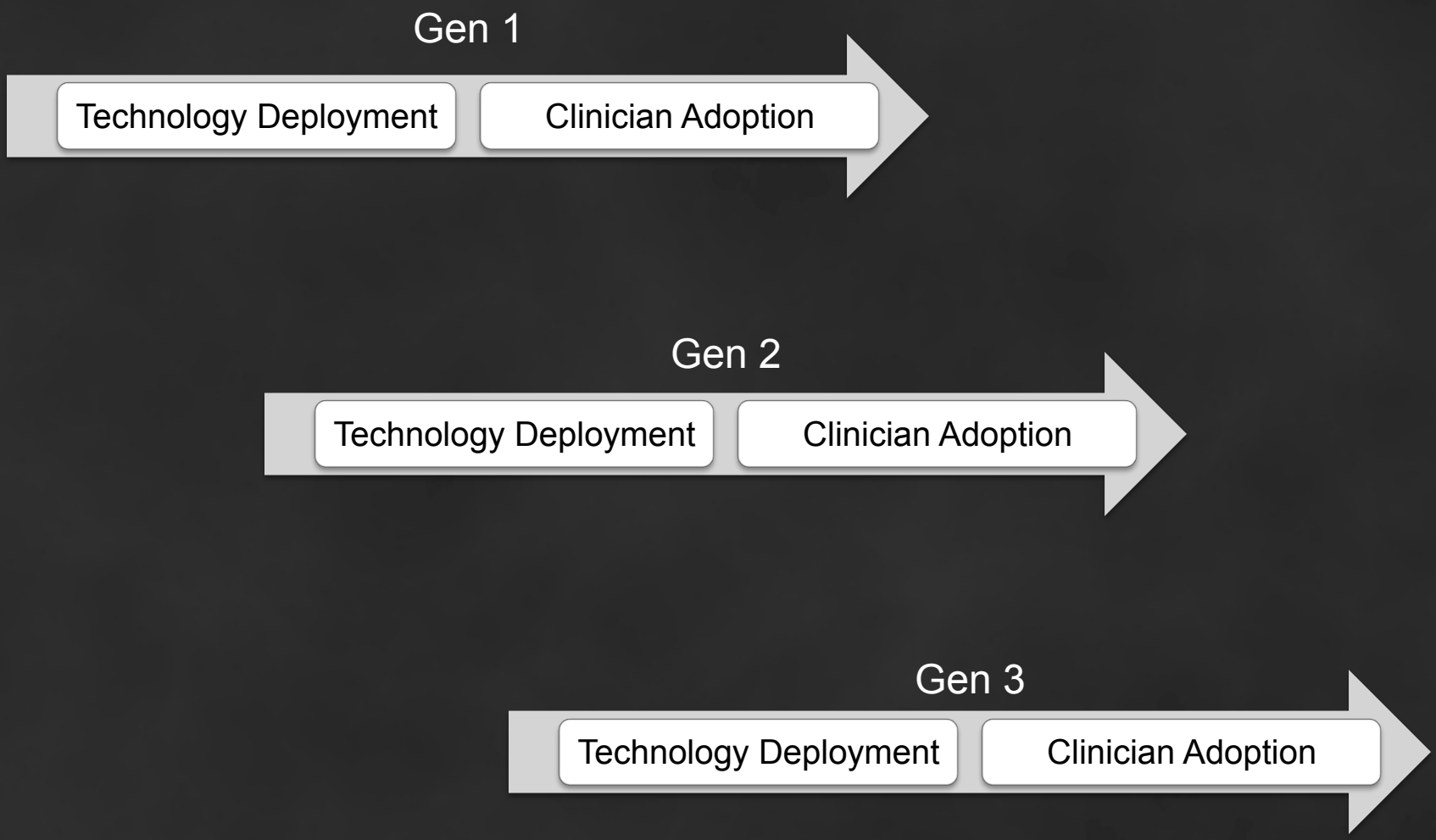
Product Development: Today



Narrow products can develop linearly.

The future is in cross-platform networks.

Product Development: Future

Technology Rollout

Effectiveness Assessment

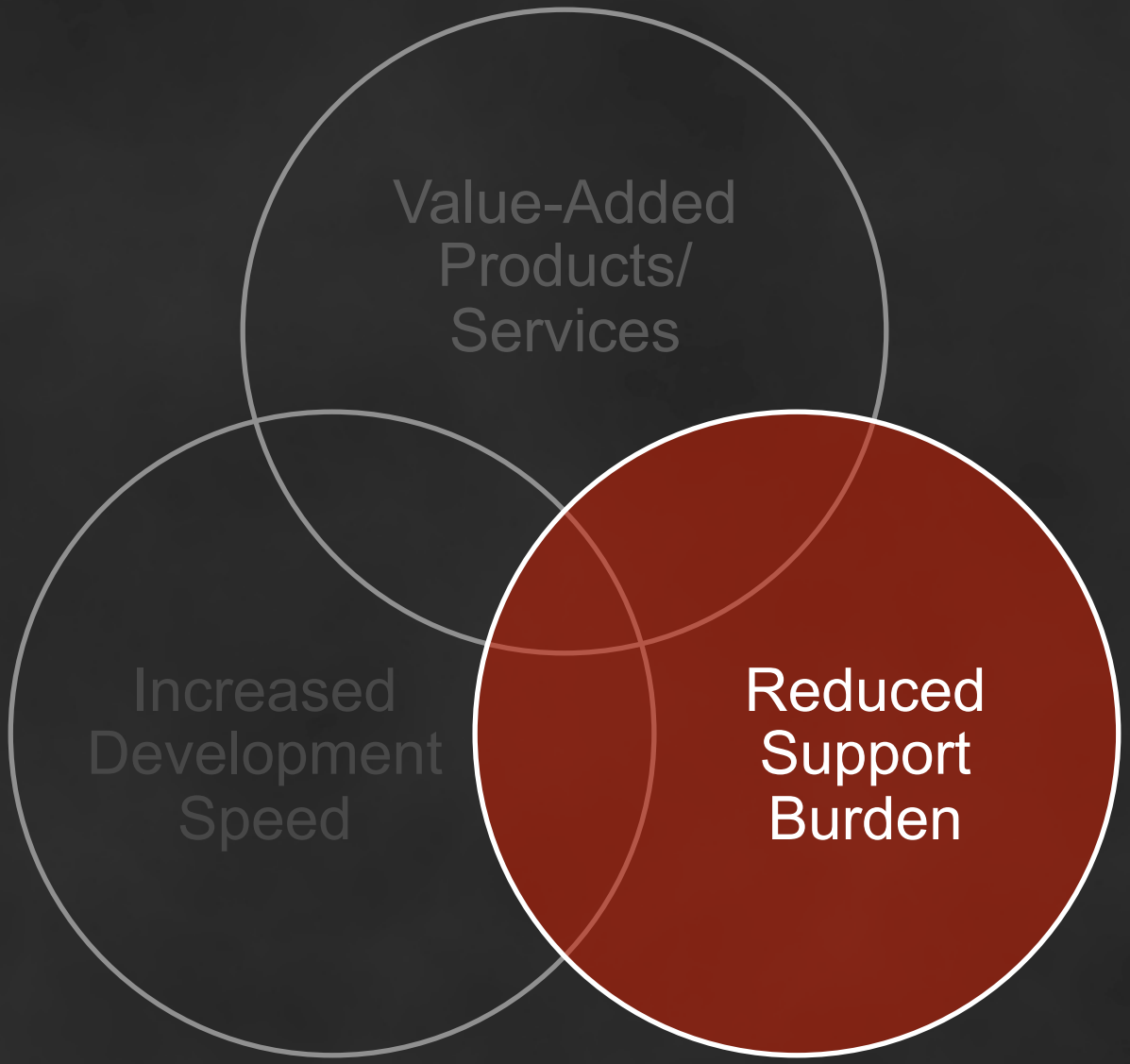
Govt, Payors

Hospitals, Mfrs

???

Clinician Adoption

So development methods must adapt.



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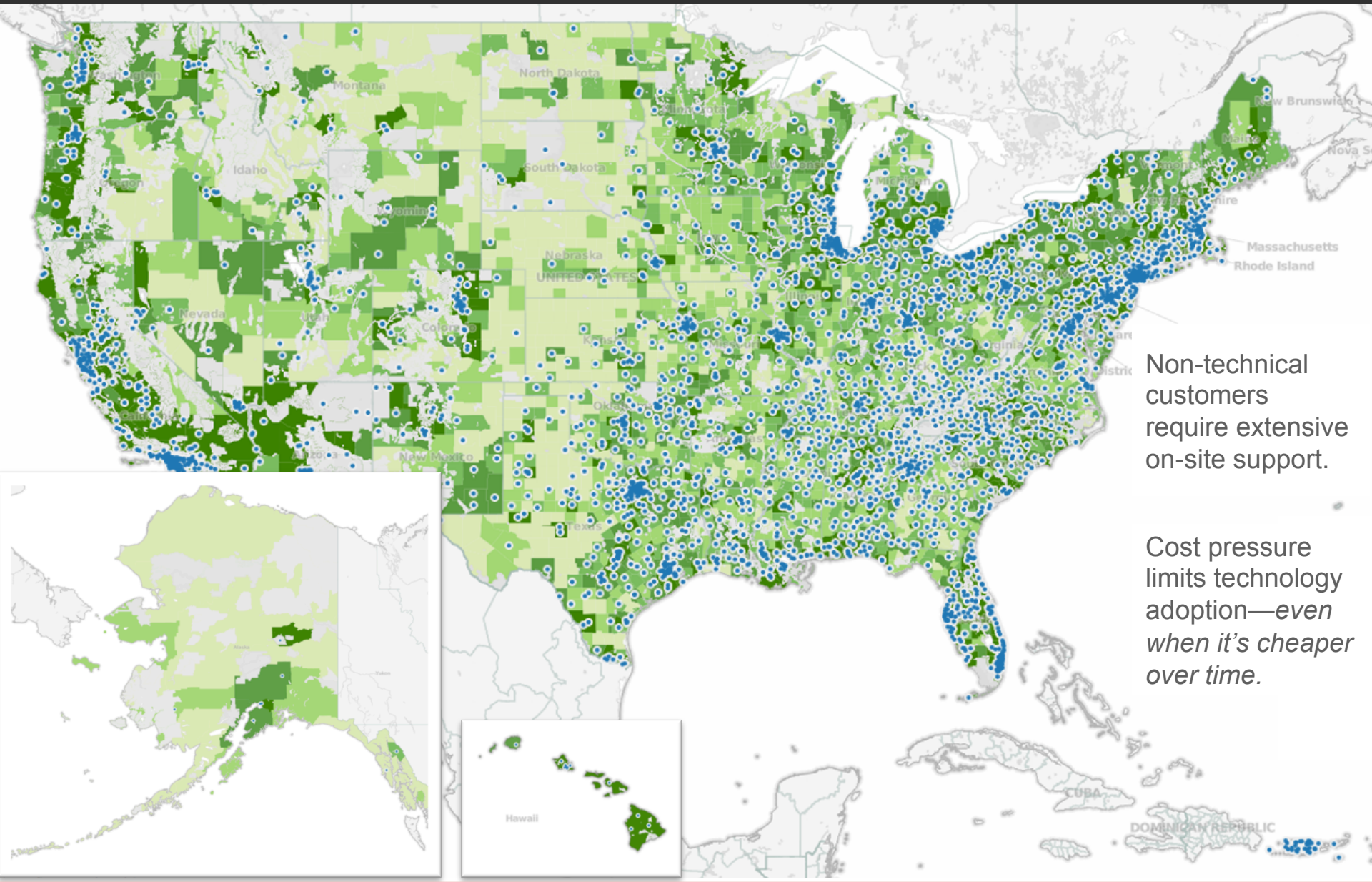
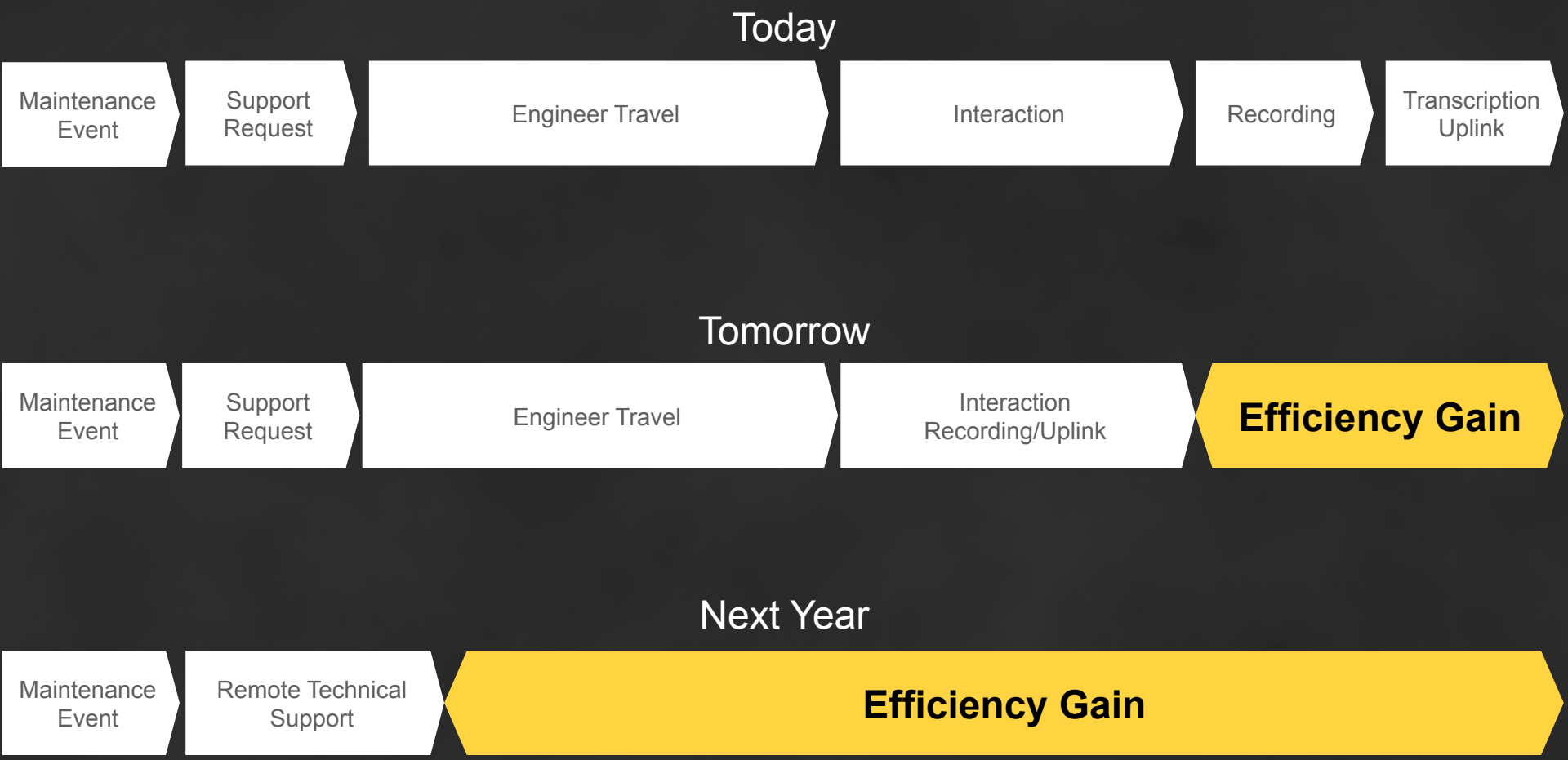
Hospitals and Population Density, U.S. 2013



Dedicated support teams are common today.

An Efficiency-First Approach

Streamline on-site visits and conduct remote service when possible.



Connected platforms will increase efficiency.

Real-World Challenges

Maintenance Event → Remote Technical Support → **Efficiency Gain (Perhaps?)**

Connectivity

- Firewalls
- Port-blocking
- Sparse link layer
- EM interference

Manageability

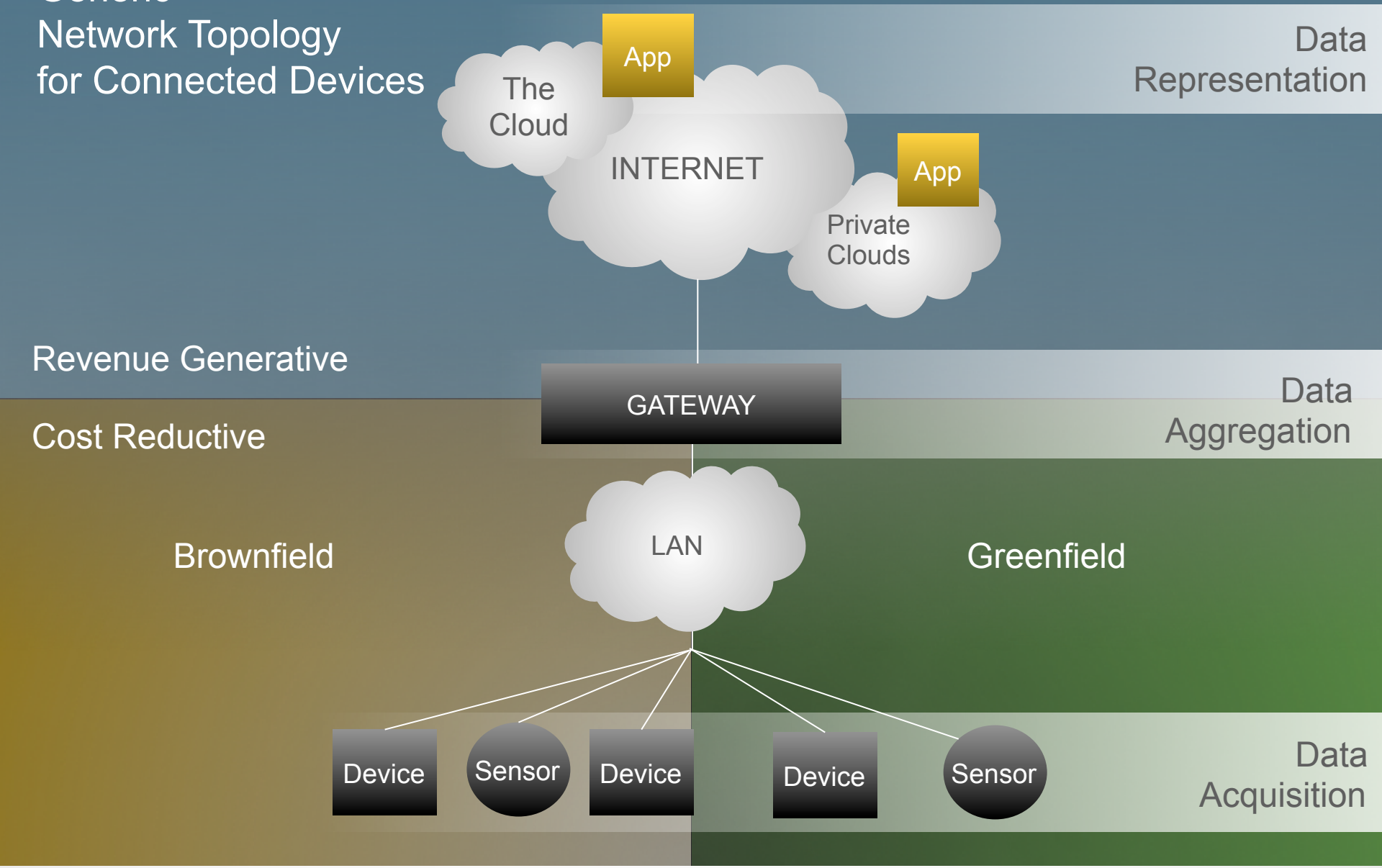
- Heterogeneous hardware
- End-user expertise
- Intermittent connections
- Updating delivery mechanism

Security

- High availability requirements
- Rights management
- Encryption
- Malware

But real-world deployment is challenging.

Generic Network Topology for Connected Devices



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