Innovation in Health Care
Delivery Systems

Patient Concerns in Health Care

Patient Control of Health Records

April 30, 2010

McCombs School of Business

Patient Expectations
Patients’ Rights
Reality
Research and Consent
Solutions

Patient expecations

Pop Quiz: Who said this?

- "Medical records would belong to patients. Clinicians, rather than patients, would need to have permission to gain access to them."
- *"Individuals have the right to control – and must have the ability to control – who can access their personal health information. All health information technology should be deployed to improve individual health, not to protect the status quo of proprietary claims to data."*
- "One thing is the federal government has got to make sure the privacy rules are strong. You're going to hear us talk about medical -- electronic medical records. And that's exciting. But it's not so exciting if you're a patient who thinks somebody could snoop on your records, to put it bluntly. I'm not interested in having my -- well, it's too late for me. (Laughter.) My medical records are pretty well known. But for those people -- there's a lot of people in America who say, good, I want there to be good information technology in the health care field, I just don't want somebody looking at my records unless I give them permission to do so."
- "Congress had a chance to look at this issue [national privacy policy] and made a very conscious decision not to preempt the state privacy and security regulations." ….. "We have to find ways to engineer the exchange of information across state boundaries so that patients can benefit when they move across state boundaries. And I think one of the solutions to that will be to give increasing amounts of control to patients over their health information."

Answers

- **Don Berwick MD, nominee to lead CMS**: *“What ‘Patient-Centered’ Should Mean: Confessions Of An Extremist***,** *A seasoned clinician and expert fears the loss of his humanity if he should become a patient”*

  In Health Affairs 28, no. 4 (2009): w555–w565

- **Newt Gingrich**, **Former Speaker of the House**, testimony March 15, 2006 before the House Subcommittee on the Federal Workforce and Agency Organization

- **President Bush** April 27, 2004 , VA Medical Center, Baltimore http://www.whitehouse.gov/news/releases/2004/04/20040427-5.html

- **David Blumenthal MD**, National Coordinator for Health IT

  In Health Affairs 29, no. 4 (2010) w 591

Americans expect control over personal health data, but……..

Where did this slide come from ? The Medical Information Bureau, which sells your health data to insurers and employers.

Health Research Data for the Real World: the MarketScan Data Bases

David M. Adamson, PhD
Stella Chang, MPH
Leigh G. Hanson, MS, MBA

Research and Pharmaceutical Division
Thomson Medstat
January 2006

Medicare and Medicaid data is for sale

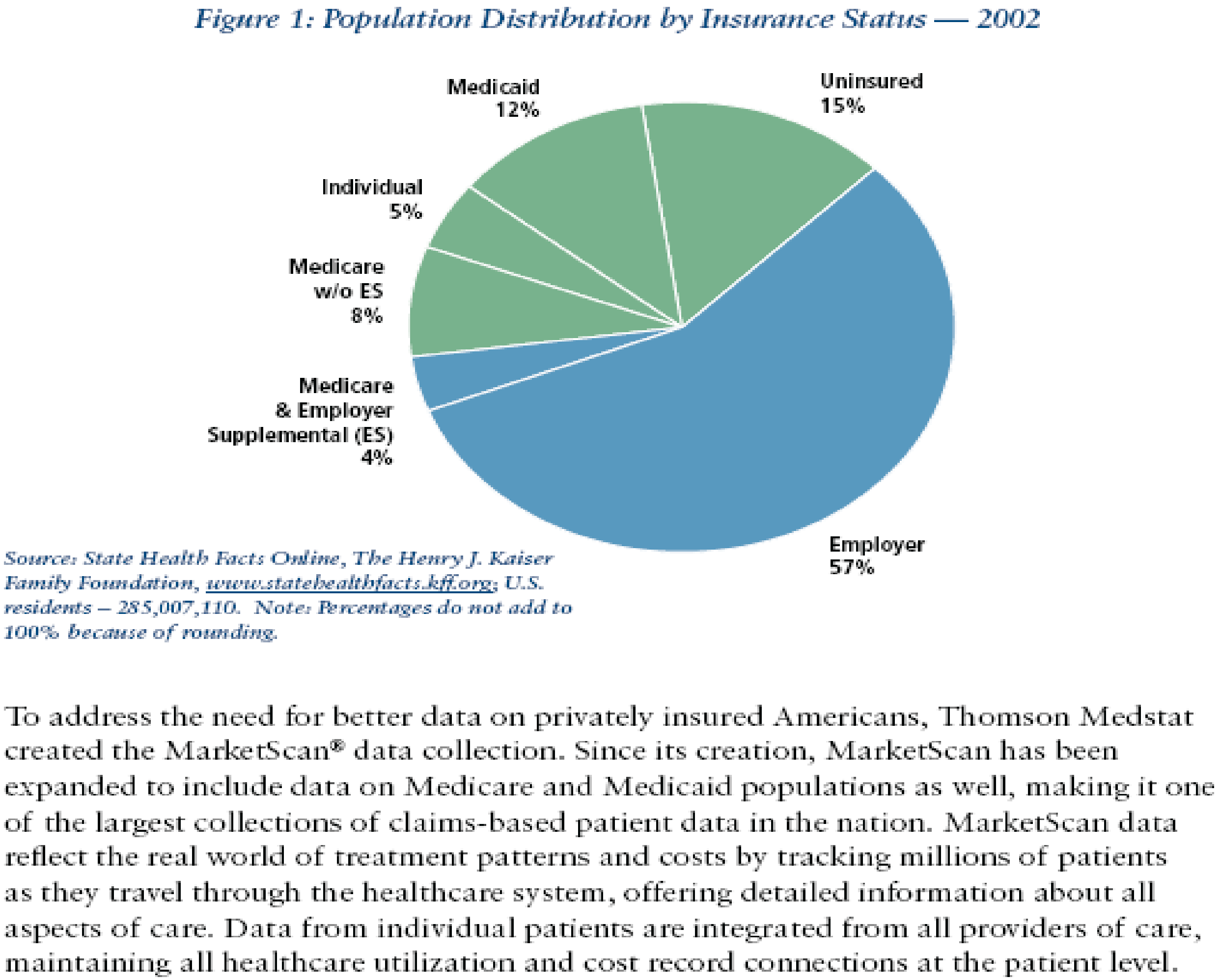


Figure 1: Population Distribution by Insurance Status — 2002

Source: State Health Facts Online, The Henry J. Kaiser Family Foundation, www.statehealthfacts.kff.org; U.S. residents – 285,007,110. Note: Percentages do not add to 100% because of rounding.

To address the need for better data on privately insured Americans, Thomson Medstat created the MarketScan® data collection. Since its creation, MarketScan has been expanded to include data on Medicare and Medicaid populations as well, making it one of the largest collections of claims-based patient data in the nation. MarketScan data reflect the real world of treatment patterns and costs by tracking millions of patients as they travel through the healthcare system, offering detailed information about all aspects of care. Data from individual patients are integrated from all providers of care, maintaining all healthcare utilization and cost record connections at the patient level.

Personal health information is for sale

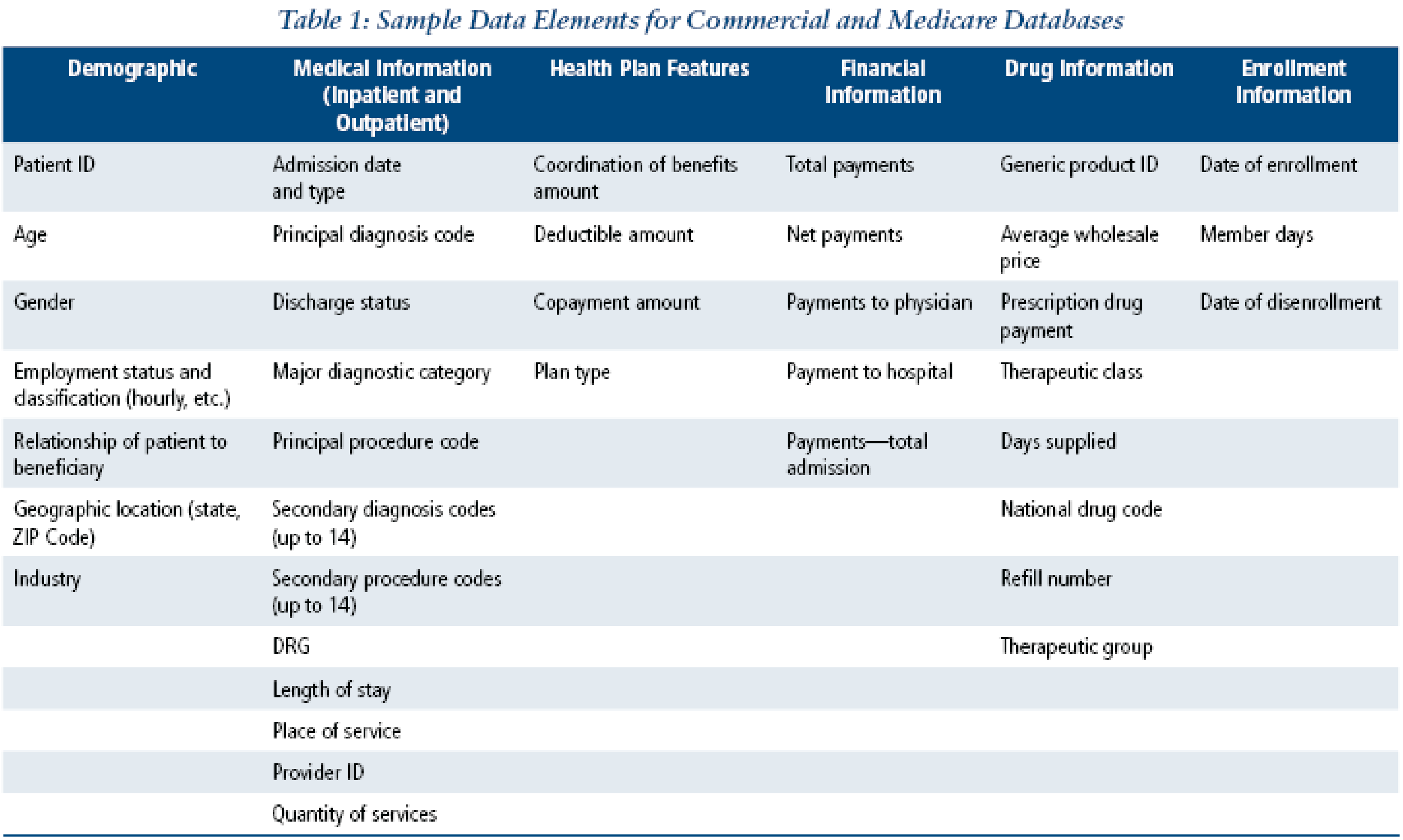
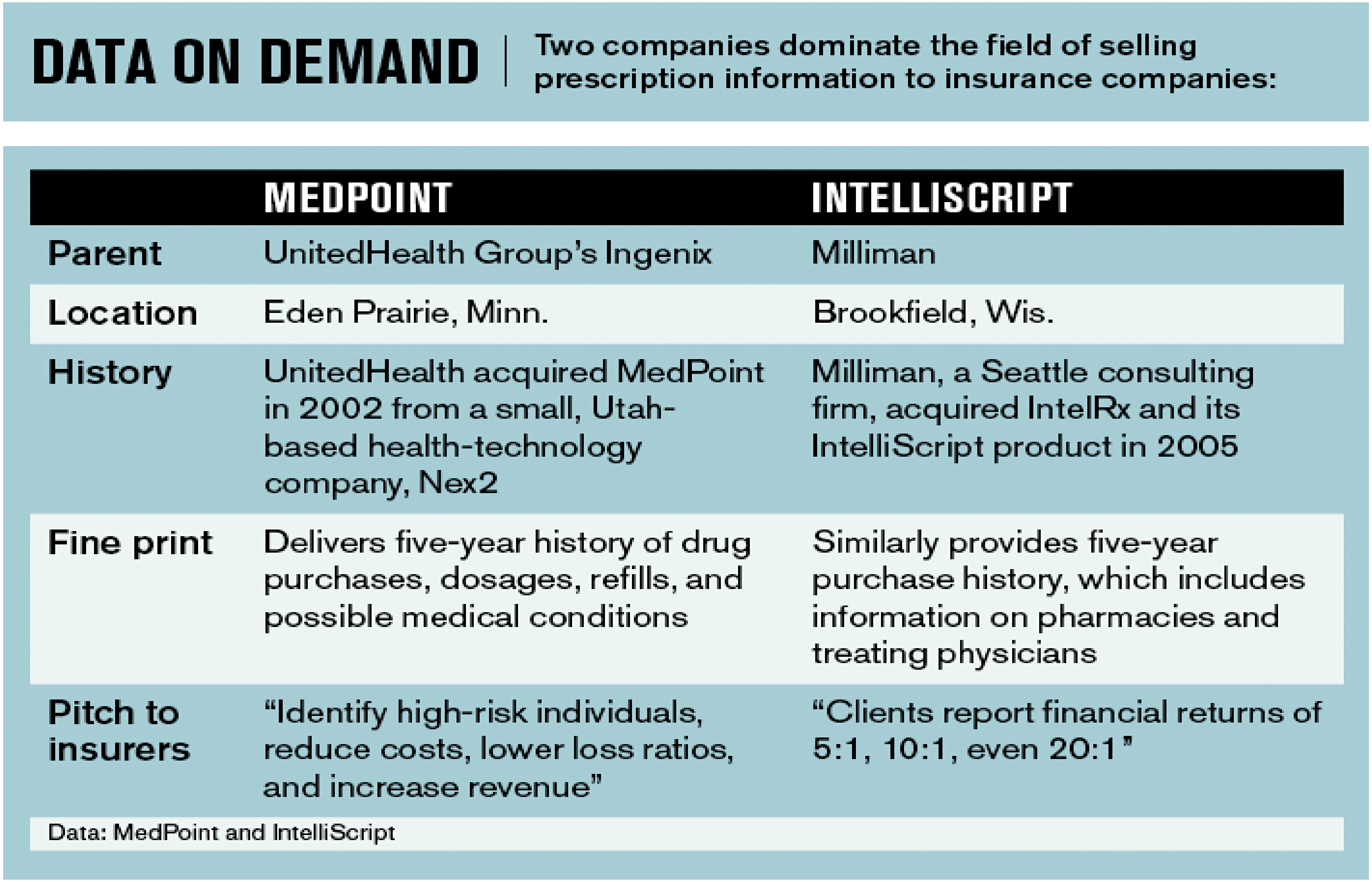


Table 1: Sample Data Elements for Commercial and Medicare Databases

Demographic	Medical Information (Inpatient and Outpatient)	Health Plan Features	Financial Information	Drug Information	Enrollment Information
Patient ID	Admission date and type	Coordination of benefits amount	Total payments	Generic product ID	Date of enrollment
Age	Principal diagnosis code	Deductible amount	Net payments	Average wholesale price	Member days
Gender	Discharge status	Copayment amount	Payments to physician	Prescription drug payment	Date of disenrollment
Employment status and classification (hourly, etc.)	Major diagnostic category	Plan type	Payment to hospital	Therapeutic class	
Relationship of patient to beneficiary	Principal procedure code		Payments—total admission	Days supplied	
Geographic location (state, ZIP Code)	Secondary diagnosis codes (up to 14)			National drug code	
Industry	Secondary procedure codes (up to 14)			Refill number	
	DRG			Therapeutic group	
	Length of stay				
	Place of service				
	Provider ID				
	Quantity of services				

Businessweek July 23, 2008: *"They Know What's in Your Medicine Cabinet, How insurance companies dig up applicants' prescriptions—and use them to deny coverage"* http://www.businessweek.com/magazine/content/08_31/b4094000643943.htm?chan=magazine+channel_in+depth



DATA ON DEMAND

Two companies dominate the field of selling prescription information to insurance companies:

	MEDPOINT	INTELLISCRIPT
Parent	UnitedHealth Group's Ingenix	Milliman
Location	Eden Prairie, Minn.	Brookfield, Wis.
History	UnitedHealth acquired MedPoint in 2002 from a small, Utah-based health-technology company, Nex2	Milliman, a Seattle consulting firm, acquired IntelRx and its IntelliScript product in 2005
Fine print	Delivers five-year history of drug purchases, dosages, refills, and possible medical conditions	Similarly provides five-year purchase history, which includes information on pharmacies and treating physicians
Pitch to insurers	"Identify high-risk individuals, reduce costs, lower loss ratios, and increase revenue"	"Clients report financial returns of 5:1, 10:1, even 20:1"

Data: MedPoint and IntelliScript

Americans expect control over personal health data, but……..

HIPAA eliminated consent

1996

Congress passed HIPAA, but did not pass a federal medical privacy statute, so the Dept. of Health and Human Services (HHS) was required to develop regulations that specified patients' rights to health privacy.

> *"… the Secretary of Health and Human Services shall submit to [Congress]…**detailed recommendations on standards with respect to the privacy of individually identifiable health information."***

2001

President Bush implemented the HHS HIPAA "Privacy Rule" which recognized the "right of consent".

> *"….a covered health care provider **must obtain the individual's consent,** in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations."*

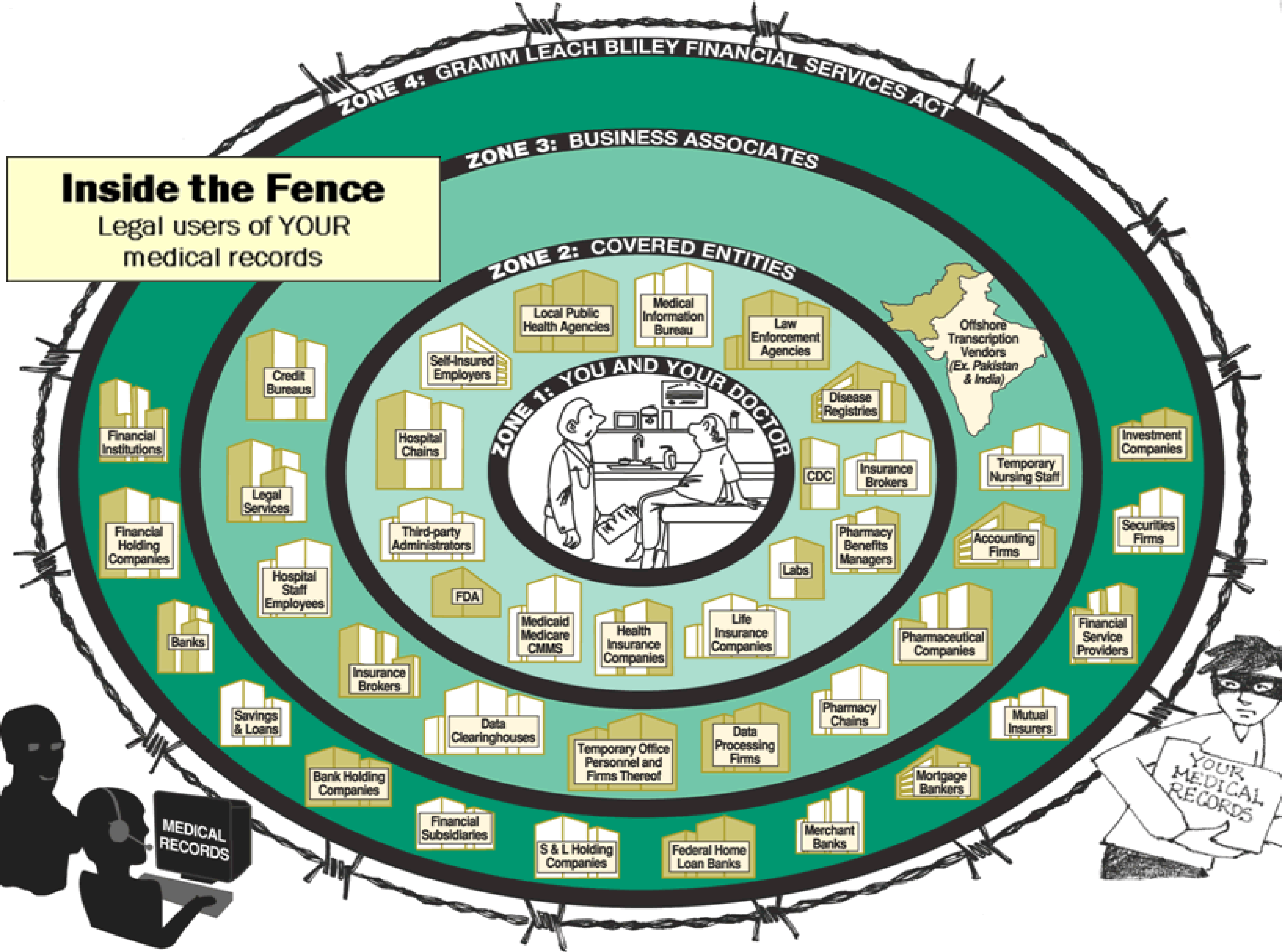
2002

HHS amended the HIPAA "Privacy Rule", eliminating the "right of consent".

> *"The **consent provisions…are replaced** with a new provision…that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment, healthcare operations."*

Inside the Fence

Legal users of YOUR medical records



AHRQ: 2009
20 focus groups

A majority want to “own” their health data, and to decide what goes into and who has access to their medical records

(AHRQ p. 6)

- A majority believe their medical data is “no one else’s business” and should not be shared without their permission. This belief was expressed not necessarily because they want to prevent some specific use of data but as a **matter of principle**. (AHRQ p. 18)

- Participants overwhelmingly want to be able to communicate directly with their providers with respect to how their PHI is handled, including with whom it may be shared and for what purposes. Most believe they should automatically be granted the right to correct misinformation. (AHRQ p.33) “there was **no support for the establishment of general rules that apply to all health care consumers**.

Participants thought that health care ***consumers should be able to exert control over their own health information individually, rather than collectively.***”
(AHRQ p. 29)

AHRQ Publication No. 09-0081-EF “Final Report: Consumer Engagement in Developing Electronic Health Information Systems” Prepared by: Westat, (July 2009)
http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09-0081-EF.pdf

NPR/Kaiser/Harvard 2009 Poll

The Public and the Health Care Delivery System

59% are NOT confident that if their medical records and PHI were stored electronically and shared online, that those records would remain confidential

NPR/Kaiser/Harvard 2009 Poll

76% believe it likely that an unauthorized person would get access to their medical records if the US adopts a system where medical records are kept electronically and shared online.

http://www.kff.org/kaiserpolls/upload/7888.pdf

Research without consent

Westin/Harris Survey for the Institute of Medicine

Results of a National Survey
Commissioned by the IOM Committee on
“Health Research and the Privacy of
Health Information: The HIPAA Privacy Rule”

Original Report - November 2007; Revised and expanded - March 2008

IOM Survey: People Won’t Participate in Research Without Privacy

- Only 1% agreed that researchers would be free to use personal medical and health information without consent
- Only 19% agreed that personal medical and health information could be used as long as the study “never revealed my personal identity” and it was supervised by an Institutional Review Board.

Research on Consent and NBS Programs

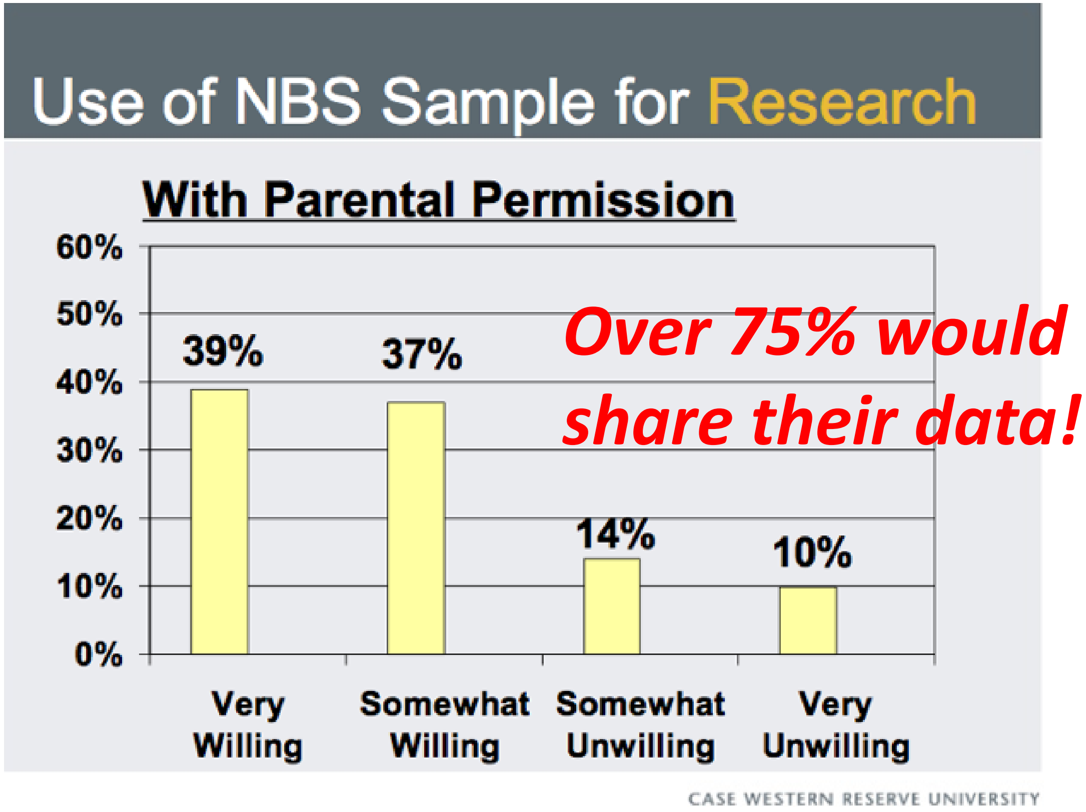
From Public Health Genomics

When Asked, Consumers Support Use of Their Data

"How willing are you to have your child's blood sample (from newborn screening) used for future research studies, with (or without) your permission?"

Four choices were:

- ***Very willing***
- ***Somewhat willing***
- ***Somewhat unwilling***
- ***Very unwilling***



Use of NBS Sample for Research

With Parental Permission

Over 75% would share their data!

Source: Dr. Aaron Goldenberg (Case Western Reserve), *Public Health Genomics*, July 9, 2009 (as reported at Genetic Alliance Conference on Newborn Screening, December 2009).

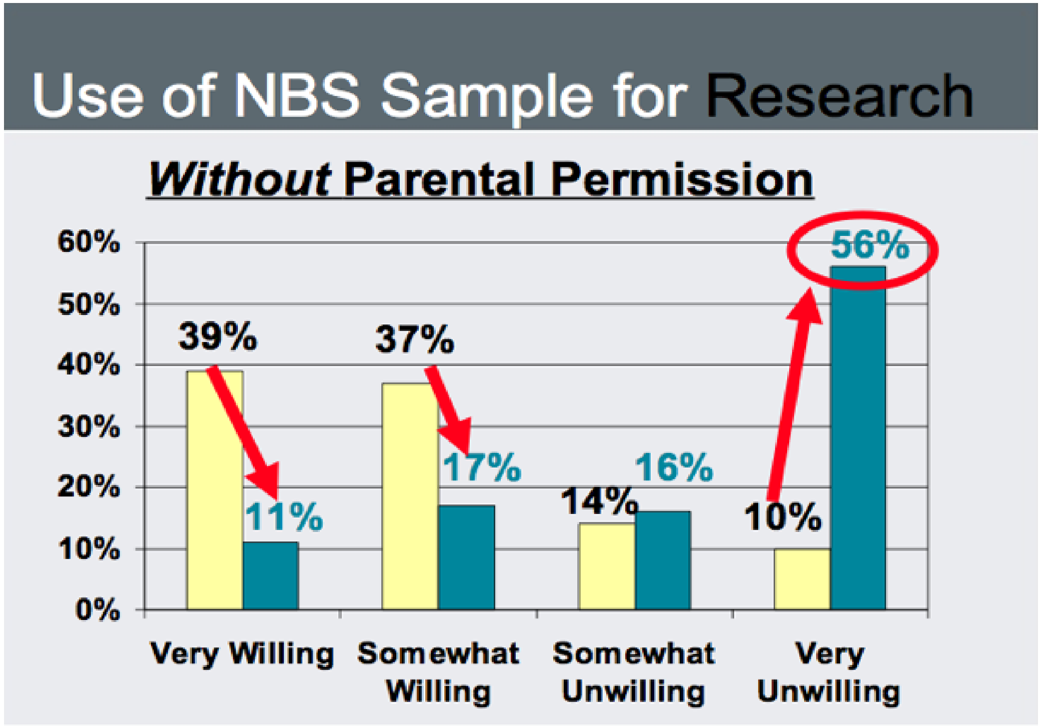
When ~~Ask~~ If ed, Consumers Support Use of Their Data

"How willing are you to have your child's blood sample (from newborn screening) used for future research studies, with (or without) your permission?"

WITHOUT CONSENT Only 28% were OK with research use and 72% were NOT OK with research

Four choices were:

- ***Very willing***
- ***Somewhat willing***
- ***Somewhat unwilling***
- ***Very unwilling***



CASE WESTERN RESERVE UNIVERSITY

Source: Dr. Aaron Goldenberg (Case Western Reserve), *Public Health Genomics*, July 9, 2009 (as reported at Genetic Alliance Conference on Newborn Screening, December 2009).

Patients rights

The right of privacy is a personal and fundamental right in the United States

See Department of Justice v. Reporters Committee for Freedom of the Press, 489 U.S. 749, 763 (1989) ("both the common law and the literal understandings of privacy encompass the individual's control of information concerning his or her person"); *Whalen v. Roe*, 429 U.S. 589, 605 (1977); *United States v. Katz*, 389 U.S. 347 (1967); *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J.,dissenting).

The opportunities to secure employment, insurance, and credit, to obtain medical services and the rights of due process may be jeopardized by the misuse of personal information.

Fed. Trade Comm’n, *Consumer Sentinel Network Data Book* 11 (2009) (charts describing how identity theft victims’ information have been misused).

As the Supreme Court has made clear, and the DC Circuit Court of Appeals recently held, "both the common law and the literal understanding of privacy encompass the individual's control of information concerning his or her person."

U.S. Dep't of Justice v. Reporters Comm. for Freedom of the Press, 489 U.S. 749, 763 (1989), cited in *Nat'l Cable & Tele. Assn. v. Fed. Commc'ns. Comm'n*, No. 07-1312 (D.C. Cir. Feb. 13, 2009).

Ethical rights
legal privileges
common law

The ethical codes of all health professions require informed consent

Since the time of Hippocrates physicians have pledged to maintain the secrecy of information they learn about their patients, disclosing information only with the authorization or the patient or when necessary to protect an overriding public interest, such as public health. ***Comparable provisions are now contained in the codes of ethics of virtually all health professionals.***"

Report to HHS, NCVHS (June 22, 2006)

Research ethics protect privacy

World Medical Association Declaration of Helsinki June 1964
Ethical Principles for Medical Research Involving Human Subjects

A. INTRODUCTION

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the needs and interests of society.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patients information, and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

Legal Privileges

A physician-patient privilege is recognized in the laws of 43 states and the District of Columbia.

The State of Health Privacy, Health Privacy Project (2000)

A psychotherapist-patient privilege is recognized in the laws of all 50 states and the District of Columbia.

Jaffee v. Redmond, 116 S. Ct. 1923, 1929 (1996)

Common Law

All 50 states and the District of Columbia recognize in tort law a common law or statutory right to privacy of personal information.

HHS finding 65 Fed. Reg. at 82,464

Ten states have a right to privacy expressly recognized in their state constitutions.

The Texas Supreme Court has determined that Texans have a right to privacy.

Reality

EHRs without consent
PHRs without consent
HIEs without consent
NHIN without consent
Research without consent

Key References:

EHRs “Your Medical Records Aren't Secure” by Deborah C. Peel in the WSJ, March 23, 2010
http://online.wsj.com/article/SB10001424052748703580904575132111888664060.html

PHRs “Who can snoop in your PHR? A Personal Health Record Report Card
http://patientprivacyrights.org/personal-health-records/

HIEs and NHIN “Designing a Trustworthy Nationwide Health Information Network (NHIN) Promises Americans Privacy and Utility, Rather than Falsely Choosing Between Privacy or Utility” by Latanya Sweeney, PhD, April 22, 2010, Congressional Briefing on the “Implementation of Health Information Technologies in a Healthcare Environment”
http://patientprivacyrights.org/wpcontent/uploads/2101/04/SweeneyCongressTestimony-4-22-10.pdf

Research “Improve Privacy in Research by Eliminating Informed Consent?” IOM Report Misses the Mark. In The Journal of Law, Medicine & Ethics, Volume 37, Issue 3 (p 507-512) by *Mark A. Rothstein.*

Liability

April 21, 2010

Indian Tribe Wins Fight to Limit Research of Its DNA

By AMY HARMON

http://www.nytimes.com/2010/04/22/us/22dna.html?ref=us

THE TEXAS TRIBUNE

DNA Destruction

Emily Ramshaw
March 9, 2010 |

In the weeks before state health officials destroyed more than 5 million newborn blood samples they had stored without consent, privacy advocates, parents and lawmakers reached a last-ditch accord to save them — but couldn’t convince the Department of State Health Services to sign on.

http://www.texastribune.org/stories/2010/mar/09/blood-drive/

Solutions

ARRA—new privacy rights and MU

Old rights under HIPAA:

- Providers may offer consent (Original HIPAA Privacy Rule), so patients can restrict disclosures---not addressed in MU
- Psychotherapy Notes require consent to disclose---not addressed in MU

New rights under ARRA:

- Ban on sales of PHI (Protected Health Information)---2010
- Segmentation---delayed
- Audit trails x 3 years---2011 or later
- Breach notice---2010
- Encryption
- Patient can prevent disclosures of PHI for ‘payment and healthcare operations’ if pays out-of-pocket--not addressed
- Consent Technologies---2014 or later

Do Not Disclose

Register on the National Do Not Disclose List

Let Congress know that you want a Do Not Disclose list.

Do you want:

- To choose who can see and use your personal information, from prescriptions to DNA?
- To protect your children’s health information, so it won’t be used against them in the future for jobs or credit?
- To get a clear explanation of how your information will be used before you decide to share it?

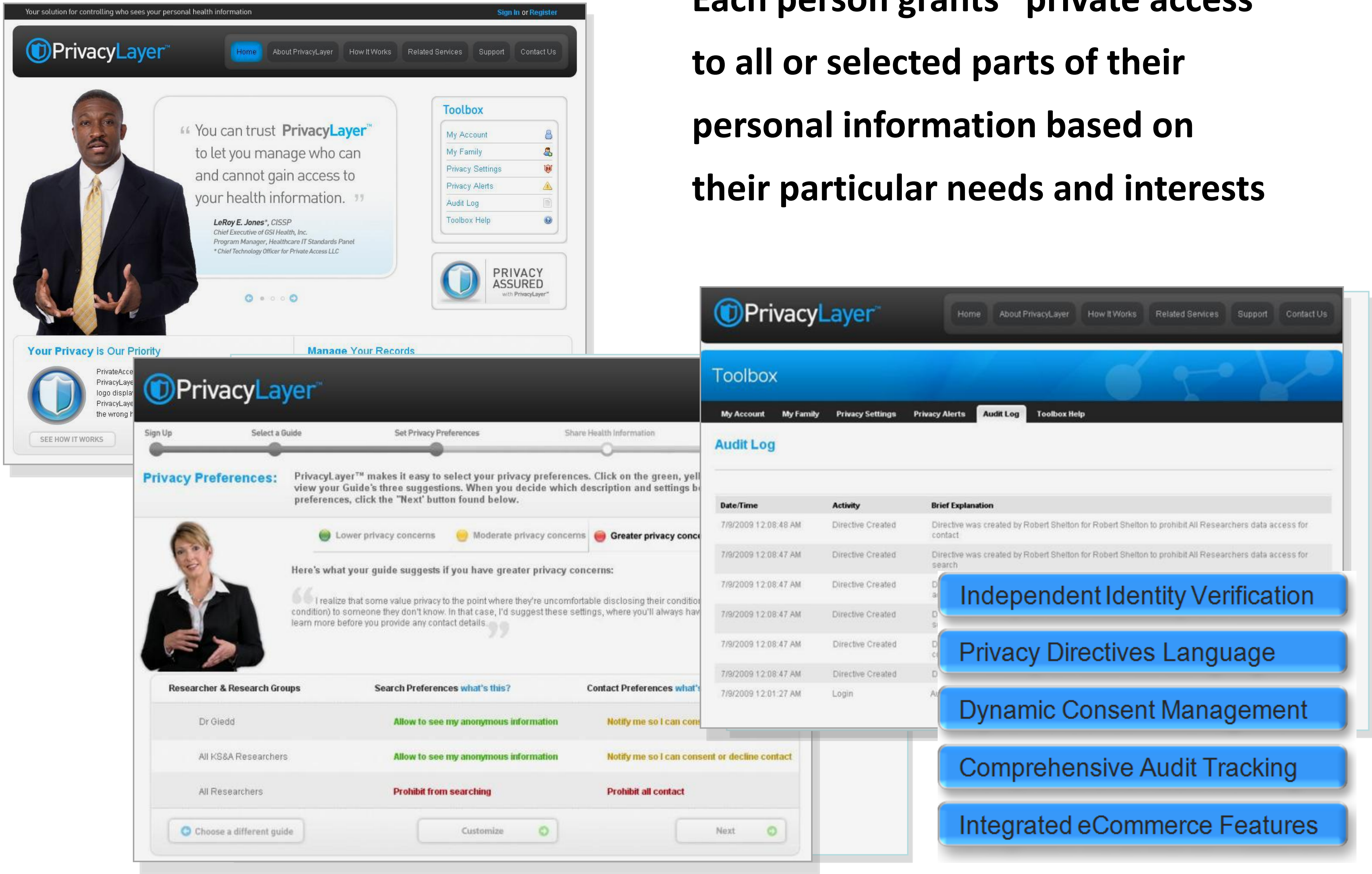
Then sign up to support the “*Do Not Disclose*” campaign!

Sign Up Today!

TELL – A – FRIEND

Consent Solutions So Far for Research Biobanks

Each person grants "private access" to all or selected parts of their personal information based on their particular needs and interests



Your solution for controlling who sees your personal health information

Sign In or Register

"You can trust PrivacyLayer™ to let you manage who can and cannot gain access to your health information."

LeRoy E. Jones*, CISSP
Chief Executive of GSI Health, Inc.
Program Manager, Healthcare IT Standards Panel
** Chief Technology Officer for Private Access LLC*

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Privacy Preferences: PrivacyLayer™ makes it easy to select your privacy preferences. Click on the green, yell
view your Guide's three suggestions. When you decide which description and settings b
preferences, click the "Next' button found below.

Here's what your guide suggests if you have greater privacy concerns:

"I realize that some value privacy to the point where they're uncomfortable disclosing their conditio
condition) to someone they don't know. In that case, I'd suggest these settings, where you'll always hav
learn more before you provide any contact details."

Researcher & Research Groups	Search Preferences what's this?	Contact Preferences what's
Dr Giedd	Allow to see my anonymous information	Notify me so I can cons
All KS&A Researchers	Allow to see my anonymous information	Notify me so I can consent or decline contact
All Researchers	Prohibit from searching	Prohibit all contact

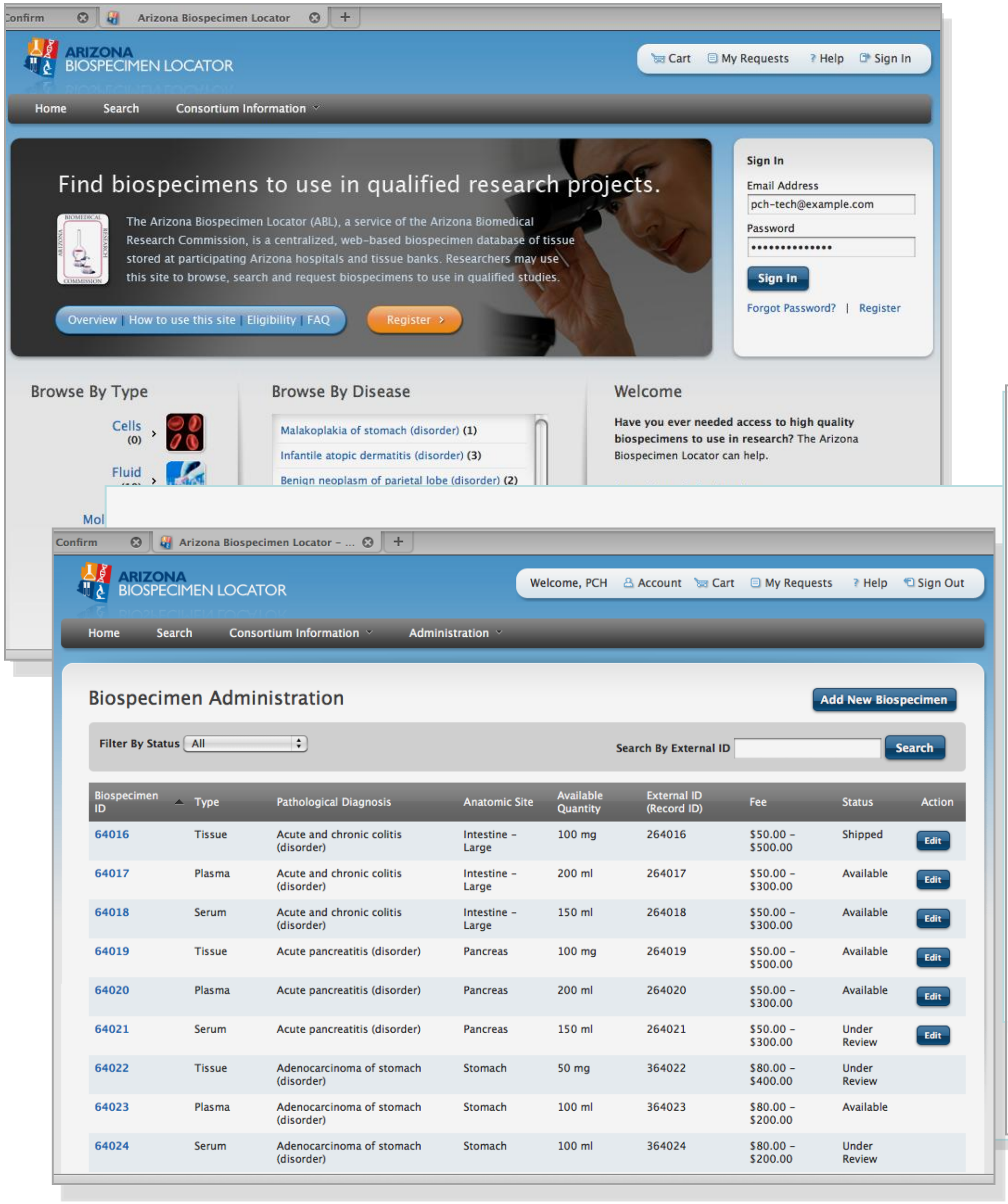
Audit Log

Date/Time	Activity	Brief Explanation
7/9/2009 12:08:48 AM	Directive Created	Directive was created by Robert Shelton for Robert Shelton to prohibit All Researchers data access for contact
7/9/2009 12:08:47 AM	Directive Created	Directive was created by Robert Shelton for Robert Shelton to prohibit All Researchers data access for search
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:08:47 AM	Directive Created	D
7/9/2009 12:01:27 AM	Login	A

- Independent Identity Verification
- Privacy Directives Language
- Dynamic Consent Management
- Comprehensive Audit Tracking
- Integrated eCommerce Features

ABRC Biospecimen Locator Service

… consent can be integrated into cutting-edge applications such as services for locating biospecimens for use in qualified research projects



Find biospecimens to use in qualified research projects.

The Arizona Biospecimen Locator (ABL), a service of the Arizona Biomedical Research Commission, is a centralized, web-based biospecimen database of tissue stored at participating Arizona hospitals and tissue banks. Researchers may use this site to browse, search and request biospecimens to use in qualified studies.

Email Address: pch-tech@example.com

Password: ••••••••••••••

Malakoplakia of stomach (disorder) (1)

Infantile atopic dermatitis (disorder) (3)

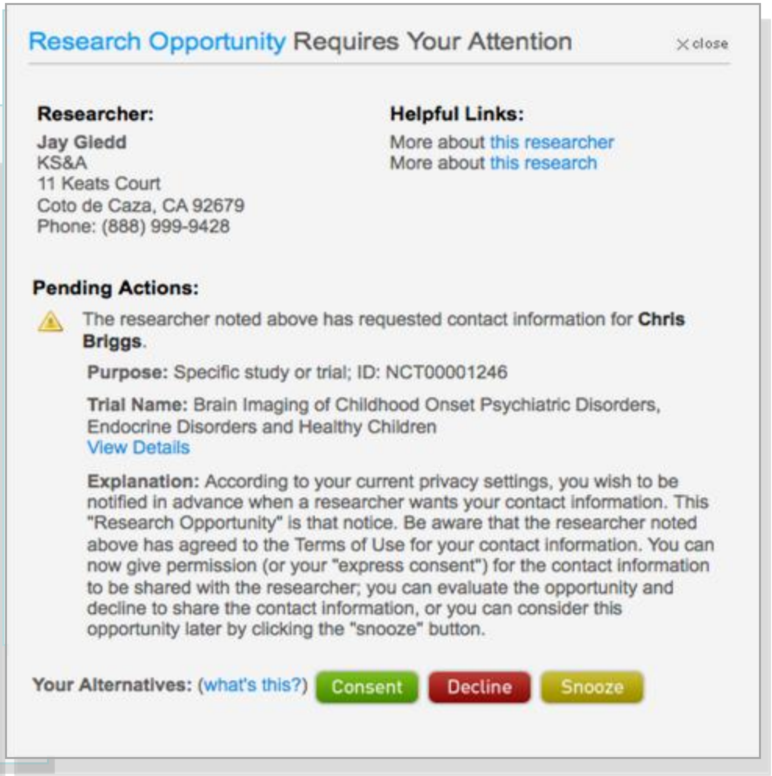
Benign neoplasm of parietal lobe (disorder) (2)

Welcome

Have you ever needed access to high quality biospecimens to use in research? The Arizona Biospecimen Locator can help.

Biospecimen Administration

Biospecimen ID	Type	Pathological Diagnosis	Anatomic Site	Available Quantity	External ID (Record ID)	Fee	Status	Action
64016	Tissue	Acute and chronic colitis (disorder)	Intestine - Large	100 mg	264016	$50.00 - $500.00	Shipped	Edit
64017	Plasma	Acute and chronic colitis (disorder)	Intestine - Large	200 ml	264017	$50.00 - $300.00	Available	Edit
64018	Serum	Acute and chronic colitis (disorder)	Intestine - Large	150 ml	264018	$50.00 - $300.00	Available	Edit
64019	Tissue	Acute pancreatitis (disorder)	Pancreas	100 mg	264019	$50.00 - $500.00	Available	Edit
64020	Plasma	Acute pancreatitis (disorder)	Pancreas	200 ml	264020	$50.00 - $300.00	Available	Edit
64021	Serum	Acute pancreatitis (disorder)	Pancreas	150 ml	264021	$50.00 - $300.00	Under Review	Edit
64022	Tissue	Adenocarcinoma of stomach (disorder)	Stomach	50 mg	364022	$80.00 - $400.00	Under Review	
64023	Plasma	Adenocarcinoma of stomach (disorder)	Stomach	100 ml	364023	$80.00 - $200.00	Available	
64024	Serum	Adenocarcinoma of stomach (disorder)	Stomach	100 ml	364024	$80.00 - $200.00	Under Review	



Research Opportunity Requires Your Attention

Researcher:

Jay Giedd
KS&A
11 Keats Court
Coto de Caza, CA 92679
Phone: (888) 999-9428

Helpful Links:

More about this researcher
More about this research

Pending Actions:

⚠ The researcher noted above has requested contact information for **Chris Briggs**.

Purpose: Specific study or trial; ID: NCT00001246

Trial Name: Brain Imaging of Childhood Onset Psychiatric Disorders, Endocrine Disorders and Healthy Children
View Details

Explanation: According to your current privacy settings, you wish to be notified in advance when a researcher wants your contact information. This "Research Opportunity" is that notice. Be aware that the researcher noted above has agreed to the Terms of Use for your contact information. You can now give permission (or your "express consent") for the contact information to be shared with the researcher; you can evaluate the opportunity and decline to share the contact information, or you can consider this opportunity later by clicking the "snooze" button.

Your Alternatives: (what's this?)

Open Source Consent Solutions

1. Adapt/use the National Data Infrastructure Improvement Consortium (NDIIC) open source electronic consent module as the minimum standard for consent tools in PHRs and for all HIT

2. Require the strong privacy protections in 43 CFR Part 2 be extended to cover all personal health information (PHI), wherever it is held.

Audit trails based on authentication

Mar 01, 2010

Imprivata's New Product Helps Hospitals Proactively Investigate and Audit Access to Patient Health Information

PrivacyAlert™ Quickly Detects Snooping and Identity Theft of Medical Records

Imprivata PrivacyAlert quickly detects snooping, identity theft and general inappropriate access of medical records through its automated pattern recognition, which delivers alerts on more than 100 patient privacy scenarios. Users can deploy automated and scalable privacy monitoring policies that assist in investigating and reporting on patient data privacy breaches.

Imprivata PrivacyAlert enables information security officers and privacy officers to deploy automated and scalable privacy monitoring solutions that assist them in investigating and reporting on patient data privacy breaches.

Ability to set and focus investigation criteria on employee, patient or combination of both.
Out-of-the-box support for all leading healthcare applications including Eclipsys,
GE Centricity Enterprise, MEDITECH Magic, Siemens Invision and others.

http://www.marketwire.com/press-release/Imprivatas-New-Product-Helps-Hospitals-Proactively-Investigate-Audit-Access-Patient-1123908.htm

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