

Linda J . L . Radach

AFFILIATIONS

Washington Advocates for Patient Safety

Patient Safety Action Network

USA Patient Network

Medical Device Problems

No Conflicts of Interest

What I Wish I Had Known Becoming an Engaged Patient





I WAS TOLD:

➤ **Newly APPROVED by the FDA**

**Not CLEARED for market
until Nov, 2009**

I WAS TOLD:

➤ WOULD LAST **X** + YEARS,
maybe for lifetime

Device Failure Rate of 8%

I WISH I HAD KNOWN...

ASK QUESTIONS

TO GET A SECOND OPINION

DOCTOR-INDUSTRY RELATIONSHIPS

COMPLICATION & INFECTION RATES

UNBIASED INFORMATION

HOW TO TALK TO THE DOCTOR

WHAT 'FDA APPROVED' MEANS

HABITS OF AN ENGAGED PATIENT

RELATIONSHIPS

INFORMATION

HABITS OF AN ENGAGED PATIENT

INFORMATION – Part One

Tip #1

BE AWARE AND CAUTIOUS



PATHWAYS TO MARKET

PMA

APPROVED

SCIENTIFIC CLINICAL TRIALS

**Provide Evidence of
Safety And Effectiveness**



PATHWAYS TO MARKET

510(k)

CLEARED

SUBSTANTIAL EQUIVALENCE

Using A Predicate Device

**NO SCIENTIFIC EVIDENCE OF
SAFETY AND EFFECTIVENESS
IS REQUIRED**



510(k)

APPLES TO ORANGES



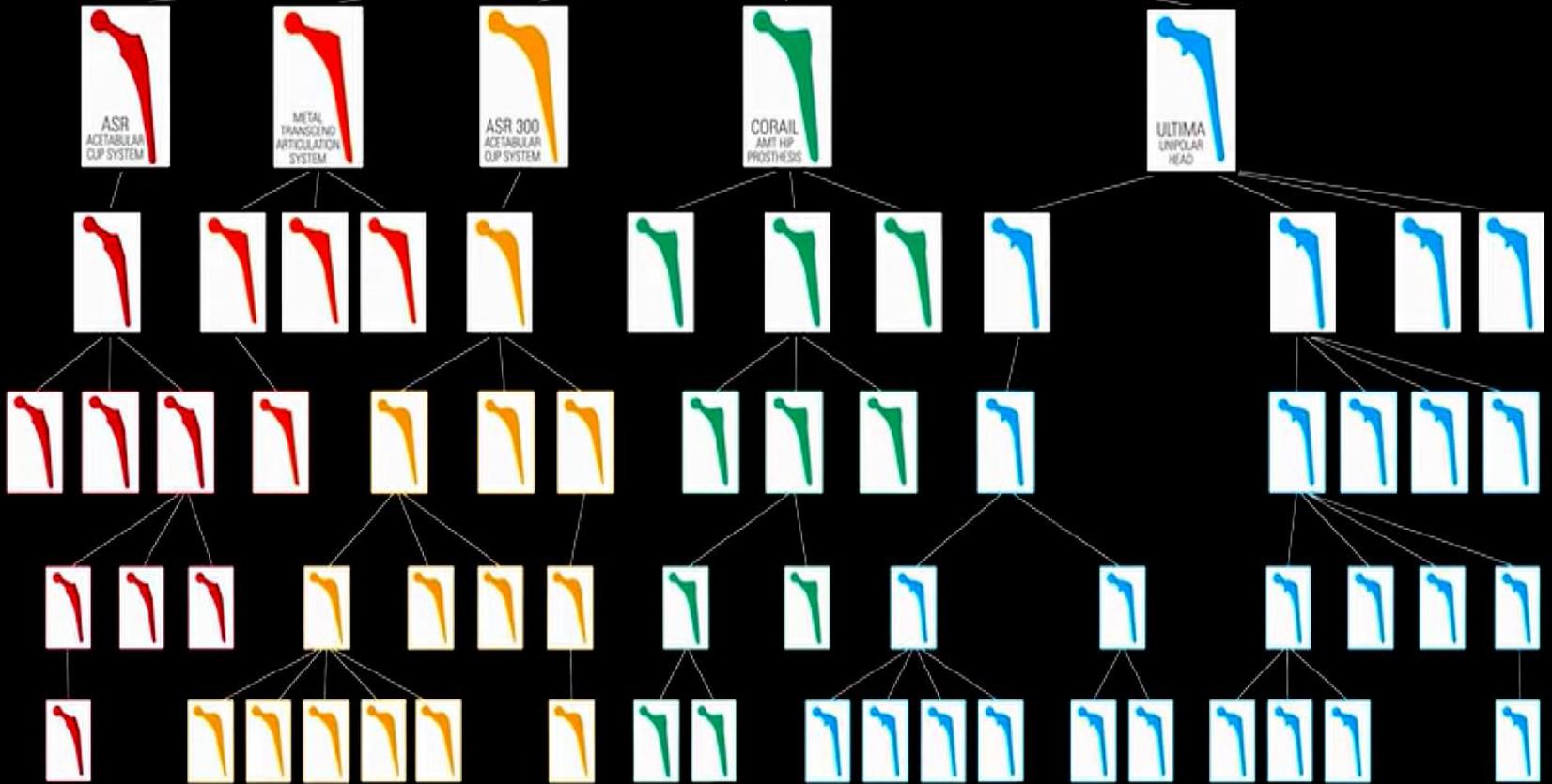
510(k)

...the new device is
assumed to be
as safe and effective
As the predicate
because of its similarity.



One predicate device.

Many offspring.



Institute of Medicine 2011 Report

510(k) clearance is not
a determination that the
cleared device is
safe or effective.



CLEARED FOR MARKET

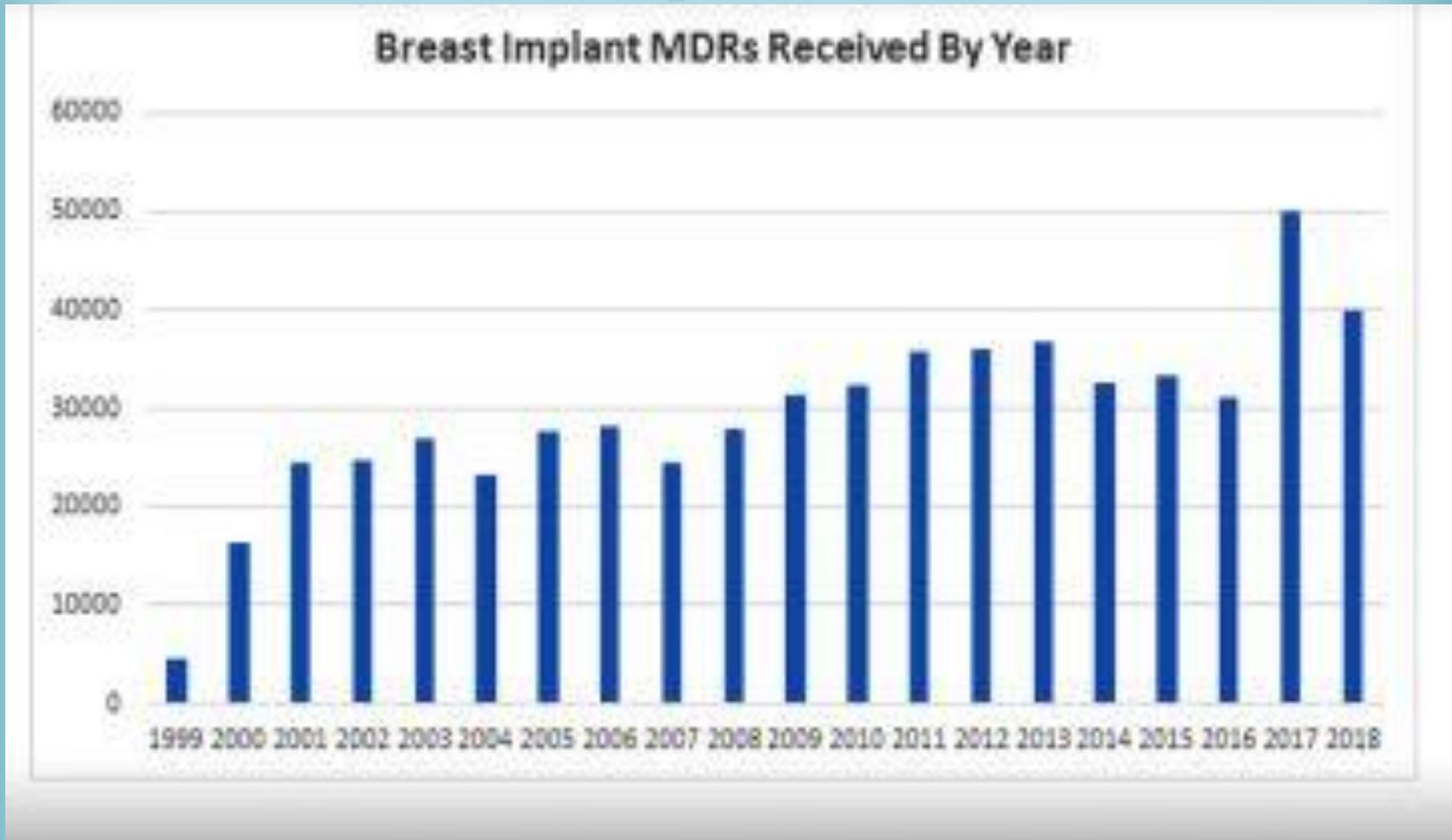
95-98%

**NEVER SCIENTIFICALLY
TESTED FOR
SAFETY AND EFFECTIVENESS**

<https://medicaldeviceproblems.com/>



75,000 per Month



RECOMENDATIONS

Implant Files

International Consortium of Investigative Journalists

<https://www.icij.org/investigations/implant-files/>

The Danger Within Us

By Jeanne Lenzer

<https://www.littlebrown.com/titles/jeanne-lenzer/the-danger-within-us/9780316343787/>



HABITS OF AN ENGAGED PATIENT

INFORMATION – Part One

Scientific/Medical Research

Tip #2

DUE DILIGENCE

Use Reputable Resources

HABITS OF AN ENGAGED PATIENT

Tip #3

KNOW THE DIAGNOSIS

Causes and Symptoms

Problems and Prognosis

Resources for information

HABITS OF AN ENGAGED PATIENT

Tip# 4

KNOW THE PLAN OF CARE

Device

Drug

Diagnostics

Other OR Wait

Referral

HABITS OF AN ENGAGED PATIENT

Tip #5

RISKS AND BENEFITS

Complications & Infections

What are the rates of infection and complications for this procedure, done by this surgeon, in this hospital?

HABITS OF AN ENGAGED PATIENT

Tip #6

Potential Industry Influence

ProPublica Dollars for Docs

<https://projects.propublica.org/docdollars/>

Centers for Medicare and Medicaid

<https://openpaymentsdata.cms.gov/search/physicians/by-name-and-location>

INFORMATION RESOURCES

Surgeon & Hospital Scorecard

<https://projects.propublica.org/surgeons/>

Vital Signs

<https://projects.propublica.org/vital-signs/>

Leapfrog Group

<http://www.leapfroggroup.org/>

CMS Hospital Compare

<https://www.medicare.gov/hospitalcompare/search.html?>

INFORMATION RESOURCES

Scientific/Medical Research

DRUGS

Physician's Desk Reference (PDR)

<https://www.pdr.net/browse-by-drug-name?letter>

drugs.com

<https://www.drugs.com/>

DRUG INFO RESOURCES

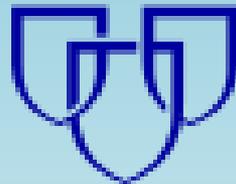
Scientific/Medical Research

CONDITIONS/DISEASES

Medscape

<https://emedicine.medscape.com/>

MAYO
CLINIC



<https://www.mayoclinic.org/diseases-conditions/index>

DEVICE INFO RESOURCES

Scientific/Medical Research

DEVICES

*MAUDE - FDA DATABASE &
REGISTRIES ARE PROBLEMATIC*

DEVICE EVENTS

<https://www.deviceevents.com/device-events-demonstration-video/>

INTERNATIONAL MEDICAL DEVICE DATABASE

<https://medicaldevices.icij.org/>

RESOURCES FOR QUESTIONS TO ASK

AHRQ

<https://www.ahrq.gov/patients-consumers/patient-involvement/ask-your-doctor/index.html>

PSAN

<https://www.patientsafetyaction.org/new-resources>

THE EMPOWERED PATIENT COALITION

<https://empoweredpatientcoalition.org/selected-resources/fact-sheets-and-checklists/>

HABITS OF AN ENGAGED PATIENT

SHARED DECISION-MAKING

INFORMED CONSENT

Tip # 7

USE A DECISION AID

<https://www.med-decs.org/en/other-decision-aid-collection-websites>



<https://decisionaid.ohri.ca/docs/das/OPDG.pdf>

HABITS OF AN ENGAGED PATIENT

REMEMBER

**GET A SECOND OR
THIRD OPINION**

Do Your Homework

HABITS OF AN ENGAGED PATIENT

Tip #8

PLAN AHEAD

Pre-Op Protocols
Tests & Diagnostics
Anesthesia
Surgery
Pain Management

PLAN AHEAD

Post-Op/Rehab

Assistive Devices

Physical Therapy

Home Safety

Follow-up Visits

Pain Control

Driving

Ambulation

Caregiver/Helper

Medications/Refills

Outcomes

HABITS OF AN ENGAGED PATIENT

INFORMATION – Part Two

Personal Health Information

Tip #9

**CREATE A PERSONAL
MEDICAL RECORD**

HABITS OF AN ENGAGED PATIENT

MEDICAL RECORDS

Medical History

Medications

Hospitalizations

Allergies

Health Conditions/Diseases

EHR Log-in Data

Insurance Information

HABITS OF AN ENGAGED PATIENT

MEDICATIONS

- ❖ Keep this list of RX and OTC current
- ❖ Know their names & why you take them.
 - ❖ Tell your doctor about reactions or if it does not seem to work
- ❖ Properly dispose of old and unused RX & OTC medications.

HABITS OF AN ENGAGED PATIENT

RELATIONSHIPS

Provider to Patient

Patient to Provider

HABITS OF AN ENGAGED PATIENT

RELATIONSHIPS

Tip #10

BUILD TRUST

MEDICAL
CARE



PROVIDER



PATIENT



SHARE THE ROAD

MEDPAGE TODAY

8 Vital Traits of the Ideal Physician

SHARE THE ROAD

Communication

**The how and the what
are equally important**

**Share symptoms,
not diagnoses**



SHARE THE ROAD

Empathetic

Identify patient concern

Respond to expression of care

SHARE THE ROAD

Passionate

Sincerity in providing care

Genuine enthusiasm

for good health

SHARE THE ROAD

Forthright

**Straightforward
with all the facts**

© 2010 Kevin Spear kevin@kevinspear.com www.kevinspear.com



"I hate cats! I want a dog scan."

SHARE THE ROAD

Professional

**Visits are conducted with
good manners and respect**

SHARE THE ROAD

Respectful

See the humanity

Give dignity

SHARE THE ROAD

Knowledgeable

Layman's Language

Research or Refer

Demonstrate Understanding

SHARE THE ROAD

Thorough

Turning Over the Rocks

Attention To Detail = Accuracy

SHARE THE ROAD

The days of paternalistic
practice of medicine are gone.
Passive medicine does not serve the
best interest of patients.
It just does not work.

~ Martine Ehrenclou

SHARE THE ROAD

“It is time to change our perceptions of the medical professionals in our lives and see them as human beings with skills we need.”

~ Martine Ehrenclou

PATIENT ENGAGEMENT IMPROVES CARE

Chronic Conditions Managed

Reduced Medical Errors

Shortened Hospital Stays

Fewer Return ED Visits

PATIENT ENGAGEMENT IMPROVES CARE

Symptom Assessment

Decision Making

Adherence and Satisfaction

Reduced Costs

**PATIENT ENGAGEMENT
BENEFITS PROVIDERS**

Reduced Staff Burnout

Healthier Work Environment

WE CAN DO IT TOGETHER

Patient Engagement from Both Sides of the Bed

Article · December 4, 2018

Susan Hassmiller, RN, PhD, FAAN & Ani Bilazarian, RN

Robert Wood Johnson Foundation

Columbia University School of Nursing

**Thank you for your
time and attention!**

Here is to good health!