



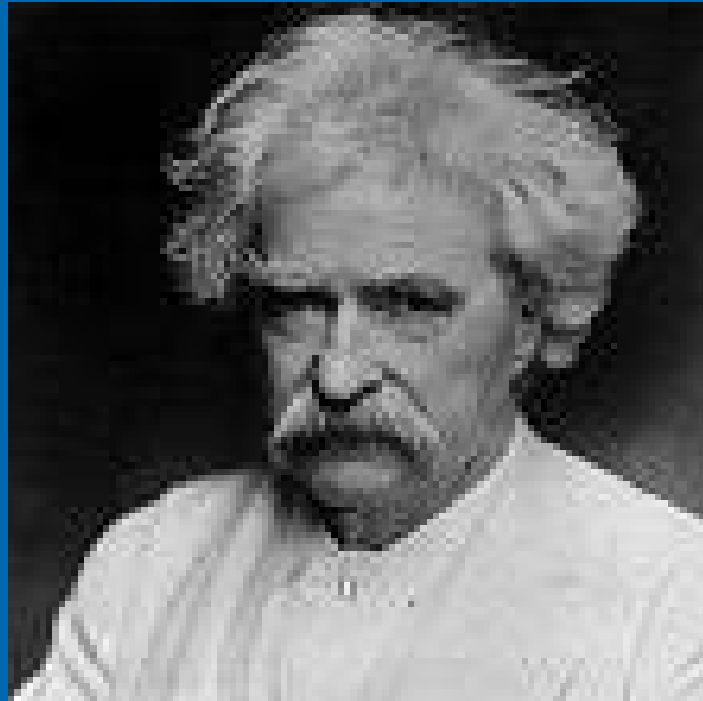
# Are Women Being Harmed by Unsafe Medical Products?

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# Statistical Evidence



**There are 3 kinds of lies:  
Lies, damn Lies, and statistics**

# There are 2 ways to “prove” an unsafe product is safe

➤ No Research

➤ Bad Research

# No Research

## Fact:

No research has been published

## Spin:

There is no evidence that this product is unsafe

# Does FDA Approval = Safety?

## Criteria for Approval of Prescription Drugs:

- Safe (over the short-term)
- Effective (compared to placebo)
- Lack of data on dangers is NOT sufficient

**CAVEAT:** studies by the company

# FDA Approval of Drugs

Safe and Effective does NOT mean

- Nobody will die from this drug
- Nobody will be harmed by this drug
- This drug is safe for long-term use
- This drug is more effective than other OR cheaper drugs on the market

# FDA Approval of Medical Devices

- Reasonably Safe
- Reasonably Effective

OR

- **Substantially Equivalent** to other devices on the market prior to 1976 –  
98% of devices are approved that way  
(510 k loophole)

# FDA Requires Short-term Studies on Implants

**Examples: Jaw Implants and Breast Implants – Grandfathered devices**

**Approval:** Based on prospective studies of 3 months to 3 years they are reasonably safe

**Justification:** If these products were unsafe, we'd know by now



# Non-FDA Epidemiological Studies on Implants

- Had implants for “up to 41 years” (CTD) and “since 1970” (cancer)

**Results:** No cancer,  
No connective tissue disease

**Spin:** The body of research shows  
implants are safe

# Breast Implant Studies

## CAVEATS:

- Women had implants for at least one **month**.
- Impossible to have breast implants for 41 years at time of study
- NCI studies found significant increases

# Substantially Equivalent Devices

## Contact Lens Solution

- ReNu with MoistureLoc approved as equivalent to another company's product
- No clinical trials required. No inspection of manufacturing plant

**RESULT:** infections and blindness

# Does FDA Learn from Mistakes?

## Contact Lens Solution Instant Replay

- Complete MoisturePlus approved with no clinical trials

**RESULT:** infections and blindness

# Does FDA Learn from Mistakes?

## NeuroStar

### Treatment for Depression

- “Substantially equivalent” to Electro Shock Therapy
- Different mechanism
- Outpatient vs. Inpatient
- Daily instead of rarely
- Ineffective

# Are these substantially equivalent?



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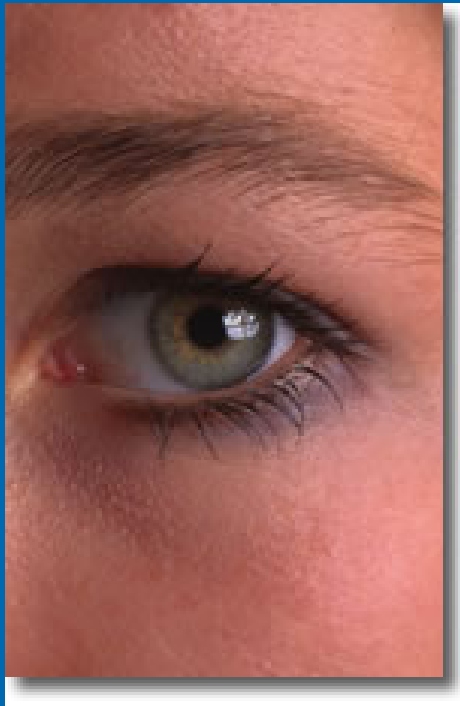


Vitek TMJ implants

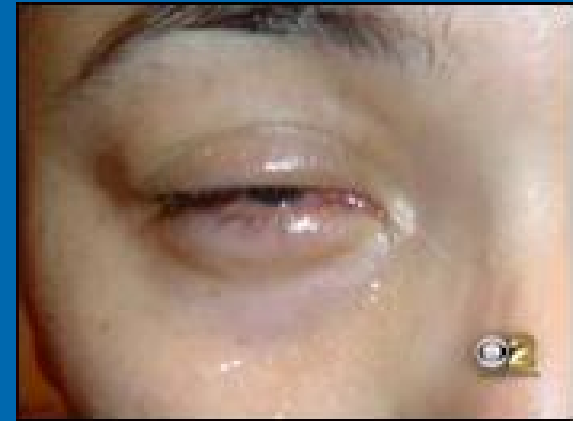


Dow silicone sheet

# Are these substantially equivalent?



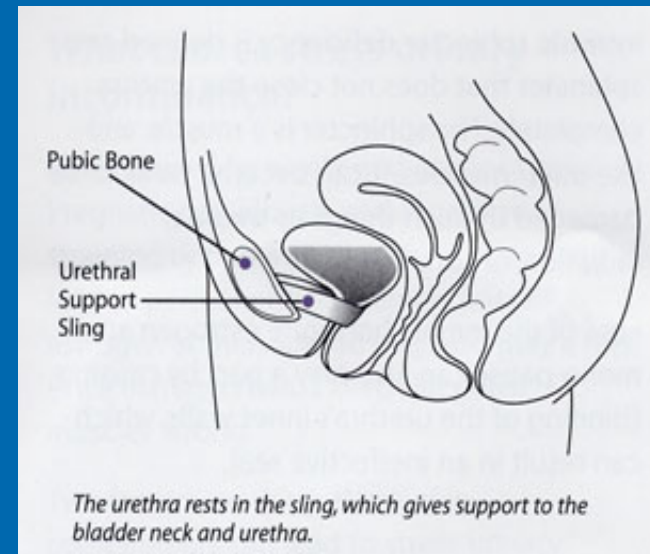
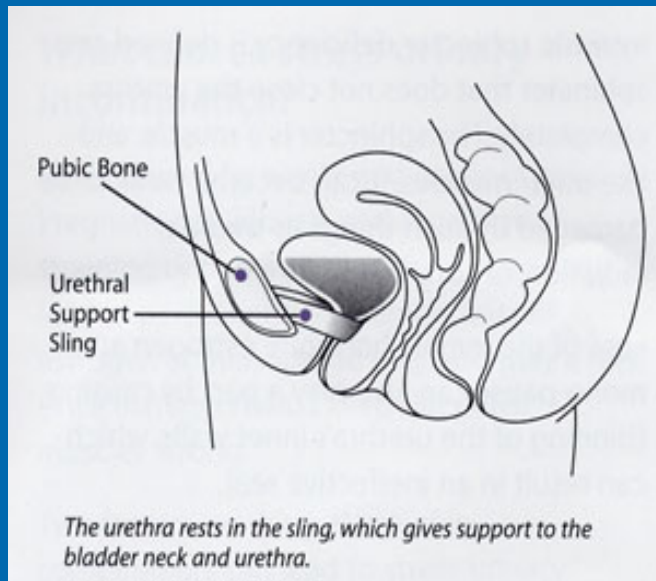
Healthy eye using most contact lens solutions



Infected eye  
Complete MoisturePlus  
Renu with MoistureLoc



# Are these substantially equivalent?



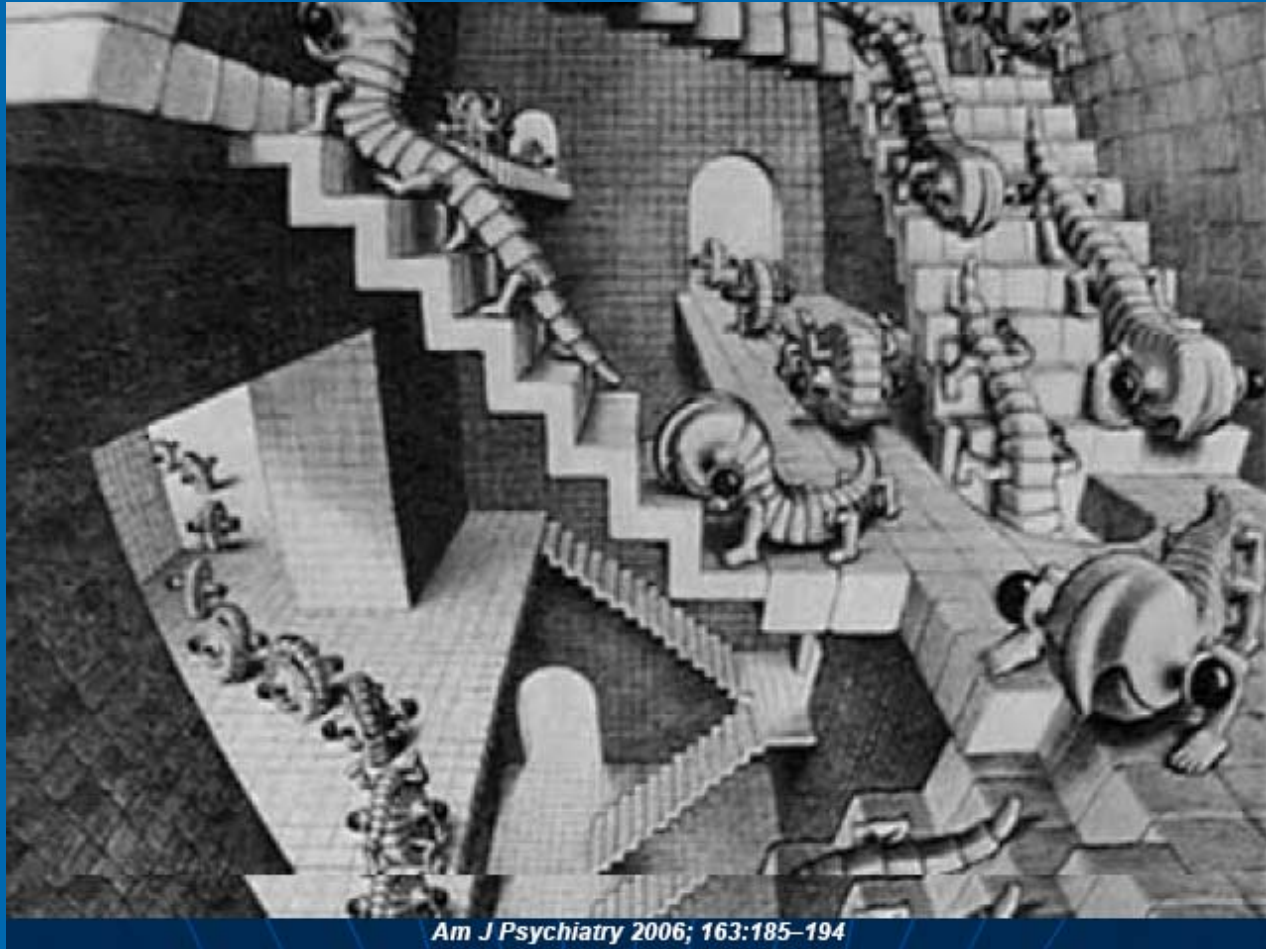
Bladder slings made with Gore-Tex

ProteGen: a bladder sling made with Hermashield, a new synthetic fabric coated with collagen

# Are these substantially equivalent?



**A = B = C = A**



*Am J Psychiatry 2006; 163:185-194*

# Conclusions

- 90% of devices approved without clinical trials
- When studies are required, they are short-term
- FDA standards of safety for devices is inadequate
- Standards for insurance coverage and Medicare are higher than FDA standards – but women's groups sometimes undermine them



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[www.center4research.org](http://www.center4research.org)