

“The best way to predict the future is to create it.”  
Peter Drucker

# BMEN 3151 Medical Device Practicum

20OCT2021 - Max Fiore



- Societal Impact of Medical Devices and Some Lessons from 40 years in Medical Device Development

# Impact of Healthcare costs on US economy

2019

\$3.24 Trillion Per year spent on healthcare – **18% of GDP**

(US Defense budget was \$686B in 2019)

\$11,072 per capita!

2027

Healthcare costs will exceed **19.4% of US Total GDP!**

**59% of the spending going to hospitals, doctors, and clinical services.**

**The Point here is we must, at all costs, keep people out of the hospital**

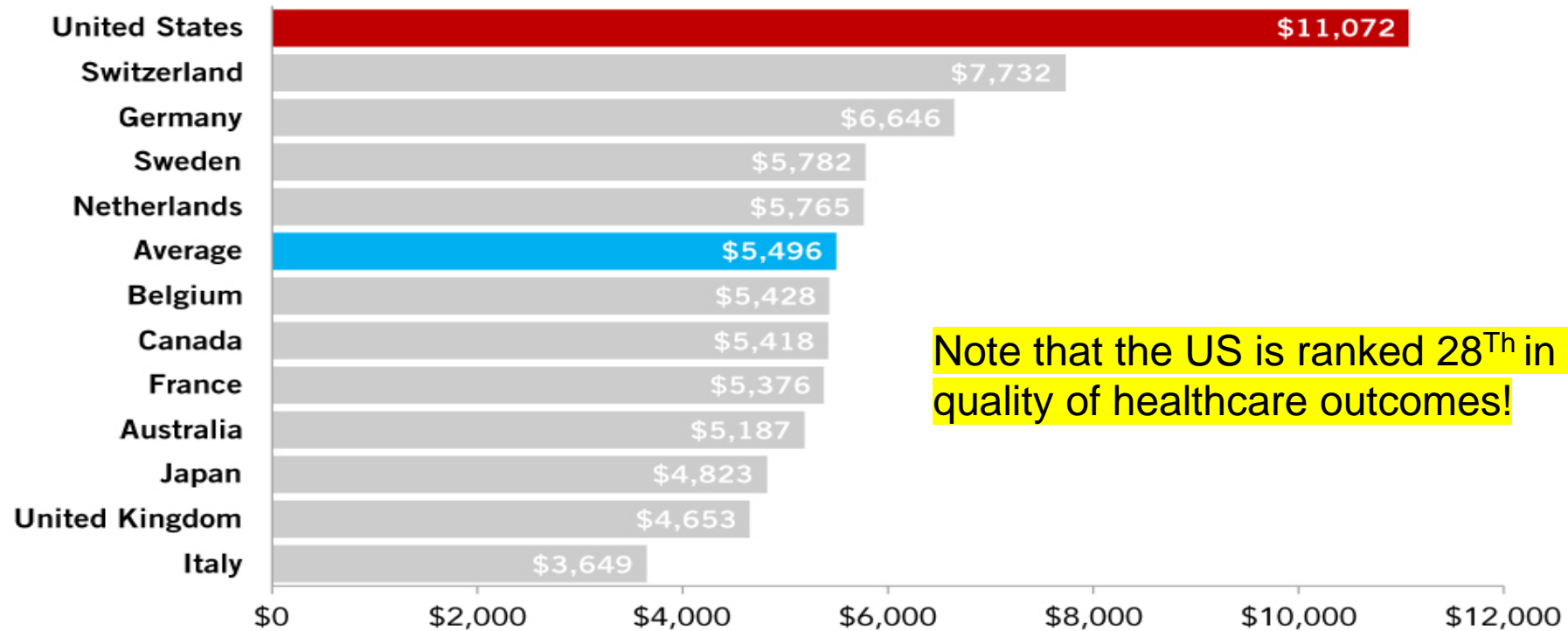
**Surprisingly, The percentage of total healthcare spend on Medical Devices – 4-5% of the total healthcare budget**

# US Spends the most on Healthcare



**U.S. per capita healthcare spending is almost twice the average of other wealthy countries**

**HEALTHCARE COSTS PER CAPITA (DOLLARS)**



SOURCE: Organisation for Economic Co-operation and Development, *OECD Health Statistics 2020*, July 2020.  
NOTES: The five countries with the largest economies and those with both an above median GDP and GDP per capita, relative to all OECD countries, were included. Average does not include the U.S. Data are for 2019. Chart uses purchasing power parities to convert data into U.S. dollars.



## Benefits of Innovative Medical Devices to Healthcare Delivery

- Reducing the cost of Healthcare
  - Moving healthcare to the home
  - Reducing labor costs
  - Reducing or eliminating hospital stay
  - Replacing pharmaceuticals for chronic diseases

# Moving Healthcare to the home - LifeScan (a J&J Company)

## Point of Care Testing

- Self Monitoring of Blood Glucose – LifeScan One Touch II
  - Optical Reflectance Readout
  - First truly easy to use SMBG technology
  - Revolutionized SMBG – Gave LifeScan a 48% market share in 1994
  - LifeScan grew in revenue from \$100M to \$750M from 1990-1995!
- Continuous Monitoring of Blood Glucose – Abbott Freestyle Libre (Developed by ex-LifeScan people)
  - TheraSense Electrochemical Technology
  - Continuous SMBG
  - Critical enabling technology to achieving the Artificial Pancreas!



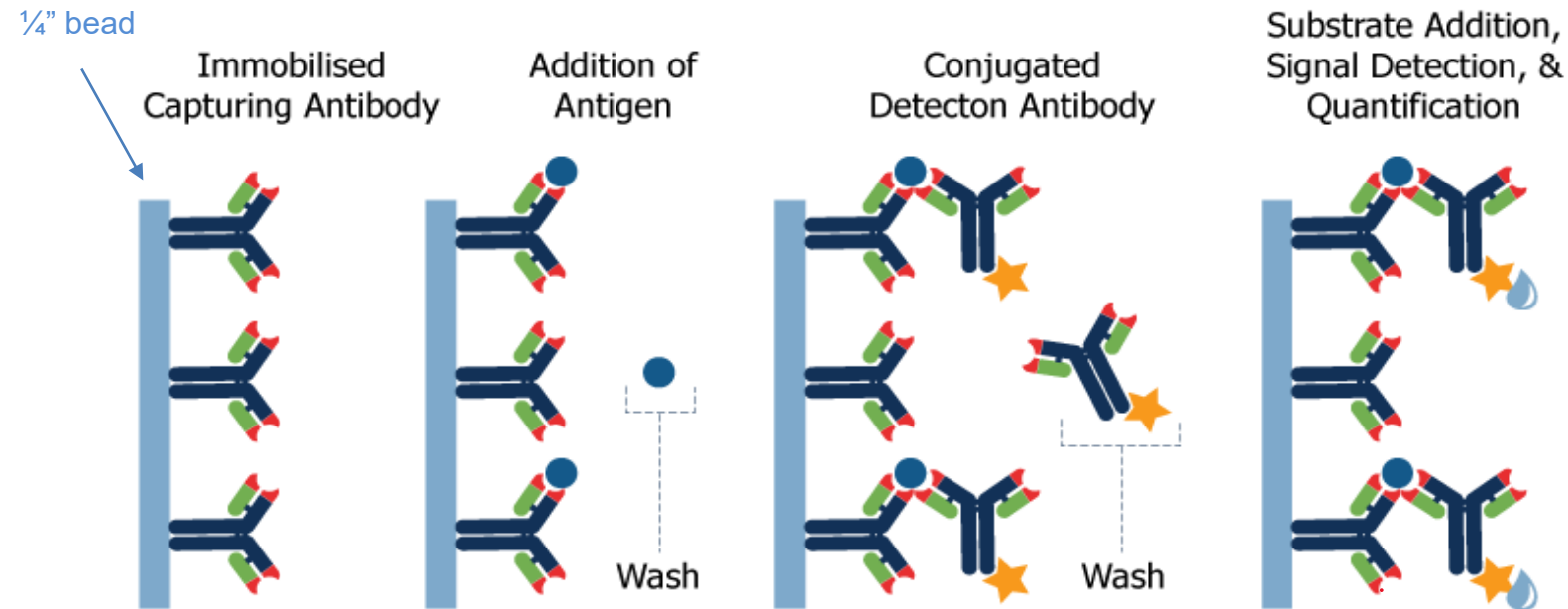
# Reducing Labor Costs – Clinical Lab

The Old Way - Manual Enzyme Immunoassay (1/4" Bead Substrate)

4 manual Steps 24 – 48 Hours for a patient result!



## Direct Sandwich ELISA



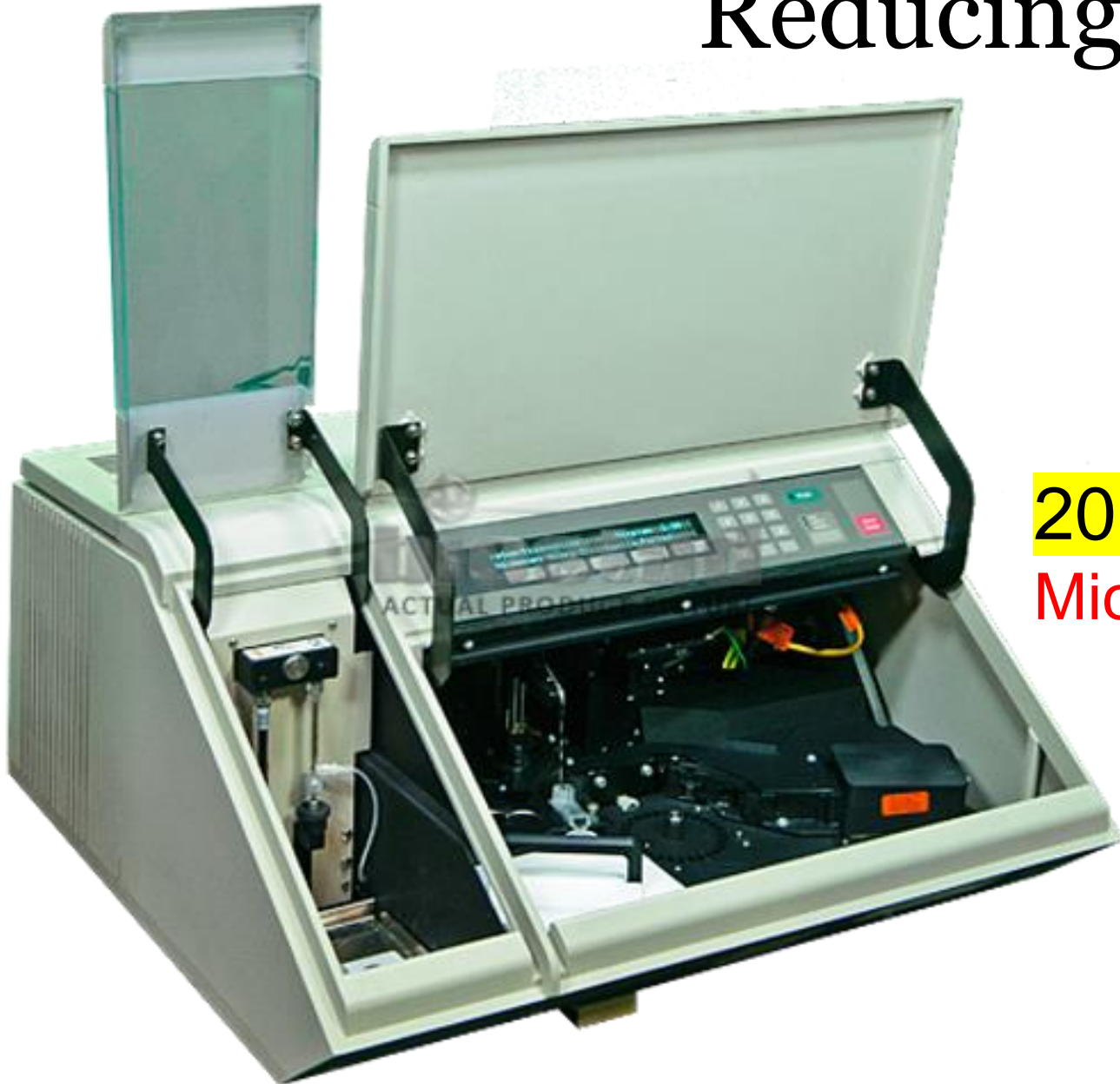
# Reducing Labor Costs

## Abbott IMx

1. Load Carousel
2. Load Reagent Pack
3. Press Run

20 minutes for 24 patient results

Microparticles replace ¼" Bead



# Lessons from the IMx Program

## Lessons

- Average age of the team was 26 years. Naivete; drive!
  - With some adult supervision
- Multiple Parallel development of key High-Risk subsystems
- Co-located core team to facilitate informal communication
  - Communication challenges – Set up first computer network at Abbott (AppleTalk with MacIntoshes)
  - Informal “Watering Hole Wednesday Evenings including spouses)
- Importance of small dedicated, autonomous teams in Product Development –
  - Art Collins – CEO of Medtronic succeeding William George and succeeded by William Hawkins.
    - “While I was at Abbott Laboratories, it was not uncommon for the Diagnostics Division to staff “tiger teams” with some of the best employees from various parts of the existing organization in order to increase focus on the launch of new products. This process was utilized when in 1988 Abbott introduced the IMx, an immunodiagnostic testing system”.
    - “The IMx launch is still regarded as the most successful in the history of the medical diagnostics industry.”



# Impact of the IMx Program

- System was in continuous production for 20 years!
  - 46000 systems placed worldwide
  - Average system generated over \$45000 in reagent revenue per year (>\$2B in revenue per year) 1988 dollars
  - If you lived in the US from 1988 to 2008 and had an Immunoassay performed it was probably done on the IMx
- First automated PSA test for prostate cancer
- Ultimately over 80 immunoassays were available on the IMx
- Assay menu tailored to specific countries and regions of the world
- IMx was launched in France and Japan before the US. Truly an international product
- IMx development and commercialization costs were recovered <8 months after launch!

# Patient Controlled Analgesia – Reducing labor costs and patient stay

- Need for analgesics is driven by the patient's *perception* of pain
- Solves the clinician's problem of making sure pain meds are available when needed

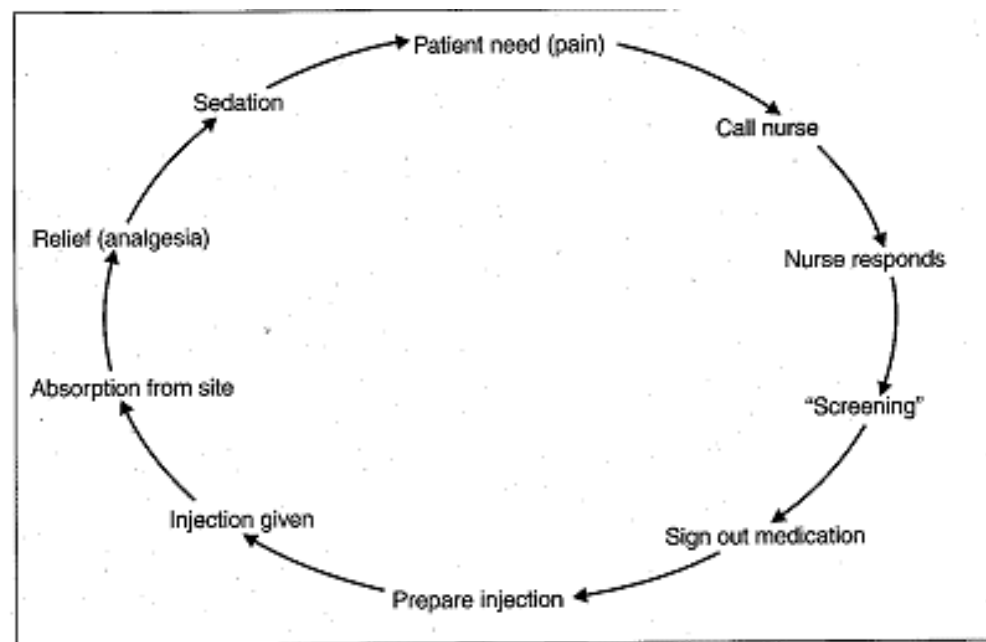


Figure 1: Cyclic Character of Conventional Analgesic Therapy—Reprinted, with permission, from Graves DA, Foster TS, Batenhorst RL, et al: Patient-controlled analgesia. *Ann Intern Med* 99:360-366, 1983.

Table. Advantages of Patient-Controlled Analgesia

- More uniform pain relief
- Less sedation during daytime hours
- Minimization of delay between analgesic request and receipt of pain relief
- Minimization of inappropriate screening
- Accommodation for diurnal changes
- Accommodation for individual analgesia requirements
- Ability to titrate the analgesic in response to the patient's need
- Increased patient control and satisfaction



© Mayo Foundation for Medical Education and Research. All rights reserved.

# Benefits of Patient Controlled Analgesia

## Safety of PCA

- Dosage selection – Only 1mg/ml Morphine allowed
- Lockout interval
- 4 hr. limit
- Locked Polycarbonate Cover
- **Economics of PCA**
- Pre-filled syringe
- Reduced nursing workload
- Physician workload reduced due to reduced pain management failures
- Exceeded \$100M/year revenue four years after launch in 1983 (Development costs returned in 6 months)
- **Subsequent studies showed that improved pain control using PCA shortened length of hospital stay!!**



# The Importance of FMEA, Product Testing and multiple layers of fault tolerance built into the design

- Accidental Overdose
  - Syringe design – dose in syringe less than LD 50
  - Alarms to prevent IV attachment to patient with syringe out of the device – anti siphon valve
  - Stepper motor drive – tolerant to electronic drive circuit faults
  - Extensive software validation – “bug bashing”
- Unforeseen Clinical Safety Issues
  - 510k approved using syringe pump as a predicate, but we did extensive clinical studies on our own. Not mandated by FDA for this product back in 1983



# Replacing Pharmaceuticals for Chronic Disease Treatment

Big Pharma has saved countless lives with its drugs (me)

Big Pharma loves drugs taken daily to treat chronic conditions

**Lifetime Patients – Anti-Hypertensives, Statins, Diabetes drugs**

Example: Benign Prostatic Hyperplasia – 1 Million new cases each year

Pharma's solution – Finasteride therapy daily. (\$3 per day, \$1095 per year) Can be taken from 10 - 20 years at the end of a patient's lifetime! (**lifetime cost > \$20000**)

Finasteride is a 5 $\alpha$ -reductase inhibitor, and therefore an antiandrogen.<sup>[7]</sup> It works by decreasing the production of dihydrotestosterone (DHT) by about 70%, including in the prostate gland and the scalp.<sup>[1]</sup>

Side effects include:

**Impotence, loss of interest in sex, trouble having an orgasm, abnormal ejaculation, swelling in your hands or feet, swelling or tenderness in your breasts, dizziness, weakness, feeling like you might pass out, headache, runny nose, or skin rash.**

# Replacing Pharmaceuticals for Chronic Disease Treatment

Example: Benign Prostatic Hyperplasia - NxThera Corporation (founded by Michael Hoey)

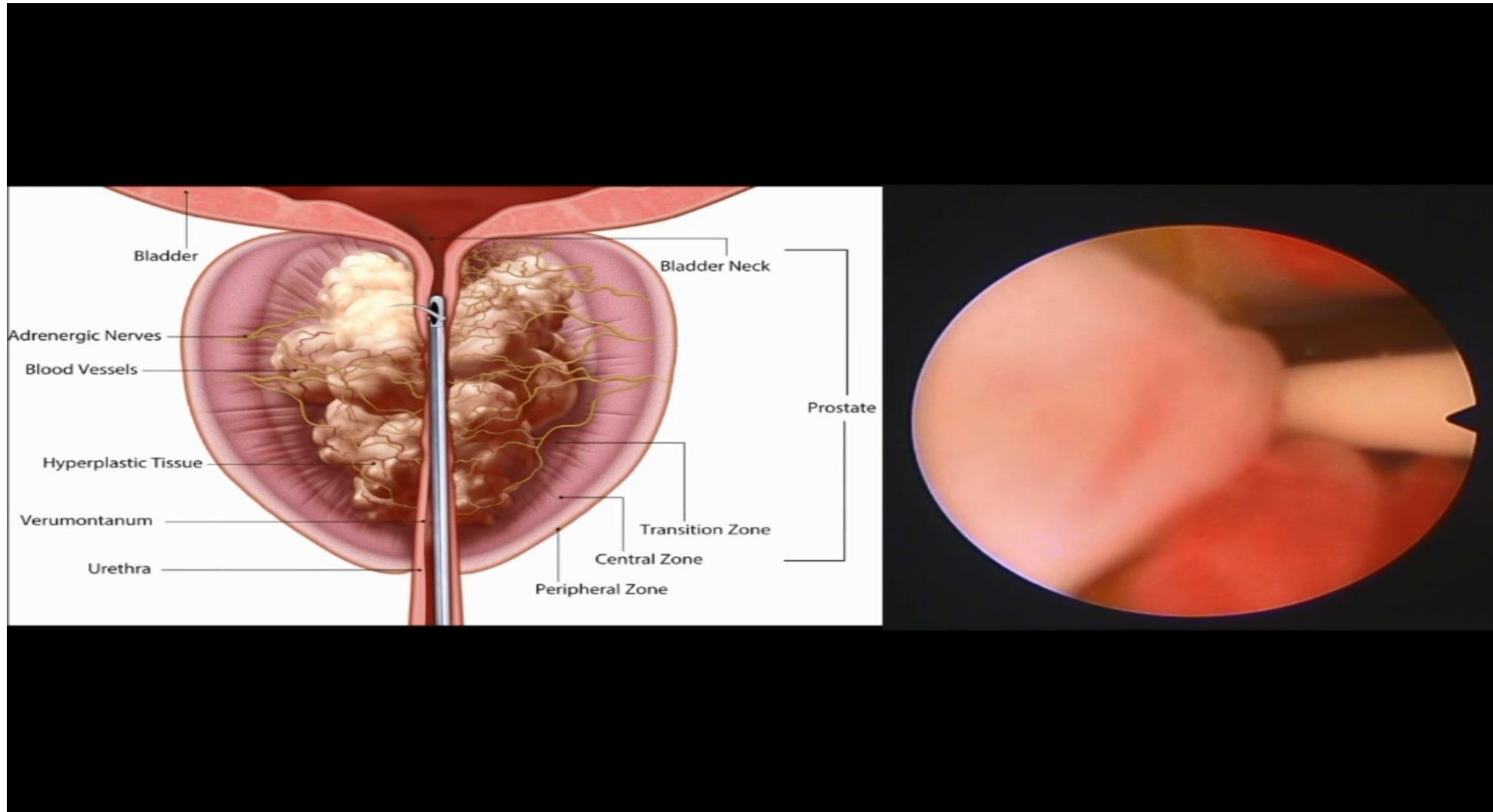
Medical Device solution – Rezum Procedure 20 minutes, performed in physician office  
cost - \$2000 one-time fee



Sold to BSX in 2018 for \$406M

# Replacing Pharmaceuticals for Chronic Disease Treatment

Example: Benign Prostatic Hyperplasia

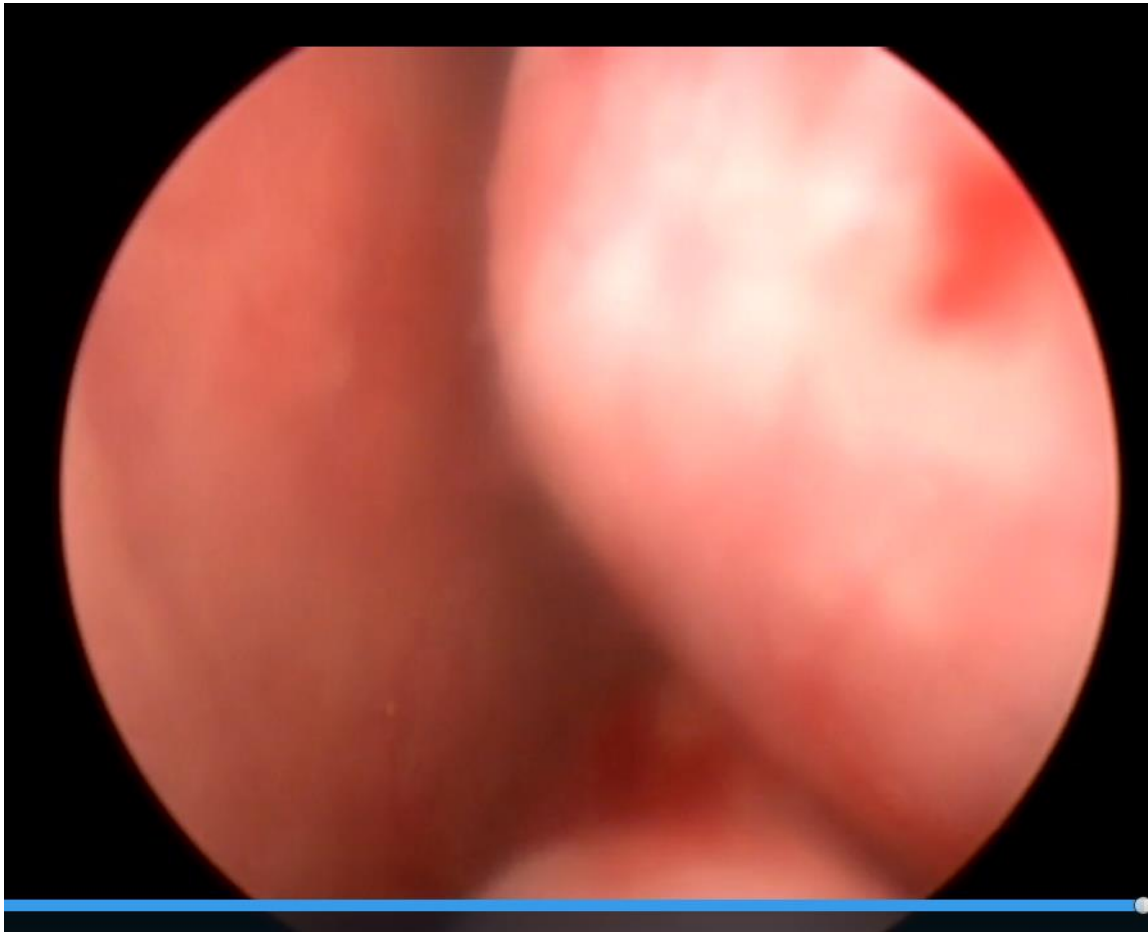


# REZUM - Clinically Significant Tissue Volume Reduction

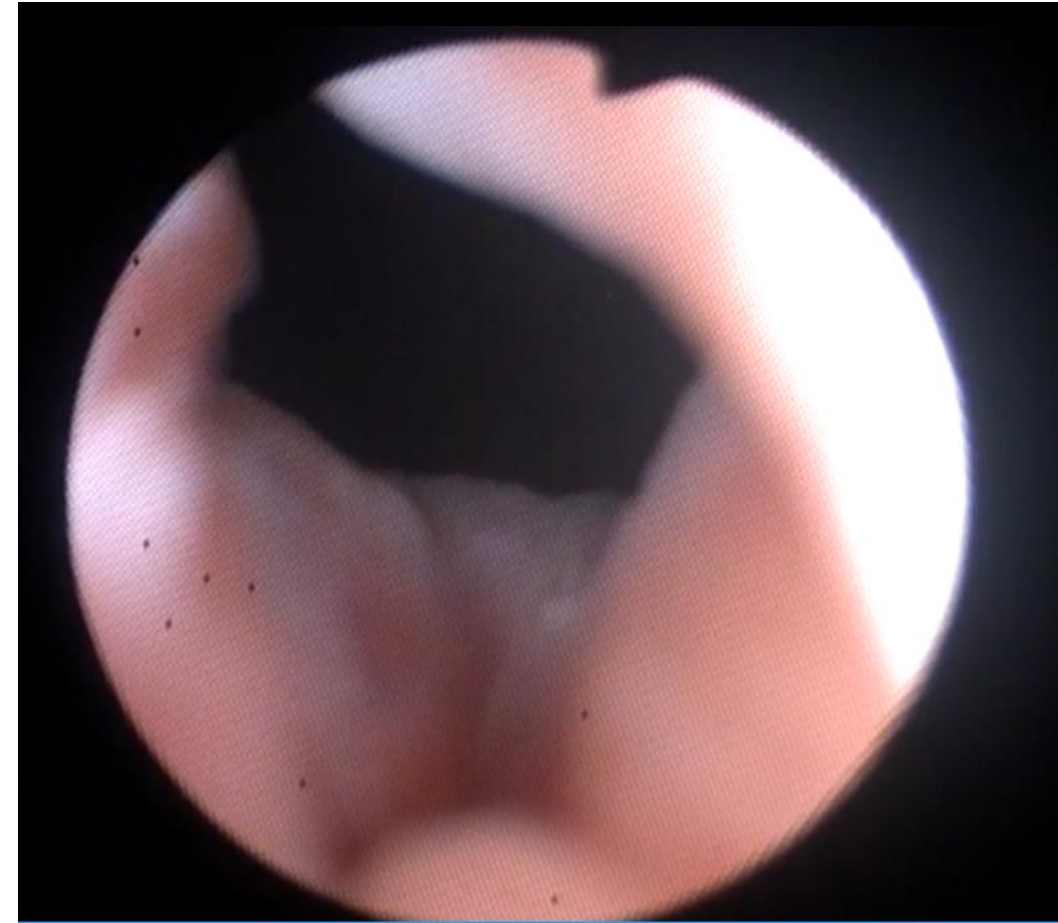
Cystoscopy Videos – Baseline vs. 6 Months Post-Procedure

52 cm<sup>3</sup> Prostate – 3Tx/RLL; 4Tx/LLL; 2 Tx/ML – 7 min. procedure


*Baseline*



*6 Months Post-Procedure*







The bottom line: Physicians care  
for one patient at a time,  
Biomedical Engineers who develop  
medical devices can help millions  
of patients every day!



I have one final word for you

- **Bioelectromagnetics!**



# Soltech Sleep Management System

- Based on low frequency magnetic field stimulation of the perineural nervous pathway to the autonomic nervous system.
  - VLF magnetic stimulation causes non-action potential signal transduction through the myelin sheath of neurons.
  - Acts directly on sleep centers in the brain
- Recent data from Martin Scharf at the Cleveland Sleep Center
  - 5 insomniacs put into deep delta sleep in 10 minutes
- **Unprecedented in Martin's 40 years of sleep research!**
- **Stay Tuned!**

# Critical Success Factors for a Career in Biomedical Engineering

- Get a degree from an excellent institution with good grades if possible
- Find a mentor in your first job
  - Engineering is an apprenticeship!
- Stay abreast of new developments in the field
  - Attend seminars regularly in design, new technology, quality and regulatory
- Eventually you may want to move into a systems engineering role

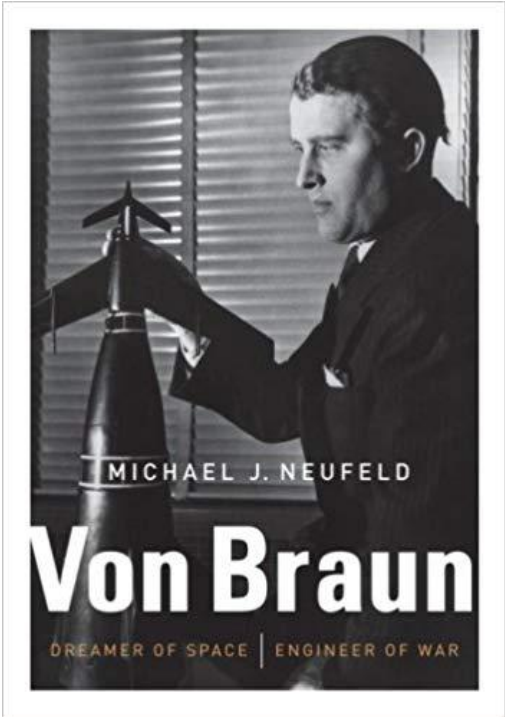
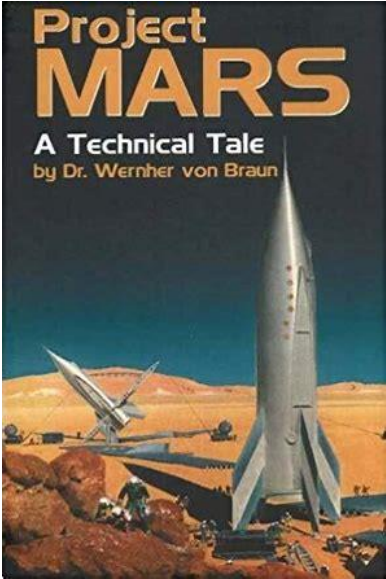
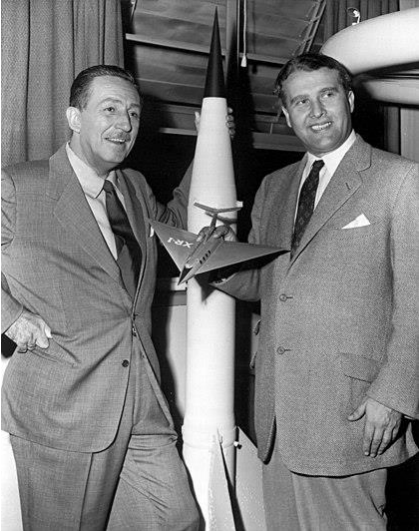


# Wait, There's More

A Few Thoughts On Systems Engineering and the Role of the Biomedical Engineer

# Reading in the 50th Year of Apollo 11

## He was the Ultimate Systems Engineer



**Von Braun was responsible for the Redstone, Jupiter and Saturn family of boosters**



His Redstone Booster got the first American satellite into orbit and also launched Alan Shepard into space. His Saturn rockets took us to the moon!



**Apollo 11 – 1969**  
5 first stage F1 engines  
producing over 7.5  
Million pounds of thrust  
lifting a 3.5-Million-pound  
vehicle!



## Why did Von Braun Succeed?

- Trained as a physicist
- Curiosity about all branches of science
- He developed the overall specification for a Booster System
- Created a list of all the necessary subsystems
- Created a master plan and organization chart of resources
- Master of motivating and driving engineers



Historical Note: Of all 32 Saturn vehicles launched (designed by Von Braun's Team at the Marshall Space Flight Center in Huntsville AL) NONE FAILED!

# Biomedical Engineers Make Great Systems Engineers

## The Biomedical Engineer:

- Has a unique knowledge of human morphology and physiology
- Provides the important link between engineering and biology
- Provides leadership from an engineering and a biological perspective
- Can be a very valuable leader on a complex biomedical device development program
  
- Note: An Engineer typically spends a fraction of his/her career doing design at the individual contributor level.