




DR. ROBOT

**JANE BAMBAUER
UNIVERSITY OF ARIZONA**

FDA REGULATION OF DEVICES


Premarket clinical trials or registration, and ongoing monitoring and assessment based on:

- Benefits
- Risks
- Uncertainty / Detectability of failure
- Firm history
- Patient tolerance and perspective
- Patient impact 

MOBILE MEDICAL APPS

Software application that is intended

- To be used as an accessory to a regulated medical device
- To transform a mobile platform into a regulated medical device




Intended to diagnose,
cure, mitigate, treat, or
prevent disease

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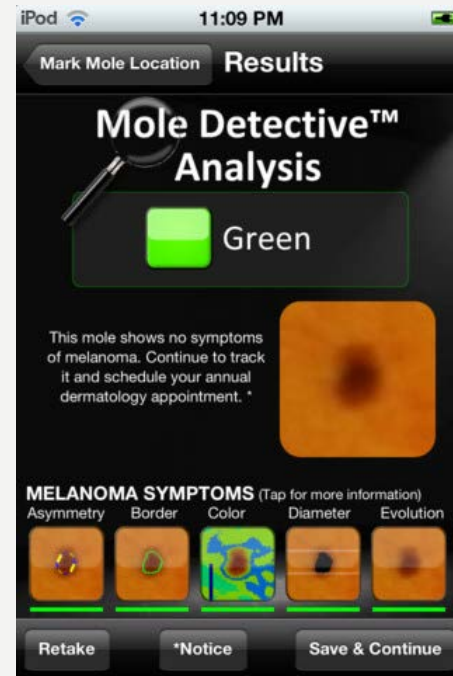
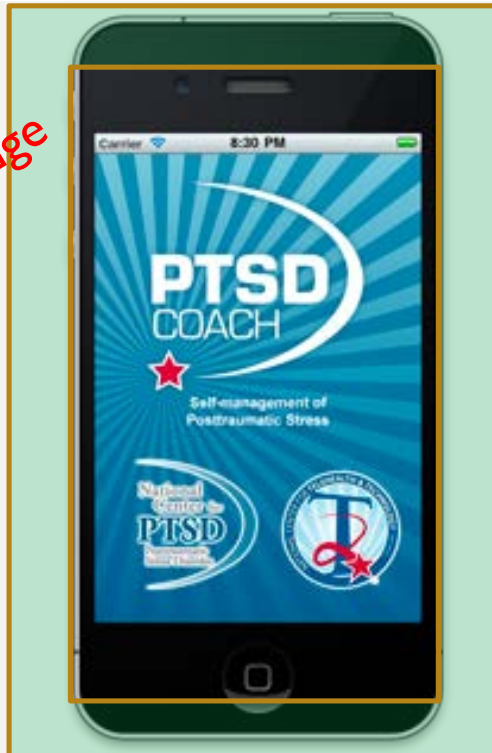


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Measurement



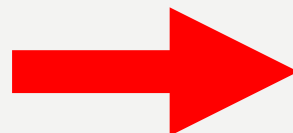
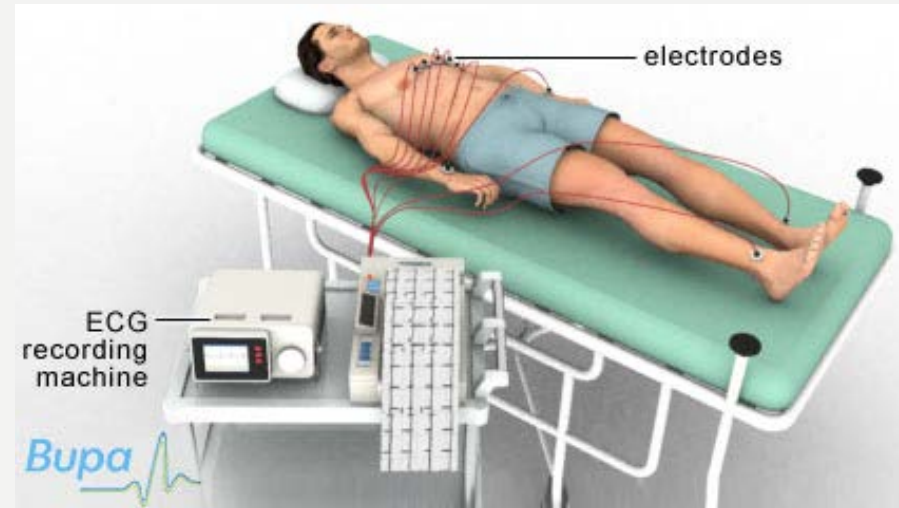
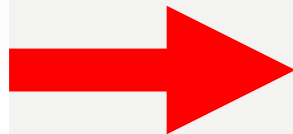
Knowledge



IBM Watson for Oncology

Get oncologists the assistance they need to make more informed treatment decisions. Watson for Oncology analyzes a patient's medical information against a vast array of data and expertise to provide evidence-based treatment options.

COMPARISONS AT THE MARGINS



OR



REGULATING AI LIKE PROFESSIONALS

- Competence < Pre-Market Licensing
Post-Market Malpractice Liability
- Conflicts of Interest
- Research and Informed Consent
- Confidentiality v. Duties to Warn

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POLITICAL ECONOMY PROBLEMS



Top Spenders

2017

Lobbying Client	Total
US Chamber of Commerce	\$82,190,000
National Assn of Realtors	\$54,530,861
Business Roundtable	\$27,380,000
Pharmaceutical Research & Manufacturers of America	\$25,847,500
Blue Cross/Blue Shield	\$24,330,306
American Hospital Assn	\$22,094,214



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85,000
50,000
30,000
40,000