“We don’t make the drug, we make the drug work better”: fact or fiction or too soon to tell?
Digiceutical?

• Whaaat?
Related terms

- Nutriceutical
- Functional Food
- Cosmeceutical
- Nutricosmetic

What they have in common:

- Some (regulatory) and validation “gaps” or, in the case of an academic enterprise...a lot of opportunity
Why did I pick this topic?

• You: Center for Drug Safety and Effectiveness
• Me: not a drug developer

• Several big relevant conferences clustering now
  – HIMSS this week
  – DataPalooza next month
  – DIA in June
Pharma Companies (branded and generic) have embraced digital tools

eg Heather Bell ex-AZ now Sanofi VP Strategy and Emerging Opportunities

• “I think that mobile health [the use of smartphones, tablets, and other mobile computing devices to record patient information] has the potential to be profoundly transformative for healthcare”

• "I believe it will usher in a realm of predictive medicine, complete with what we might call digital biomarkers and digital drugs."
Beyond the pill—collaborations between pharma and digital health

Top 20 app makers by number of apps--
Bayer, Merck, Novartis and Pfizer are leaders

Source: Pocket.md as of 12/2/2013
Two big categories

- General patient generated information

- Specific drug or disease-state information
Why?:

• Short term: facilitate clinical trials

• Medium term: drive compliance and stickiness in face of competition

• Theoretically: enhance patient engagement and improve drug effectiveness
Disruptive Innovations in Pharma trials 2014

Mobile Health 2.0: The Rise of Digiceuticals

The first wave of mobile health brought the platform capabilities of mobile health-oriented data collection to the consumer space. The next iteration will validate mobile data analytics, creating a “digital biome” where data collected from the patient’s pocket constitute digital biomarkers of disease.

A patient-centric philosophy which creates an engaging and inviting environment for the user combined with back-end data gathering can create an ecosystem where both patient and investigator benefit. Apps which are inherently useful to the user and driven by analytics validated in rigorous trial settings may garner uptake and reimbursement not unlike traditional pharmaceutics. This is Mobile Health 2.0, and the rise of Digiceuticals.
“Patient-centric drug development”

- Patient generated data before, during, and after trials
Non-traditional Companies Entering Healthcare

- Apple
- Google
- Microsoft
- IBM

- Nintendo
- Samsung
- Intel
- GE
- AT&T
- Ford
New players driving research tools

“Now everybody can do their part to advance medical research.
Medical researchers are doing some of the most important work in the world, and they’re committed to making life-changing discoveries that benefit us all. To help, we’ve created ResearchKit, an open source software framework that makes it easy for researchers and developers to create apps that could revolutionize medical studies, potentially transforming medicine forever.”
Moving beyond trial into more routine clinical (not recreational) use...

- 1000+ apps = mass confusion
- With the market for mobile health apps expected to grow at more than 26.7% per year until 2018, according Markets and Markets, the need for reliable information about these apps is increasing.
- void left by FDA
  - Happtique
  - IprescribeApps
  - IMS
  - UK National Health Service

There are physicians early adopters, especially as part of a chronic disease treatment paradigm

• “Much of what I do as a physician could be better done by either machines or patients themselves”
  • Dan Hoch, Neurologist, Mass Gen

• Fill in the dots between visits
User friendly interfaces, sensor technologies embedded in various devices: CONSUMER FOCUSED.
Compliance

• Most of the apps current designed by/for pharma are to improve health literacy and motivate patients to take their medications.

• According to CDC non-adherence to medications result in $290 billion in costs
  – WHO estimates that by 2020 the number of Americans affected by at least one chronic condition requiring medication will grow to 157 million
  – Medication prescriptions never filled: 20%-30%
  – Medication not continued as prescribed in about 50% of cases

Are Mobile Medical Apps Good for Health?

A new study by Research Now indicates that physicians and patients say ‘Yes’

- Study engaged 500 HCPs and 1,000 users
- Key findings:
  - 46% of HCPs say they will introduce mobile apps to their practice in next 5 years
  - 86% of HCPs believe that health apps will increase their knowledge about patients’ conditions
  - 96% of users think that health apps help to improve their quality of life
  - 72% of HCPs believe that health apps will encourage patients to take more responsibility for their health

Source: Research Now Group
Currently more “faith” than data….

Fortune: “Apple’s new platform will amplify a broad set of new opportunities we are calling “Digiceuticals” — where software, sensors and apps are standalone treatments for disease and integrated into comprehensive care plans alongside drugs and medical devices.”

Source:
Fortune, Mar 2015 Why Apple’s ResearchKit Signals Golden Age for HealthCare Zen Chu Maulik Majmudar
Stanford implements ResearchKit

- Within 24hr of implementing ResearchKit for a cardiac study at Stanford, 11,000 people had signed up
- Objective: is to study ways to encourage people to modify their behavior to improve heart health by utilizing the GPS and accelerometer on the phone to track activity; and to determine what type of coaching is most effective at improving fitness
# Active Task Modules in ResearchKit

<table>
<thead>
<tr>
<th>Category</th>
<th>Task</th>
<th>Sensor</th>
<th>Data Collected</th>
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<tbody>
<tr>
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<td>Correct and actual sequences</td>
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<td>Voice</td>
<td>Phonation</td>
<td>Microphone</td>
<td>Uncompressed audio</td>
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Big unresolved issues exist

• Data integrity, security, accessibility, integration...what is the real-time value of “big” data to the individual contributor?

• Digiceutical validation: both of functionality (feature claims) and benefit claims

• Interface safety
BASF

• In almost every brand awareness test,
• its 25-year-old North American commercial tagline –
• "We don't make a lot of the products you buy. We make a lot of the products you buy better" - ranks among the most recognized corporate slogans.
“We don’t make the drug, we make the drug work better”

My verdict:

• The jury is still out
  – Better and more efficient trials: probably
  – Better post market surveillance: probably
  – More effective drug use: possibly/too soon to tell
  – More effective management: possibly

• What is my take-away?
  – Not all digiceuticals are created equally
  – To be effective similar rigor needs to be applied as is applied to other components of therapy
  – The potential exists to “make the drug work better”
How to accomplish this came together for me last week when I met with Alain Labrique

- There are undoubtedly too many apps to curate
- The focus on getting them reimbursed is slow, tedious and has limited yield to date
- But we see the promise
- definitely need “prescription-strength” apps
  = structural integrity
  + analytical integrity
  + clinical validity
What is “Prescription-Strength”? 

“Prescription-Strength” App Development follows an analogous process to drug development.
From this perspective....

• Digiceutical development should not wait until (after) drug launch
• Patient-generated data can indeed generate clinically-relevant digital biomarkers of disease or wellness state
• Physicians may prescribe them and in so doing take (some) responsibility for monitoring the patient outcome (“Rx-strength” vs. OTC)
• The system will need to accommodate “more continuous patient management” which clearly makes physiological sense.