Pinney Associates

• Science drives all of our work at Pinney Associates as we help our clients navigate complex regulatory issues and protect public health

• We pride ourselves on being an agile, responsive partner

• A team of 30 scientists, policy experts, researchers, statisticians/data managers and support staff

• We help our pharmaceutical and consumer healthcare clients to reduce their regulatory risk and enhance the commercial value and public health impact of their life sciences products
“We always overestimate the change that will occur in the next two years and underestimate the change that will occur in the next ten. Don't let yourself be lulled into inaction.”

-- Bill Gates
23-Jun-2008
Consumers’ Thirst for mHealth Apps

• Two-thirds (66%) of Americans would use a mobile app to manage health-related issues*

• Top interests:
  • Tracking diet/nutrition (47%)
  • Medication reminders (46%)
  • Tracking symptoms (45%)
  • Tracking physical activity (44%)

• 229,000 mHealth apps currently available**

* Research 2 Guidance’s mHealth App Developer Economics 2016
• Not all apps are regulated
  o Educational tools
  o Generic aids, general purpose products
• FDA uses discretion when regulating, e.g.:
  o Self-management of disease or conditions via specific treatment suggestions
  o Location-based apps (e.g., GPS location for asthma triggers)
  o Tracking of symptoms, medication usage and adherence
• FDA does intend to regulate apps that:
  o Control medical devices (e.g., insulin pumps)
  o Use display screens that reproduce medical device data (e.g., ECG signals)
  o Do dose calculation or “sophisticated analysis” of patient data to produce treatment recommendations
• Many apps have received 510(k) approval: 43+ as of Jan 2017
• Also, NSURE would (if ever?)
  o “Address the undertreatment of common diseases or conditions by allowing prescription drug products to be available as non prescription through the use of new technologies or other conditions of safe use”
mHealth: Value to Pharma

✓ Increase brand awareness
✓ Increase odds of product trial
✓ Increase rates of re-purchase
✓ Enhance effectiveness
• Enable switching of products that might otherwise struggle to meet self-selection or actual use study endpoints
• Enable management, habit formation, and better outcomes for chronic diseases, requiring extended, even lifetime use of products
  - Hypertension
  - Obesity
  - Hypercholesterolemia
  - BPH
  - Osteoporosis
OTC Hypertension Survey

- N = 155 concerned they might have high blood pressure
  - Mean age = 39
    - 48% male, 85% Caucasian
  - 79% concerned because of a family history of high BP

- How would mHealth app availability affect:
  - Willingness to try OTC BP med?
  - Willingness to pay more for an OTC BP med?
Willingness to try OTC BP med?

- More likely to try: 70%
- Neither more nor less likely to try: 17%
- Less likely to try: 12%

Willingness to pay more for an OTC BP med?

- Wouldn’t pay more: 49%
- +$2/month more: 25%
- +$4/month more: 4%
- +$8/month more: 18%
- +$16/month more: 4%
“We’ve gotten into the health arena and we started looking at wellness... if you don’t care about reimbursement, which we have the privilege of doing, that may even make the smartphone market look small.”

-- Tim Cook, CEO
Apple, Inc.
8-Aug-2016
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