REGULATORY EXPERIMENTATION AT THE FDA

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Why Apple Dumbs Down Your Smartphone

Scott Gottlieb  Contributor  Pharma & Healthcare

As Apple advances the medical promise of its watch and smartphones, it has also made clear that its foremost aim is to steer clear of Food and Drug Administration regulation. Many assert that this imperative has rendered the health features in its sensor-laden watch underwhelming. Apple didn’t want to cross the lines that would class its new watch as a “medical device” in the eyes of regulators.

Why Your Phone Isn’t as Smart as It Could Be

Silicon Valley is eager to produce health-related apps, but fear of FDA regulation is slowing innovation.

By Scott Gottlieb And Coleen Klasmeier
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There’s growing frustration among entrepreneurs in Silicon Valley who are finding that the road to improving medical technology ends not in Palo Alto but in White Oak, Md.—at the headquarters of the Food and Drug Administration. “Health is just so heavily regulated,” Google co-founder Sergey Brin complained last month to a group of high-tech CEOs, “it’s just a painful business to be in.”

The pain has become especially acute in the burgeoning field of mobile medical apps and health-care “wearables.” Apple is reportedly making a health-information platform a key component of its next iPhone operating system—which is expected to be in the new iPhone it will unveil next month. Other handset makers are following similar paths. But these smartphones will be purposely dumbed down, according to early reports on their features, in order to manage the uncertain risk of unwieldy FDA regulation.
IT'S NOT INNOVATIVE IF IT DOESN'T WORK.
THREE EXPERIMENTS IN MEDICAL PRODUCT REGULATION

1. Pre-market to post-market
2. Product to firm
3. Government to third-party
THE FDA’S PHILOSOPHY (SO FAR)

- Risk-based stratification
- Human intervention?
- Pre or post? (Why not both?)
- Focus on firm, not product
- Clinical relevance & validity?
- Transparency & audit-ability?
AI software that helps doctors diagnose like specialists is approved by FDA

“It makes the clinical decision on its own”

By Angela Chen | @chengela | Apr 11, 2018, 1:25pm EDT

For the first time, the US Food and Drug Administration has approved an artificial intelligence diagnostic device that doesn't need a specialized doctor to interpret the results. The software program, called IDx-DR, can detect a form of eye disease by looking at photos of the retina.
USING AI TO HELP STROKE VICTIMS WHEN 'TIME IS BRAIN'
First FDA Approval For Clinical Cloud-Based Deep Learning In Healthcare

Bernard Marr, CONTRIBUTOR

I write about big data, analytics and enterprise performance  FULL BIO

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The first FDA approval for a machine learning application to be used in a clinical setting is a big step forward for AI and machine learning in healthcare and industry as a whole.
Dermatologist-level classification of skin cancer with deep neural networks

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FDA FACT SHEET

CDRH’S APPROACH TO TUMOR PROFILING NEXT GENERATION SEQUENCING TESTS

The Food and Drug Administration (FDA) has recently announced the marketing authorization of three tumor profiling next generation sequencing (NGS) tests, Thermo Fisher Scientific’s Oncomine Dx Target Test, MSK-IMPACT and Foundation Medicine’s FoundationOne CDx which are important advancements in the real-world application of precision oncology. The approach taken to the regulation of these tumor profiling NGS tests includes several key features described below.

Three-Tiered Approach for Reporting Biomarkers in Tumor Profiling NGS Tests

FDA is committed to and works individually with test developers to use the least burdensome approach for its review of tests. Multiplexed tumor profiling tests assess many biomarkers that may have a range of clinical evidence associated with them that is constantly changing as new science emerges. Below, we discuss the three levels of biomarkers addressed collectively in the Oncomine Dx Target Test, MSK-IMPACT, and FoundationOne CDx authorizations, as well as the analytical and clinical evidence used to support claims for those biomarkers.

Level 1: Companion Diagnostics

Companion diagnostics (CDx) are test that provide information that is essential for the safe and effective use of a corresponding therapeutic product, such as a drug. Tumor profiling NGS tests may include CDx claims that are prescriptive for a specific therapeutic product, such as the Table 1 claims listed in the intended use for the Oncomine Dx Target Test and FoundationOne CDx. Such claims are supported by analytical validity of the test for each specific biomarker and a clinical study establishing either the link between the result of that test and patient outcomes or clinical concordance to a previously approved CDx.
counterfactual: development without fda oversight?
Up to 40 percent of DNA results from consumer genetic tests might be bogus

A new study has found that direct-to-consumer genetic tests, like those marketed by 23andMe, Ancestry.com, Family Tree DNA, and MyHeritage, can be used to obtain inaccurate results.

**Data dump:** Most of these tests use a technique called genotyping to provide information about a person's ancestry, risk of developing certain disorders, or status as a carrier of specific diseases. Some companies also make the raw genotyping data available to customers upon request. People can then take that data to third-party companies to interpret for a fee.

**Lost in interpretation:** Scientists at Ambry Genetics, a diagnostics company that also interprets data from consumer DNA tests, looked at this raw genotyping data from 49 people. They found that 40 percent of the variants noted in the raw data were false positives— that is, they indicated that a particular genetic variant was present when it wasn’t. Most of the false-positive calls were of cancer-linked genes. In eight instances, third-party interpretation services misunderstood the variants present.

**Buyer beware:** Unlike clinical genetic tests that require a physician’s sign-off, direct-to-consumer tests are not meant to provide a diagnosis, and they offer risk information for only a limited number of conditions. If a consumer DNA kit uncovers a surprising or noteworthy genetic variant, the authors advise people to seek out doctor-ordered genetic tests to confirm the results.
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