The Need for Dynamic Governance of Algorithm-Based Technologies

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The Problem

- Previous Products
  - Products tended to be simple mechanical, chemical or biological constructs
  - Products were static – product was not modified after regulatory approval
  - Approved product “locked down”
- Today’s Products
  - Often involve digital algorithms
  - Products are dynamic – algorithms constantly being updated
  - Approved product subject to constant modifications

Molecular Diagnostics: Paradigm Shift

- Existing paradigm:
  - Static, single-analyte tests
    - e.g., glucose test
  - Regulatory model: one time pre-market review or clearance
- New paradigm:
  - Complex test measuring dozens or hundreds of analytes; integrated output from constantly evolving algorithm
    - e.g., immunosignature profiling on peptide/protein arrays
    - multiplex nucleic acid profiling (eg. oncology, infectious disease, pharmacogenetics)
    - next-generation sequencing panels for whole exome and whole genome analysis plus epigenetic profiling
  - Regulatory model: ?

HealthTell™

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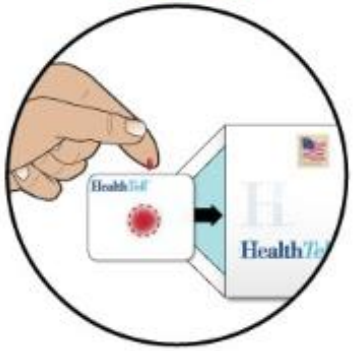

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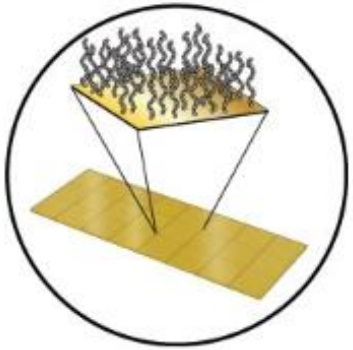

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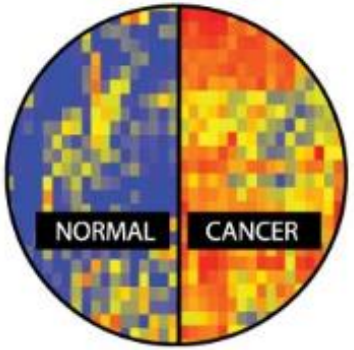

HealthTell News

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#healthtell

HealthTell @HealthTell 18 Feb
@privatedoctors #HealthTell is coming to The Big Easy! Stop by our booth Feb. 21st-22nd to learn more! #AAPP #NOLA
pic.twitter.com/Z9aho8vGIE

Expand

HealthTell - OneTest™

HealthTell is an early stage start-up company that is developing powerful new tools to help individuals monitor their health status. This technology has already been demonstrated to work for over 30 diverse illnesses, ranging from cancer to infectious disease. The test is simple and inexpensive, and can be performed with only a single drop of blood.

One of the largest challenges in modern medicine is the ability to detect the presence of disease much earlier, before it spreads or becomes difficult to treat. Unfortunately, this generally requires complex, expensive monitoring systems capable of detecting small numbers of cancer cells, viruses, or other pathogens in the bloodstream.

HealthTell has taken a radically different approach to solving this problem. Instead of trying to measure the pathogen directly, we are measuring the body's unique response (it's "immunosignature") to a given disease or disease state. By understanding what each immunosignature means and how it changes over time, we can provide a broad menu of highly accurate tests that are capable of detecting diseases much earlier and less invasively than is

FDA's Policies on Modifications to Approved Medical Devices

- Manufacturer must submit a supplemental application unless it can determine that the modification will not affect the device's safety or effectiveness
- Since health care providers cannot evaluate the effect of modifications to proprietary algorithms, FDA is only check on safety and effectiveness of modified product
- Presents a problem for products being changed on a regular basis

Potential Precedent: Whole Genome Sequencing(WGS)/ Next Generation Sequencing (NGS) :

Desired Features of a Regulatory Framework

- Accommodate multiple test configurations on a single instrument.
  - Variations in library, informatics, etc. depending on use and what is being detected (e.g., CNVs, SNVs)
  - Users can select the right configuration if they have proper controls in place.
- Enable improvements by incorporating the ability to easily modify a test
  - Users can modify if they have proper controls in place
- Recognize that evidence supporting the clinical relevance of results will come from the community, not from the test developer.
  - Need to take advantage of high quality sources of evidence and community efforts
- Enable physicians and patients to access and understand genomic test results to advance clinical decision-making
- FDA oversight to ensure analytical and clinical performance

Summary

- NGS tests are unique among existing IVDs because of -
  - the amount of data that can be generated
  - the lack of an a priori definition of what will be detected
  - the number of clinical interpretations that can be made from a single patient sample
- Multiple options under consideration (need efficiency to allow innovation while protecting patients) -
  - computational solutions and standards-based approach to analytical performance of NGS tests
  - mechanisms to assure those standards are met
  - use of centralized curated databases containing up-to-date evidence to support clinical performance
- Public meeting on February 20, 2015 - for FDA to gather information to craft a specific proposal for the regulation of NGS
- Public docket for feedback - Docket FDA-2014-N-2214, open through March 20, 2015
  http://www.regulations.gov/#!docketDetail;rpp=100;so=DESC;sb=docId;po=0;D=FDA-2014-N-2214

Many Other Algorithm Examples

- Motor vehicles/engine control modules
- Autonomous cars
- Aircraft software programs
- Medical software
- mHealth devices
- Search engines
- Insurance rating
- Data collection/Web tracking
- Securities market algorithms?
- Market concerns
- Banking/Lending

Conclusion

- Will need a new regulatory paradigm in this age of algorithms
- Shift regulatory model from one time pre-market approval to a more dynamic ongoing surveillance that involves notification and monitoring of real-world impacts
- Challenges:
  - Transparency
  - Regulators' competency
  - Trust (Volkswagen!)