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Regulation of Consumer Genomics

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Agenda

1. Defining “Regulation”
   i. Activities for Regulation
   ii. Sources of Regulation
   iii. Purpose of Regulation
2. Evolution of Genomic Testing Regulation

Regulation of Consumer Genomics

Regulation of What?

- Laboratory performing testing
- Sale of testing services
- Claims about testing
- Test ordering
- Software used to interpret NGS data

Regulation by Whom?

- Federal agencies
  - CMS
  - FDA
  - FTC
- States
- Professional organizations
- Courts
- Payors

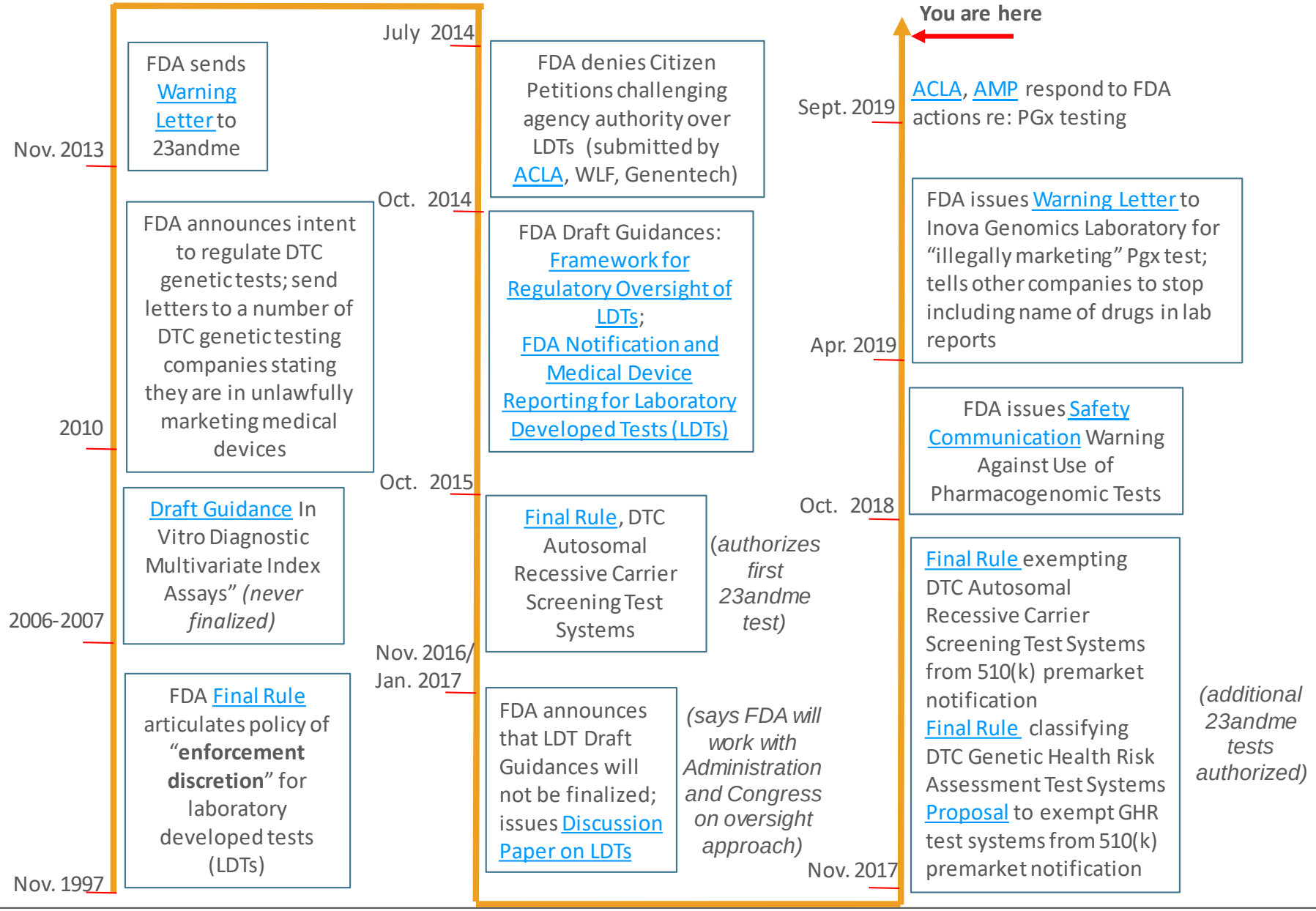
Regulation for What Purpose?

- Analytical validity
- Clinical validity
- Clinical utility
- Comprehensibility of information
- Access to information
- Protection/promotion of public health

Regulation of Consumer Genomics

Regulation of what	Regulation by whom	Scope of regulatory authority
Laboratory performing testing	CMS (pursuant to Clinical Laboratory Improvement Amendments (CLIA)	Quality of personnel and facilities operation; analytical validity
	New York State Clinical Laboratory Evaluation Program (CLEP)	Laboratories operating in or testing specimens from NYS; quality of personnel and facilities; analytical validity; clinical validity (for LDTs)
	College of American Pathologists (CAP)	Third-party accreditation body (voluntary)
Commercially distributed laboratory tools (instruments, reagents, etc.)	FDA (pursuant to medical device authority under the Federal Food Drug & Cosmetic Act)	Safety and effectiveness for intended use Specific oversight requirements depend on manufacturer claims/level of risk
"Laboratory Developed Tests"	[CLIA, NYS, CAP – per above] *FDA?*	*"Enforcement discretion" for most LDTs* *Episodic statements, warning letters, untitled letters*
Advertising claims	Federal Trade Commission (FTC Act and similar state laws)	prohibits unfair trade practices, including false/misleading advertising

FDA Oversight of LDTs (abridged)



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Recent Developments: PGx testing

Date	Action	Summary
Oct. 31, 2018	FDA issues Safety Communication Warning Against Use of PGx Tests	Warns HCPs that *"for most medications, the relationship between DNA variations and the medication's effects has not been established."* Advises HCPs to *"seek information in the FDA-approved drug label regarding whether genetic information should be used for determining therapeutic treatment"* Warns patients that *"most genetic tests that make claims about the effects of a specific medicine are not supported by enough scientific information or clinical evidence."* Recommends that test developers/manufacturers assure that *"test report and any labeling support an intended use that is consistent with the FDA-approved use of the medication"* ** Applies to PGx tests whether physician ordered to accessed by consumers directly* *** Safety Communication and subsequent communications by FDA do not acknowledge CPIC/PharmGKB as providing valid information re: relationship between genetic variations and drug response*
Apr. 4, 2019	FDA issues Warning Letter to Inova Genomics Laboratory	Alleges that MediMap genetic test lacks clinical validity: *"we are unaware of data establishing the relationships between the genotypes assessed by your tests and your assertions regarding drug response for multiple drugs."* Asserts that tests *"pose significant public health concerns as inaccurate test results could impact the decision-making of healthcare providers and patients in ways that are seriously detrimental to patient health.*
2019	FDA contacts various entities offering PGx testing	*"Following issuance of the safety communication, FDA reached out to several firms marketing pharmacogenetic tests with claims to predict how a person will respond to specific medications in cases where the relationship between genetic (DNA) variations and the medication's effects has not been established. Most firms addressed the FDA's concerns by removing specific medication names from their labeling, including promotional material and patient test reports." (FDA website)*
Sept. 2019	ACLA submits letter to FDA; AMP issues statement on "best practices" for PGx testing	ACLA Letter: FDA's actions will take away actionable information relied on by HCPs to make informed prescribing decisions, which will adversely affect patient care and increase medical costs. FDA's actions undermine progress in developing comprehensive legislative solution and amount to inappropriate "back door" regulation of LDTs. AMP Statement: Encourages the use of CPIC gene-drug practice guidelines. States that clinically meaningful PGx tests can improve patient care and professional practice, provided certain conditions are met. Proposes best practices for clinical PGx testing.

Conclusion

- Regulation of genomic testing is not “one-stop shopping”
    - Delivery of genomic testing comprises a number of different activities that are or could be regulated
    - Different regulatory bodies are responsible or potentially responsible for these activities
- Jurisdiction over some activities remains unclear, while there has been a lack of coherent or consistent regulatory framework with respect to others
- As amount of genomic information available to physicians and patients continues to increase, it is increasingly important to develop consensus regarding the key objectives of regulation and the entities that are best placed to develop and implement policies to achieve these objectives. All stakeholders would benefit from clarity and consistency in the application of regulatory requirements