



cap

A Genomic Medicine Policy Framework

The College of American Pathologists
Debra G.B. Leonard, MD, PhD, FCAP

NHGRI Genomic Medicine V
May 28, 2013

Pathology and Genomic Medicine

- **CAP multi-year strategic planning process concluded**
 - Genomics essential to future of pathology
 - Pathologists key for cancer genomics
 - Tissue selection, integration with histopath & other pathology test results
- **CAP genomic medicine initiatives**
 - Genomics education for pathologists
 - Accreditation standards for NGS
 - Proficiency testing program for NGS

CAP Genomic Medicine Advocacy

- Many requests to CAP from Congress and federal/regulatory agencies for comments on genomic medicine issues/policies/bills
- No framework for responses
- Reactive, not proactive, approach to genomic medicine advocacy
- In 2012, initiated development of a genomic medicine policy framework to guide responses & move to proactive advocacy

Genomics Medicine Policy Framework Development Process

- Collaboration between
 - Council on Government & Professional Affairs (CGPA)
 - Personalized Healthcare Committee (PHC)
- Identified major issue categories*
- Divided writing by issue, covering topics:
 - Background of issue
 - Work by CAP and others to date
 - Needs
 - Recommendations
- Unified sections into coherent document*

* Approval by both committees (final in Jan 2013)

CGPA-PHC Work Group Members

- Debra G.B. Leonard, MD, PhD, FACP (Chair)
- W. Stephen Black-Schaffer, MD, FCAP
- Alexis Byrne Carter, MD, FCAP
- James Crawford, MD, FCAP
- Jeffrey A. Kant, MD, PhD, FCAP
- Jan Anthony Nowak, MD, PhD, FCAP
- John David Pfeifer, MD, PhD, FCAP
- Karl V. Voelkerding, MD, FCAP
- Louis D. Wright Jr., MD, FCAP
- Michael Misialek, MD, FCAP
- Fay Shamanski, PhD, CAP Staff

CAP Genomic Medicine Policy Framework White Paper

- Introduction
- Overview of issues
- Principle Statement:
Pathologists in Genomic Medicine
- 12 Issues
 - Background
 - Needs
 - Work to date
 - Recommendations
- Summary of recommendations

Genomic Medicine Issues (1)

- 1. Pathologists' Visibility in Genomic Medicine**
- 2. Infrastructure and Resource Needs**
- 3. Impact of Patents and Exclusive Licensing**
- 4. Interoperability and Other Health Information Technology (HIT) Issues**

Genomic Medicine Issues (2)

5. Federal Regulatory Oversight of Genomic Testing
6. Pathologists as Patient Consultants for Genomic Medicine
7. Payment for Genomic Testing, Interpretations and Consultations
8. Privacy, Ethical, Legal and Social Issues for Genomic Medicine

Genomic Medicine Issues (3)

9. Population and Public Health Genomics, Genomic Epidemiology and Clinical Outcomes Analysis
10. Genomics Education and Training for Pathologists
11. Education of Healthcare Providers and Patients on Role of Pathologists in Genomic Medicine
12. Coordinated Care Models and Genomic Medicine

CAP Genomic Medicine Policy Framework 2013

Provides a global perspective for the role of pathologists in genomic medicine

Discusses issues affecting incorporation of genomic testing into pathology practices

Makes recommendations to guide genomic medicine advocacy efforts for pathologists

Moving Forward

- Developing advocacy approaches to key issues
- Planning annual review of Policy Framework

Genomic Medicine Issues Overview

1. Pathologists' Visibility in Genomic Medicine
2. Infrastructure and Resource Needs
3. Impact of Patents and Exclusive Licensing
4. Interoperability and Other HIT Issues
5. Federal Regulatory Oversight of Genomic Testing
6. Pathologists as Patient Consultants for Genomic Medicine
7. Payment for Genomic Testing, Interpretations & Consultations
8. Privacy, Ethical, Legal and Social Issues
9. Population and Public Health Genomics, Genomic Epidemiology and Clinical Outcomes Analysis
10. Genomics Education and Training for Pathologists
11. Education of Healthcare Providers and Patients on Role of Pathologists in Genomic Medicine
12. Coordinated Care Models & Genomic Medicine



cap