Reaping the Full Health Benefits of the Human Genome: The Duty to Warn and The Need to Establish a Comprehensive Federal Regulatory Structure for Genetic Testing

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FDA should be responsible for review, approval and labeling of genetic tests.

American Academy of Pediatrics Genetic Counselor (2)

Genetic Counselor (should expand dept that CLIA resides in, currently working on issues)

American College of Medical Genetics (tests have significant impact practice of medicine components that would be exempt from FDA oversight, worried
| Importance of Informed Consent | American Academy of Pediatrics  
Genetic Counselor  
Genetic Counselor (thinks should be for all, not just predictive)  
Oncology Nursing Society (supports standardization of content of informed consent documents, suggests issues to consider)  
National Society of Genetic Counselors (genetic tests requiring high oversight should require written informed consent; genetic test inserts should contain basic stipulations, such as imp of patient communication of tests results to family members and info on how to locate genetics professional)  
American Association of Clinical Chemistry (before predictive tests; labs should be able keep specimen for clinical research if patient identifiers removed, no consent required when using archived, anonymous samples)  
Consumers, Genetic Alliance (patient/advocacy group – written informed consent should be required for all genetic tests)  
Hypertrophic Cardiomyopathy Assoc. (patient advocacy group thinks penalties should be imposed for incomplete or inadequate consumer info)  
College of American Pathologists – written informed consent should be obtained for tests for predictive purposes, but should be reviewed disease-by-disease basis, consider medical necessity and admin burden, should be promulgated through consortium including lab reps)  
Rowley (MD Academic) – good that informed consent SHOULD be vs Required to be obtained so as not to deter practitioners; use “informed choice” rather than “informed consent” – benefits and risks!  
Certified Genetic Counselor (Palmer – replace word should with MUST for informed consent, also informed consent for other predictive tests)  
Orchid Biosciences – thinks once pharmacogenetic test accepted in clinical practice, no need for informed consent  
Public member – not as much consent for those don’t reveal inherited genetic info  
Association for Molecular Pathology (not all tests need informed consent – esp if only one component of diagnostic evaluation; if informed consent required, lab shouldn’t be responsible)  
Academic (Stephen Cederbaum): concerned w/requirement of informed consent for predictive testing – DNA tests aren’t different from other predictive tests |
| Against Genetic Exceptionalism | **Industry** (believes that existing CLIA regs should be enhanced to provide adequate quality for all medical tests) – e.g. Orchid, BIO (con two-tiered reg system), Genzyme Genetics, Affymetrix Consumers, Genetic Alliance (patient/advocacy group) | **College of American Pathologists** (against genetics specialty under CLIA, thinks existing regs re: highly complex clinical lab tests enough) |
| Pro Improving CLIA regulations for genetic testing | **American College of Medical Genetics**  
**American Association of Clinical Chemistry**  
**BIO** (pro enhancing existing regulatory schemes like CLIA rather than creating new one)  
**Holtzman – Academic**  
**MD, MPH** (in applying for CLIA certification, labs should indicate tests are developing, recently developed and HCFA should pass info to FDA)  
**Athena Diagnostics, Affymetrix** (enhance so appropriate level of quality ensured for ALL medical tests) |
| Pro Distinction btw Predictive vs Diagnostic Genetic Tests (less reg for latter) | Exact Lab (request narrowing defining nomination of genetic test to reflect different concerns, not impede diagnostics) |

| Re: Who Develop Guidelines for Genetic Research and Testing | American Association of Clinical Chemistry (include professional societies) |