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**Analysis of Public Comments on the
SACGHS Genetic Testing Oversight Draft Report**

Introduction

The Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) on November 5, 2007 released a draft report, “U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS.” The report details the current state of genetic testing oversight, concludes that current oversight has failed to ensure public health and recommends specific ways of improving the system. SACGHS invited the public to comment on the draft through December 21, 2007. Sixty-four comments were received from professional/trade organizations, government agencies, corporations, academicians, patient advocates, payors associations, and individuals.

The Genetics and Public Policy Center examined the comments, including content and context. This report provides an overview of the topics most commonly addressed in these comments.

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Comment Overview

Sixty-four comments were received from 62 distinct individuals/organizations, including 25 professional organizations, 10 government agencies, nine corporations, five academicians, five health professionals, three payor associations, three patient advocacy organizations, and two individuals.

Comment #	Submission	Organization	Genetic Test Registry	Subspecialty	FDA Oversight	Regulated Analytes	Genetic Exceptionalism	Defining Genetic Test	Financial Concerns	Direct-to-Consumer Tests	Evidence Evaluations	Communication Concerns	Other
1	The Queen's Genetics Laboratories	health professional		X									
2	Leininger, Anna, MS, CGC	health professional											X
3	Heller, Karen, MS, CGC	health professional							X				
4	American Clinical Laboratory Association	professional/trade	X		X								
5	International Society of Nurses in Genetics	professional/trade						X		X			
6	College of American Pathologists	professional/trade			X		X		X				
7	American Proficiency Institute	professional/trade				X							
8	NIDDK	government agency											X
9	HRSA & ACHDGDNC	government agency							X				
10	NCI	government agency											X
11	Stanley, Donald E., MD	health professional								X			
12	American Association for Clinical Chemistry	professional/trade	X		X	X			X	X	X		
13	NCI	government agency									X		
14	American Nurses Association	professional/trade	X			X				X	X	X	
15	International Society of Nurses in Genetics	professional/trade	X			X				X	X	X	
16	CMS	government agency	X					X					
17	American Association of Clinical Endocrinologists	professional/trade					X		X			X	
18	World Privacy Forum	patient advocate								X			
19	Affymetrix	industry		X					X	X			
20	European Molecular Genetics Quality Network	professional/trade											X
21	FDA	government agency											X
22	NIH	government agency	X	X					X				
23	Pfizer	industry	X		X			X	X		X		
24	ParagonDx	industry											X
25	Genzyme	industry	X		X		X		X	X	X		
26	American Society for Clinical Pathology	professional/trade						X					
27	AHRQ	government agency									X	X	
28	Center for Public Health and Community Genomics	academician						X		X	X		

Comment #	Submission	Organization	Genetic Test Registry	Subspecialty	FDA Oversight	Regulated Analytes	Genetic Exceptionalism	Defining Genetic Test	Financial Concerns	Direct-to-Consumer Tests	Evidence Evaluations	Communication Concerns	Other
29	PHG Foundation (UK)	professional/trade					X	X					
30	American Society of Human Genetics	professional/trade									X		
31	Cooley, James & Judy Devore, RN, PhD	individual							X				
32	American Clinical Laboratory Association	professional/trade	X				X						
33	Helicos BioSciences Corporation	industry								X			
34	Genetics and Public Policy Center	academician	X	X	X	X				X			
35	National Business Group on Health	payor							X	X	X		
36	American Medical Association	professional/trade	X							X	X	X	
37	College of American Pathologists	professional/trade	X		X		X		X		X	X	
38	ACHDGDNC	government agency					X	X					
39	NSGC & American Board of Genetic Counseling	professional/trade	X									X	
40	Roche Diagnostics Corporation & F. Hoffmann-La Roche AG	industry	X		X								
41	Personalized Medicine Coalition	professional/trade		X					X	X	X	X	
42	Benkendorf, Judith, MS, CGC	health professional						X			X		
43	Blue Cross and Blue Shield Association	payor		X	X					X	X		
44	Association for Molecular Pathology	professional/trade	X			X	X	X				X	
45	American Dietetic Association	professional/trade	X							X		X	
46	Biotechnology Industry Organization	professional/trade	X		X								
47	America's Health Insurance Plans	payor							X			X	
48	American Society of Clinical Oncology	professional/trade	X	X	X					X			
49	AdvaMed	professional/trade	X		X								
50	Coalition for 21st Century Medicine	professional/trade	X		X	X			X	X	X		
51	American Heart Association	professional/trade	X		X					X			
52	H. Lee Moffitt Cancer Center	academician						X	X				
53	Association of Pathology Chairs	professional/trade	X	X		X	X	X					
54	American College of Medical Genetics	professional/trade		X	X		X		X		X	X	
55	AstraZeneca	industry									X		
56	Public Citizen's Health Research Group & Neil A Holtzman	patient advocate	X	X	X								
57	DNA Direct	industry							X	X			
58	Genetic Alliance	patient advocate	X	X	X	X							
59	FDA Division of Personalized Nutrition and Medicine	government agency											X
60	Charache, Patricia, MD	academician											X
61	Merck	industry										X	
62	Dorsey, Ray, MD, MBA	academician											X
63	Liss, Polly	individual											X
64	Clinical Laboratory Standards Institute	professional/trade											X

Genetic Test Registry

Broad support for a test registry for genetic tests was apparent, with 21 comments in favor and none opposing. Fifteen organizations urged that the registry be mandatory, while four supported a voluntary registry. Those advocating a mandatory registry included pharmaceutical and genetic testing companies as well as patient advocates and professional/trade organizations. One pharmaceutical company and three pathology professional/trade organizations advocated for a voluntary registry. Two comments also suggested that the registry be evaluated in fewer than five years.

While the SACGHS draft suggested housing the registry at GeneTests, several organizations urged that the registry be housed and managed by a federal regulatory body. Six comments referenced FDA as a potential host, while four comments from pathology and clinical laboratory professional/trade organizations supported CMS. One patient advocacy organization suggested either FDA or NIH. There were several comments that suggested a registry outside of CMS would duplicate CMS efforts. However, in its comments, CMS said that it does not collect test-specific data.

Comment #	Submission	Organization	Support	Mandatory	Voluntary	at FDA	at CMS
34	Genetics and Public Policy Center	academician	X	X		X	
22	NIH (NHLBI, NIMH, NINDS, NCRR, NIAAA, NHGRI)	government agency	X	X			
25	Genzyme	industry	X	X			
23	Pfizer	industry	X		X		
40	Roche Diagnostics Corporation & F. Hoffmann-La Roche AG	industry	X	X			
58	Genetic Alliance	patient advocate	X	X		X	
56	Public Citizen's Health Research Group & Neil A Holtzman	patient advocate	X	X		X	
49	AdvaMed	professional/trade	X	X		X	
12	American Association for Clinical Chemistry	professional/trade					X
4	American Clinical Laboratory Association	professional/trade					X
32	American Clinical Laboratory Association	professional/trade	X	X			X
45	American Dietetic Association	professional/trade	X				
51	American Heart Association	professional/trade	X	X		X	
36	American Medical Association	professional/trade	X	X			
14	American Nurses Association	professional/trade	X	X			
48	American Society of Clinical Oncology	professional/trade	X	X			
44	Association for Molecular Pathology	professional/trade	X		X		X
53	Association of Pathology Chairs	professional/trade	X		X		X
46	Biotechnology Industry Organization	professional/trade	X			X	
50	Coalition for 21st Century Medicine	professional/trade	X	X			
37	College of American Pathologists	professional/trade	X		X		X
15	International Society of Nurses in Genetics	professional/trade	X	X			
39	NSGC & American Board of Genetic Counseling	professional/trade	X	X			

Selected Comments on Genetic Test Registry

"This voluntary system will not be sufficient... ISONG asks the Committee to reconsider this recommendation and institute a mandatory system to assure that all stakeholders are held to the same standards" – International Society of Nurses in Genetics (Comment #15)

"Maximum education potential and optimal participation will be achieved only if all 'covered' tests are required to be listed in a mandatory registry" – Genzyme (Comment #25)

"We believe that the assessment of the success of a voluntary system of genetic test registration may be made within three years, rather than five" – Pfizer (Comment #23)

"We also believe that the registry should be housed at and managed by a federal regulatory body, such as the FDA, to maintain its credibility and independence" – Biotechnology Industry Organization (Comment #46)

"AMP is concerned that creation of a voluntary registry would be a duplicative effort as CMS is already provided this information" – Association for Molecular Pathologists (Comment #44)

"CMS doesn't collect test specific data. The task would be physically impossible to maintain for 200,000 labs! However, CMS is happy to work with GeneTests to cross reference to their database for GT" – CMS (Comment #16)

Genetics Subspecialty under CLIA

Eleven comments referred to CMS's decision not to develop a genetics subspecialty; only one of the comments supported CMS' decision. Disapproval of CMS's decision was evident in the remaining comments by patient advocates, and professional/trade organizations, as well as an academic center, GPPC, a payor, and a device manufacturer.

Comment #	Submission	Organization	Support	Oppose
34	Genetics and Public Policy Center	academician	X	
22	NIH (NHLBI, NIMH, NINDS, NCRR, NIAAA, NHGRI)	government agency	X	
1	The Queen's Genetics Laboratories	health professional	X	
19	Affymetrix	industry	X	
58	Genetic Alliance	patient advocate	X	
56	Public Citizen's Health Research Group & Neil A. Holtzman	patient advocate	X	
43	Blue Cross and Blue Shield Association	payor	X	
54	American College of Medical Genetics	professional/trade	X	
48	American Society of Clinical Oncology	professional/trade	X	
53	Association of Pathology Chairs	professional/trade		X
41	Personalized Medicine Coalition	professional/trade	X	

Selected Comments on CLIA Subspecialty

"We are concerned that the language of the recommendation may dismiss the possibility of such a specialty being considered at all, despite its potential as a means to improve oversight" – NHGRI (Comment #22)

"Lack of a genetics specialty guarantees genetic LDTs the least stringent regulatory review" – Blue Cross and Blue Shield Association (Comment #43)

"We support the recent announcement by CMS that there should not be specialty accreditation of genetic laboratory practices" – Association of Pathology Chairs (Comment #53)

FDA Oversight of LDTs

Many of the comments discussed in detail the role of FDA in genetic testing oversight. Thirteen comments from many different sources indicated support of FDA oversight of LDTs, while four professional/trade organizations urged that FDA play only a consultative role in LDT oversight. One professional/trade organization (in two comments) urged that the IVDMA draft guidance and ASR guidance both be delayed pending HHS’s implementation of the SACGHS recommendations.

Comment #	Submission	Organization	Support	Oppose
34	Genetics and Public Policy Center	academician	X	
25	Genzyme	industry	X	
23	Pfizer	industry	X	
40	Roche Diagnostics Corporation & F. Hoffmann-La Roche AG	industry	X	
58	Genetic Alliance	patient advocate	X	
56	Public Citizen's Health Research Group & Neil A Holtzman	patient advocate	X	
43	Blue Cross and Blue Shield Association	payor	X	
49	AdvaMed	professional/trade	X	
12	American Association for Clinical Chemistry	professional/trade	X	
4	American Clinical Laboratory Association	professional/trade		X
54	American College of Medical Genetics	professional/trade		X
51	American Heart Association	professional/trade	X	
48	American Society of Clinical Oncology	professional/trade	X	
46	Biotechnology Industry Organization	professional/trade	X	
50	Coalition for 21st Century Medicine	professional/trade	X	
37	College of American Pathologists (#37)	professional/trade		X
6	College of American Pathologists (#6)	professional/trade		X

Selected Comments on FDA Oversight of LDTs

"FDA should regulate laboratory-developed tests using a risk-based approach" – American Heart Association (Comment #51)

"Current FDA device regulation is based on risk and intended use; this approach is appropriate for the regulation of laboratory-developed tests" – Roche Diagnostics Corporation and F. Hoffmann-La Roche (Comment #40)

"We strongly encourage the Committee to recommend that HHS require FDA to wait both to enforce its final ASR guidance and to issue any final IVDMA (or other related) guidance" – American Clinical Laboratory Association (Comment #32)

Expansion of Regulated Analytes for PT

Five professional/trade organizations indicated support for expanding the CMS list of regulated analytes. GPPC expressed concern that the mechanism of expanding CMS-regulated analytes to ensure PT participation may be insufficient, suggesting instead that all laboratories engaged in non-waived testing enroll in approved PT programs. A proficiency test provider expressed concern that a government agency would require PT for unregulated analytes. Three comments suggested considering a methodology-based approach to PT for genetic testing.

Comment #	Submission	Organization	Support	Oppose	Suggest technology challenges
34	Genetics and Public Policy Center	academician		X	
58	Genetic Alliance	patient advocate			X
12	American Association for Clinical Chemistry	professional/trade	X		
14	American Nurses Association	professional/trade	X		
7	American Proficiency Institute	professional/trade		X	X
44	Association for Molecular Pathology	professional/trade			X
53	Association of Pathology Chairs	professional/trade	X		
50	Coalition for 21st Century Medicine	professional/trade	X		
15	International Society of Nurses in Genetics	professional/trade	X		

Selected Comments on Expansion of Regulated Analytes

"CMS should seek advice from an appropriate constituent group of relevant experts to determine which genetic tests should be added to the list of regulated analytes" – International Society of Nurses in Genetics (Comment #15)

"We are concerned about the mechanism proposed to implement this recommendation; through expansion of the list of regulated analytes included in the CLIA regulations" – Genetics and Public Policy Center (Comment #34)

"There is a concern, however, that some health systems and government agencies are requiring proficiency testing for unregulated analytes" – American Proficiency Institute (Comment #7)

"Technology-challenges may be an efficient means to assess proficiency for a large number of disorders, but potential problems must be resolved prior to full implementation" – Association for Molecular Pathology (Comment #44)

Genetic Exceptionalism

Of the 10 comments on genetics exceptionalism, eight were concerned that some of the recommendations would, if implemented, have an adverse impact on other specialties. Two comments from professional/trade organizations pointed out some of the differences between genetic testing and other specialties.

Comment #	Submission	Organization	Concerns	How genetics is different
38	ACHDGDNC	government agency	X	
25	Genzyme	industry	X	
17	American Association of Clinical Endocrinologists	professional/trade		X
32	American Clinical Laboratory Association	professional/trade	X	
54	American College of Medical Genetics	professional/trade	X	
44	Association for Molecular Pathology	professional/trade		X
53	Association of Pathology Chairs	professional/trade	X	
6	College of American Pathologists	professional/trade	X	
37	College of American Pathologists	professional/trade	X	
29	PHG Foundation (UK)	professional/trade	X	

Selected Comments on Genetic Exceptionalism

"The foundation is very much against genetic exceptionalism, the notion that genetic tests, interventions and information should in some way be subject to different or more robust regulatory regimes than those applied to other medical tests" – PHG Foundation for Genomics and Population Health (Comment #29)

"Not all LDTs are genetic tests, and therefore this recommendation has ramifications far beyond genetics...Requiring FDA approval for every LDT is harmful to patients because of unintended consequences: it would stifle innovation, drive up the cost of healthcare, limit access to beneficial laboratory tests, and slow the implementation of new tests" – College of American Pathologists (Comment #37)

"Genetic tests differ from conventional laboratory tests in their permanence and potential implications for other family members" – American Association of Clinical Endocrinologists (Comment #17)

"Molecular genetic testing is unique in the pre- and post-analytic phases" – Association for Molecular Pathology (Comment #44)

Definition of Genetic Test

Six of the 11 comments addressing the issue of the genetic test definition expressed concerns and felt that the definition of genetic test used by SACGHS was overly broad.

Comment #	Submission	Organization	General comment	Concern about definition
28	Center for Public Health and Community Genomics	academician	X	
52	H. Lee Moffitt Cancer Center	academician		X
38	ACHDGDNC	government agency	X	
16	CMS	government agency		X
42	Benkendorf, Judith, MS, CGC	health professional	X	
23	Pfizer	industry	X	
26	American Society for Clinical Pathology	professional/trade		X
44	Association for Molecular Pathology	professional/trade		X
53	Association of Pathology Chairs	professional/trade		X
5	International Society of Nurses in Genetics	professional/trade		X
29	PHG Foundation (UK)	professional/trade	X	

Selected Comments on Definition of a Genetic Test

"The CAP is concerned that the broad definition of genetic tests used in the report captures many non-genetic tests that have not raised public concern" – College of American Pathologists (Comment #6)

"SACGHS uses a very broad definition of a 'genetic test,' going beyond heritable changes to include somatic variations, and going beyond DNA and RNA to include proteins" – Association for Molecular Pathology (44) and Association of Pathology Chairs (Comment #53)

Financial Concerns

Eighteen comments explicitly address financial concerns. Fourteen comments were concerned about inadequate reimbursement for genetic testing and services. A genetic test provider and a device manufacturer advocated expanding coverage to predictive/preventative genetic testing. Three comments addressed modification of CPT codes for genetic test procedures as well as genetic counseling services. Five comments warned that implementation of the oversight recommendations may lead to undue burdens on the laboratories thereby limiting access and test development. In addition, one professional/trade organization expressed concern that federal funding may not be sufficient to implement the SACGHS recommendations.

Comment #	Submission	Organization	Reimbursement	CPT code adjustment	Test development costs	Funding initiatives
52	H. Lee Moffitt Cancer Center	academician			X	X
9	HRSA & ACHDGDNC	government agency	X			X
22	NIH (NHLBI, NIMH, NINDS, NCRR, NIAAA, NHGRI)	government agency			X	
3	Heller, Karen, MS, CGC	health professional	X			X
31	Cooley, James & Judy Devore, RN, PhD	Individual	X	X		
19	Affymetrix	Industry	X			
57	DNA Direct	Industry	X			
25	Genzyme	Industry	X			
23	Pfizer	Industry	X			
47	America's Health Insurance Plans	Payor	X			
35	National Business Group on Health	Payor	X	X		
12	American Association for Clinical Chemistry	professional/trade				X
17	American Association of Clinical Endocrinologists	professional/trade	X		X	
54	American College of Medical Genetics	professional/trade			X	
50	Coalition for 21st Century Medicine	professional/trade	X			X
6	College of American Pathologists	professional/trade	X	X	X	
37	College of American Pathologists	professional/trade	X			
41	Personalized Medicine Coalition	professional/trade	X			

Selected Comments on Financial Concerns

"Third party denials and inadequate and inconsistent reimbursement have an additional chilling effect on genetic test performance" – American Association of Clinical Endocrinologists (Comment #17)

"We recommend that SACGHS push Medicare to reimburse preventative genetic tests and the use of genetic testing in personalized medicine" – DNA Direct (Comment #57)

"Current procedure coding for genetic testing lacks specificity" – National Business Group on Health (Comment #35)

"A recommendation focusing on the establishment of new CPT codes designed to represent the services performed by genetic counselors would better serve the purposes of this report" – College of American Pathologists (Comment #6)

"One of the critical failures of the Draft Report is that it ignores the financial issues which are significant for individual clinical genetics laboratories" – American College of Medical Genetics (Comment #54)

"The proposed increase in oversight will likely result in cost increases and delays" – NIAAA (Comment #22)

"AACC...is concerned that HHS funding may not be available for these endeavors. We suggest that SACGHS develop alternate options for accomplishing these tasks should federal funds not be forthcoming" – American Association for Clinical Chemistry (Comment #12)

Direct-To-Consumer Genetic Testing

Twelve comments expressed concern for genetic testing available DTC and the harms that may result. Four organizations urged SACGHS to consider the benefits of DTC testing in increased access.

Comment #	Submission	Organization	General comment	Concerns about DTC	Supports DTC
28	Center for Public Health and Community Genomics	Academician		X	
34	Genetics and Public Policy Center	Academician		X	
11	Stanley, Donald E, MD	health professional	X		
19	Affymetrix	Industry			X
57	DNA Direct	Industry			X
25	Genzyme	Industry	X		
33	Helicos BioSciences Corporation	Industry			X
18	World Privacy Forum	patient advocate		X	
43	Blue Cross and Blue Shield Association	Payor		X	
35	National Business Group on Health	Payor	X		
12	American Association for Clinical Chemistry	professional/trade		X	
45	American Dietetic Association	professional/trade		X	
51	American Heart Association	professional/trade		X	
36	American Medical Association	professional/trade		X	
14	American Nurses Association	professional/trade		X	
48	American Society of Clinical Oncology	professional/trade		X	
50	Coalition for 21st Century Medicine	professional/trade	X		
5	International Society of Nurses in Genetics	professional/trade		X	
15	International Society of Nurses in Genetics	professional/trade		X	
41	Personalized Medicine Coalition	professional/trade			X

Selected Comments on DTC Genetic Testing

"Direct to consumer advertising of genetic tests and consumer initiated genetic tests have the potential for adverse patient outcomes and cost implications for the healthcare system" – American Nurses Association (Comment #14)

"AMA discourages direct-to-consumer genetic testing, and recommends that it be disallowed by states" – American Medical Association (Comment #36)

"We suggest that you consider the potential benefits of DTC testing such as opportunities to engage in preventative care and improved access to genetic testing services" – Affymetrix (Comment #19)

Little harm has been documented thus far from direct to consumer testing and marketing" – DNA Direct (Comment #57)

Evidence Evaluations

In 18 comments, there was broad support for evaluation of genetic tests for validity and utility and the participation of stakeholders in the process. However, one professional/trade organization expressed concern about whether the EGAPP approach will be successful. Also, a professional/trade organization pointed out that potential harms of genetic testing to individuals are anticipatory, not actual.

Comment #	Submission	Organization
28	Center for Public Health and Community Genomics	academician
27	AHRQ	government agency
13	NCI	government agency
42	Benkendorf, Judith, MS, CGC	health professional
55	AstraZeneca	industry
25	Genzyme	industry
23	Pfizer	industry
43	Blue Cross and Blue Shield Association	payor
35	National Business Group on Health	payor
12	American Association for Clinical Chemistry	professional/trade
54	American College of Medical Genetics	professional/trade
36	American Medical Association	professional/trade
14	American Nurses Association	professional/trade
30	American Society of Human Genetics	professional/trade
50	Coalition for 21st Century Medicine	professional/trade
37	College of American Pathologists	professional/trade
15	International Society of Nurses in Genetics	professional/trade
41	Personalized Medicine Coalition	professional/trade

Selected Comments on Evidence Evaluations

"We believe a high priority should be placed on developing decision supports for test ordering, standardized lab reporting formats, and evidence-based guidelines for clinicians" – Blue Cross and Blue Shield Association (Comment #43)

"Most find this approach [EGAPP finding insufficient evidence] disappointing since more research is invariably called for without reference to the cost of conducting it" – Personalized Medicine Coalition (Comment #41)

"the arguments relating to potential harms to individuals from medical genetic testing are anticipatory rather than actual, and certainly not inherent in or limited to genetic testing" – American College of Medical Genetics (Comment #54)

Communication Concerns

Thirteen organizations concurred with SACGHS’ recommendation for improved communication among caregivers, laboratories, and patients. One organization took issue with the seeming exclusion of genetic counseling services from discussions of communication enhancements. Five comments suggested inclusion of genetic information in electronic health records (EHRs). A payor association requested that SACGHS defer questions on EHR incorporation to the AHIC.

Comment #	Submission	Organization
27	AHRQ	government agency
61	Merck	industry
47	America's Health Insurance Plans	payor
17	American Association of Clinical Endocrinologists	professional/trade
54	American College of Medical Genetics	professional/trade
45	American Dietetic Association	professional/trade
36	American Medical Association	professional/trade
14	American Nurses Association	professional/trade
44	Association for Molecular Pathology	professional/trade
37	College of American Pathologists	professional/trade
15	International Society of Nurses in Genetics	professional/trade
39	NSGC & American Board of Genetic Counseling	professional/trade
41	Personalized Medicine Coalition	professional/trade

Selected Comments on Communication Concerns

"To limit the definition of effective communication to the laboratory component de-emphasizes the importance of pre- and post-test assessments and counseling by the clinician" – National Society of Genetic Counselors and American Board of Genetic Counseling (Comment #39)

"We need to be proactive to ensure EMRs have the capacity to contain gene-based information" – AHRQ (Comment #27)

"The SACGHS final report should defer public policy decisions related to EHRs and interoperability to the AHIC" – America’s Health Insurance Plans (Comment #47)