PUBLIC COMMENTS ON PRELIMINARY CONCLUSIONS AND RECOMMENDATIONS ON OVERSIGHT
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48. New York State Department of Health
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PUBLIC COMMENTS ON PRELIMINARY RECOMMENDATIONS ON OVERSIGHT

#	*Name/Address*	*Affiliation*	*FAX*	*E-mail*	*Mail*	*New*	*Second comment*	*Comments*
1	Barbara R. Seidman 24 Foxtail Lane Monmouth Junction, NJ 08852-2006 Coordinator of the NJ chapter of the Friends of the Polycystic Kidney Research Foundation	Patient/Advocacy Group						- Report does not mention privacy protections for genetic information
2	Anita Rao Anitarao_us@yahoo.com	Public						- Concerned about FDA workload and effective review of new genetic tests; suggests that the new FDA subdivision that is assigned this task should review genetic tests only; could focus its attention on particular issues related to genetic tests, particularly clinical utility
3	Stephen Cederbaum scederba@ucla.edu	Academic						- If recommendations are implemented in their entirety, will likely stifle genetic testing completely (most genetic tests are of such small scale and are a cottage industry, these requirements are almost unmeetable) - report gives no credence to common sense of physicians - IRB requirements would be difficult to implement - draft report is a "one size fits all" and does not consider the large number of rare and orphan diseases - concerned with requirement of informed consent for predictive testing (many common medical tests are predictive, would informed consent be required for these as well?); why are DNA tests any different from other medical tests?
4	Karen Eanet KEANET@gbmc.org Genetic Counselor, Harvey Institute for Human Genetics and Region II	Genetic Counselor/ Professional Organization						- Include information about National Society of Genetic Counselors; consider recommending legislation ensuring that genetic counseling and other services are reimbursable by health insurance

	Representative, National Society of Genetic Counselors							
5	Linda R. Price, R.N. rlprice@starpower.net Board Member, Hypertrophic Cardiomyopathy Association	Patient/Advocacy Group						- Pleased to see report address issue of informed consent; stress necessity of adequately educated health providers; penalties should be imposed for incomplete or inadequate consumer information
6	Elizabeth M. Prence, Ph.D. eprence@neogenscreening.com Director of Biochemical Genetics, NeoGeo Screening	Industry						- Definition of genetic testing should include analysis of metabolites as well - In Issue 2, criteria for categorization should include level of complexity of test interpretation - Do not address how routine clinical tests will be classified or affected by informed consent regulations - Recommend that laboratory directors be involved in any committees created for oversight of genetic testing
7	Mary Kay Richter, Executive Director National Foundation for Ectodermal Dysplasia	Patient/Advocacy Group						- General impressions of the report are positive and commend the committee on a good effort
8	Lou Tougas tougas@mailcenter.csap.af.mil	Public						- Concur with report's findings and recommendations
9	Deborah O'Brien 6268 Bernhard Richmond 94805	Public						- Strong bias that infants should be tested if the test could in any way help them, i.e. placing the infant on a restricted diet
10	Wendy and Chris Nawn wendynawn@malvernconsulting.com	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
11	Mike and Jacque Bradford jbradfor@mms-inc.com	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
12	Tera and Dallas Mize Douglasville, GA tera@bestlender.net	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids

13	brownjg@epix.net	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
14	Peter T. Rowley, M.D. University of Rochester Medical Center Peter_Rowley@URMC.Rochester.edu	Academic						- Emphasis on clinical utility of genetic tests indicates that the Committee regards a genetic test as a component of a genetic service; what needs to be evaluated is the clinical service, not just the test per se; if so, clinical trials may be needed (worthwhile to list desirable features of a clinical trial of a new genetic service?) - Glad to see statement on informed consent (should be obtained vs. require); requiring informed consent may discourage practitioners from appropriate use of tests - "informed choice" may be better than "informed consent" (report appears to favor an even-handed presentation of benefits and risks) - "test for cancer" may be replaced with "test for genetic susceptibility to cancer" - central clearinghouse for recording discovery of mutations of given gene might be encouraged - sample submission directly by patients might be discouraged as well as advertising directly to patients
15	Katherine Trusty 1405 Girvin Road Jacksonville, FL 32225 trusty@gateway.net	Public						- Has child with biotinidase deficiency; wants for all parents to know that inborn errors of metabolism exist that are treatable and the importance of early detection; even if hospital does not offer comprehensive newborn screening, parents can arrange to have it done elsewhere
16	Kirsten and Lance Day 2830 Devil's Half Acre Road Accident, MD 21520 Jerrie and Care Thistel 727 E. Lake Avenue Baltimore, MD 21212	Public						- Made 70 comments/edits/suggestions throughout the report, including need for definition of accuracy; individual choice should be respected; enforcement policies; strongly support IRB review of all research protocols for genetic tests; support continued development of tests for rare diseases absent profit
17	Iolanda E. Low, M.D. 377 Waverly Avenue Newton, MA 02458	Physician						- All tests (whether diagnostic or predictive) should undergo careful evaluation - Possible conflict of interest of increasing use of patents and commercial secrecy vs. need of data sharing and open analysis for success of genetic testing

								- Concern of IRBs' ability to assess genetic testing programs - Need for education and counseling - Concern for direct marketing through television and Internet
18	Chris and Teri DePaolo 1924 S. Pine Street Port Angeles, WA 98362 trose@olypen.com	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
19	Emily and Hilton Boover emmie70@yahoo.com	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
20	Robbin Palmer, Ph.D. rpalmer@nnps.reno.nv.us	Certified Genetic Counselor						- Disappointed that Committee has not adequately translated stated concerns about genetic education and counseling and health provider competency into recommendations for oversight; has written two weakly worded recommendations regarding counseling and informed consent; recommend replacing word 'should' with 'must'; informed consent recommendation sidesteps issue of informed consent for other than predictive tests - neither of these last recommendations addresses competency of individual providing genetic education and counseling or obtaining informed consent (certification and training)
21	Carl Hugo chugo@epix.net	Public						- Implore that comprehensive newborn screening (tandem mass spectrometry) be performed for all kids
22	Vysis Michele Schoonmaker, Ph.D. Director, Medical Reimbursement and Government Affairs	Industry						- Believe that including 'social issues' in ranking risks and benefits for regulatory purposes is problematic; the definition of social issues, delineation of who will decide a significant social issue, and measures of the effect of social issues needs further conceptualization for implementation; many facets comprising social issues are beyond scope of FDA review; believe these issues would be best addressed in anti-discrimination or universal health care legislation, not as part of regulatory process per se for genetic tests - Better coordination is needed between existing federal agencies to remove redundancy in collection of medically relevant data - Oversight document should clarify that tests already on the market that have been reviewed and approved or cleared by FDA

								will not require further evaluation from regulatory perspective beyond CLIA requirements once the tests are implemented as laboratory services; if the regulatory process is too cumbersome or expensive, delivery of new tests for diagnosis and management of disease will be greatly impeded - Manufacturer representation is critical to address overall concerns to society of genetic testing - Please consider ramifications of increased regulation in the context of all laboratory testing (would be a disservice to laboratory medicine to discourage use of beneficial DNA tests simply because regulation of other methodologies is less stringent)
23	M. William Audeh, M.D. Cedars-Sinai Cancer Center 8700 Beverly Blvd. Los Angeles, CA 90048 Baudeh@csccc.com	Health care provider						- Expect identification of large numbers of "weakly" penetrant genes with high attributable risk in the population for diseases such as cancer. Their weakly penetrant character may suggest a significant environmental component to the ultimate appearance of disease and may lead to potential intervention for high risk individuals. This would argue for making tests for low penetrance available sooner rather than later; would oppose overly stringent review of such tests - Agree with need for safeguarding accuracy of test results, strongly disagree with overly stringent criteria for availability of "effective interventions"; theoretical and immediate endpoints should be adequate - Found that the most useful recommendation is need for federal legislation to protect public from misuse of information and public education promoting understanding of its importance; these should be given greatest priority over the less important "medical industry policing" activities - The majority of guidelines are aimed at protection from lab error, erroneous claims of utility, and misinterpretation by uninformed doctors; however, the greatest threat is really fear and ignorance (fear that information will be misused and ignorance about its meaning)
24	American Academy of Pediatrics Donald E. Cook, M.D., President 141 Northwest Point Blvd. Elk Grove Village, IL 60007	Professional organization						- Support views expressed in overarching principles - Difficult to understand how social issues will be used as a criterion to assess benefits and risks of a test; social acceptability may well be used as a criterion, but is recommended that acceptability be considered from the perspective of diverse social

								groups within population - In regard to genetic testing of children, AAP does not support testing in absence of an effective intervention; predictive genetic testing should be deferred until child/adolescent can make his or her own voluntary and informed decision - Support recommendation that informed consent should be obtained for all testing that is predictive - Believe the collection of data regarding analytical and clinical validity should be collected under purview of an IRB; data sharing efforts should protect confidentiality of data and privacy of individuals - Appropriate that FDA be lead agency responsible for review, approval, and labeling of all genetic tests - Applaud recommendation that IRB's oversee all research protocols that utilize identifiable samples; also believe that pre- and post-marketing data collection and analysis should be made readily available and IRB oversight be applied during these periods; SACGT should provide additional guidance about how confidentiality and privacy could be assured - Suggest that access to genetic testing in general is an issue; believe that the issue of access to genetic testing will have the potential to lead to further stratification of level of services that different groups enjoy; two other issues should be addressed in this context: oversight of cost of testing and follow-up of individuals who test positive
25	Elizabeth Gettig, M.S., C.G.C. Assistant Professor of Human Genetics University of Pittsburgh A-300 Crabtree 130 DeSoto Street Pittsburgh, PA 15261 bgettig@helix.hgen.pitt.edu	Genetic Counselor						- Strongly concur with overarching principles and support recommendation that FDA provide oversight - Expert panel is suggested which would provide an appeals process for review of decisions regarding high and low risk testing designations; found the designation of high and low risk to be vague and ill-defined in document - Document dwells upon risks of testing; please provide examples of benefits with equal vigor - In section on differentiating categories of tests, suggest including variables of cost, genotype/phenotype correlations, and anticipation and expressivity - Support regular review of test since risk analyses may shift - Clarify definition of genetic test (does it include cholesterol testing or serum ferritin?)

								- Criteria should be established as to what constitutes a standard in testing for a specific mutation or condition - Although genetic counseling is important, believe emphasis should be informed consent (present text in this area was weak in construction and lacking vision); lack of legal references or legal implications - Should strengthen recommendations for competency and education of health professionals ordering testing - One agency should house data, but confused as to how private groups will be 'forced' to provide post-test data - Inclusion of consumer input occurs too late in document and looks superficial - Exceptions must be made for rare conditions - Believe a voluntary program to review currently available tests would be reasonable (don't think you can retro-fit rules to existing tests) - Reimbursement issues need to be addressed for geneticists and genetic counselors; no CPT code for genetic counseling
26	Affymetrix Thane Kreiner, Ph.D., Vice President, Business Operations and Public 3380 Central Expressway Santa Clara, CA 95051	Industry						- Applauds recommendation advocating legislation prohibiting genetic discrimination in employment and health insurance - Believe that the personal right to know about one's genetic information must be protected; genetic information may enhance the quality of life outside the medical realm - Are concerned with any recommendation leading to differential regulation of information generated by genetic tests; believe that same high standards of privacy and confidentiality should apply to all medical information; no clear line exists between genetic information from genetic tests and other routine sources of medical information; attempts to draw this line would be challenging and possibly counterproductive (much genetic disease is diagnosed through direct clinical observation and family history) - The limitations of accuracy and replicability ascribed to genetic tests in the report are not unique to these tests - Suggest that existing CLIA regulations be enhanced to afford appropriate levels of attention to quality of all medical tests - Believe that exceptional treatment of genetic information will only exacerbate public apprehension about misuse and privacy issues

27	Alexis Poss, M.S., C.G.C. Alexis.Poss@hsc.utah.edu	Genetic Counselor						- What about newborn screening issues such as availability of an intervention and number of people affected? (may be useful criteria to assess benefit) - Would like to see data on the relevance of the mutation/polymorphism to quality of health - In addition to risks of testing, there are limitations - Why use FDA as lead agency rather than expanding the department that CLIA resides in?; would require less education if we took people that are currently working in the field and expanded the regulations - Concerned about implications of FTC recommendation for international transfer of samples for testing
28	American College of Medical Genetics R. Rodney Howell, M.D., President Michael S. Watson, Ph.D., Advisor	Professional Organization						- Have concerns about recommending that FDA assume responsibility for reviewing, approving, and labeling of all new genetic tests; these tests have significant practice of medicine components that would be exempt from FDA oversight - In the absence of fiscal and personnel resources to FDA, we are concerned that continued development of appropriate oversight of genetic testing will not progress at a rate paralleling the growth of the field - Strongly concur with Task Force's recommendations that there be significant contribution and participation of professionals and consumers in programs developed to address SACGT recommendations - Two approaches can be taken to direct FDA to enhance oversight: all of genetic testing can be assessed by FDA to identify those types and uses of tests which should be afforded increased oversight or those already identified as needing more oversight could be directed to FDA - Concur with recommendation supporting legislation prohibiting genetic discrimination - In considering the definition of genetic tests, it would seem beneficial to sub-divide the various types of tests since many don't include the pre- and post-analytic issues of most concern to the public (i.e., for germ line tests, could divide them at several levels including intended use and target pop., technical complexity, medical complexity, and social implications) - Specific tests for specifically stated uses that have reached

								standard of care status should not be subjected to full review - Stage of test development is also an important consideration - CAP Laboratory Survey program offers a well-developed vehicle through which some types of problems are identified and offer the opportunity to identify laboratories performing at the highest levels - Agree that CLIA regulations can be significantly improved for genetic testing
29	GlaxoWellcome Allen Roses, M.D., Vice President and Worldwide Director Five Moore Drive P.O. Box 13398 North Carolina 27709	Industry						- Generally supports principles outlined in document - Is premature to take the position that pharmacogenetics testing is included in the oversight recommendations; report has not specifically addressed through discussion or illustrated by use of examples how the recommendations would specifically apply to pharmacogenetics - Fully understand that FDA would regulate pharmacogenetics testing performed in the context of drug development; recommends that SACGT explicitly state in its report that conclusions and recommendations do not apply to pharmacogenetic issues of drug safety, efficacy, and post-marketing surveillance of medicines unless and until further examination demonstrates that the same mechanisms are appropriate as are for other types of tests
30	Orchid Biosciences, Inc. Dale R. Pfost, Ph.D., Chairman and CEO; Michael T. Boyce-Jacino, Ph.D., Vice President, Research and Development 303 College Road East Princeton, NJ 08540	Industry						- Support recommendations that appropriate use of genetic testing may require genetic education, genetic counseling, and strong medical privacy safeguards - While Orchid strongly supports appropriate regulation and legal safeguards around genetic testing, we are strongly concerned about preliminary recommendations for increased regulatory oversight beyond comprehensive and appropriate oversight currently enabled through CLIA and related regulation - Believe that SACGT's position on two core points is flawed: 1) distinction between genetic and non-genetic tests (there is nothing unique about laboratory testing that is based upon genetic analysis), and 2) lack of distinction between testing for genetic disease predisposition and pharmacogenetic testing (important to emphasize distinction between tests, genetic or not, that are predictive of disease risk or predisposition, and those that provide information regarding the safety and effectiveness of drug

								therapies) - The fact that existing tests already address issues similar to those raised by genetic testing undercuts the argument for special treatment - SACGT's position on these issues could result in blanket regulations that have the potential to hamper both availability of highly beneficial pharmacogenetic tests as well as scientific progress of the emerging field of pharmacogenomics - The report's lack of clarity and specificity regarding "strengthened and expanded" oversight and regulation without indication of what that would entail is especially troubling - SACGT also fails to recommend active participation by industry in defining any new regulation which overlooks the substantial knowledge and insight that industry experts can contribute to the process - Comprehensive regulatory and oversight mechanisms already exist via current CLIA and FDA authority and activities and therefore, no substantive rationale supports the application of new and possibly more stringent regulatory oversight for genetic tests than those that currently exist for 'non-genetic' clinical tests for presence of disease, for disease predisposition, and for predicting the efficacy of therapeutic interventions - Disagrees with statements about deficiencies in CLIA and FDA ASR regulations as applied to pharmacogenetic testing; strongly believes that these regulations are sufficient to ensure analytic and clinical validity of pharmacogenetic tests from development to post-market evaluation - All medical information should be handled in a highly confidential way, regardless of how it is derived; genetic information is no more or less confidential than any other type of information that is informative of an individual's health - Pharmacogenetic tests are used in circumstances in which alternative therapeutic interventions and options for improved treatments are almost always possible; thus, it is inappropriate to apply arguments for possible increased scrutiny of predispositional tests, used in contexts in which no evidentiary-based treatment exists, to pharmacogenetic tests - In addition, once a pharmacogenetic test has been accepted into clinical practice, Orchid believes that having to obtain a written informed consent is unnecessary and could retard the adoption of

								highly useful pharmacogenetic testing - Believes that the public's welfare is best served by a public-private partnership that would ensure an incrementally appropriate approach to oversight of genetic testing
31	Joy Yacaitis 110 Summer Street Watertown, Ma 024721	Public						- Pleased to see the recommendation supporting federal legislation to prohibit genetic discrimination - Concerned though that the preliminary report does not differentiate between tests that identify genetic make-up of individuals from those that do not reveal specific inherited genetic information - although I support to have some level of regulation for genetic tests which do not reveal any inherited genetic information, I would suggest that these regulations do not have the same extensive consent procedures you have recommended for those that do (hope that recommendations distinguish between acquired and inherited mutations)
32	Exact Laboratories Barry M. Berger, M.D., FCAP, Vice President, Laboratory Medicine and External Affairs	Industry						- The requests for a narrowing of the definition of genetic testing and an explicit distinction between acquired and germ line mutations are not adequately reflected in preliminary recommendations; current definition is too broad - If definition is not narrowed to reflect public's concern with predictive testing, DNA/RNA-based tests that are not predictive of germ line mutations will bear unnecessary and detrimental burden of informed consent and regulation in daily clinical practice - The use of a test that measures changes in DNA/RNA from a neoplasm that is already present should not be subjected to additional regulatory burden (should continue to be regulated by CLIA and FDA in the manner that they are currently) - Informed consent for screening tests looking for tumors that have already developed can be done in the same manner as for any other routine laboratory test - Because of the breadth of the definition of genetic tests, recommendations in Issues 4 and 5 will lead to increased system cost, decrease utilization of appropriate screening tests for acquired mutations and poor patient care
33	Debra J. Mathews	Public						- Believe that concerns related to off-label uses should be more

	Case Western Reserve University Dept. of Genetics and Center for Biomedical Ethics Dr. Chakravarti's Lab 747B BRB 2109 Adelbert Road Cleveland, OH 44106 Djm9@po.cwru.edu							explicit - The wording regarding need for genetic education and counseling is not strong enough - Would be appropriate for providers to be required to fill a certain number of their CME credits with genetics and genetic testing related activities - Should be more emphasis on implications of genetic testing for the families
34	Ellen Wright Clayton Ellen.w.clayton@vanderbilt.edu	Academic						- Most systemic concern has to do with trying to control use of genetic tests once they reach the market - It is laudable that SACGT calls for substantial showing of validity and utility to be adjudicated by FDA and ongoing supervision by CLIA; also laudable that SACGT recommends development of guidelines by USPSTF, but guidelines may have little or no force and can be inconsistent - Fear of litigation is an external force that will affect clinicians' willingness to follow guidelines; SACGT should acknowledge these issues - Urge that SACGT define how particular tests would be identified as ones meriting particular scrutiny and to suggest what the special oversight body should look like
35	Susan Metosky Student, University of Michigan School of Public Health, Interdepartmental Concentration in Public Health Genetics smetosky@umich.edu	Public						- May wish to consider defining more clearly what constitutes an accurate test result; be more specific in the definition of access (affordability, availability, acceptability, and accommodation); be clearer in the definition of informed consent - May wish to conclude the report with a list of other issues/areas that are also important to consider
36	The First Church in Chestnut Hill The Rev. Mr. Joseph Alden Bassett 26 Suffolk Road Chestnut Hill, MA 02467	Religious group						- More attention should be paid to the original meaning of 'bioethics' - In Issue 1, from a patient's perspective, the categories go the other way: social issues and clinical validity first assuming scientific validity and analytic validity - Issue of stigmatization is very important; privacy must be protected in a serious, robust, and enforced way - In Issue 2, predictive tests are all dangerous; affirm all the criteria you have set up - Is Issue 3, what is the data in this issue – the testing process or

								results of the tests; privacy in and out of databases are our primary concern - All 4 forms of oversight (under Issue 3, suggested as options) have a weakness and are inadequate: is wholly private; national oversight is too spaced out; FDA can't keep up as is; and what about the ELSI's as well as clinical applications - In Issue 4, prefer to integrate all three suggested directions of oversight - Lack of informed consent on non-govt. protocols is shocking - Who decides what is an appropriate genetic counselor?
37	Melisa Siegler, M.S., C.G.C. Dean Medical Center/St. Marys Hospital 707 S. Mills St. Madison, WI 53715 Siegler_Melisa_A@ssmhc.com	Genetic Counselor						- Feel it is imperative that a well-organized, formal evaluation take place for existing tests - Glad to see recommendation on informed consent, however, do not feel the limitation to predictive tests is appropriate; informed consent should occur now and should recommend written informed consent be obtained for all genetic tests - Support efforts to ensure that individuals having any genetic testing be given the opportunity to receive genetic counseling by a certified provider; preferably as part of the informed consent, the lab would have a counselor/educator as well - Oversight needs to include checking that labs have obtained informed consent and that a certified counselor/educator was involved
38	Oncology Nursing Society Paula Trahan Rieger, RN, MSN, CS, AOCN, FAAN, President; Pearl Moore, RN, MN, FAAN, Chief Executive Officer 501 Holiday Drive Pittsburgh, PA 15220	Professional Organization						- Agrees with overarching principles - ONS believes education of health care providers who render genetic counseling and genetic testing is a crucial area justifying SACGT's attention; standardized criteria for education and competencies would be critical to assure that health care providers have sufficient knowledge and expertise; recommends that minimum competency standards be established for those providing specialty genetic counseling - Concerned that potential discrimination may occur with testing and applauds SACGT's strong recommendations for appropriate legislation; special attention must be focused on issues unique to diverse populations and those of varying cultural backgrounds - ONS acknowledges need for coordinated effort by various government regulatory agencies for oversight of genetic testing as well as role for state health agencies and private sector

								- ONS sees role of FDA as central to providing accurate testing and information to consumers; AHRQ and NIH must also play an integral part in coordination of genetic research efforts; HRSA must play a role in protecting at-risk populations and the medically underserved - Issue of informed consent warrants further discussion in relation to recommendations forwarded for appropriate use of genetic tests; this requirement would strengthen the process and vital need for counseling; ONS supports efforts that would provide for standardization of content of informed consent documents - Recommends that the following issues be considered in consent procedures: why a person wishes to be tested; whether testing will be performed within context of clinical trial; nature of genetic test; how test will be performed; accuracy of test; type of answers that may be obtained from test - Other issues to be considered for oversight: cost of test, time required to perform test, how information is documented in medical record, ability to target individuals and families who require high-risk screening, ability to determine risk status, ability to determine whether mutation is heritable, relief from uncertainty, risks of testing, psychological distress, non-paternity, management and treatment options, permission to do research on stored tissues samples, and right to not be tested/or be tested and receive results
39	American Association of Clinical Chemistry Frank A. Sedor, Ph.D., President	Professional organization						- In general, support flexibility outlined in SACGT's approach and continued reliance on existing federal regulatory framework - AACC supports a number of recommendations: federal legislation against genetic discrimination; creation of a consortium of relevant govt. agencies, industry, and professional groups to gather and share genetic testing information; changing CLIA to address specific concerns about genetic testing; requiring that health professionals obtain written informed consent from patients prior to performing a predictive test; recognizing role of professional societies in developing guidelines for genetic research and testing; focusing FDA oversight on predictive genetic tests - Suggests SACGT expand last point by explicitly recommending that FDA include representatives from biotechnology and laboratory communities in future deliberations regarding which tests receive high and low scrutiny and how the process is structured

								- Supports IRB review for all research for genetic tests involving individually identifiable subjects or samples; further suggests adding language that investigators using archived, anonymous samples do not need to obtain informed consent and that laboratories can maintain a specimen for clinical research once the requested test is performed and patient identifiers removed - Concerned that SACGT is recommending that new federal legislation be enacted to protect privacy of genetic information in medical records; we believe that such protections should cover all patient data; recommend that SACGT support improving recent DHHS recommendations on privacy
40	BIO Michael J. Werner, Bioethics Counsel 1625 K Street, NW, Suite 1100 Washington, DC 20006	Industry Organization						- Agrees with preliminary conclusion that more education about genetic tests is needed - Has several concerns regarding treatment of genetic information and genetic tests differently than other medical information and tests; the focus on issues such as discrimination, privacy, and social impact while providing no meaningful discussion about regulation of genetic tests and implication of different regulatory approaches on development, availability and access to tests; recommending new regulatory schemes even though existing CLIA regulations constitutes a sufficient oversight mechanism; recommending review of tests already on the market without adequately discussing regulatory schemes and oversight mechanisms; including in the report only a subset of the many opinions by members of the public - BIO believes that genetic information is an integral part of medical information and cannot be separated from it; genetic testing provides information that is comparable to that which is obtained by using other diagnostic methods (this is fundamental flaw of report) - Singling out genetic information and testing for separate regulatory treatment could inappropriately stigmatize genetic information in public's mind and inhibit benefits it could potentially provide; report could have the unintended and harmful affect of exacerbating public anxiety - BIO supports legislation to protect Americans from misuse of medical, including genetic, information; as important as this is though, BIO believes that they are not relevant to the questions posed to SACGT by Dr. Satcher (prohibiting discrimination will

								not increase patients' understanding of genetic tests or improve the quality or validity of the test - BIO supports updating and enhancing existing regulatory schemes such as CLIA rather than creating a new regulatory scheme - BIO opposes development of a two-tiered regulatory system - Report provides no compelling justification for why tests already on the market should be evaluated - SACGT did not discuss impact of regulation on cost and availability of testing and no analysis was performed about compliance by laboratories with existing regulatory schemes and the feasibility of a new approach
41	Diana Stein dstein@mtholyoke.edu	Academic						- In fifth recommendation of Issue 3, not clear who laboratories should make data available to nor by what mechanism - All genetic tests could have a predictive element and is not clear how informed consent recommendation would apply -- needs clarification - Proper genetic counseling is necessary whether results are positive or negative - Find it worrisome that so many groups are involved in oversight - A common method of disseminating information through the web seems highly desirable where the public can access it, even if different methods of collecting information are needed - Do not think that we should go backwards on this; believe that genetic tests that are currently performed is appropriate and the word 'genetic' might turn people away (such as PKU testing)
42	Jane L. Schuette, M.S. Division of Pediatric Genetics 1924 TC, Box 0318 University of Michigan Health System Ann Arbor, MI 48109 janesc@umich.edu	Academic						- Concerned about the length of time that will be necessary to review, approve, and label a particular genetic test; will have a direct impact on its availability and accessibility - Applaud the attention given to issues surrounding predictive testing, especially for conditions for which no medical intervention is available; recommend that genetic testing of minors be deferred unless there is a medical benefit
43	American Medical Association E. Radcliffe Anderson, Jr., M.D., Executive Vice President and CEO	Professional Organization						- Generally agrees with recommendations - AMA must underscore the frequent gap between ability to provide genetic testing and the absence of therapeutic alternatives

	515 North State Street Chicago, IL 60610							whose selection may be influenced by results of genetic testing - Concerned that there may be rush to provide testing that is of unknown value to differential treatment planning - AMA shares public's concerns regarding discrimination based on genetic information - Believes that FDA will require substantial new resources to review genetic tests in a timely fashion - To facilitate FDA's involvement and to prevent duplication of efforts, AMA suggests that a public-private consortium (such as SACGT) provide oversight of genetic testing issues; this would ensure continued public involvement while bringing together practicing physicians and professional organizations - AMA believes that collection of post-market data from genetic testing could compromise privacy and confidentiality of genetic information; AMA policy calls for review and approval of such proposed research applications by an independent review body; also, adequate funding must be allocated to maintain such long-term data and to conduct on-going data analysis - Collection of pre-market data may also present a challenge to both commercial developers and the regulatory body; collection of such data could delay easy access by patients wishing to undergo genetic testing - SACGT should play an important coordinating role in providing oversight of genetic tests; SACGT should not provide test by test review but rather serve as a forum for public discussion of evolving concerns about issues raised in the approval, release, and ongoing review of genetic tests - AMA strongly believes that patients who seek genetic testing should do so through a physician referral (see AMA's policy on direct to consumer advertising)
44	Neil A. Holtzman, M.D., M.P.H. Director, Genetics and Public Policy Studies The Johns Hopkins Medical Institutions Professor of Pediatrics, Health Policy, and Epidemiology The Johns Hopkins University	Academic						- Recommendations regarding acceptable standards for analytical validity, FDA review of all new genetic tests, post-market data collection, and IRB review of genetic test research protocols in which individually identifiable subjects or samples are used are important and constructive in assuring safe and effective genetic testing - Recommend clearly delineating investigational stage of test development -- in investigational stage (where clinical validity is

	Baltimore, MD							established), results may be reported back to patient; in research stage (where analytical validity is established), results cannot be reported back (FDA distinctions) - Genetic tests under development, particularly predictive tests, should be treated as 'significant risk devices' requiring their sponsors to have an FDA-approved IDE application prior to beginning clinical investigation - Collection of data on clinical validity will require cooperation of health care practitioners and/or patients; test developers should be encouraged by FDA to enlist help of organizations representing medical specialists who are most likely to order new genetic tests in designing and implementing investigational studies; would increase the likelihood of well-designed protocols and provide public with greater assurance of quality of investigations - In notifying FDA of their intent to market new genetic tests, sponsors should not only provide validity data but also indicate the intended and potential uses of the test - All marketed tests should be subject to post-market surveillance; laboratories that develop and offer genetic test services should be required to update analytical and clinical validity data - In applying for CLIA certification, laboratories should be asked to indicate tests they are developing or that they recently deployed which would provide a mechanism for FDA to become aware of laboratories developing new tests (HCFA should ensure information is conveyed to FDA) - FDA should require data on clinical validity for genetic tests already being marketed as laboratory services; if they cannot, the test should be withdrawn from the market; agrees with SACGT's recommendation that a body similar to USPSTF assess clinical utility of these tests - Need to provide additional guidance to both public and private sectors on the areas of clinical validity of new genetic tests and assuring clinical validity of tests already marketed in order to implement the broad framework it has already provided
45	Anne Marie Comeau, Ph.D. Deputy Director New England Newborn Screening Program	Academic/Public Health						- Because one could interpret newborn screening as meeting the definition of a predictive genetic test as written in the report, the recommendation of informed consent would be a blanket statement that could imperil one of the more successful public

	University of Massachusetts Medical School 305 South Street Jamaica Plain, MA 02130							health services; trust that the final recommendation would not interfere with 'traditional newborn screening' - Acknowledge the need for consent during evaluation of population-based pilot programs and this should be considered for inclusion in the recommendation
46	The American Society of Human Genetics Ronald Worton, Ph.D., President 9650 Rockville Pike Bethesda, MD 20814	Professional Organization						- Supports overarching principles - General agreement of five issues SACGT addressed, though two underlying questions are evident that determine the effect that some of the recommendations would have - Unclear whether SACGT intends their recommendations to apply only to genetic tests that are offered commercially or also to tests done in the research setting; ask for clarification; if so, perhaps an alternative and less stringent mechanism of oversight than FDA review might be proposed to allow 'clinical' testing to be done by approved research laboratories if no commercial testing is available - There are problems with the definition of what exactly constitutes a 'genetic test' that should require additional oversight; suggest restricting the definition of genetic tests that would require additional oversight to those that test for a particular nucleotide sequence directly or indirectly (would include all DNA/RNA testing, protein truncation and similar tests of expression that are based on DNA/RNA sequence, and FISH or equivalent kinds of molecular cytogenetic testing) - Some ASHG Board members had specific concerns: in Issue 2, SACGT has done a good job of identifying several factors that affect level of scrutiny, but we worry it is perhaps oversimplified in the recommendations; suggest that additional consideration be given to dimensions that will determine the degree of oversight; particular concerns were raised about weighting tests on basis of availability of an intervention or on features of the condition such as penetrance and prevalence (the importance of these and other factors will vary by condition and will have to be considered on a case by case basis) - In Issue 3, ASHG Board members support recommendations that the responsibility for generating initial data on analytical/clinical validity should rest with test developer; some members have expressed concern that collecting long-term data on clinical

								validity and utility would place an undue burden on academic laboratories - In Issue 4, it is generally agreed that special oversight of genetic testing is appropriate in light of societal fears, however we do not know if these fears are warranted or not; suggest that mechanisms for heightened oversight be provisional, with their effectiveness and necessity being reviewed every 5 years - There are also concerns about FDA being the lead federal agency; concerned that too much regulation and oversight by FDA might inhibit research; IRB approval and informed consent should be sufficient for genetic testing in development - Testing for rare diseases may reside in research laboratories and never become commercialized; cumbersome FDA/CLIA regulations may make rare disease testing no longer available - Suggest that report recommend additional support of training programs in clinical genetics and genetic counseling and appropriate reimbursement for genetics services to assure this expertise continues to be available - Ask SACGT to bear in mind that any regulatory changes must not undermine further research required for understanding and developing treatments for disease, particularly rare diseases; also critical that oversight be sufficiently flexible to ensure continued participation in research by patients and the scientific community
47	Heather L. Shappell, M.S. Yale Cancer Center New Haven, CT 06514 Heather.shappell@yale.edu	Cancer Genetic Counselor						- Criteria established to identify risks and benefits of genetic tests are well-stated - Utility of categorizing tests is questionable if it is intended to be used as short-cut to identifying worthwhile tests; if categorization is to be employed, it should be broadly based - The unique characteristics of each individual test should be stressed in an effort to prevent untrained professionals from ordering genetic tests - Genetic counselors should be considered primary providers of pre- and post-testing and be recognized as the most equipped individuals to educate the lay public, insurance companies, etc.
48	New York State Department of Health Ann M. Willey, Ph.D., Director, Laboratory Policy	State Health Department						- Disappointed that the document remains vague both in its reflection on the issues and in it suggested remedies; it provides little guidance to the laboratory community or the ordering

								practitioners as to what the real underlying issues are or what their obligations should be - The recommendation of FDA having primary oversight of new tests is both surprising and of concern; creates greater complexity; absent a clearly defined link to CLIA permit issued to laboratories, compliance and enforcement will be problematic - Report continues to emphasize either unspecified or anecdotal risks and therefore has a negative tone - Although the document discusses importance of medical expertise, it fails to discuss existing systems for training, accrediting, and recognizing medical genetics professionals
49	Sandra Picot Associate Professor and Sonya Ziporkin Gershowitz Endowed Chair in Gerontology University of Maryland, School of Nursing 655 W. Lombard Street Baltimore, MD 21201 Picot@son.umaryland.edu	Academic						- Preliminary conclusions are quite comprehensive and do not have any additional suggestions at this time
50	Athena Diagnostics, Inc. Division of Elan Pharmaceuticals Robert E. Flaherty, President and CEO Four Biotech Park 377 Plantation Street Worcester, MA 01605	Industry						- Recommendations calling for additional regulation and oversight are unjustified because it has not conducted a meaningful discussion on the topic - Recommending the review of tests already on the market without adequately discussing regulatory schemes and oversight mechanisms is not in the public interest - Support increasing stringency of CLIA regulations - Inappropriately singled out genetic testing and genetic information as different from other medical testing and information and has not provided sufficient justification for drawing this conclusion - Do not believe that sufficient time has been provided for SACGT to deliberate, or for the public to participate in the issues on adequacy of oversight - Would echo the SACGT's comments on the need for additional education in the area of genetic testing and information - Should SACGT choose to finalize these preliminary recommendations, there should be a caveat expressing industry's

								concerns that the report does not represent clear consensus nor has careful consideration of the impact of these recommendations been fully analyzed
51	Judith L. Benkendorf, M.S., C.G.C Judith.benkendorf@mail.house.gov	Genetic Counselor						- Support overarching principles; commend SACGT for endorsing need for federal legislation and concluding that FDA is the appropriate agency for oversight of genetic tests - Federal oversight must reach beyond standard parameters and include recommendations about the minimal acceptable level of genetic counseling/patient education to be included in the testing process (FDA should convene a panel of genetics professionals/genetic counseling experts to establish the minimum level of genetic counseling necessary for each test - Urge that all aspects of the oversight process be as public as possible, including access to information databases - Outside panel of experts (including consumers) or similar mechanism should be established and retained to assess ethical and social ramifications of genetic tests for individuals, families, and communities since this is beyond the purview and expertise of FDA - Healthcare financing infrastructure must become more genetics friendly; this should include adequate coverage for genetic testing and counseling as indicated through Medicare, Medicaid, and private payors
52	National Society of Genetic Counselors Wendy R. Uhlmann, M.S., C.G.C. 233 Canterbury Drive Wallingford, PA 19086	Professional Organization						- Strongly concur with overarching principles proposed by SACGT and support recommendation that FDA be lead agency to provide oversight for genetic testing - Strongly recommend that a genetics advisory panel be appointed to work with FDA to initially develop a screening system to guide decisions on level of oversight for genetic tests (prototype algorithm attached as an addendum to comments); panel would also be involved in final review of oversight decisions; an appeals process will need to be established as well - Develop a mechanism for consumer input in testing implementation - Be more specific about criteria to assess benefits and risks of genetic tests; should provide guidance as to what is an acceptable level for stated criteria; needs to be established criteria as to what level a test must perform to upgrade it from ‘research’ to ‘clinical’

								test - Expand review criteria for differentiating categories of tests: detection rate, false positive rate, rates dependent on what population is being tested, variable expressivity, anticipation, genotype/phenotype correlations known - Establish criteria for regular review of genetic tests - Establish a clearer definition of genetic testing - Establish what constitutes standard genetic testing for a specific condition - Incorporate genetic counseling as an integral part of genetic testing; depending on the specific test, the level of counseling and education will differ - Ensure informed consent for testing; at minimum, genetic tests requiring a high level of oversight should also require written informed consent - Provide solid recommendations for competency and education of healthcare professionals ordering genetic tests; SACGT should strengthen their recommendations for competency and education of healthcare professionals ordering genetic tests that require a high level of oversight; should also encourage govt. to establish funds to promote genetics education and subsidize training - Establish centralized data collection that is housed by one agency and well-funded; support efforts to develop internet-based database systems to have this widely accessible - Require laboratories to make pre- and post-marketing data on genetic tests available - Establish oversight criteria that meet the unique needs of tests for rare diseases - Review oversight of current genetic tests: level of oversight for these existing tests will need to be established and should be consistent with what will be in place for new tests - Increase access to genetic counseling and testing; encourage SACGT to make appropriate agencies aware of current problems of billing and reimbursement for genetic services - SACGT should consider that genetic test inserts contain basic stipulations: importance of patient communication of test results to family members; need to test family member affected with genetic condition before testing at-risk family members; genetic testing should not take place of genetic evaluation; DNA banking should be listed an option; information provided on how to locate a

								genetics professional
53	Association of American Medical Colleges 2450 N Street, NW Washington, DC 20037	Professional Organization						- AAMC finds most of the overarching principles to be sound and shares SACGT's view that particular genetic tests for use in clinical practice need strengthened oversight - Agrees with overarching principles except that AAMC believes that all personally identifiable medical information should be treated as potentially sensitive and that no subset of information should be separated for special treatment - The most significant and fundamental point of concern is the entirely too encompassing and therefore unworkable definition that SACGT uses for 'genetic test'; believes that a crisp, unambiguous, and appropriately constrained definition is key to implementation of any of the recommendations (SACGT employs a sweeping definition of genetic testing) - Current definition fails to distinguish between somatic and germline mutations, between tests performed for research purposes and those used in clinical testing, and between predictive testing on asymptomatic individuals and populations and diagnostic testing carried out in the course of providing medical care - Though SACGT acknowledges categorizations of genetic tests that can be useful when considering oversight and review (which AAMC agrees with), it inexplicably concludes that additional oversight is warranted for *all genetic tests*; AAMC strongly disagrees with this sweeping and unjustified conclusion and urges SACGT to utilize scientifically and medically sound distinctions of genetic tests in determining those that legitimately warrant additional oversight - SACGT does not address how the criteria listed in Issue 2 would actually be used to differentiate categories of tests; urges SACGT to employ distinctions for which tests require additional oversight - AAMC supportive of recommendations surrounding collection, sharing, and analysis of clinical validity and utility; however, AAMC believes that data and analyses should be in public domain and not proprietary - AAMC is deeply uneasy about emerging practice of patenting gene-based diagnostic laboratory tests and restrictively licensing them - AAMC finds worrisome the implication that additional oversight

								would include genetic tests that are used strictly for research purposes; AAMC strongly recommends that SACGT not apply recommendation for additional oversight and review to genetic tests used strictly for research purposes where results are not reported to patients - AAMC strongly encourages that any additional federal oversight mechanisms be limited to development of genetic tests for heritable mutations that will be used for predictive purposes in presymptomatic persons for clinical practice; oversight mechanisms should not constrain use of diagnostic tests already accepted in routine care - Recommendation that FDA review all new genetic tests seems appropriate assuming the definition of genetic tests is adequately circumscribed - AAMC supports expansion of Common Rule to protect all human subjects in research; only concern resides with definition of 'identifiable'; believe that encrypted medical information or samples, even though linkable through a code, should not be considered identifiable - Agree with recommendation that Secretary consider development of mechanism to ensure identification and appropriate review of tests that raise major concerns, but caution that mechanism should not be duplicative of already existing private or govt. mechanisms, such as SACGT - Would support review of tests already on the market, but a crisp definition of genetic test is key to implementation - Although recommendation on appropriate genetic education and counseling resources appears sound, AAMC urges SACGT to provide discussion of workforce requirements and cost issues inherent in its implementation - Applauds SACGT's decision to discuss issue of informed consent more fully before providing specific recommendations
54	Genzyme Genetics Stirling M. Puck, M.D., Medical Director 2000 Vivigen Way Santa Fe, NM 87505	Industry						- Disagrees with SACGT's distinction of genetic testing and information from all health care information; such separation would legitimize public's misperception that medical genetics is somehow foreign and mysterious - The report focuses on discrimination, privacy, and social impact of genetic tests, while failing to adequately address its charge to examine regulatory concerns; while the issues addressed are

								important, they are no different in genetics than in infectious disease or other areas - Strongly support legislation to prevent discrimination on any medical information - Concerned that adding FDA review to every new diagnostic test or test enhancement will result in significant negative impact on provision of quality of health care - SACGT appears to have incorporated only a subset of available options and is lacking opinions from those actually delivering medical laboratory testing - Existing regulation of CLIA/CAP could be extended to these molecular technologies - Proposed oversight by FDA has potential to require the traditional outcomes data applicable to pharmaceutical industry; this would be highly impractical for a number of reasons
55	Mary Davidson, Executive Director, Genetic Alliance Sharon Terry, Vice President for Consumers, Genetic Alliance; President, PXE International sterry@pxe.org	Patient/Advocacy group						- In overarching principles, recommend stating that the main goal is to improve the health and well-being of families, rather than stating it as one of the main goals - In fourth overarching principle, broaden it to include all medical information; genetic information should not be separated from medical information and treated differently - Recommend that written informed consent should be obtained for all genetic tests - Give special consideration to testing for rare diseases - Test developers, in dialogue with consumers, clinicians and researchers, should decide which categories their belong in , not just test developers alone - Consumer organizations and participation should be included as members of any proposed consortium and data collection efforts - Consider recommending role for lay advocacy groups in oversight of genetic tests on a par with professional organizations - Critical that lay advocacy organizations be considered equal partners in any dialogue and/or consortium developed
56	National Patient Advocate Foundation 780 Pilot House Drive, Suite 100-C Newport News, VA 23606	Patient/Advocacy Group						- Coordination between various organizations is essential and SACGT or its designated committee should be available to review such problems - It is essential that efforts to regulate genetic tests be flexible enough to respond quickly to new technology

								- Genetic testing should not be available except through a medical provider and a counseling mechanism should be in place for laboratories offering testing - Health plans or insurance companies should not be allowed to act based on a patient's genome without full patient consent - Until problems with genetic testing can be identified, it would seem prudent to err on the side of having less rather than more federal oversight and regulation
57	College of American Pathologists Paul Bachner, MD, FCAP, President 325 Waukegan Road Northfield, IL 60093	Professional Organization						- Genetic tests are not fundamentally different from other highly complex clinical laboratory tests - Agrees with overarching principles with exception that federal legislation is needed to protect privacy of genetic information; CAP believes all medical information is highly sensitive and no subset of information should be separated out for special treatment - Agrees with Issue 1 and Issue 3 recommendations - Confused about Issue 2; there is no specific recommendation, but a discussion of categorization based on a number of criteria; categorization of tests as high and low scrutiny should not be regulated but be performed through consensus among expert group; each new genetic test must be evaluated individually with regard to its own unique features - Disagrees that additional oversight of genetic tests is needed; adequate standards of conduct are included under current CLIA regulations - Opposed to FDA oversight for several reasons: many of tests defined in report do not differ from other laboratory tests and therefore do not need special oversight; questions ability of FDA to develop flexible mechanisms for review of genetic tests; wonders if system for review by FDA could be implemented in timely fashion; since CLIA already mandates standards developed according to complexity, CAP questions whether additional levels of scrutiny (high and low) are needed - Against establishing a genetics specialty under CLIA - CAP agrees with concept of sliding scale for certain tests (regarding FDA review of tests used to predict diseases for which no safe and effective intervention is available) - CAP believes that any review of tests already on the market should be conducted with input of laboratory representatives - Agrees with counseling and education recommendation

								- Agrees that written informed consent should be obtained for certain tests used for predictive purposes, but requirement should be reviewed by experts on disease-by-disease basis - Recommendation that written informed consent should be obtained for tests used for predictive purposes implies that written informed consent should be obtained for all predictive genetic tests; recommendation needs to be carefully reconsidered in terms of medical necessity and administrative burden; need for informed consent should be identified by, and promulgated through above mentioned consortium - CAP strongly recommends that practice of genetic testing be governed through consensus among practitioners via professional organizations; advocates formation of genetic testing consortium of expert medical and scientific organizations; disagrees that govt. should oversee introduction of new genetic tests - Definition of genetic test currently used is too broad and vague and would include almost all laboratory tests; CAP defines genetic tests as those that provide information used for diagnosing or predicting an inherited condition, susceptibility or carrier state; need to recognize difference between germline and somatic disorders and the tests that diagnose them; broad definition would result in over-regulation and increased costs for tests which do not raise unique issues or concerns
58	Association for Molecular Pathology Debra G.B. Leonard, M.D., Ph.D, President 9650 Rockville Pike Bethesda, MD 20814	Professional Organization						- AMP strongly endorses CAP comments - Believe that non-DNA-based genetic tests are fundamentally no different from the new DNA-based genetic tests when used for diagnostic purposes - Believes that genetic testing is properly regulated by CLIA standards for high complexity standards; additional oversight specifically targeted at genetic tests is not necessary and would be redundant with existing regulations that already provide sufficient oversight - AMP has concerns with the broad definition of genetic tests; would emphasize the need to distinguish between germline and somatic mutations and the importance of excluding tests for somatic mutations, which are not inheritable, from the definition of genetic tests - Standards must be set for each genetic test individually and not through categorization of tests as low, medium, or high risk

								- Guidelines for performance, interpretation, and clinical use of genetic tests is best established with primary input from medical and laboratory professionals; would welcome establishment of genetic testing consortium - Review and approval of all genetic tests by FDA is an inappropriate and unworkable mechanism for oversight - AMP believes that not all genetic tests require written informed consent, esp. when considering multigenic medical diseases for which genetic test results are only one component of a diagnostic evaluation - When informed consent is recommended, the laboratory performing the test should not be responsible - Concerned that the proposed increase in oversight is unnecessary and will add to the time and cost of performing genetic tests with no improvement in quality

PUBLIC COMMENTS ON PRELIMINARY CONCLUSIONS AND RECOMMENDATIONS ON OVERSIGHT

Alphabetical Listing of Commenters (Comment #)