February 23, 2015

The Honorable Lamar Alexander
Chairman, Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
217 Russell Senate Office Building
Washington, DC 20510

submitted electronically via Innovation@help.senate.gov

RE: Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation’s Medical Product Discovery and Development

Dear Chairman Alexander, Ranking Member Murray and Senator Burr:

The Alliance of Specialty Medicine appreciates the opportunity to provide comments in response to the Innovation for Healthier Americans report. The Alliance is a coalition of national medical societies representing specialty physicians in the U.S. and is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. We greatly appreciate your leadership to improve the discovery, development and delivery that support continued innovation in our health care system.

The Alliance offers specific comments on the following questions posed in the report.

V. FROM BENCH TO BEDSIDE: THE ROLE OF BASIC RESEARCH IN NEW MEDICAL PRODUCTS

How can we improve the appropriate sharing of data and information and enhance the impact of our biomedical research?

The FDA does not allow pharmaceutical, biological and medical device companies to actively distribute key clinical information, even if it is related to the on-label indication, unless it is explicitly referenced in the package insert. By limiting the sharing of information, physicians are hampered in their ability to gain all of the firm scientific rationale and sound medical evidence needed to treat patients. Scientific and medical developments on pharmaceuticals, biologicals and medical devices should be shared with
physicians, with appropriate safeguards, in order to optimize patient care. We recommend that the Committee develop standards for qualifying real world data, through a public process; expand the current process of review of materials beyond what is included in the package insert to also cover other key data, such as subpopulation, pharmacoeconomic or comparative cost data; and ensure a timely review process for such information.

Regarding clinical data registries, the Alliance would support the U.S. Department of Health and Human Services (HHS) in making Medicare, Medicaid, and CHIP claims data available to all clinical data registries. Registries should have unfettered access to federal claims data, which, when combined with more robust clinical data, can result in more accurate evaluations of quality and value performance.

The Alliance also supports the promotion of bi-directional, interoperable exchange of information between electronic health records (EHRs) and registries. It is critical that HHS adopt and better enforce interoperability standards to ensure the seamless exchange of information between certified EHRs and qualified clinical data registries. The most significant current barrier to integration of EHR data in registries is EHR vendor refusal to share data with registries or charging excessive fees for such access. We urge Congress to mandate that EHR vendors adopt interoperability standards as a condition of receiving federal certification.

Current regulations for informed consent are outdated and create unnecessary regulatory barriers that limit the ability of registries to engage in prospective, systematic tracking of practice patterns and patient outcomes that lead to better care. The Alliance supports an exception to the Common Rule for registries and other entities that collect identifiable data, but have no direct interaction with patients and comply with all applicable HIPAA regulations.

Additionally, the Alliance strongly urges the Committee to clarify that peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirement under the Sunshine Act.* Physicians must have access to the most up-to-date independent medical knowledge to support their delivery of high quality patient care.

VI. OPPORTUNITIES TO IMPROVE CLINICAL TRIALS

How can Congress remove barriers and facilitate innovation in the administration and design of clinical trials to reduce the time and resources it currently takes to conduct these trials?

The Alliance encourages efforts to streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites. We urge the Committee to consider the recently released NIH draft policy on the use of a single IRB for multi-site research. The Alliance also supports the use of centralized IRBs for review of investigational device exceptions.

Ultimately, what needs to be done to ensure that the regulatory environment supports and embraces new clinical trial approaches and designs that reflect the most current understanding of medicine and help to get the best treatments and cures to patients?

A data sharing framework should be established to enable patients and physicians to better identify ongoing clinical trials. The clinical trials registry should be easy for physicians and patients to access and
entries and results data should be easily compared in a standardized format employing comprehensive health care terminology that includes clinical trial inclusion and exclusion criteria.

VIII. REGULATORY SCIENCE: THE FDA MUST BE PREPARED TO REVIEW MEDICAL PRODUCTS IN THE FUTURE

How can we better leverage the regulatory science initiatives to ensure that novel medical products are reaching American patients in as timely a manner as possible?

What specific policy or practice changes would facilitate the timely adoption of new tools such as biomarkers or informatics?

The Alliance supports establishing a transparent process at FDA with specified timeframes for the development of evidentiary standards and the review and qualification of surrogate endpoints for broader utilization in regulatory decision-making. It is critical to support innovation in the drugs, biologicals and devices that diagnose, treat and monitor our patients. We support efforts to help expedite the development and approval of safe and effective drugs for unmet needs. We urge the committee to be mindful of patient data collected through privately-administered registries as we believe such data should be the sole property of the private entity administering the registry, and public agency access to those data should be at the discretion of their private entity owner. The Alliance stands ready to work with the committee on clinical registry issues based on the collective experience of our member organizations in establishing and running registries.

The Alliance appreciates this ongoing process toward the introduction of bipartisan legislation and looks forward to continuing to work with you on this initiative. Please let us know if our expertise may be of assistance, especially as you seek additional feedback or would like assistance in developing specific provisions.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

CC: Members, Senate HELP Committee
*NASS has not yet taken a formal position on this issue and remains neutral.