AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ®

Executive Office
444 East Algonquin Road • Arlington Heights, IL 60005-4664
847-228-9900 • Fax: 847-228-9131 • www.plasticsurgery.org

May 20, 2015

The Honorable Fred Upton
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
United States House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Joseph R. Pitts
United States House of Representatives
420 Cannon House Office Building
Washington, DC 20515

The Honorable Gene Green
United States House of Representatives
2470 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
United States House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

Re: H.R.6: 21st Century Cures Act

Dear Chairman Upton, Ranking Member Pallone, Health Subcommittee Chairman Pitts, Health Subcommittee Ranking Member Green, and Representative DeGette:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments in response to the 21st Century Cures May 13th discussion draft. The American Society of Plastic Surgeons (ASPS) is the world's largest association of plastic surgeons. Our over 7,000 members represent 94 percent of Board-Certified Plastic Surgeons in the United States. ASPS promotes not only the highest quality in patient care, but also in professional and ethical standards. Our members are highly skilled surgeons who improve both the functional capacity and quality of life for patients, including treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer reconstruction.

Outlined below are provisions we see as likely to contribute to our efforts to advance these priorities and values.

TITLE I, SUBTITLE G – FACILITATING COLLABORATIVE RESEARCH (Section 1124)

ASPS and its research and charitable arm, the Plastic Surgery Foundation (PSF), are collaborating with the Food and Drug Administration (FDA) to develop a registry of women with breast implants who have developed anaplastic large cell lymphoma (ALCL). Because of the success of this relationship thus far and the potential it holds going forward, ASPS is **generally supportive of this provision, particularly the use and disclosure of Protected Health Information (PHI) by research**

institutions. We would encourage its inclusion in the final legislative language if clarification is made with respect to data ownership, as outlined below.

ASPS would like to thank you for clarifying the HIPAA Regulations to allow for the definition of health care operations to explicitly include research. The varying requirements regarding the use and disclosure of PHI for health care operations as compared to research activities has been unclear. Through this revised definition, registries with a business associate agreement will not need to obtain individual authorization or institutional review board wavers prior to the use or disclosure of PHI for research purposes. We fully support this provision, which will provide registries with greater flexibility in conducting research.

Additionally, we support the new requirement to revise the HIPAA Regulations to allow a covered entity to receive payment in exchange for PHI when PHI is used for research purposes. This new provision will allow registries to purchase access to a covered entity's health care database for research purposes without the individual's authorization. In addition, the one-time authorization for the use and disclosure of PHI will allow for greater data to be collected and analyzed.

Still, ASPS has concerns about the possible implications of this section regarding ownership of data collected through private-public partnerships. We believe that patient data collected through privately-administered registries should be the sole property of the private entity administering the registry, and we believe that public agency access to those data should be at the discretion of their private entity owner. We respectfully request clarification on this question in the final legislative language.

TITLE II, SUBTITLE O – STREAMLINING CLINICAL TRIALS (Section 2262)

This provision will improve the research process for ASPS organizationally, for our members individually, and for all physicians who are in private practice and wish to conduct research. ASPS supports this provision as it will allow for review by a centralized institutional review board, and we recommend that it is included in the final legislative language.

The PSF coordinates multi-center studies and is familiar with the red tape that entails. We see this provision as likely to streamline the regulatory challenges we face, and in doing so, streamline and improve the research and discovery process for our members participating in PSF-coordinated studies. It will also improve the research and discovery process for our members seeking to conduct research outside of our institutional programs and for all physicians who do not have access to the research infrastructure necessary to get protocols through an IRB. This is a common and significant challenge for physicians participating in private practice.

TITLE III, SUBTITLE A - INTEROPERABILITY

Interoperability between electronic health records is an essential part in ensuring that physicians can securely and efficiently access patient information no matter where the patient was previously treated. For this reason, ASPS supports this provision.

To date, efforts to drive meaningful use of EHRs have faltered in part due to problems with health IT platforms. These problems have contributed to reduced provider time spent giving direct care, and they have resulted in misappropriated penalties. EHR vendors should have greater responsibility for delivering products that allow providers to meet the objectives of the meaningful use mandate, and they should bear full risk for any penalties that come in the event that interoperability is not achieved.

TITLE III, SUBTITLE C – ENCOURAGING CONTINUING MEDICAL EDUCATION FOR PHYSICIANS (Section 3041)

The Physician Payments Sunshine Act ("Sunshine Act") was enacted with the intent of promoting transparency surrounding transfers of financial value between physicians and the medical device and pharmaceutical industries. The originally enacted legislative language and congressional intent bear this out, and organized medicine largely supported this objective. The Sunshine Act included twelve exclusions from reporting requirements, and among these were educational materials that directly benefit or are used by patients. These commonsense statutory exceptions were then misconstrued in the rulemaking process as CMS concluded that medical textbooks, peer-reviewed journals, journal reprints and journal supplements did not offer direct benefit to patients. **We fully support the inclusion of this provision in the final legislative language and thank you for working to correct this mistake by clarifying that the aforementioned educational materials are exempt from reporting.**

TITLE III, SUBTITLE D— DISPOSABLE MEDICAL TECHNOLOGIES (Section 3061)

ASPS sees clear benefits for patients and providers in creating a new category of covered durable medical equipment, Substitute Disposable Medical Technology (SDMT). As such, we **support the original intent of this provision as outlined in the January draft and recommend its inclusion in the final legislative language.** This new category will allow Medicare beneficiaries to access new, cutting edge technology in various settings, leading to flexibility in treatment options and a reduction in access disparity among Medicare patients. The current Medicare Durable Medical Equipment (DME) category is used primarily in hospital or facility settings, which inherently limits patient and provider options. The SMDT category will include technologies that can be used in an outpatient or home care setting for less cost. This is a natural, commonsense evolution of Medicare payment policy, and it will foster more appropriate, more patient-centered, and – through greater patient compliance – more effective care.

ACCELERATING INNOVATION IN MEDICINE

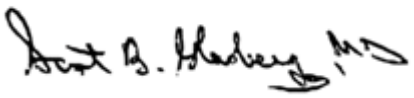
ASPS supported this provision after the first release of the 21st Century Cures Act discussion draft. Accelerating Innovation in Medicine (AIM) Act provisions were subsequently removed from the bill during the May 13 discussion draft. **ASPS strongly encourages the inclusion of AIM within the final legislative language,** as it will provide seniors and individuals with disabilities with immediate access to new FDA-approved medical devices that are not currently covered by Medicare. In addition, this provision will relieve some of the regulatory burden that can inhibit access to innovative new

products, foster the collection of data that can support a future Medicare coverage decision, and save the federal government money.

This provision seeks to provide an option for medical device manufacturers to "opt-out" of the Medicare coverage determination process for at least three years to allow time to obtain the necessary clinical evidence in support of a stronger case for a future Medicare coverage decision. This change would reduce the obstacles Medicare beneficiaries face in trying to access these new technologies, ensure they are informed of the costs, and allow them to self-pay before Medicare coverage is sought by the manufacturer. By allowing beneficiaries to have this option, clinical studies and data collection can take place and these innovative technologies will help patients in the United States, instead of solely in foreign countries.

Thank you for your consideration of these comments, and thank you for your ongoing commitment to improve the pace and process of medical innovation in the United States. Your inclusive process has consistently sought input from patients, providers and other stakeholders, and ASPS believes that a continued commitment to diverse input and diverse ideas will result in an excellent final legislative product. Please do not hesitate to contact Patrick Hermes, Senior Manager of Advocacy and Government Affairs, with any questions – Phermes@plasticsurgery.org or (847) 228-3331.

Sincerely,



Scot B. Glasberg, MD
President, American Society of Plastic Surgeons

cc: Debra Johnson, MD – ASPS Board Vice President of Health Policy & Advocacy
Loren Schechter, MD – Federal Chair, ASPS Legislative Advocacy Committee
J. Peter Rubin, MD – Regulatory Chair, ASPS Legislative Advocacy Committee
Loree Kalliainen, MD – Chair, ASPS Health Policy Committee