AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ®

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December 2, 2016

The Honorable Orrin Hatch
President Pro Tempore
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Majority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Harry Reid
Minority Leader
United States Senate
522 Hart Senate Office Building
Washington, DC 20510

The Honorable John Cornyn
Majority Whip
United States Senate
517 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Durbin
Minority Whip
United States Senate
711 Hart Senate Office Building
Washington, DC 20510

RE: 21st Century Cures Act

Dear Leaders of the United States Senate:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments regarding the 21st Century Cures Act. ASPS is the world's largest association of plastic surgeons, with over 7,000 members and 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.

ASPS strongly supports the goals of the 21st Century Cures Act, because it will spark innovation and increase access to safe, effective and life-saving medical care. While ASPS does not feel this bill is ideal, the current iteration of the 21st Century Cures Act is well crafted. Outlined below are provisions we feel are most likely to benefit our patient population and those areas we would seek improvement within the provisions. While hoping our concerns are addressed, we offer our support for this legislation and request its passage.

SECTION 2063 – FACILITATING COLLABORATIVE RESEARCH

ASPS and its research and charitable arm, the Plastic Surgery Foundation (PSF), in collaboration with the Food and Drug Administration (FDA) have developed a registry of women who have developed breast implant-

associated anaplastic large cell lymphoma (BI-ALCL). Because of the importance of this public/private collaboration, ASPS is supports the facilitation of such research, particularly the necessary use and disclosure of Protected Health Information (PHI). However, ASPS requests two amendments.

First, the requirements regarding the use and disclosure of PHI for health care operations versus research activities are unclear. Data Registries play a key role in tracking healthcare quality. It is imperative that registries with a business associate agreement need not obtain individual authorization or institutional review board waver prior to the use or disclosure of PHI for research purposes. ASPS respectfully requests reinstatement of language from the July 13, 2015 21st Century Cures Act providing registries with greater flexibility in conducting research.

ASPS is concerned about implications regarding ownership of data collected via registries. Patient data collected through privately administered registries should remain the sole property of the private entity administering the registry, and public agency access to this data should be at the discretion of the private entity owner. We request clarification on this question.

SECTION 2021 – SUPPORTING YOUNG SCIENTISTS

ASPS commends your commitment to expanding opportunities for scientific researchers and believes improved health research will yield benefits for U.S. citizens. Still, we believe this section could be strengthened to allow review by a centralized institutional review board (IRB). Such a change would streamline and facilitate research conducted by ASPS and by our members individually. Our PSF coordinates multi-center studies and is familiar with the bureaucratic red tape that entails. Centralizing the IRB process would alleviate this and hasten clinical research that would help patients.

SECTION 3033 – ACCELERATED APPROVAL FOR REGENERATIVE ADVANCED THERAPIES

ASPS has been working with a host of stakeholders and the FDA for the past two years to ensure that the products which form the basis for these new therapies – cellular and tissue-based products – are appropriately regulated. ASPS's position has consistently mirrored that of the FDA, specifically that patient safety remains paramount in exploring new therapeutic alternatives. We believe this provision respects that balance and can lead to innovative new therapies reaching the market more quickly.

We are particularly pleased with the creation of a new "regenerative advanced therapy" designation. We believe potential breakthrough regenerative therapy products should be investigated as quickly as possible via an expedited FDA meeting timeline, eligibility for priority review and accelerated approval, fewer clinical trial sites, and the ability to use real-world evidence for post-approval studies. Most importantly, this language has been crafted to utilize existing FDA approval structure that does not undermine safety and efficacy standards.

SECTIONS 4001, 4003, 4004 & 4005 – EHRs, HIT INTEROPERABILITY & INFORMATION BLOCKING

Inefficient, costly, and cumbersome electronic health records (EHRs) have created an undue burden on the health care delivery system. The heavy administrative documentation burden on physicians and other health care providers, the lack of interoperability between systems, and data/informational blocking by bad actors are factors making EHR mandates a plague rather than a panacea. ASPS is grateful that the 21st Century Cures Act takes direct aim at this issue.

Reducing Administrative Burden

ASPS strongly supports efforts to reduce the administrative burdens related to electronic health records on physicians with the goal of increasing the quality of care for patients. EHRs should be tools that improve the delivery process, not bog it down.

Interoperability

Interoperability between electronic health records would ensure physicians could securely and efficiently access patient information no matter where the patient was previously treated. Coordinated care is a cornerstone of health reform, and this legislation requires EHR vendors to (1) responsibly deliver products that allow providers to meet meaningful use, and (2) bear full risk for any penalties for non- interoperability. ASPS supports this provision.

Information Blocking

In the same way that interoperability improves provider-to-provider exchange of health information, preventing information blocking by health IT vendors – and, frankly, some providers – can unlock the potential of technologies designed to leverage that information for quality, cost and practice improvement. This provision meaningfully addresses these problems and we support it.

ASPS appreciates the opportunity to comment on this legislation, and thank you for your ongoing commitment to medical innovation in the United States. ASPS respectfully requests a vote in favor of the 21st Century Cures Act. 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,

Debra Johnson, MD
President, American Society of Plastic Surgeons

Cc: Members of the United States Senate