



AMERICAN SOCIETY OF  
PLASTIC SURGEONS®



THE PLASTIC SURGERY  
FOUNDATION®

Executive Office

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November 30, 2016

The Honorable Paul D. Ryan  
Speaker  
United States House of Representatives  
1233 Longworth House Office Building  
Washington, DC 20515

The Honorable Kevin McCarthy  
Majority Leader  
United States House of Representatives  
2421 Rayburn House Office Building  
Washington, DC 20515

The Honorable Nancy Pelosi  
Minority Leader  
United States House of Representatives  
233 Cannon House Office Building  
Washington, DC 20515

The Honorable Steve Scalise  
Majority Whip  
United States House of Representatives  
2338 Rayburn House Office Building  
Washington, DC 20515

The Honorable Steny Hoyer  
Minority Whip  
United States House of Representatives  
1705 Longworth House Office Building  
Washington, DC 20515

**RE: 21<sup>st</sup> Century Cures Act**

Dear Leaders of the United States House of Representatives:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments regarding the 21<sup>st</sup> 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 21<sup>st</sup> 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 21<sup>st</sup> 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 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 waiver prior to the use or disclosure of PHI for research purposes. ASPS respectfully requests reinstatement of language from the July 13, 2015 21<sup>st</sup> 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 21<sup>st</sup> 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.

### **SECTION 4009 – ENCOURAGING CONTINUING MEDICAL EDUCATION FOR PHYSICIANS**

The Physician Payments Sunshine Act (“Sunshine Act”) intended to promote transparency regarding transfers of financial value between physicians and industry. The originally enacted legislative language and congressional intent bear this out. Organized medicine largely supports 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. This commonsense exception was 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.

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 21<sup>st</sup> Century Cures Act. Please do not hesitate to contact Patrick Hermes, Senior Manager of Advocacy and Government Affairs, with any questions – [phermes@plasticsurgery.org](mailto:phermes@plasticsurgery.org) or (847) 228-3331.

Sincerely,

A handwritten signature in black ink that reads "Debra Johnson MD". The signature is written in a cursive, flowing style.

Debra Johnson, MD  
President, American Society of Plastic Surgeons

cc: Members of the United States House of Representatives