



February 6, 2015

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Office of the National Coordinator for Health IT/Office of the Secretary  
Department of Health and Human Services

**RE: Federal Health Information Technology (IT) Strategic Plan 2015-2020**

Dr. DeSalvo,

RTI Surgical Inc. is a leading global surgical implant company providing surgeons with safe biologic, metal and synthetic implants. RTI's implants are used in sports medicine, general surgery, spine, orthopedic, trauma and cardiothoracic procedures and are distributed in nearly 50 countries. Our company is accredited in the U.S. by the American Association of Tissue Banks (AATB) and is a member of the Advanced Medical Technology Association (Advamed).

I am writing in response to the *Federal Health IT Strategic Plan (2015-2020)*. The plan, which considers feedback from more than 35 federal agencies, offices and partners with an interest in furthering the use of health IT to improve health, health outcomes, and potentially reduce health care spending. Through streamlined information exchange among relevant stakeholders, your strategic plan offers a robust and actionable blueprint for addressing many issues specific to collecting, sharing and using health IT.

We are particularly interested in objectives outlined as part of Goal 2: *Advance Secure and Interoperable Health Information* and Goal 4: *Advance the Health and Well-being of Individuals and Communities*, which speak to advancing standards for documentation of medical device use by unique device identifier and methods for adverse event reporting, and the need for interoperable health information to detect, track, and manage disease outbreaks, as well as to conduct and contribute to medical product safety surveillance. To that end, we would like to draw your attention to a related area of critical interest to RTI Surgical that is not addressed in the document – the ability to use health information technology to track and trace human tissue from a donor to a recipient.

Human tissue products are used in more than a million medical and dental procedures per year, including wound care management, hernia repair, orthopedic and sports medicine procedures, bone and gum grafting and repair, among many others. Most of these services are routinely performed on Medicare and Medicaid beneficiaries and, in total, account for a significant volume of spending in federal health programs.

## Background

The ability to track and trace human cell, tissue, or cellular or tissue-based product (HCT/Ps) from a donor to a recipient is a serious, ongoing public health concern largely hindered by a lack of appropriate standardized identification standards and a mechanism by which to collect, store and share HCT/P data for public health, clinical and research purposes. Previous efforts to address this issue at the federal

level, through standards and accrediting organizations, have not resulted in a meaningful solution to the problem.

### *Federal Requirements*

The United States Food and Drug Administration's (FDA) Current Good Tissue Practice final rule requires certain establishments to use methods and controls to prevent the transmission of communicable disease by HCT/Ps; specifically, that tissue establishments track each HCT/P to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. According to the guidance, the tracking system must (1) involve tracking from the donor to the consignee (e.g., hospital or clinician) for final disposition, as well as from the consignee to the donor; and (2) include a distinct identification code. Unfortunately, health care and dental facilities that obtain HCT/Ps for implantation do not fall under the regulatory jurisdiction of the FDA, and therefore, are not bound by these requirements, thereby creating a gap in regulation requiring tracking of tissue implants all the way to the patient.

Similarly, the FDA's Unique Device Identifier (UDI) regulations only apply to HCT/Ps "***regulated as a device***" [emphasis added]. HCT/Ps that are not regulated as medical devices, which are the bulk of these products, are not subject to the UDI requirements. Thus, there remains a lack of standardized identification protocols for HCT/Ps not regulated as medical devices in current regulation.

### *Recognized Standards*

The American Association of Tissue Banks (AATB) requires its accredited tissue banks to maintain adverse reaction files and recall procedures, as well as establish recipient follow-up collection protocols. While the tissue establishments are required by FDA to notify the consignee of their specific tissue tracking, there is no similar FDA or AATB requirement that the consignee participate in the tissue establishment's tracking system, simply due to the jurisdictional limitations of both entities.

The College of American Pathologists (CAP) has included tissue standards for its accredited labs, and the Association of Perioperative Registered Nurses (AORN) has developed "recommended practices" that mirror AATB expectations for tissue handling. The AATB is pursuing the inclusion of tissue handling standards in requirements of the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF), the Healthcare Facilities Accreditation Program (HFAP), and Det Norske Veritas Healthcare, Inc. (DNV). It also plans to collaborate with the American Dental Association (ADA) and the American Burn Association (ABA) to garner their support for their constituencies to voluntarily use safe tissue handling practices.

### *Public/Private Collaboration*

Beginning in 2005, the Centers for Disease Control and Prevention (CDC) collaborated with other federal and private-sectors stakeholders in the development of a communication network for the tracking and reporting of suspected disease transmissions following transplantation of organs and tissues. A pilot of this network – the Transplantation Transmission Sentinel Network (TTSN) – was developed and hosted by the United Network for Organ Sharing (UNOS) under a cooperative agreement with CDC. Recent efforts on the TTSN have largely fallen flat.

## Facilitating Solutions

Since 2013, RTI Surgical has engaged in a dialogue with federal agency and Congressional leaders to devise a long-term solution. And, while simultaneously working to develop a comprehensive solution, RTI Surgical has been working toward implementation of UDI-compliant tracking of its non-device HCT/Ps.

### *Legislative Efforts*

In the 113<sup>th</sup> Congress, Congressman Phil Roe introduced the Biological Implant Tracking and Veteran Safety Act of 2014 (H.R. 4374). As introduced, the bill directs the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants (including HCT/Ps) by the Department of Veterans Affairs, and for other purposes. RTI was instrumental in developing the legislation, working directly with the Veteran's Affairs Committee and other Congressional staff.

According to conversations that RTI Surgical has had, Rep. Roe plans to re-introduce the legislation this Congress. The continued introduction demonstrates the desire of Congressional leaders to facilitate a solution to this long-standing public health concern for the veteran population.

### *Agency Efforts*

In May 2013, RTI Surgical met with staff in the Office of the National Coordinator for Health It (ONC) to discuss the challenge of HCT/P track and trace and foster collaboration among our organizations to identifying solutions. We suggested the potential for leveraging ONC's Electronic Health Record (EHR) Certification Criteria and the Centers for Medicare and Medicaid Services (CMS) "meaningful use" criteria, as included in its Medicare and Medicaid EHR Incentive Program, to capture and track HCT/P data and information, similar to pending requirements that would capture medical device data via the UDI.

We also urged ONC to support a Challenge Grant that would identify and pilot an option for addressing this issue, which would ultimately help inform a more permanent solution. We prepared a Challenge Grant application, as well as identified other interested stakeholders, including the Department of Defense (DOD)/Veteran's Administration (VA) Interagency Program Office (IPO), the American Podiatric Medical Association (APMA), and the ADA, who supported the concept. Some months later we learned that a high-level working group inside the Office of the Assistant Secretary for Health (OASH) intended to address policy around biologics and tissue safety, and therefore, the Challenge Grant could not be pursued by ONC.

### *Standards Development*

In 2013, we approached the ADA's Standard Committee on Dental Informatics (SCDI), an American National Standards Institute (ANSI) accredited standards developing organization (SDO), with broad concerns about the ability to track and trace HCT/Ps. Spurred by our mutual concern, the ADA embarked on a standards development activity that could assist in facilitating HCT/P track and trace issues in dentistry. Specifically, the SCDI formed Working Group 11.8 on Track and Trace for Implantable Devices (including HCT/Ps) among other products used in dentistry. Once completed, this standard could be recognized by the federal government and appropriately scaled and applied more broadly to other health care settings.

### *Other Private Sector Engagement*

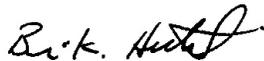
RTI Surgical has approached other potential stakeholders to include surgical specialty societies developing clinical data registries, including the American College of Surgeons (ACS), in hopes of identifying partner that could pilot test ideas similar to those described in the Challenge Grant. We continue to seek opportunities for collecting data on HCT/P products through clinical data registries and other health information technologies.

## **Conclusion**

RTI supports the development of a comprehensive, standardized tracking system for HCT/Ps. Not only would this data be useful for public health, clinical and research purposes, it would also improve our efforts to connect donor families with recipients. Making these important connections enhances the value of donation as well as reduces the potential for exploitation.

We appreciate the opportunity to comment on the *Federal Health IT Strategic Plan (2015-2020)*, and look forward to continuing dialogue on this important issue. If you have any questions about our comments, please contact Wendy Crites Wacker at [wwacker@rtix.com](mailto:wwacker@rtix.com) or 386-418-8888 x4220.

Sincerely,



Brian K. Hutchison  
President and CEO  
RTI Surgical Inc.