Determining a product's intended use is a critical component of Food and Drug Administration (FDA) regulation. The agency determines whether a product should be regulated by the FDA, and if so, how it should be regulated.

A famous analogy is water. If water is intended to quench thirst at mealtimes, then it is not considered a drug. If water is intended to cure cancer, then the FDA can regulate the claims being made by the water bottling company, inspect the manufacturing facilities, take enforcement action, and potentially impose criminal penalties.

A product's intended use matters, and what evidence can be used to glean intended use can have a significant impact on whether the government can regulate the product and its manufacturer. To regulate human cells, tissues, and cellular and tissue–based products (HCT/Ps) as devices, the FDA uses the term "intended use."

The parallel concept for HCT/Ps in Section 361 of the Public Health Service Act is "manufacturer's objective intent." Specifically, 21 CFR 1271.10(a)(2) notes that to be regulated solely under 1271 – and thus be a "361 HCT/P" – "the HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent."

In 2015, the FDA proposed deleting this sentence from the intended use regulation, but never finalized the deletion. Instead, in January 2017, the agency finalized the rule, keeping the sentence and adding a "totality of the evidence" standard – effective March 21, 2017. This was a great disappointment to the regulated industries.

On Feb. 8, 2017, pharmaceutical industry groups (including PhRMA and BIO) filed a Petition to Stay and for Reconsideration, asking the FDA not to move forward with this final rule. Likely in response to the petition and to give the Trump administration time to review the implications of the final rule, the FDA announced on March 20, 2017, it would delay the effective date until March 19, 2018. The agency even implied there might be a final rule issued after the one–year delay.

As part of that overall process, the AATB has been diligently working to ensure the voice of tissue banks is being heard. In a fall 2016 oral presentation to the FDA, the president and CEO of AATB, Frank Wilton, urged the agency to also examine issues related to "manufacturer's objective intent" to ensure that the parallel concepts are treated similarly. This topic was raised again with the FDA during the AATB-FDA liaison meeting in December 2016.

Recently, the AATB and the AATB Tissue Policy Group (TPG) sent a letter to the FDA with several key recommendations, including that FDA should treat 351 and 361 HCT/Ps similarly in defining the type of communications that will be deemed relevant in determining "intended use" or "manufacture's objective intent." The letter further noted that the exchange of scientific information should not be included as part of "intended use" or "manufacturer's objective intent."

FDA Workshop: Infectious Disease Risks of HCT/Ps

The FDA hosted a public workshop Feb. 8–9 to promote a scientific discussion of the methods available for identifying and characterizing infectious disease risks associated with human cells, tissues, and cellular and tissue-based products (HCT/Ps). Key AATB members presented at the workshop, including Michael D. Strong (Northwest Tissue Center); Ted Eastlund, M.D.; David J. Gocke, M.D. (Musculoskeletal Transplant Foundation); and Jaime Shamonki, M.D. (California Cryobank). For a summary of the meeting, visit: USFDA Public Workshop: Identification and Characterization of Infectious Disease Risks of Human Cells, Tissues and Cellular and Tissue-Based Products.

Biological Implant Tracking and Veteran Safety Act

For the past several years, the AATB and the AATB TPG have been working with Congress to sign into law the Biological Implant Tracking and Veteran Safety Act – legislation to enhance the ability to "track and trace" implants at facilities serving veterans. This critical legislation contains two key items:

- A requirement that tissue procured by the facilities only be sourced from tissue processors accredited by the AATB or a similar national accreditation organization.
- Clarification that procured human tissue can be labeled with any of the three systems already identified by the FDA, specifically GS1, the Health Industry Business Communications Council (HIBCC), and ICCBBA.

On Jan. 3, Rep. Phil Roe, M.D., R–Tenn., chairman of the House Veterans' Affairs Committee, introduced 2017 Biological Implant Tracking and Veteran Safety Act (HR 28). Later that day, the House passed it by voice vote. On Jan. 4, Sen. Bill Cassidy, M.D., R–La., introduced the Senate version of the bill (S 23). Sen. Jon Tester of Montana, ranking Democrat on the committee of jurisdiction, joined as a co-sponsor on Jan. 9.

Not only have the AATB and AATB TPG sent a letter of support for this legislation but also on Feb. 17, members of the AATB TPG lobbied key senators in support of the legislation. Those efforts have borne fruit; the Senate Veterans' Affairs Committee has signaled that it plans to include this legislation in its first legislative hearing of the year. This is a key step to realizing the ultimate goal – getting the legislation signed into law.

Learning UDI Community

Representatives and members of the AATB TPG have joined the Learning UDI Community (LUC) – a broad–based coalition of health care leaders across sectors whose goal is to develop a common understanding and approach to adopting Unique Device Identification (UDI). The LUC is a joint effort of the FDA and the Association for Healthcare Resource and Materials Management (AHRMM). While the AATB TPG's expertise has been helpful to a number of work groups, most of its efforts have been focused on the LUC work group focused on HCT/Ps (Read the Work Group Charter here). The key point of advocacy for the AATB TPG has been to ensure that all three issuing agencies are fairly and appropriately represented in the final recommendations of the LUC, especially in light of AATB's survey of tissue processors. The survey suggests that our accredited tissue banks have appropriately opted to use all three available issuing agencies for UDI (Read survey results here).

FDA Tissue Guidance

Starting in the fall of 2015, the FDA began to release several guidance documents, which could have a dramatic impact on human cells, tissues, and cellular and tissue-based products (HCT/Ps). The AATB and AATB TPG have commented extensively on these guidance documents [read Key Letters here] and testified at the Part 15 hearing on the documents Sept. 12–13, 2016 (read Frank Wilton's transcript here).

Twice a year (usually in January and June), the FDA Center for Biologics Evaluation and Research (CBER) releases or updates its guidance document agenda. In January 2017, CBER released its document, and key HCT/P guidance documents were noticeably absent. Thus, at least at this time, the FDA plans to take some time to review the comments received from the docket before proceeding.

Key documents:

- Homologous Use of Human Cells, Tissues, and Cellular and Tissue–Based Products: Draft Guidance for Industry and FDA Staff
- Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue–Based Products: Draft Guidance
- Draft Guidance for Industry: Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception
- Human Cells, Tissues, and Cellular and Tissue–Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance

Scott Gottlieb, FDA Commissioner

On April 5, the Senate Health, Energy, Labor, and Pensions (HELP) Committee conducted a confirmation hearing for Scott Gottlieb, M.D., President Trump's nominee for FDA commissioner. Gottlieb, who served as a senior adviser at the FDA under President George W. Bush, has spent much of his time working for venture capital and investment banking firms that invest in biomedical startups, as well as his own consulting firm. He has also repeatedly testified as an expert on the industry before Congress.

In a presidential administration whose confirmation hearings have sparked more than a few contentious moments, Gottlieb–s hearing was remarkable for how unremarkable it was. Senators from both parties asked questions on the full range of the FDA's jurisdiction, and Gottlieb's experience combined with his clear preparation resulted in an uneventful, two–and–a–half–hour hearing.

Gottlieb was sworn in as FDA commissioner on May 11.