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Disruptor Series: 3D Printing

before

The Committee on Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade

U.S. House of Representatives

February 26, 2016

Mr. Chairman, Ranking Member Schakowksy, and members of this distinguished subcommittee, thank you for the invitation to address you today.

I am honored to discuss a critically important topic— how additive manufacturing (or 3D printing) is revolutionizing the delivery of health care.

Thirty Years of Invention and Solution Adoption

In 1983, my company's founder -- Chuck Hull invented 3D printing, applying a process called stereolithography to physically replicate a plastic eye-cup that was designed and digitally drawn on a computer. His patent was granted in 1986 and the business took off from there.

More than 30 years later, the industry is in full-throttle. For its own part, 3D Systems is the world leader in additive manufacturing, and the only major US-based 3D printing company. From the outset, we've catalyzed continuous innovation in health care—

In the early 1990s we revolutionized manufacturing of hearing aids, rapidly customizing the form and fit to an individual's ear with unparalleled precision, helping build wireless devices with comfortable biocompatible materials. Today, 99.5 percent of all hearing aids are 3D-printed world-wide.

A decade later, we helped two graduate students from Stanford University discover a better way to straighten teeth. With our technology, they manufactured what became Invisalign clear orthodontic aligners. Today, Align is a world leader in mass customization, accuracy, and comfort, producing over 20 million individual aligners in the last 12 months alone.

Promise of Precision Medicine

3D printing continues to advance significant breakthroughs in the field of "Precision Medicine" – a movement championed by the Food and Drug Administration that tailors medical treatments intensively to individual characteristics of each patient. As part of this movement, together with genomics,

regenerative medicine, computational biology, and medical imaging, 3D printing is once again revolutionizing the practice of saving and improving lives.

Today, let's concentrate on three key areas: virtual surgical planning, fabrication of advanced implants and devices, and new modeling processes.

Virtual Surgical Planning. VSP empowers surgeons with unparalleled precision in the most complex procedures. It significantly reduces time in the surgical theater and saves lives. Our experts interact directly with doctors, receiving data from CT scans, and then design and build surgical guides that are placed on a patient to support a particular procedure. We are showing a video in the hearing room today highlighting the case of Blessing Makwera. He sustained a landmine injury to his upper and lower jaws, tongue, lips and teeth. Blessing's spirit and courage are truly inspirational; and today he can smile.

3D Systems worked with Dr. Joel Berger, oral and maxillofacial surgeon at Sharp Memorial Hospital in San Diego, California to rebuild Blessing's face and give him new teeth. The fibula free flap operation involves taking bone, tissue and vessels from the fibula and reconfiguring them to form an upper and lower jaw connected to blood vessels in the neck. We used CT scans to extract 3D anatomical information needed to visualize the surgery in 3D and map out the surgical plan.

Blessing required a number of 3D printed tools, including a mandible and maxilla cutting tools to guide the surgeon's saw blades in the operating room.

It's an inspiring story among tens of thousands over the last several years.

Models and Simulation. Aside from the surgical guides, Blessing's surgeons also used 3D printed models for reference during the operation. These models show surgeons what is hidden beneath layers of soft tissues. They gave surgeons hands-on experience with Blessing's jaw anatomy before starting surgery.

Advanced implants. Outside customized tools, 3D printing is also transforming whole-sale production of medical devices and implants. I brought a titanium component of a hip transplant which was 3D printed. Rather than go through the onerous process of building a cast mold, shaping, cooling, and then coating a single part, metal 3D printing allows us to consolidate the supply chain—saving time and resources. It also allows us to add functions to the part, with designs that maximize bone cohesion—structures that simply cannot be built via any other manufacturing process.

Doctors and device manufacturers can send us data to engineer 3D models and then we use direct metal printing to build dozens of these titanium cups in a single build process. We have been working with U.S. and European regulators to ensure appropriate quality assurance in the process for an array of implants and devices.

Keeping Pace with Innovation

In all these areas, we have a strong and constructive partner in the federal government. As we work to receive appropriate qualification for these products, it is essential we maintain an appropriate balance between promoting innovation and ensuring safe delivery of care to patients. As 3D printing improves the economics in the production of critical health care tools, I am hopeful we might someday see these efficiencies translate to lower costs for the patient. Integrating these novel processes and tools will require a greater understanding not only by regulators but the health insurance industry as well. In due time, perhaps it will be common place for these tools to be integrated into conventional billing processes. It is time for 3D printing to be appreciated as an important instrument for mainstream, quality care.

I look forward to discussing this and other issues with the Committee today.