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ADVANCING ETHICS, COOPERATION AND EDUCATION

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Amazing Medical Device Developments

Innovation and excitement are alive and well in the health care industry. Rapid developments in additive manufacturing (AM), or three-dimensional (3D) printing, along with Augmented Reality (AR), also known as virtual reality, are driving phenomenal improvements in patient care.

AM promises an expansion of device production utilized to custom design and manufacture many products including medical devices and jet engine parts, among others. Some estimate that the growth of 3D printers will reach 200 percent in 2015 based upon its ability to fabricate cost-effective, safe, and reliable products with shortened production times and less equipment.

AR presents unbelievable virtual environments to health care providers, not only for training, but also for real-time delivery of care.

As with most innovation, the benefits of scientific and engineering breakthroughs such as AM and AR bring concomitant risks, including liability exposure and challenges in assessing the risk of producing products with short-run manufacturing in the case of AM products and device malfunction or failure for AR products. We will explore this topic in our seminar.

I. Additive Manufacturing (3D Printing) and Augmented (Virtual) Reality in Healthcare: An Overview

A. What is 3D Printing and Application?

3D printing is any of various processes to make a three-dimensional object. In 3D printing, additive processes are used, in which successive layers of material are laid down under computer control. These objects can be of almost any shape or geometry, and are produced from a 3D model or other electronic data source.

3D printing initially referred to processes that sequentially deposit material onto a powder bed with inkjet printer heads. More recently the meaning of the term has expanded to encompass a

wider variety of techniques such as plastic extrusion and sintering based processes. Technical standards use the term additive manufacturing for this broader sense. [1]

There are myriad applications for AM technologies, including architecture, construction (AEC), industrial design, automotive, aerospace military, engineering, dental and medical industries, biotech (human tissue replacement), fashion, footwear, jewelry, eyewear, education, geographic information systems, and food.[2]

While the cost per item is higher than conventionally manufactured items, set up expenses are far lower. For example, one aerospace firm cut its construction time by 70% and overall costs by 80% when it switched to manufacturing cable housing by 3D methods rather than using conventional manufacturing.

Another benefit to the technology is the ability to customize a product to its end user's requirements. For example, custom built earphones designed to fit the customer's ear canals, based upon photographs, can now be built in a couple of days.

Since the start of the 21st century there has been a large growth in the sales of AM machines, and their price has dropped substantially. The market was $3.1 billion in 2013. It is expected to grow to $12.5 billion by 2018 and to $21 billion by 2020 according to a November 2014 Financial Times article. 3D printers are now being manufactured for home use to make novelty items such as action figures.

One of the largest challenges to the growth of this industry is obtaining regulatory approval for products made in this fashion. Regulators are concerned about the safety of these products due, in some cases, to the uniqueness of each item. In other cases, the materials being used are not the same as those being used by conventionally manufactured products, whose properties are well known and which have stood the test of time. Regulators wish to ensure these products meet or exceed their predecessors particularly in the health and aerospace industries. They are therefore struggling with how to test these products to ensure they meet the standards.

B. What is Augmented Reality and Its Applications?

Augmented reality or virtual environments and related technologies are allowing medical practitioners to help their patients in a number of innovative ways. The following are some examples:

- As the technology develops, a surgeon will be able to operate on a patient in a remote location. Today's remote telesurgery is being developed for the military to enable a

[1] Wikipedia
[2] Extracted from Wikipedia

surgeon to assist medics in the battle arena. The Advanced Research Projects Agency (ARPA) Advanced Biomedical Program has demonstrated its robotics surgery system using wireless transmission, with the surgical site located a kilometer away from the "robotics arms."

- Virtual environments are useful for local as well as remote surgery. An example of the local use of virtual environments is in endoscopic surgery. Surgeons manipulate instruments by viewing a television monitor and manipulating a tool inserted through a tube into the patient.

- Virtual environments are being used to create simulators or trainers. These systems reduce the cost of training surgeons and the risk to the patients. For example, a heart-cauterization simulation allows the trainee to guide a balloon catheter through a hollow guide wire to the obstruction, and inflate the balloon to expand the artery and restore regular blood flow.

- Therapeutic uses of virtual environments include creating interactive systems that help reduce anxiety or stress. For example, dentists are using 3-D eyeglasses to divert patients; attention while in the chair.

- Virtual environments are also used to reduce phobias, to develop skills, and to train those with disabilities. One example of the use of virtual environments for training is a program that substitutes virtual bus rides for the real thing so that disabled individuals can learn to use public transportation system.[3]

These AR products are having meaningful and immediate impact in a host of health care delivery vehicles such as:

- Surgical procedures (remote surgery of telepresence, augmented – or enhance – reality surgery, and planning and simulation of procedures before surgery)

- Medical therapy

- Preventive medicine and patient education

- Medical education and training

- Visualization of massive medical databases

[3] http//www.cybertherapy.info/pages/survey.htm

- Skill enhancement and rehabilitation

- Architectural design for health-care facilities

II. What Liability Challenges Will These Technology Advances Present?

A. Additive Manufacturing

Will the private individual's ability to purchase such equipment lead to the rapid proliferation of new products manufactured in-home? With the growing distribution of products over the internet, will distribution of such products increase exponentially?

Basic questions that will arise have to do with the obligations of the designer or product manufacturer. How will they know that these products will stand up over time? What type of testing must they do prior to marketing these products? What will be the exposure of the manufacturer of the 3D printing machines if a product fails during usage? How should contracts between these two parties be drafted to mitigate exposures?

Will these products require any changes to traditional product liability doctrines? Strict liability? Breach of Warranties? Negligence? Will any changes be required?

Will loss exposures expand for manufacturers of such products? How should these exposures be financially protected? How will the growth of private manufacturing by in-home practitioners impact financial responsibility? How can brokers and underwriters be educated to better appreciate and anticipate these exposures? What implications will this have for the insurance industry?

Finally, from a loss control perspective, what are the known shortcomings of these processes and how can manufacturing and testing processes be designed to reduce these exposures?

B. Augmented Reality

Although far different form a medical device, augmented reality products face so many of the same liability and risk management issues as AM products. Some key differences include the emphasis that will be placed on the proper training of health care providers on this technology.

Failure-to-train claims have long been popular with claimants counsel, and there is no reason to believe this theory of liability will lose any of its appeal for AR technology. And given the complexity of these products, it is certain that manufacturers and health care facilities will require the assistance of a manufacturer sales representative during the delivery of care. The presence of a sales representative likely will, in turn, invite claims that a sales representative failed to prevent a product misuse, failure-to-warn, or even engaged in the unauthorized practice of medicine.

As with many evolving technologies, the risks of off-label use may be particularly high with AR products as designers, manufacturers, and providers continue to unleash the potential of this technology.

Of course, the health care provider, particularly the physician, bears ultimate responsibility for the quality of patient care. Thus such potential liability theories may invoke traditional devices, where available, such as the learned intermediary doctrine.

How the theories of liability, defenses, and regulatory requirements for these innovations will develop has and will remain the topic of serious legal and other academic speculation.

III. Claims Perspectives

A. Types of Potential Claims

Claims brought from injuries sustained due to the alleged use of medical devices include several different types of allegations. When using a device, health care professionals must insure they have the right size, shape, make and model for the installation of everything from bone grafts to hip Implants to heart valves. If an error is made by implanting the wrong product, or failure to bring a replacement for a product found to be defective in the OR, any resultant injury may also result in claims. Typical claims brought against the manufacturers include strict liability allegations of defective design and defective manufacture, other claims may be brought against the manufacturer for failure to warn and inadequate instructions for use. In addition, claims may be brought against sales representatives or device brokers including: missing implantation instruments, incorrect size product and need for revision surgery, expired implant used and delay in providing components. As with other sophisticated medical devices, AR and AM manufactures may face claims that allege negligence against their sales representatives in the OR based on failure to correct the physician in device usage, or misuse of a product, invasion of privacy, and unauthorized practice of medicine, to name but a few.

B. Tradition Products Liability and Potential Exposures

Now we consider the impact of these types of claims against traditional products liability theories. The main impact appears to be the insertion of a new layer of players i.e. the 3D printing equipment manufacturers and those who choose to produce product using these devices. The 3D equipment manufacturers do not control the use of their devices, but do have a responsibility to design and manufacture equipment that can be relied upon to produce the designed product properly. Potential exposures may relate to clarity of instructions provided with initial set-up to include the quality of the input material, accessibility of trouble shooting protocol, and product maintenance instructions. As to those who design and produce the product via 3D printers, in the case of product failure, there will be questions as to the integrity of the design, the suitability of the materials selected and the quality assurance procedures undertaken prior to marketing.

The companies that produce the 3D equipment are likely to be insured similar to any other manufacturer. The concern will come in as to the financial protection secured by private individuals who decide to use this equipment to produce and market product. Will they appreciate their potential liability for defective design, manufacture and failure to warn and purchase insurance? Will they have adequate financial wherewithal to protect the users of their products? Will they perform any testing and quality assurance prior to releasing their products? Will they develop the necessary labeling and warnings to accompany their products?

C. Sharing the Liability

Additionally, how do these products impact the comparative negligence calculus? Traditionally, under strict liability, liability is pushed up the chain to the manufacturer. Who will be considered to be the manufacturer when this type of equipment is utilized? Rarely does an injured party go after the company who made the machine that the producer of the product utilized. Will this change in cases of bodily injury or property damage arising out of the usage of 3D printing devices? Or will liability stop at the feet of those who use this new technology?

Traditional risk sharing doctrines such as "joint and several" that protect the injured party where some but not all of the tortfeasors are insured, have been significantly weakened via tort reform in recent years. How will state legislators react should there develop a number of situations where significant numbers of injured claimants are unable to recover for their injuries because products were manufactured by uninsured private parties? Will this burgeoning industry force changes in tort liability doctrines or cause new laws to be enacted with respect to financial responsibility?

IV. Underwriting Perspectives

A. Insuring the Exposure

The use of advanced technology Medical devices brings many different liability issues into play. The main exposures for medical device manufacturers arise from injuries caused by product misuse, or defects in design or manufacture. The potential financial loss associated with these exposures includes, in many instances, significant costs to defend against a claim. With augmented reality and advanced technology devices, training on these devices is a critical issue. This presents underwriters with another angle to be concerned about. What training regimen does the manufacturer provide, and more importantly, what is the doctor required to do to maintain proficiency?

Representatives of the manufacturer are oftentimes present in an operating theater, and fall into two categories: employees and contractors. When the representatives are employed directly by the manufacturer, the insurance must be procured by the manufacturer and would include coverage for the employees and the company for the actions of its employees. Contractors often work alone and can find it difficult to purchase individual policies. For this reason, insurance is often purchased as a pool through associations known as benefit groups. What are those reps

doing? Are there guidelines at the institutions for what those reps can and cannot do? State laws forbid reps from touching a patient, as do most institutional guidelines.

When using a device, health care professionals insure they have the right size, shape, make and model for the installation of everything from bone grafts to organs. If they make an error by bringing the wrong product, or do not have a replacement for a defective product, any resultant injury may also result in allegations against the manufacturer for failure to warn, inadequate instructions for use, not to mention strict liability for an actual defect. Now that custom 3D biomedical printing of devices and even organs is being used, doctors, institutions and device manufacturers must concern themselves with entirely new sets of issues. Who is responsible when the 'manufacturing' of a device is both decentralized AND bespoke?

B. Risk Management and Loss Control

The most obvious exposure with respect to medical devices has always been the product liability derived from complications due to a defective device. However, with today's advances in systems and technology, the training and teamwork that go into the use of these systems are equally important. The use of remote surgical applications bring issues of appropriate licensing and oversight into the picture. Malpractice coverage applicability may be impacted by this.

Often the limits of coverage are dictated by requirements of the hospital and manufacturer. It is the underwriter's responsibility to confirm these parties are not carrying limits higher than other potentially liable parties and end up as a potential deep pocket.