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A LOOK INTO THE FUTURE IN LIFE SCIENCES LITIGATION

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I. Products to Watch in 2015

A. Google Glass

What is Google Glass? They are glasses without lenses and are similar to smart phones in that they can run apps, have photographic and audio capabilities and can facilitate live transmission of data via wireless access to the internet.

Can wearables in the OR improve clinical outcomes? A recent Stanford study shows that they can. The study was conducted by Stanford Medical Group and in it 20 Stanford residents performed two types of surgeries on dummies - one with the help of glass and one without. Their performance was markedly better while using glass.

The residents wearing glass looked up at monitoring equipment far less during surgery, which allowed them to stay focused on the patient and the procedure. The study resulted in compelling preliminary evidence that the head mounted display can be used in clinical setting to enhance situational awareness and patient safety.

Glass has the potential to enhance intraoperative consultations – for example, if a surgeon encountered an unexpected condition in the OR, she could use a voice command such as "record video" and send real-time video to an expert in a remote location.

Glass will also improve communication. With the video camera perched just above the right eye of the user, the device allows for real time transmission of exactly what the surgeon is seeing. Clinical officers – who are individuals other than physicians that provide clinical care in low and middle income countries – can utilize the glass during an unfamiliar situation to obtain assistance. For example, if a patient presents after a motor vehicle accident and needs a splenectomy, the clinical officer wearing the glasses could bring up the expertise required form another surgeon thousands of miles away.

There are limitations to Google glass and some necessary enhancements need to be made before the device can be used to its fullest potential. These include increased battery life, sharper resolution, improved Wi-Fi connectivity and improved voice recognition capability.

Although industry experts agree the device could have a beneficial role in providing quality health care, functionality enhancements are needed before the tool can become part of the surgeon's day to day experience.

Apps are also available on smart phones to collect data about the user's health. As an example, Vital Signs is an app that allows the user to collect information regarding heart rate and breathing by pointing the phone at the user's face.

It will become increasingly more common and easy for people to monitor, analyze and in some cases diagnose aspects of their health. This does not mean that doctors will become obsolete. It means that people can be more aware of health problems they have and share the information with doctors.

B. Protective Wear for Ebola

The most current outbreak of Ebola started in December 2013 with a 2 year old boy but was not officially recognized until March 2014. During that time, the virus spread. Today the World Health Organization reports that 8 countries are affected; 9000 people have been infected and 4500 have died. These numbers are probably wrong according to WHO and the real numbers are much higher.

The fatality rate for the current strain is 70%. To put this in perspective, the Spanish flu killed 50 million people worldwide in 1918 with a case fatality rate of only 2.5 percent. According to the World Health Organization, the current Ebola outbreak is the most severe, acute health emergency seen in modern times. 20,000 new cases are expected this month.

The use of personal protective equipment can be difficult and dangerous. Several of the nurses at Texas Health Presbyterian that treated the first Ebola case in the United States claim the hospital did not have proper protocols for dealing with Ebola and did not know what type of personal protective equipment should be used. According to Dr. Aileen Marty, a WHO physician, no amount of protection is going to help workers who do not put on or take off the layers carefully.

Companies are doing their best to keep up with the demands for impermeable gowns and body suits. These gowns and body suits are intended to be designed with material that does not absorb fluids and is crucial to preventing the spread of Ebola and other viruses. Impermeable gowns and body suits are Class II devices that fall under the classification of "Surgical Apparel" pursuant to 21 C.F.R. § 878.4040. The regulation describes the apparel as "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particular material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns . . ."

A recent class action filed against Kimberly Clark related to their surgical gowns has sparked a new wave of litigation and threatened the current supplies made available to hospitals and other treating facilities.

C. Over the Counter Topical Acne Products

The FDA reported that it has received over 131 reports of skin reactions since 1969, most of which were reported after 2012. Of these cases, most are related to anaphylactic claims; the patients also had respiratory or cardiovascular problems in addition to skin swelling, hives, flushing and other symptoms. Hospitalization was required in about 44% of the cases and 38% were anaphylactic hypersensitivity. About 42% of the reactions occurred within minutes to 24 hours of product use, according to the FDA.

To date, the FDA has not required any label changes for the products. FDA is continuing to monitor and investigate the safety concerns with the use of the OTC acne medications.

D. Morcellators

Morcellators are hand held tools that typically use a fast spinning, tube shaped blade to remove either non cancerous fibroids or the uterus in laparoscopic procedures. The FDA estimated the tool was being used in 50,000 hysterectomies a year.

Although uterine fibroids are common and usually benign, about 1 in 350 women undergoing hysterectomies or fibroid removal have an unsuspected uterine sarcoma, a type of uterine cancer. If laparoscopic power morcellation is performed in these women, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long term survival.

The FDA began approving morcellators in 1991. Over two decades, the FDA cleared at least 10 such morcellators from various companies through the 510(k) process. The agency did not start studying how morcellators might harm women until December 2013 after a Wall Street Journal article highlighted the device's hazards.

II. Cases to Watch in 2015 - Failure to Update Claims

The issue of whether generic drug makers can be held liable for failure to timely update their labels to match the corresponding brand's update and failure to adequately communicate updated labeling was heavily litigated across the country in 2014, causing a split in federal and state appellate courts.

In *Huck,* the Iowa Supreme Court ruled that *Pliva* could be liable for injuries from its insufficient warnings. The Justices stated that the Supreme Court's ruling in *Mensing* does not preempt all state law tort claims against drug makers. *Pliva* had argued that state tort law claims are preempted. In November, *Pliva* asked the Supreme Court to overturn the Iowa Supreme Court's ruling. In its petition for a writ, *Pliva* said the Iowa high court took the wrong side of a pre-existing circuit split in federal and state appellate courts. *Pliva* went on to state that the need for

the Supreme Court to resolve the widening split on this recurrent and important issue of federal law is pressing.

Another case that will be closely watched is *Pikerie*. On June 13, 2014, California's fourth district court of appeal denied the generic defendants' appeal of the denial of the demurrer based on federal preemption. The appeal was limited to whether the claims alleged in the complaint were preempted by federal law. The court found that not all state law claims are preempted by the Federal Food, Drug and Cosmetic Act (FDCA), rather, only those state laws which are in direct conflict with the FDCA. Specifically, the court found that the allegations that the generic defendants failed to update the labels to match the RLD (Reference Listed Drug) labeling were not preempted; but did state that any claims that the generic defendants failed to update the label to say something more than or different from the approved label would be preempted.

The court also analyzed whether the failure to communicate argument is preempted and found that it was not. The court opined that it is not impossible for the generic defendants to send dear doctor letters advising health care professional of the risks identified in the updated labels. Teva filed a petition for writ of certiorari on February 7, 2014.

III. Legislation to Watch in 2015 - Generic Drug Labeling Rules

The FDA has not finalized the controversial rule it proposed in 2012 that would allow generic drug makers to unilaterally change their warning labels. The rule, if finalized, could result in generic drug companies being found liable for injuries if they fail to warn of their drugs' risks.

It was expected that the rule would be finalized by the Agency in 2014; however, the projected date was recently changed to September 2015. The agency claims the date for finalizing the rule was extended due to the great deal of public input the FDA has received during the comment period. The agency went on to state that they are committed to reviewing and considering all comments received as the final rule is developed.

The Generic Pharmaceutical Association has vowed to sue if the proposal is ratified. The Association argues the FDA should avoid taking action that could imperil the affordability of generic medication by creating huge new litigation costs.

Such a rule would undercut the precedent established by the US Supreme Court in the *Mensing* and *Bartlett* cases, finding failure to warn and design defect claims against generic drug makers preempted.

IV. Government Actions against Life Sciences Companies

Within the past two to three years, there has been a significant spike in the numbers of actions brought by governmental entities against drug and device companies. Increasingly, Attorneys General for the various states are focused on consumer fraud/deceptive trade practices statutes with civil penalty provisions as the basis for these actions. Federal and State investigative activity is on the upswing, even as State Medicaid fraud units become less active. Attorney General investigations often follow Department of Justice (DOJ) subpoenas and grand jury activity or settlement agreements. Attorneys General may also be spurred on by product liability

litigation and lobbying by plaintiffs' groups. It is significant to note that State Actions rarely occur first.

This poses a very real risk to drug and device companies. Defending against these cases is expensive, time consuming and difficult due to the State's subrogation of certain police powers to the firms hired to bring these actions on behalf of the State. In addition, there are reputational implications to the companies involved with the product as most citizens believe State Actions are taken against products or situations which are clearly or imminently dangerous.

A. State Attorneys General Actions

State Actions exist because the States need the money afforded by the settlement. Accordingly, State Attorneys General will continue to interpret consumer protection laws broadly using relaxed standards to aid in recovery. For example, in at least one case, the State based its complaint on the tendency to mislead versus actual deception. Often these State Actions take the kitchen sink approach to Consumer Fraud alleging false advertising, off-label promotion, inadequate adverse event reporting and Federal regulatory violations. Civil penalties sought are anywhere from $500-$25,000 per violation which can amount to substantial amounts of money. For example, in past cases, a violation was found to have occurred for every sales call during a nine month period or every single time that a DHCP letter was mailed to doctors.

B. Department of Justice Actions

The Federal Government (through Justice Department) has not lagged behind actions taken by the States. In 2014, the US DOJ collected $24.7B in fines and penalties including a single settlement of $1.6B from Johnson and Johnson for its off-label (unapproved) promotion and marketing of Risperdal. The FDA (through the DOJ) is pursuing increasing numbers of companies for civil and criminal penalties through actions such as False Claims Act, Qui Tam, and even criminal actions against corporate officers and directors of target companies. However, off-label use is a necessary corollary of the FDA's regulation. It is a compromise between regulation of the practice of medicine, and regulating drugs. In fact, the FDA permits limited off-label promotion subject to restrictions and rules as exemplified by its Good Reprint Practices document of 2009. So why the increasing number of actions raised by the FDA and prosecuted by the DOJ against drug and devices companies? Partly, it is due to increased funding of the FDA due to a series of user taxes. It is a trend that is unlikely to change. Companies need to be aware of the possibility of these actions and take steps to protect themselves.

V. Procedural Trends in Coordinated Proceedings and Associated Defense Strategies

Coordinated Proceedings are the predominant litigation battleground for life sciences matters, most particularly for pharmaceutical and medical device cases. While such proceedings are certainly not novel, they are on the increase. Understanding that the investment in a one-off pharma or medical device case may not be worthwhile for a variety of reasons, plaintiffs' attorneys are increasingly banding together and focusing their efforts on amassing as many cases as possible before a single Federal or State court.

The procedural stages of a mass tort proceeding remain fairly unchanged, though plaintiffs' tactics to force resolution have certainly evolved, and the defense's ability to out maneuver those tactics also continues to develop. Two important and relatively novel trends affecting the mass tort life cycle are addressed below.

A. Common Benefit Orders

A common benefit order ("CBO") is a mechanism by which plaintiffs' attorneys appointed by the court to leadership positions in a coordinated proceeding ensure that they are reimbursed for litigation expenses out of any settlements or judgments that are obtained. The orders typically require payment of a percentage of any recovery into a common fund, from which typical expenses such as filing fees, travel, deposition expenses, and the like, may be reimbursed to those in leadership. Most importantly, they allow plaintiffs' leadership to recover fees for their services, which purportedly are performed for the benefit of all. This is why the infighting for leadership appointments among the plaintiffs' bar has become so extreme – they can be incredibly lucrative. Even an attorney with only one or two cases in the proceeding can ultimately make millions in fees, in the performance of work "for the common benefit."

Plaintiffs often urge the entry of the CBO early in the litigation, just after leadership appointments are finalized. Plaintiffs' will position entry of the order as an issue that belongs solely to them, arguing that the defense should have nothing to say about the way that the plaintiffs' bar decides to dole out recovery proceeds. Nothing, however, could be further from the truth. The trend over the past several years is to impose increasing obligations on the defendant. These obligations include payment deadlines with which the defense may not be comfortable, yet ultimately has to meet because they become part of a court order early on in the litigation. CBOs often impose extra administrative burdens on the defense, requiring the issuance of multiple checks to the various fee and expense funds that the plaintiffs have established. Most problematically, more and more CBOs impose reporting obligations that jeopardize the confidentiality of settlements and allow plaintiffs a view into the defendant's settlement strategies, which should be covered by work product protections.

The reason that CBOs have become increasingly broad and burdensome over the years is because some defendants have stipulated to the entry of such orders, perhaps because their settlement strategies did not involve individual case settlements, so they did not view more burdensome orders are really affecting their finance departments or their litigation strategies as a whole. The problem is that now, when a defendant actually takes a stand to oppose a CBO, these excessively broad CBOs are held out to the court as the current gold standard, persuading some courts to actually enter them.

To combat this trend, defendants must take a stand against any CBO that imposes anything but the most minimal obligations upon them. There is at least one decision holding that a CBO that imposes <u>any</u> obligation on a defendant should not be entered, since the defendant gets absolutely no benefit whatsoever from the operation of a CBO. It is this policy that must become the prevailing one, so that plaintiffs' efforts to extend the reach of CBOs can be curtailed.

B. Bellwether Mediations

In mass tort proceedings, cases have typically been coordinated because they involve similar injuries associated with the same product. The product, for example, may have led one group of plaintiffs to suffer a heart attack, another to suffer a stroke, and so on. The cases are grouped with the idea that if a value can be determined as to one, that value might be ascribed to all cases within a particular group. The primary mechanism for determining the "value" of a case has typically been a "bellwether trial" – the trial of one case within a particular group that is considered to be generally representative of the others. A review of the history of mass tort proceedings reveals that global settlements typically occur after one or more bellwether trials have occurred.

The challenge with this system is that trials are expensive. It typically takes many many years of costly discovery to position the first bellwether case for trial. And then often times the losing side will argue that the case tried was not actually representative of the others, and therefore cannot be relied upon to set case values.

A recent trend, therefore, is toward bellwether mediations. A bellwether mediation process is one whereby, relatively early on in the litigation – after the defense has produced core documents and the plaintiffs have produced fact sheets – the defendant and the plaintiffs' attorneys in leadership (or those who control the most number of cases) each select a small number of a certain agreed-upon "simple" group of cases for mediation. If the cases are resolved at mediation, case values and data points for an ultimate, global resolution can start to be set. Eventually, additional plaintiffs' firms as well as bellwether groups, such as the most extreme and serious injury cases, can be added to the mediation process, setting even more values and data points for representative matters that can eventually be ascribed to the whole.

Bellwether mediations that ultimately lead to global resolution appeal to the plaintiffs' bar, because plaintiffs' attorneys get paid sooner than they would otherwise. Such mediations appeal to the defense for cost and peace of mind reasons as well. This trend toward bellwether mediations is one that, if it continues, might result in a more efficient handling of mass tort proceedings as a whole.

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