Welcome to the 2016-17 Winter edition of the Double Helix. This communication authored by various members of Arthur J. Gallagher & Co.’s Life Sciences Practice group and will be distributed on a quarterly basis. It is intended to be a tool for sharing industry information, new regulations and Gallagher Life Sciences products.

Arthur J. Gallagher & Co.’s Global Life Sciences team assists our clients in obtaining coverage throughout all areas of the life sciences industry. We understand that risk management solutions for life sciences companies are both complex and specialized. Partnering with Gallagher’s Life Sciences Practice provides our clients with access to a team of insurance professionals with thorough knowledge of the industry and the regulatory environment. With more than 3,000 clients and decades of experience, our team will leverage the marketplace on your behalf to help protect your company’s bottom line from the financial devastation that could result from a loss or lawsuit. Our experts will work with you to customize risk management and insurance solution programs that meet your unique needs and protect your organization under the best possible terms and conditions.

Please give our team a call if we can assist you with any of your risk management needs.

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Medical Device Consolidation

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The healthcare industry has undergone dramatic changes over the past ten years, changing the landscape of business and medicine. Medical device companies have been gobbling each other up at a rapid rate, sending a ripple effect throughout the healthcare industry.

This consolidation has resulted in increased regulation and has companies trying to squeeze out as much revenue as possible. The Affordable Care Act is partly to blame as it instituted an excise tax of 2.3 percent on all medical devices. This, coupled with the unpopular United States corporate tax structure, has resulted in many companies moving their operations overseas. With profits dwindling, there is less money being spent on research and development and more focus on current margins. The Food & Drug Administration (FDA) also requires most medical devices to have a Unique Device Indicator (UDI), and the increased oversight is increasing the cost of doing business.

Moreover, hospitals are being acquired at record rates by major healthcare delivery organizations and small physician groups are joining larger enterprises. Individual private practices are becoming a thing of the past. This shift is also changing manufacturer-buyer dynamics. Medical device companies are fighting to obtain contracts with Group Purchasing Organizations (GPOs) to do business at hospitals. The GPOs have tremendous bargaining power; they are negotiating price decreases of as much as 40 percent in some transactions. Medical device companies are at their mercy and can either accept it or walk away with nothing.

Supplier reduction is another problem resulting from the consolidation process. Hospital administrators don’t have the time or resources to consider smaller medical device companies to be approved at their institutions. Administrators are facing increased pressure to cut costs. Bigger companies have the power and leverage to beat smaller medical device companies on pricing. As a result, hospitals are reaching out to those companies that already have the biggest market share for price proposals. These businesses are also consolidating so they can create instant scale to compete in the marketplace.

Consequently, there are more challenges in the insurance coverages that protect these medical device companies. The M&A environment has brought more emphasis on comprehensive D&O coverages. With increased regulations throughout the healthcare industry, E&O insurance has also become a critical coverage. The healthcare landscape has certainly made it more challenging to do business. However, with these challenges there are new opportunities.
FDA Regulations, 3D-Printing and the Life Sciences Market

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3D-printing is a recent development in the life sciences market. With 3D-printing, pharmaceuticals and medical devices can be printed into custom layers and shapes to speed up or control absorption rates, and surgical implants that can be uniquely customized may shorten surgery times and lead to quicker recoveries.

In 2015, the FDA approved the first 3D-printed drug, Spritam, produced by Aprecia Pharmaceuticals to treat seizures and epilepsy. Spritam went on the market amid questions as to whether the same guidelines that apply to traditionally manufactured pharmaceuticals would apply to 3D-printed pills. The FDA has also cleared more than 85 3D-printed devices, including hearing aids, dental crowns, skull plates, facial implants, screws and surgical instruments. Typically, when a new drug is introduced, there are several markers that the company must follow. Many Life Sciences companies are now wondering if the same rules apply to a drug that is 3D-printed. The Food and Drug Administration (FDA) has issued “technical guidance” but not regulatory requirements¹. Additionally, Underwriters Laboratories (UL) and the International Organization for Standardization (ISO) are beginning their processes for developing standards.

The potential risks posed by 3D-printing span many areas, including intellectual property, environmental regulation, product liability and general liability. This new manufacturing process may cause underwriters to adjust how they view these types of risk. Underwriters may examine manufacturer’s supply chain and all agreements a company has in place to address insurance/indemnification/limitation of liability provisions.

Quality assurance is one of the biggest questions surrounding 3D-printing in terms of products liability. Underwriters are concerned with the implications of what will happen and who will be responsible if there is a software glitch that causes a defect in the final product.

We will continue to monitor this new development and offer guidance on the coverages that will be available to address these emerging risks.

Clinical Trials Overseas

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Overseas clinical trials can be a minefield because most countries have their own laws and regulations. For example; Does the policy need to be in the local language? Do we need a fronting company in place? What tax is payable?

Over the past year, Arthur J. Gallagher & Co. has dedicated resources to gain expertise in this area and we now have the internal capabilities to write clinical trials all over the world. At any time Gallagher is working with 30 current trials in different countries.

We understand that all clinical trial research programs are different and that it is vital to maintain a flexible approach so that we are able to offer each client the best possible solution.

Working with our Lloyds of London partners, we can issue a fully compliant Clinical Trial Insurance policy, on a direct basis, in the following countries: Australia, Greece, New Zealand, Austria, Hong Kong, Norway, Bahamas, Hungary, Poland, Belgium, Iceland, Portugal, British Virgin Islands, Ireland, Slovakia, Bulgaria, Israel, Slovenia, Canada, Italy, Singapore, Colombia, Jamaica, Romania, Croatia, Latvia, South Africa, Cyprus, Liechtenstein, Spain, Czech Republic, Lithuania, Sweden, Denmark, Luxembourg, Switzerland, Estonia, Malawi, Thailand, Finland, Malta, Turkey, France, Mauritius, United Kingdom, Germany, Gibraltar, Namibia, Netherlands, United States and Zimbabwe.

For countries where Lloyd’s is not licensed to write insurance on a direct basis, through reinsurance cooperation we can offer fully compliant Clinical Trial Insurance Policy documentation in the following countries: Albania, Kenya, Philippines, Azerbaijan, Kosovo, Serbia, Bahrain, Kuwait, Sierra Leone, Bangladesh, Macedonia, South Korea, Bolivia, Malaysia, Sri Lanka, Cambodia, Mexico, Taiwan, China, Moldova, Tanzania, Costa Rica, Mozambique, Tunisia, Georgia, Nigeria, Uganda, India, Qatar, Uruguay, Indonesia, Pakistan, Vietnam, Jordan, Peru and Zambia

For countries not listed above, we will work through our Global Alliance to explore available insurance solutions.
Why Choose Arthur J. Gallagher & Co. as Your Insurance Broker?

1. EXPERTISE IN REGULATIONS AND RISK MANAGEMENT.
The professionals that work in Arthur J. Gallagher & Co.’s Life Sciences Practice understand the macro issues surrounding biotechnology. We monitor and communicate information to our clients regarding new regulations and how these regulations will impact ongoing and future synthetic biology developments. Our team is proactive and contemplates unforeseen and latent risks.

2. STRATEGIC RESOURCES
Gallagher has more than 680 offices worldwide and more than 100 dedicated employees working for our Life Sciences team specifically in risk management for biotechnology. This extensive and focused framework of expertise allows us to tailor the risk management and insurance needs for each of our clients.

3. INTEGRITY AND TRUST
We are proudest of our commitment to integrity and fairness to our clients and our employees. In 2016, we were named one of the World’s Most Ethical Companies for the fifth consecutive year by the Ethisphere Institute.¹

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