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BioMarketing Insight



February 15, 2017

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

We have a new look to our newsletter. Love to receive your [feedback](#).

Last month I covered "Your Mother Telling You to "Eat Healthy and Get Enough Sleep" is Now Related to Longevity." If you missed last month's article, click [here](#) to read it. This month's newsletter will cover, Why the Spine Market is Growing so Rapidly, and What is Needed to be Successful in a Fiercely Competitive Market.

Read on to learn more about this topic and other current news. The next newsletter will be published in the new year on March 15th, 2017.

We encourage you to share this newsletter with your colleagues by using the social

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Commercial Consultant
[BioMarketing Insight](#)

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Table of Contents

[Developing a Product? Commercializing a Product?](#)
[Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell Design Be Made to Cure All Types of Cancers and Will It Be Covered?](#)
[Save the Date: 5th Annual Medical Informatics World Conference - May 22-23, 2017](#)
[Why the Spine Market is Growing so Rapidly, and What is Needed to be Successful in a Fiercely Competitive Market](#)
[Closing Thoughts](#)
[Previous Newsletters](#)

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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.

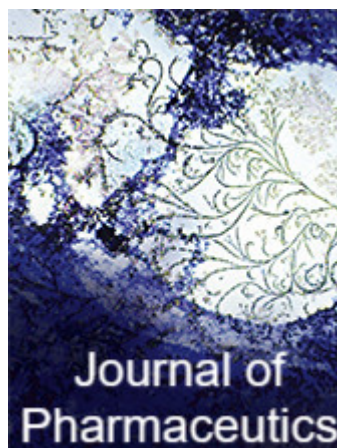
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[Product Development](#)

[Market Development](#)

[Marketing Strategies](#)

[Top](#)



Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell Design Be

I am pleased to announce that my article on "Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click [here](#).

[Top](#)



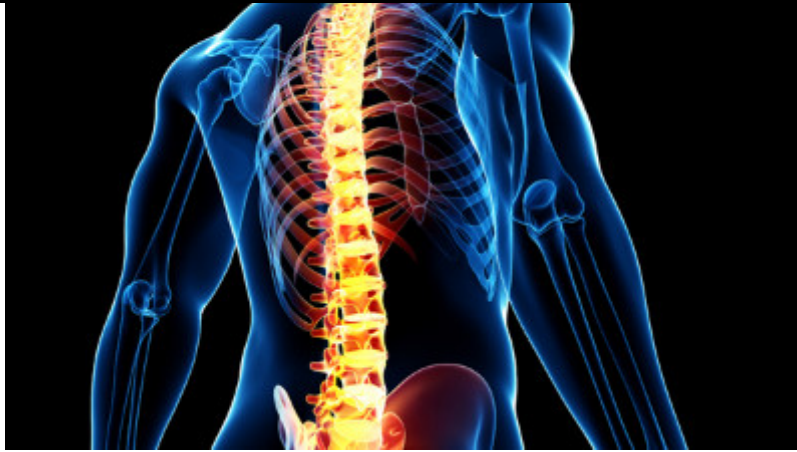
Save the Date: 5th Annual Medical Informatics World Conference - May 22-23, 2017

I am pleased to announce that I will chair the [opening session](#), Perspective: Large Medical Centers in the Telehealth Integration and Implementation Track on Monday May 22, 2017 at 10:55 AM right after the Keynote Speakers.

I will also moderate a [breakout discussion](#) group Monday afternoon entitled "Improving Health and Reducing Costs Through Traditional and Innovative Approaches to Coordinated Care and Patient Engagement."

Please join me at the Medical Informatics World conference as this event has become the critical meeting place for health IT executives and innovators, delivering the knowledge-sharing needed to continue improving patient care and outcomes. Click [here](#) to learn more about the conference. As a subscriber of my newsletter, you will receive a 10% discount off the registration fee with the keycode "1766BMI" when registering for this event. Offer is valid on new registrations and does not apply to workshop registration. To register, click [here](#).

[Top](#)



Why the Spine Market is Growing so Rapidly, and What is Needed to be Successful in a Fiercely Competitive Market

In 2011, the global spine surgery market was projected to reach anywhere between (USD) [\\$9.3 billion](#) to [\\$14.8 billion](#) by 2017, depending on which source you use. The spine surgery market consists of three (3) main segments: 1) Spinal fixation devices, which is the largest of the three areas; 2) Spinal fusion devices that immobilize the spine, although it is a mature segment, it's nevertheless projected to grow at the fastest compounded annual rate of [8.2%](#); and 3) Spinal implants, more specifically artificial discs, which have been rapidly adopted as one of the motion preservation technologies, used in lieu of spinal fusion to enable a better quality of life.

There are five (5) reasons contributing to the need for advanced procedures and technologies for the spinal market:

1) Aging population - as one ages, bone density declines and can lead to the chronic back problems so common in elderly people; 2) Obesity - the more weight one carries, the greater the pressure and stress on joints and bones; 3) Pain management - Spinal surgery is a popular back pain treatment after all conventional therapies have failed and has been in practice for several years; 4) Increased number of vehicle accidents and work related injuries, as there are more cars on the road and many jobs that require physical labor, from coffee shop barista to welder, in developed countries and as income rises in developing countries the same scenario will occur; and 5) Increased level of physician and patient awareness, with over 3.0 million spinal procedures performed globally each year and growing.

Five (5) factors are fueling the growth of the spinal surgery market:

1) Minimally invasive surgery and robotics - Minimally invasive surgery has become more wide-spread in every field of surgery because it eliminates the need for blood transfusions due to blood loss, recovery times and hospital stays shorten and outcomes

devices, some procedures can now be done in the outpatient setting, which reduces the cost to the healthcare system.

Robotics is an example of one of the newer technologies. Robotics allow for more precise movements, such as a [pedicle screw](#) placement, that reduces the amount of radiation exposure for both patient and surgeon as compared to fluoroscopy and makes the procedure more reproducible, resulting in better outcomes.

2) [Spinal fusion alternatives](#) - Artificial intervertebral discs are an ideal alternative to spinal fusion for Degenerative Disc Disease (DDD) treatment. Although spinal fusion offers pain relief by immobilization of the spine, artificial discs used to replace affected discs preserve motion at operative levels and offer a better quality of life.

In addition, spinal fusion requires bone graft and thereby gives rise to pseudo arthritis, bone graft donor site pain and other complications. The [artificial disc](#) market is expected to reach \$1.6 billion by 2022.

3D printing of artificial discs, both polymers and cellular, will help to fuel the artificial disc market even further, as each disc can be customized to each patient and the discs can be produced almost immediately. Disc regeneration is another rapidly growing field but still in its infancy, even in the United States.

The global spinal implants market is estimated to reach [\\$17.27 billion](#) by 2021, at a CAGR of 5.3% in use during the forecast period. Spinal implants are devices used by surgeons to treat deformities, stabilize and provide strength to the spine and expedite the fusion process. Spinal implants are used to treat spine related disorders, including degenerative disc disease, scoliosis, kyphosis, fracture and spondylolisthesis.

3) [3D Printing](#) - in the last several years, 3D printing has taken off in every aspect of the medical field, from printing out spinal cages to treat scoliosis, to artificial discs and regenerative medicine, such as a living heart, kidney, or liver.

3D printing can also be used by surgeons to plan how they will approach procedures, based on each patient's unique anatomy, before they operate, reducing the risk of complications and reducing the procedure time.

4) [Payers](#) - Payers are looking for new technologies that can reduce morbidity and mortality, increase the quality of life for patients and save the healthcare system money. They will reimburse for new technologies under these guidelines. For pain management, where artificial disc replacement will eliminate the use of drugs for long-term pain management, physical therapy and workmen's compensation when patients can't perform their job due to being incapacitated, they will pay for it and this is evident is the

Payers are looking for significant improvement or clearly improved efficacy and not incremental upgrades, because most new technologies cost more than the current standard of care. That is why minimally invasive surgical procedures are reimbursed.

Better outcomes result from technologies that make it easier for the physician to perform the surgery, reduce the risk of complications and enable the patient to return to work or their daily lives faster, eliminating post-treatments such as physical therapy or other rehabilitation devices.

5) Global expansion - As a global economy, device companies are expanding beyond the US and Europe and into the developing countries. The Asia-Pacific spinal implant and bone graft substitute market is expected to double through 2022, reaching nearly (USD) \$7 billion.

Competition

Competition is fierce in this growing market. As of 2015, [Medtronic](#), PLC (Ireland) held the leadership position in the global spinal implants market. The company has adopted product innovation and new product launches as its key business strategy for advanced spinal implants and spinal devices, to address the unmet needs of the end users for spine surgeries. DePuy Synthes (US), Stryker Corporation (US), NuVasive, Inc. (US), Zimmer Biomet Holdings, Inc. (US), Globus Medical, Inc. (US), Alphatec Holdings, Inc. (US), Orthofix International N.V. (Netherlands), K2M Group Holdings, Inc. (US) and RTI Surgical, Inc. (US) are some of the other key players in this market.

When I first examined this market, there were fewer than a dozen companies in this space. Today, there are numerous players in or entering the market. In addition to those listed above, Here is a [list](#) of 35 more companies making an impact; and here is a [list](#) of over 100 start-ups that focus on the spine market.

What You Need To Be Successful in the Spine Surgical Market

Since the spine market is fiercely competitive, the only way a company is going to be successful in this market is to address the critical unmet needs of the end users for spine surgeries, as well as the rest of the stakeholders involved, who determine whether physicians and patients will gain access to the device. This is Medtronic's approach and shows why the company is the leader in spinal implants and devices.

Here are the steps you need to take. Each of these strategies will make your product stand out from the rest.

1) Critical Unmet need - If you start with the critical unmet need or what is termed "a must have" first, it accomplishes two things: 1) The end users are ready to adopt/buy

universal around the world, this is potentially an enormous market opportunity.

2) Market access - In order for the physician and patient to be able to use or have the product, that product needs to obtain regulatory approval and reimbursement. You're familiar with the regulatory process but you may not be as familiar with the reimbursement process. As mentioned in the previous section under payer, the product needs to show significant improvement from the standard of care and demonstrate that it saves the healthcare system money.

In order to accomplish this, you must start planning in concept for reimbursement in product development, as you work on the first point (#1, above) and product adoption. There are two important reasons for this:

1) You can develop your hypothesis regarding your product's value proposition and determine the health economic value by conducting the business due diligence when talking to customers for feedback and you can start talking to payers about what their needs are regarding reimbursement.

2) You need to gather health economic data in your clinical trials to validate your hypothesis and prove to payers that you are saving the healthcare system money.

In addition, by conducting the business due diligence or getting feedback from all your stakeholders early in concept before you develop the product, you can develop your overall strategy with validation and avoid going down the wrong path. Oh, and don't forget the other healthcare professionals in the hospital who are also stakeholders in allowing access to your product.

3) Competition and product adoption - This is a very competitive market with over 100 companies in the space. How do you distinguish yourself from the rest of the companies? By doing all the things I mentioned above for the following reasons:

a) If you start with the critical unmet need, the technology to solve this unmet need will come easier because you'll know what you need for a solution, and in so doing avoid creating a technology in search of a problem to solve.

b) The technology also has to be significantly better than the current standard of care otherwise, why would your customer use it and pay more money if it is only incrementally better?

c) The technology has to be easy to use for the physician or patient, and if the patient is the end user, then the technology must not adversely impact his/her routines. It's very hard to get someone to change their habits or routine, especially if the new technology is

d) The technology should be disruptive in improving the quality of care for surgeon and patients. For example, 3D printing in customizing artificial discs specifically for each patient.

[Top](#)



Closing Thoughts

The more you know and understand your customers and the market, the easier it will be for you to identify the critical unmet needs and the best solution that resolves those unmet needs. You will be able to develop the value proposition and economic value of your product. You will also be able to identify the needs of each stakeholder and understand the steps that will lead to gaining product adoption successfully. The stakeholders, or what I define as the (seven) 7 P's, are physician, patient, payer, policy (regulatory), other healthcare professionals, politics and the public. All are important to the process that will determine whether there will be access to the product and product adoption.

Doing the business due diligence or market research in concept will guide you and your team to the right path and prevent a time and money wasting journey down the wrong path, early on. Time to market is still a critical juncture as to whether a company will succeed or fail.

Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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