

*January 10, 2013*

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**In This Issue**

The world of medical devices is changing fast. Requirements for getting new products cleared by the FDA and into clinical use has become more and more complex. In a presentation at the North American Spine Society meeting, it was presented that in the year 2000 a study showing product efficacy would require 200 patients, 75% follow-up at a cost of about \$15M. In 2010 that same product would require to prove safety in 400 patients, 85-90% follow-up at a cost of \$50M. It is projected that by 2020 it will have to prove a risk/benefit to current products with 90+% patient follow-up at a cost of \$100M. With requirements like that, we've included an article by Marcy Rogers, M.Ed. on the importance of getting studies done to bring technologies to market "On Schedule, On Budget and In Compliance".

As the new year begins and sales targets are set, it's a good time to implement some new tools. We came across a methodology of setting objectives and interim goals that is unique in that it starts not with how do we add the next customer but what do we need to do just before we achieve our objective and works back to the next steps going forward. It is borrowed from "mind coach" Dave Diggle who works with professional and Olympic level athletes. We hope it provides another method or tool that you can use in establishing your sales objectives and measuring successes along the way to keep you and/or your sales team moving forward throughout the year.

Change is afoot as we all know in the medical device arena. In addition to addressing the clinical and regulatory issues referenced above in Marcy's article, we want to address the changes coming on the distribution side of the market. Changes are coming and some may be very significant to you and your business. Several models of what the market could become doesn't have distributors as we know them providing sales services to the companies nor case coverage to the surgeons and hospital staff. Take a look at the potential changes and let us know what you think in the "What's New in the Market" section!

Finally, I would be remiss if I did not recognize the passing of a great contributor to the medical device industry. Gerry Carlozzi, most recently retired as COO of Integra LifeScience passed away on Christmas day from pancreatic cancer. I had the pleasure of working directly for Gerry in 1996 at Synthes and had many dealings with him since.

We are confident this edition of Vistas will provide you with valuable information. If there is anything in particular you would like to see us cover in future issues just let us know.

Thanks and best regards,  
Bill

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## **Bring Products to Market on Schedule, on Budget, and In Compliance**

Spine, as a niche field in healthcare, is facing challenges from all segments of the market. Third-party payors are denying, bundling or discounting payments for fusions and treatment of degenerative disc disease, while CMS has launched a 120-day review program for preauthorization of costly spine and orthopedic procedures instead of trying to recover funds from payments. New products with and without evidence to support coverage and efficacy must overcome coding obstacles and ongoing denials of coverage for being "investigational."

**[Read and download the full article by Marcy Rogers M.Ed.](#)**

**through the link below:**

**[Helping Companies Bring Their Product to Market](#)**

## **Implementation of Methods for Goal Setting, Measurement and Targeted Sales Objectives Outcomes**

A new year is a great time to implement sales planning techniques and goal measurement because we typically have just received our sales targets from the companies and it's time to make the plan. As many of you know, outside of High Ground Medical I am a coach. That has me listening to various presentations around the country covering a variety of motivational and mental training topics among others; some applicable to sales or orthopaedics and some not. I will not spend time on an appropriate blocking scheme for a spread offense against a 4-3 defense, but I do want to share information from a "mind coach" on rewards for sustainable goal achievement and achieving targeted outcomes.

**[Implementation of Methods for Goal Setting](#)**

## **What's New in the Market**

**What we're seeing that you might not**

We believe there are major changes afoot in the medical device sales arena; orthopaedics will be prime territory for this change. Current distribution models will be largely a thing of the past so prepare now for the future. A perfect storm is setting up and to see the future you just need to look at the past and current activities of hospitals.

We believe that the factors that are currently aligning are going to change the distribution networks as we know them today. Wherever you are in that model it is better to be prepared for what is coming rather than be surprised by it. It is a question of when not a question of if.

Read the Full Article Here:

**[The Changing Face of Distribution in Orthopaedics](#)**

If you have any feedback on this please feel free to send it to [Bill@hgmed.com](mailto:Bill@hgmed.com)

High Ground Medical, Inc.  
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Managing the confluence of technology and distribution



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