

Client Alert

October 2010

FDA Attempting to Rescind ReGen Clearance

Dear Clients and Friends of the Firm,

ReGen is the poster-child for FDA's never-ending attempts to tell us all how broken the 510(k) program is and how FDA will rescue society from all the bad devices out there today and in the future. The Agency, and in particular, CDRH Director Dr. Jeff Shuren, won't let this company go. On December 18, 2008, FDA granted 510(k) clearance to ReGen Biologic's Menaflex™ device. This week CDRH decided to "*rescind*" ReGen's clearance, although it's not clear they have the legal authority to do so. Is this a political maneuver or a new way of doing business at FDA or both?

Timeline:

- *December 2008* -- ReGen obtains clearance for the Menaflex device ([K082079](#)).
- *March 2009* -- Commissioner Hamburg is nominated to lead FDA and is confirmed in May.
- *May 2009* -- Agency whistleblowers claim the clearance process for ReGen's device was inappropriately influenced by four New Jersey Congressmen and FDA's management including former Commissioner Von Eschenbach and then sitting CDRH Director Dan Schultz.
- *August 2009* -- CDRH Center Director Dan Schultz resigns under pressure.
- *September 2009* -- CDRH commissions the Institute of Medicine to take an "independent" look at the 510(k) program.
- *September 2009* -- the Agency releases a report, written by Dr. Jeff Shuren, who was then "*Associate Commissioner for Policy and Planning*," that concludes the ReGen clearance process was compromised.
- *January 2010* -- Dr. Shuren becomes the Director of CDRH.
- *March 2010* -- Dr. Shuren convenes the Orthopaedic and Rehabilitation Devices Panel (the "Panel") to evaluate ReGen's Menaflex device. The Panel concludes the device is "safe."
- *June 2010* -- Curiously, CMS announces a national non-coverage decision. Frustrated, ReGen states it didn't solicit a coverage decision and that Menaflex isn't intended for a Medicare population.
- *September 2010* -- FDA publishes a 120-page report containing changes it recommends for the 510(k) program.

- *October 2010* -- FDA announces it will rescind ReGen's clearance for the Menaflex device.

Strangely, Dr. John D. Kelly, Chair of the Panel that declared the Menaflex device "safe" the second time, told the *Wall Street Journal* that he agrees with FDA's decision. However he added, "The FDA put the brakes on a product with some promise." He opined that the product should go through the PMA process. This reveals the central issue with FDA right now – regulatory unpredictability. The *Wall Street Journal* also reported:

"Menaflex wasn't perfect, but the idea had potential, Kelly says. 'It wasn't a Cadillac, more like a Model T.' With the increase seen in meniscus-repair surgery, surgeons are desperate for a device that might shorten recovery time and limit pain, Kelly says."

This underscores two other significant issues with the current Agency. First, what they fail to appreciate is that innovation occurs through scientific and technological evolution. Devices, just like any other technology, evolve incrementally. It took a while to get from the phonograph to the iPod™. FDA doesn't seem to appreciate this concept. Second, underlying FDA's view is that it seems to believe that only perfect, blockbuster devices, tested for many years, deserve to come to market. Gone is the idea that the vast majority of devices are developed over time and will never be perfect, but are a necessary link in the lineage of future devices. This is a very risk-averse position and essentially guarantees that FDA will freeze most innovation and the practice of medicine using these devices into place in the year 2010. FDA's policies and review of devices today are seriously stifling innovation and investment in innovation. The irony is that most device innovations in the world are invented in the U.S. but U.S. patients are the last in the world to enjoy them. We remain convinced that Earl Bakken (Medtronic) would've never gotten the world's first pacemaker to market through today's FDA.

ReGen followed the rules. ReGen lawfully obtained a clearance in 2008. Yet FDA plans to rescind their clearance. We are not sure what FDA's theory for rescission is, but we are confident, absent fraud, FDA does not have the legal grounds for rescission. What FDA seems to be confident in is that ReGen may not have the financial wherewithal to defend itself. If so, a clearly inappropriate and illegal rescission challenge may stand. FDA's use of publicity has certainly destroyed the market for the product anyway—a case of being judged guilty before the opportunity to prove innocence.

In the wake of FDA activity lays a suffering patient population with few treatment options for meniscus repair, patients with permanent implants from a company that will probably disappear because of the rescission, and laid-off ReGen employees looking for work in a suffering economy. Who gains? If a CDRH Director and two expert panels determined the device was "safe," why is it being taken off the market? Out of concerns of efficacy? Aren't practicing physicians in the marketplace capable of determining a device's efficacy?

FDA continues to frustrate and confuse industry and deny patients of life-benefiting technologies. When will it stop? Twelve members of Congress wrote Commissioner

Hamburg last week to voice their concerns over the proposed changes in the 510(k) program. Their letter can be viewed on Politico.com here:

http://www.politico.com/pdf/PPM143_101012_concerns_fda_letter_101210.pdf.

Minnesota's congressional delegation continues to work in a bi-partisan fashion to make FDA more reasonable, predictable and transparent. As we have stated before, when FDA uses the term "predictable" they mean *predictably more onerous* (and they are very transparent about it).

Unfortunately this development raises more questions than it answers. ReGen spent \$30,000,000 and 58 months to commercialize a technology deemed safe by the government not once but twice only to have it taken away in what appears to be bureaucratic fiat stemming from politics. If FDA is trying to instill confidence in its physicians, patients, medical device companies and investors, it's failing miserably. And remember, *your device could be next*. DuVal & Associates will keep you abreast of further developments.

Our Upcoming Events:

Venture Capital Roundtable Discussion—panelist with

[Janice Hogan](#) , Hogan Lovells US LLP and [Hal Mathews, MD, MBA](#) - Medtronic Spine & Biologics, Moderated by Robin Young, PearlDiver / RRY Publications

Musculoskeletal New Ventures Conference, Memphis, Tennessee

Monday, October 25

Register here: <http://www.mnvc.org/>

“Commercializing New Technology, Begin with the End in Mind,”

LifeScience Alley, New Brighton, Minnesota,

Wednesday, October 27

Register here: http://www.lifesciencealley.org/programs_events/detail.aspx?id=547

“Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA”, Mark DuVal and Mark Gardner,

Compliance Online, Irvine, California (full day seminar)

Thursday, December 2

Registration information coming soon

“Clear as Mud: Obtaining and Marketing Your 510(k) With Today's FDA”, Mark DuVal and Mark Gardner,

Compliance Online, San Francisco, California (full day seminar)

Friday, December 3

Registration information coming soon

“Using Social Media & Direct to Consumer Marketing in a Regulatory Environment,”

Mark Gardner, moderator

LifeScience Alley--Minneapolis, Minnesota

Wednesday, December 8

Register here: <http://www.lifesciencealleyconference.org/>



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DuVal & Associates understands the corporate interaction between departments like regulatory affairs, sales, marketing, legal, quality, clinical, compliance, R&D, manufacturing, finance, etc. Because of our industry experience in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We actually work with FDA every day on pre-market submissions, clinical trials inspections, warning letters, administrative appeals, and the like. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results, while practical, timely advice can help companies succeed. For more information, visit our website at www.duvalfdalaw.com or call us today for a consult at (612) 338-7170.

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