
From: Steven Victor MD [REDACTED]
Sent: Friday, August 16, 2013 12:17 PM
To: [REDACTED]
Subject: Fwd: Maxim Group: Regenerative Cell Therapy - Osiris Graffix highlights a Back Door. Is there an Achilles heel in Cell Therapy with a KISS (keep It Simple Stupid).
Attachments: image003.jpg; image004.png; Cell_Therapy_Industry_8.16.13.pdf

Steven Victor MD
IntelliCell BioSciences

[REDACTED]

-----Original Message-----
From: Steven Victor <[REDACTED]>
To: admin <[REDACTED]>
Sent: Fri, Aug 16, 2013 8:14 am
Subject: FW: Maxim Group: Regenerative Cell Therapy - Osiris Graffix highlights a Back Door. Is there an Achilles heel in Cell Therapy with a KISS (keep It Simple Stupid).

Steven Victor MD

[REDACTED]

From: Jason Kolbert <[REDACTED]>
Date: Friday, August 16, 2013 7:44 AM
Subject: Maxim Group: Regenerative Cell Therapy - Osiris Graffix highlights a Back Door. Is there an Achilles heel in Cell Therapy with a KISS (keep It Simple Stupid).

Regenerative Cell Therapy: Osiris Grafix highlights a Back Door.
Is there an Achilles heel in Cell Therapy with a KISS (keep It Simple Stupid)!

Unlocking a Rich commercial Pathway through a backdoor?
Source: Cartoonstock

This week Osiris Therapeutics Inc. (OSIR - \$19.76 - NR) demonstrated the utility of Grafix, the company's allogeneic product for diabetic foot ulcers (DFU), long a graveyard of failed therapies. Grafix, is a 3D cellular matrix comprising endogenous mesenchymal stem cells (MSCs) and growth factors. It has been sold in the U.S. to treat chronic wounds, under FDA regulatory pathway 21 C.F.R. Part 1271. We examine this regulatory pathway and try to make sense of what implications does it have in cell therapy space?

The FDA has allowed this "back door" as a pathway into the market place with no pre-market review or approval. If they are regulated solely under PHS sec. 361 and 21 C.F.R. Part 1271. To meet this criteria: 1) the cells have to be minimally manipulated 2) Homologous use 3) not combined with another article (with limited exceptions) 4) Either (i) cells do not have a systemic effect and is not dependent upon the metabolic activity of living cells for its activity or (ii) does have a systemic effect or is dependent upon the metabolic activity for its primary function, and is for autologous, allogeneic or reproductive use.

In addition to marketing of Osiris' Grafix under 361, recently RTI biologics (RTIX - \$3.52 - \$80 - NR) may also be in the market shortly with MAP3 cellular allogeneic bone graft, which incorporates Athersys (ATHX - \$1.89) MAPC stem cells, under 361 as well. This opens the question what other cell therapy products can come to the market under 361. For example we believe the stromal vascular fraction that IntellicellBioscience (S=FC) qualifies under these rules.

Our conclusion: Under this regulatory framework, companies can claim that a product meets the "361" requirements which leaves the FDA to confirm the claim or enforce (block) the products sale. This opens up a backdoor for companies to bring products to market simply by claiming that they fall under the PHS sec. 361 and 21 C.F.R. Part 1271 and then simply wait and see if the FDA agrees or disagrees. In meantime the product can be marketed. We believe many products do meet these standards such as Osiris Grafix and RTIX's bone graft. We also believe that the stromal vascular fraction made by IntellicellBioscience meets this definition. With that said "361" does not allow product claims (without a supporting trial). So is Grafix showing us an Achilles heel and can it be so simple as a KISS of Stromal Vascular Fraction? Only clinical trials will tell us.

Jason Kolbert
Maxim Group LLC

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