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]

-----=riginal 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 highli=hts a Back Door. Is there an Achilles heel in Cell Therapy with a KISS (ke=p 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 C=ll Therapy: Osiris Graffix highlights a Back Door.
Is there an Ac=illes heel in Cell Therapy with a KISS (keep It Simple Stupid)!=/div>

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

ØThis week Osiris Therapeuti=s Inc. (OSIR - $19.76 - NR) demonstrated the utility of Grafix, the compan=’s allogeneic product for diabetic foot ulcers (DFU), long a grave=ard 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 regulato=y pathway and try to make sense of what implications does it have in cell therapy space?

ØThe FDA has allowed this =E2��back door” as a pathway into the market place with no pre-=arket review or approval. If they are regulated solely under PHS sec. 361 =nd 21 C.F.R. Part 1271. To meet this criteria: 1) the cells have to be minimally manipulated 2) Homologous use =) not combined with another article (with limited exceptions) 4) Either (i= cells do not have a systemic effect and is not dependent upon the metabol=c activity of living cells for its activity or (ii) does have a systemic effect or is dependent upon the =etabolic activity for its primary function, and is for autologous, allogen=ic or reproductive use.

ØIn 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 allog=neic 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 exa=ple we believe the stromal vascular fraction that IntellicellBioscience (S=FC) qualifies under these rules.

ØOur conclusion:<=b>Under this regulatory framework, companies can claim that =hat a product meets the “361” requirements which leaves th= 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 fal= under the PHS sec. 361 and 21 C.F.R. Part 1271 and then simply wait and see if the FDA ag=ees 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 s=romal vascular fraction made by IntellicellBioscience meets this definitio=. With that said “361” does not allow product claims (with=ut a supporting trial). So is Graffix showing us an Achilles heal and can it be so simple as a KISS of Stromal Vacular Fraction? Only c=inical trials will tell us.

Jason Kolbert
Maxim Group LLC=span style="font-size: 12pt; font-family: Arial, sans-serif; "></=iv>

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