Commercializing Disruptive Medical Technologies in an Evolutionary World

presented by: ***Michael Drues, Ph.D.***

Most product development in medical technology is evolutionary, i.e. make a drug or medical device then modify it slightly to create a new drug or device. There are many advantages to this approach but there are disadvantages as well. For example, the light bulb did not evolve from the candle nor did the car did not evolve from the horse. You can tweak a horse as many times as you want but you will never end up with a car! The light bulb and the car are examples of revolutionary a.k.a. destructive technologies. Our current regulatory environment was designed for and indeed encourages evolutionary advancements. However, when it comes to bringing revolutionary or disruptive technologies to market, the regulatory challenges are immense. Using case studies from 3-D printing, pharmacogenomics, tissue engineering and nanotechnology, this presentation will discuss the regulatory challenges of commercializing revolutionary technologies in an evolutionary world and how manufacturers can successfully meet them. Suggested length: 30 minutes

Speaker Biography



Michael Drues, Ph.D., is President of Vascular Sciences (www.VascularSci.com), an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programing, brain-storming sessions, prototype design, product development, benchtop & animal testing, innovative regulatory strategy & completive regulatory intelligence, clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

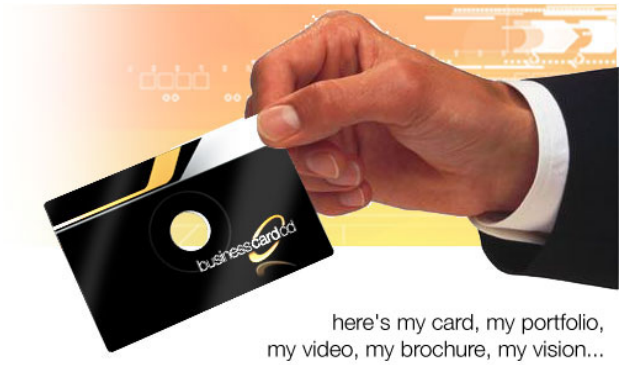
Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues.

© Copyright 2014 by Vascular Sciences. All rights reserved.

Commercializing Disruptive Medical Technologies in an Evolutionary World

Want to keep up with me?



Connect with me on LinkedIn or give me your business card!

www.linkedin.com/in/michaeldrues

Please remember to include the presentation and date!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.



Here's what we'll talk about...

August, 2014

- ✓ Evolutionary vs. Revolutionary Product Development
- ✓ Incentives vs. Disincentives
- ✓ Examples of Disruptive Technologies
  - Personalized medicine, i.e., 3-D Printing and Pharmacogenomics
  - Tissue Engineering, i.e., Regenerative Medicine
  - Biomedical Nanotechnology
- ✓ What are the regulatory challenges?
- ✓ Final thoughts…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

What's the difference between evolutionary and revolutionary product development



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

How have we created incentives and disincentives



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

How about some examples



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Can we "print" a medical device?



Short answer:

We're already doing it…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

3-D Print Surgical Instruments





- ✓ Simple medical devices, i.e., umbilical cord clamps, are currently being 'manufactured' in Haiti!
- ✓ Devices are 3-D printed for ***direct use*** in local clinics with ***on-demand manufacturing***.
- ✓ Hyper-local manufacturing will bypass inefficient and corrupt import systems.
- ✓ With rapid prototyping tools and internet capabilities, complex 3D models can be exchanged between Haiti and other countries for production, distribution, and direct connection to the global market.
- ✓ 3D printers in Haiti - what will they think of next? 3D printing in space?

3D Printing Umbilical Cord Clamps in Haiti (Makezine.com, Oct. 18, 2013)

Many problems are solved including:

Hospital: inventory… ordering, storing, etc.

and reusing (cleaning & sterilizing)… use once and throw away.

Manufacturer: *packaging, sterility, shelf-life, stability*

Bottom line: ***if we can do this in Haiti, we should be able to do it anywhere!***

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Can we "print" a permanent implant?



Short answer:

We're already doing it…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Case Study: *3-D-Printed Skull*



Woman Has Her Skull Replaced With A 3-D-Printed Plastic One (Popular Science, March 26, 2014)

What are the clinical challenges?
What are the engineering challenges (i.e., biomaterials)?
What are the regulatory challenges?
i.e., regulatory pathway (CDE vs. new?) ? clinical trial (n=1?) ?

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Case Study: Printing a Trachea



Doctors Use 3-D Printing To Help A Baby Breathe (NPR, March 17, 2014)

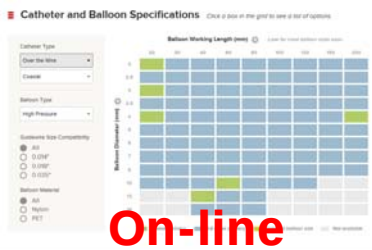
- ✓ autologous is a huge advantage… *no immunosuppressants!*
- ✓ need vs. demand… *think beyond organ replacement!*
- ✓ printing scaffolds... *just the beginning*!

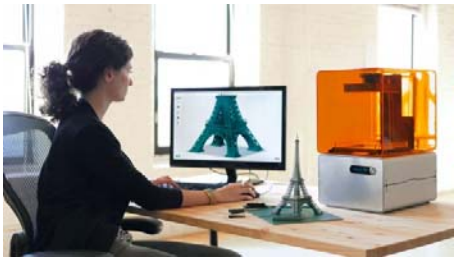
© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

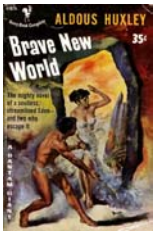
Where are we heading? Here's one possibility…





On-line Medical Device Design + **Home-Based 3-D Printing**





⇓

of medical devices!

Imagine new business model:

Sell designs not devices!

http://www.ventionmedical.com/ModCath/

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Can we "print" a drug?



Short answer:

We're already doing it…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Can we "print" living tissue?



Short answer:

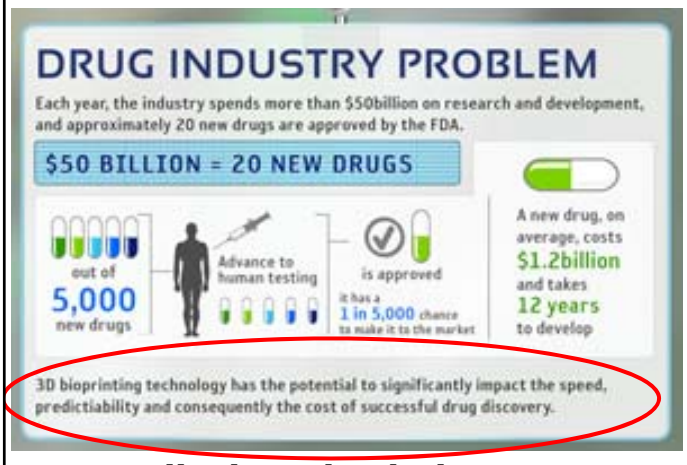
We're already doing it…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Bio-Printing for organ replacement?

…interesting but to obvious!

How about drug clinical trials?



How Can You Print the Human Body? (MDDI, Dec. 2, 2013)

Medical Device industry meet Big Pharma!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Question:

How are clinical trials, combination products and 3-D printing related?



We must always look for similarities…

even when no similarities seem to exist!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Does what we do make sense?

Traditional drug-development model:

In vitro (bench-top/computational) testing → Animal testing → Human trials

Result:

~ 20 – 50% of drug candidates fail (animal → human) at a cost of up to $500M!

More importantly… we assume

if not safe/effective in animal → not safe/effective in human

How many good products have been scrapped because they didn't work in animals?

For many reasons…

very inefficient process… there has got to be a better way!

So what if we modify the model?

In vitro (bench-top/computational) testing → ***Engineered Human Tissue*** → Human Trials

Not nearly as far off as some might think!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

What are the regulatory challenges of personalized medicine?



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Is there precedent for 3-D printing?

The regulatory ball is rolling...

i.e.,

precedent is being established but...

are we going in the right direction?

In other words...

Is the 510k, PMA, de novo, HDE, etc. the right pathway to use?

Hartford Business, August 19, 2014 available here.

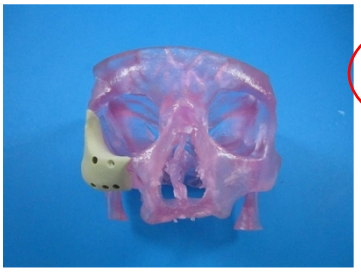
HARTFORD BUSINESS.COM
A PUBLICATION OF THE HARTFORD BUSINESS JOURNAL

Home | News | Our Events | Calendar | Special Ed
LATEST HEADLINES | BEYOND CT | MOVERS & SHAKERS | POLLS | PRINT EDITION

Print Email Order a PDF

AUGUST 19, 2014

S. Windsor manufacturer gets FDA clearance for facial implant



SUBMITTED PHOTO
Oxford Performance Materials' OsteoFab Patient-Specific Facial Device.

South Windsor's Oxford Performance Materials said it has received clearance from the U.S. Food and Drug Administration to market its 3-D printed facial implant.

The implant can be custom-printed for each transplant patient using MRI or CT scan images. OPM prints the implants using its proprietary powder formulation, which are similar to bone and support bone attachment.

OPM received similar approval early last year for a cranial implant. The company said that the two implants could be combined into one for certain complicated cases.

Biomet Inc. will be the exclusive global distributor for the new implant. Biomet also distributes the cranial implants.

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

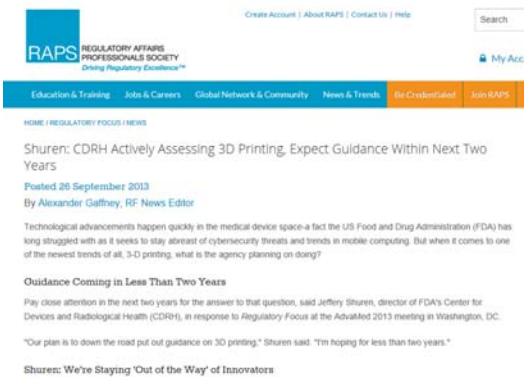
Commercializing Disruptive Medical Technologies in an Evolutionary World

Why is this taking so long?

"Our plan is to down the road put out guidance on 3D printing, I'm hoping for less than two years."

Dr. Jeff Shuren, Director, CDRH

(RAPS Focus, Sept, 2013 available here)


RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

Shuren: CDRH Actively Assessing 3D Printing, Expect Guidance Within Next Two Years

Posted 26 September 2013

By Alexander Gaffney, RF News Editor

Technological advancements happen quickly in the medical device space-a fact the US Food and Drug Administration (FDA) has long struggled with as it seeks to stay abreast of cybersecurity threats and trends in mobile computing. But when it comes to one of the newest trends of all, 3-D printing, what is the agency planning on doing?

Guidance Coming in Less Than Two Years

Pay close attention in the next two years for the answer to that question, said Jeffery Shuren, director of FDA's Center for Devices and Radiological Health (CDRH), in response to *Regulatory Focus* at the AdvaMed 2013 meeting in Washington, DC.

"Our plan is to down the road put out guidance on 3D printing," Shuren said. "I'm hoping for less than two years."

Shuren: We're Staying 'Out of the Way' of Innovators

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.


FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3-D Printing; Public Workshop; Request for Comments

A Notice by the Food and Drug Administration on 05/19/2014

TABLE OF CONTENTS

Back to Top

- SUPPLEMENTARY INFORMATION:
- I. Background
- II. Topics for Discussion at the Public Workshop

following public workshop entitled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3-D Printing." The purpose of this workshop is to

challenges and solutions of 3-D printing. The Agency would like input regarding technical assessments that should be considered for additively manufactured devices to provide a transparent evaluation process for future submissions.

Dates and Times: The public workshop will be held on October 8 and 9, 2014, from 8 a.m. to 5 p.m.

Font Controls

PDF DEV PRINT

PUBLIC INSPECTION

Agencies:

Department of Health and Human Services

Notice

Action:

Notice of public workshop; request for comments.

Document Citation:

79 FR 28732

Page:

My response:

Its about time!

Why must regulation always lag inovation?

Federal Register (May 19, 2014) available here.

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Personalized Drug Trials

The FDA will need to "turn the clinical trial paradigm on its head" in order to allow more specifically targeted, personalized drug therapies to get on the market faster. ***We are going to have to change the way drugs are developed... period,"*** said Janet Woodcock, MD, head of FDA/CDER.

Answering every question needed from regulators about targeted therapies – such as who should receive the drug, at what dose, and with what expected side effects – won't be possible in a traditional clinical trial. Instead of embarking on traditional clinical trials, drugmakers and clinical investigators need to work in different ways to select patients for what will inevitably be smaller trials she said.

"Ever smaller subsets of patients are being identified, and we're really going to have to put our heads together and figure out how do you study these small subsets of diseases. What types of trials and development programs do you do? And when does a subset get so small that you're not going to be able to do a randomized trial?"

Anywhere from an eighth to half of companies' drug pipelines are targeted therapies, Woodcock said. **About a third of new entities approved by the FDA last year had some type of genotyped biomarker in its marketing application.**

But in order to develop trials to test these drugs, ***the FDA and drug developers need a "new definition of clinical trials"*** that recognizes therapies will be targeted at subsets of conventionally defined diseases, Woodcock said.

FDA Rethinking Personalized Drug Trials (MedPage Today, May, 2013)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Personalized Drug Trials

Rather than doing a single trial in all patients with a particular disease, developers need to stratify patients into needed subsets based on certain biomarkers. Only then will trials be able to test the safety and effectiveness of their drug candidates.

The way trials were developed in the past should not influence or govern the way things are done in the future, Woodcock said. **For decades, the agency has requested two randomized, controlled, non-inferiority trials. But *those may not be possible with the small number of patients possible in trials.***

In order to identify these subset of patients – which may be very few in number – k drugmakers may have to work together or work with third parties like patient advocacy groups to identify them she said.

"We haven't seen a lot of this so far," Woodcock said. "We're hoping that independent groups set up these trial networks and standing trials, so that then companies are comfortable coming together through a third party to do development of their drugs."

The personalized cystic fibrosis drug ivacaftor (Kalydeco), which treats the disease arising from the G551D-CFTR mutation, was developed through such a patient group network, Woodcock said. But there are other challenges the agency and developers must tackle too.

Such targeted therapies have had difficulty receiving insurance coverage, in part because of their price. Woodcock noted this trend has slowed development of diagnostics that accompany such products.

FDA Rethinking Personalized Drug Trials (MedPage Today, May, 2013)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Copyright 2014, Michael Drues, Ph.D.

Commercializing Disruptive Medical Technologies in an Evolutionary World

Personalized Drug Trials

Therefore, targeted therapies need to slow or stop chronic diseases and not just show a positive short-term benefit to silence critics. "If we can cure Hepatitis C, there's not going to be a peep from anybody because the cost effectiveness of that will be absolutely clear," she said. "Same with cancer."

The FDA is also thinking about how to translate prescribing information to providers, who want simple, easy-to-understand instructions. **"[Doctors] want directions. They don't want education. They don't want to be taught genetics,"** Woodcock said**. "They want [to know] 'what do I do. please tell me.' "**

Therefore, diagnostics that accompany drugs and information in labeling needs to be detailed and accurate but also easily understood.

That path ahead won't be easy and ***will require a grand change in the way clinical trials are thought about*** by drug regulators and developers. ***"We're going into uncharted waters here,"*** Woodcock said. ***"I think it's going to be a big challenge for everyone."***

My response:

It's about time!

FDA Rethinking Personalized Drug Trials (MedPage Today, May, 2013)

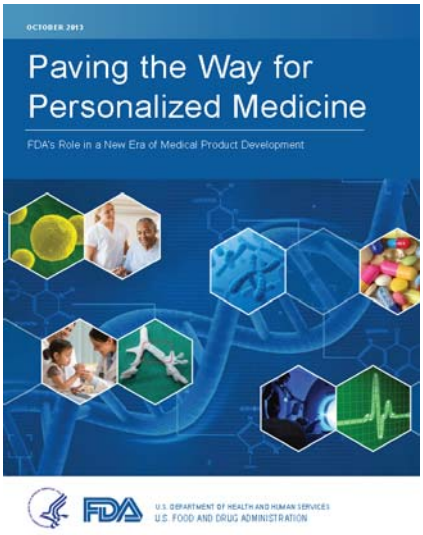
© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Regulatory Change is in the Air

- ✓ Report outlines ways FDA has modified traditional approaches to drug ***and*** device regulation in new era of products tailored toward specific patient subtypes rather than broad diagnostic groups
- ✓ EU definition of personalized medicine, "Providing the right treatment to the right patient, at the right dose at the right time"
- ✓ Since 1998 FDA has approved >100 drugs with specific information about biomarkers on label
- ✓ FDA approved 4 cancer drugs for use in patients with tumors that have specific genetic characteristics identified by companion diagnostics
- ✓ FDA granted emergency use exemption to create bioresorbable airway splint constructed with 3-D printer to treat infant with airway collapse

⇓

New regulatory paradigm prompting collaboration of multiple centers (CDER, CBER and CDRH)



FDA Report Outlines Approach to Personalized Medicine (Medscape, October 29, 2013)

Personalized Medicine (FDA, October, 2013)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Could things finally be changing?

Did FDA Just Announce A Major Reorganization?

FDA Commissioner Peggy Hamburg announced Friday, in an internal email (pasted below) that she was forming a "**Program Alignment Group**" charged with "identifying and developing plans to modify FDA's functions, processes, and possibly its structure in order to address these matters and best achieve mission-critical Agency objectives."

By the sounds of it, the new task force (which comprises the agency's most senior leaders) is going to look for ways to bring better alignment between the FDA's different offices and medical product centers. **This is a critical endeavor since more of the products that FDA is tasked with regulating don't fit into the traditional categories in which FDA has historically divided its work.**

Many new medical products transcend boundaries between drugs, devices, and biologics. Many cosmetics contain particles that mirror the nano-technology found in devices. Many foods have drug-like features. In such a world, the boundaries between FDA's different centers may no longer make as much sense.

Regulation is increasingly being based on the function of a product, rather than its traditional definition of food, drug, device, biological, and cosmetic. But will FDA have the fortitude to break up its existing functional divisions, and adopt a real program orientation? It's unlikely to happen in the near term.

There will be a lot of internal resistance. A major re-organization will create a lot of dislocation. Big bureaucracies don't respond well to this sort of dramatic change.

(Forbes, Sept. 8, 2013)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Speaking of medical devices…

Custom Medical Devices *vs.* Pharmacogenomics

Question:

Is there a regulatory parallel to pharmacogenomics on the medical device side of the world?

Short answer:

Absolutely... it's the custom medical device!

Here is a more challenging question:

How does pharmacogenomics compare to custom medical devices?

Hint:

You will likely have to think to answer this one!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Looking for precedent…

What model does this represent?



Genetic Engineering News, Sep 13, 2010

Personalized Medicine = (Ultimate) Orphan Drug or Humanitarian Device Exemption (HDE)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

What is Tissue Engineering?

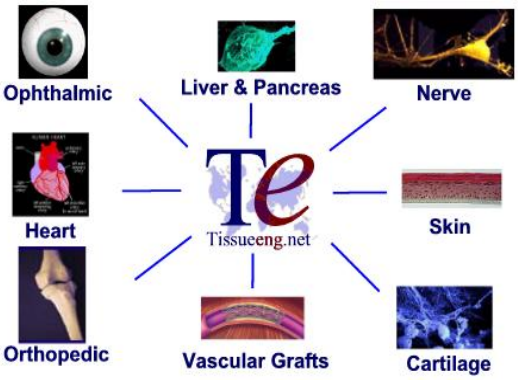
Simply put – "growing tissues" (groups of cells) either:

in vitro… including stem cell technology

and/or

in vivo… why grow cells our selves if the body can do it for us!

Very broad field including many applications:



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Question:

What is the *single biggest* ***disadvantage*** of monotherapy treatment?

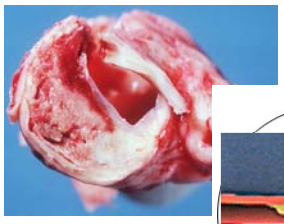
i.e.,

using medical devices, drugs and (most) biologics alone?

Let's look at one (of many!) examples…

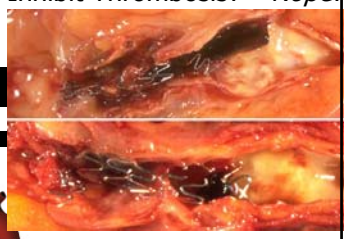
© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

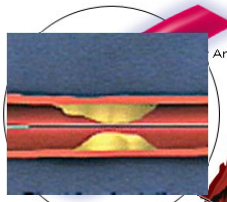
What stents do and don't do!

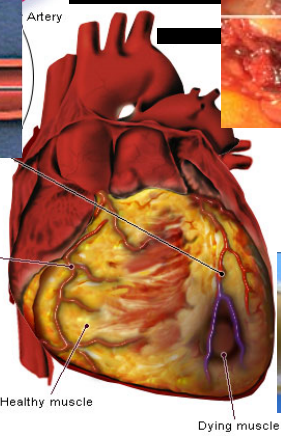


Treat atherosclerosis? *Nope!*

Inhibit Thrombosis? – *Nope!*







Control Hyperplasia? *Perhaps…*





Restore function? – *Absolutely not!*

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

So it's sort of ying-yang…



The *single biggest <u>disadvantage</u>* of monotherapy treatments…

is identical to

Single biggest advantage of 'sophisticated' combination products

Please note (and with all due respect):

Drug-Eluting Stent ≠ Sophisticated Combination Product

So what is a sophisticated combination product…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Tissue engineering represents the quintessential example of a combination product!

Why?

because we have <u>cells</u> (biologics)
producing <u>proteins</u> ("biotech drugs")
growing on polymer <u>scaffolds</u> (medical devices)

Can't have more of a combination than that – *or can we?*

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Why do we need tissue engineering?

because quite simply…

Medical devices, drugs and biologics alone

don't always work!

They are not always very effective!

and

They are not always very appropriate!

We can do much better!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Power of Tissue Engineering



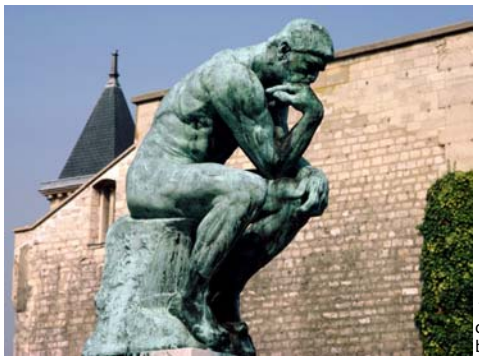
"Regenerative medicine has the potential to *eliminate the need for expensive supportive treatments* like dialysis and organ transplants."

Dr. Andrew von Eschenbach, former FDA commissioner (2006 to 2009)
"Andrew von Eschenbach: Toward a 21st-Century FDA" (WSJ, April 16, 2012)

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World



Who is your competition?

The Thinker, a bronze and marble sculpture by Auguste Rodin, cast in 1902, now in Paris. It depicts a man in sober meditation battling with a powerful internal struggle.

For those working on catheters, stents, vascular grafts, etc., consider this:

When (not if) we can grow new blood vessels in the body (what I call *in vivo tissue engineering*),

how many catheters, stents, vascular grafts, etc. do you think we will be using?

Something to think about…

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Will we be using fewer medical devices in the future compared to today?

Absolutely NOT!

We will be using many more devices in the future than we do today but…

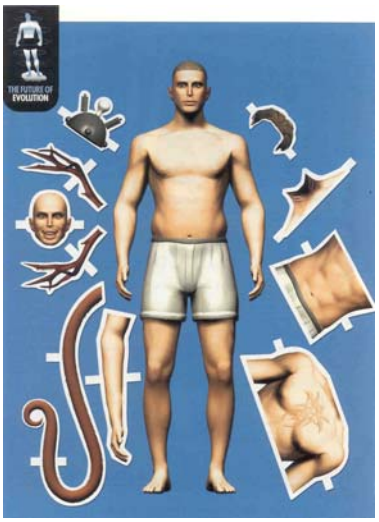
we will be using them in drastically different ways than we do today!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Where are we headed?

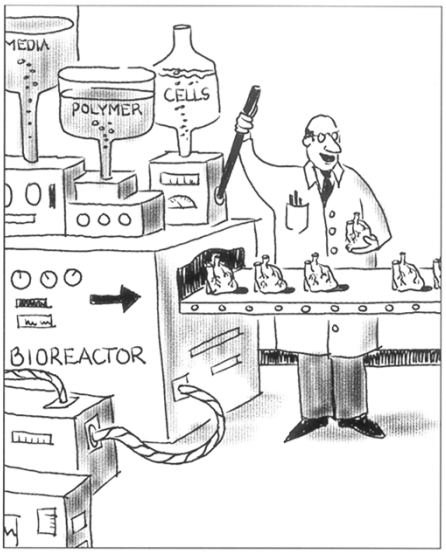


How about interchangeable body parts?

Why not… we do it for cars, for computers, why not for people?

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Growing organs on demand?



"Hearts!?? No, No, …We wanted livers!"

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

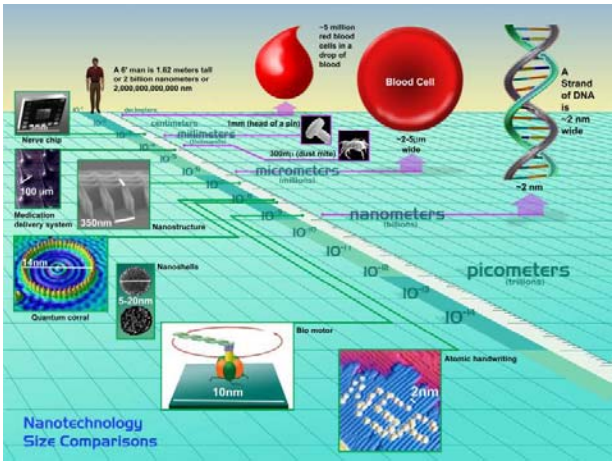
Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Consider the bigger picture by looking even smaller…

Is nanotechnology limited thinking?

Scale is a continuum…
today nanotechnology?
someday picotechnology?
femptotechnology?
beyond?





Don't think it's possible?

Read Dr. Seuss' Horton Heats a Who

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

We use lots of medical devices in many clinical specialities…

Cardiology	Urology
Gastroenterology	Oncology
Neurology	Obstetrics and Gynecology
Orthopedics	and on and on and on…

But not in immunology – why?
How about a *mechanical macrophage?*



Anyone think this is cool? How about wicked cool?

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

What is this?

A DNA Repair Nanobot or a mechanical ribosome?



How should this be regulated? By whom?
i.e., what is the PMOA of a DNA Repair Nanorobot?
What is the PMOA of a ribosome? i.e., is it mechanical, pharmacological or biological?
Does asking these questions make sense? Or is it 'silo' thinking?
To some, the DNA robot appears to act mechanically (fixing damaged DNA). If so, it could be regulated as a medical device, but…
At the molecular scale, cannot ALL drugs and biologics be viewed as mechanical devices? i.e., at the quantum level, there is NO difference between physics and chemistry... it's called physical chemistry or better, quantum mechanics. Similarly, at that scale, mechanical devices become chemical, and biologics become meaningless... drawing such lines, which PMOA forces us to do, becomes futile! What does that say about PMOA for nanotech???

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Nothing is impossible…

the impossible just takes a little longer!

Any sufficiently advanced technology is indistinguishable from magic.

Arthur C. Clarke, "Profiles of The Future" 1961 (Clarke's third law)



Sir Arthur Charles Clarke, (1917 – 2008) was a British science fiction author, inventor and futurist, famous for his short stories and novels, including *2001: A Space Odyssey*.

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World



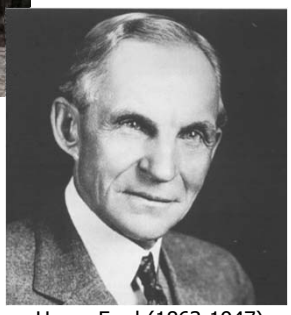
Think buggy whips…





and so…

no more buggy whips!

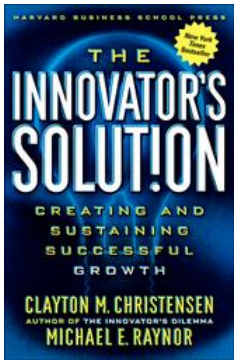


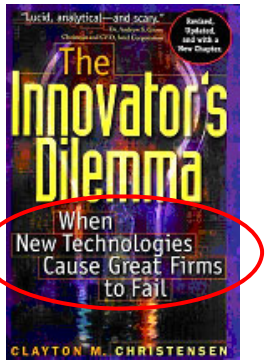
Henry Ford (1863-1947)

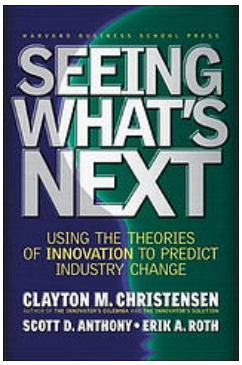
© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

What some call "disruptive technology"









Disruptive technology is a term coined by Harvard Business School professor Clayton Christensen to describe a *new technology that "unexpectedly" displaces an established technology.*

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Is it possible to think regulatory?

"Science is a way of thinking much more than it is a body of knowledge."

Carl Sagan (1934–1996)
American astronomer, author and science journalist



So how about this?



"Regulatory affairs is a way of thinking much more than it is a body of rules and regulations."

Michael Drues (1964–)
Regulatory Strategist and Amateur Philosopher ☺
www.meddeviceonline.com/author/michael-drues

Maybe Carl Sagan would be proud!

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

How do we view the world?



"Discovery is seeing what everyone else has seen and thinking what no one else has thought."

– Albert Szent-Gyorgi , 1937 Nobel Prize in Physiology and Medicine

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Commercializing Disruptive Medical Technologies in an Evolutionary World

Where are you aiming?



The greatest danger for most of us is not that our aim is too high and we miss it...

but that it is too low and we reach it.

Michelangelo Buonarroti (1475–1564) was an Italian architect, painter, poet and sculptor.

© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Taking inspiration from one of best...



"Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo. You can quote them, disagree with them, glorify or vilify them. About the only thing you can't do is ignore them. Because they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do."

Steve Jobs (1955 – 2011), entrepreneur, marketer and inventor, the co-founder of Apple Inc. and widely recognized as a pioneer of the personal computer revolution.

More importantly…

"Imagine where we could be if discontent for the status quo was the norm rather than the exception."

Can you guess who said this?



© Copyright 2014 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Want the handout? the podcast? Visit www.vascularsci.com/handout

Copyright 2014, Michael Drues, Ph.D.