

# INTEGRATING NEW PRODUCTS & TECHNOLOGIES INTO PRACTICE



NAVIGATING THE BADLANDS OF PROPRIETARY OFFERINGS



SEMINARS ON THE ARTS AND SCIENCES OF

# WOUNDS



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[arimedica.com](http://arimedica.com)

Phoenix, Arizona

2009



# NO DISCLAIMER

## Why Am I Giving This Talk?

I use new products, figure out how to make them work, do science and report on them.



## The Necessity of Manufactures

Without products and the companies of skilled tradesmen who make them, we would have none of what makes civilization so.



## Products & Proprietary Names

The products that keep us out of caves all have names, not pretentious, sanctimonious, overrighteous, politically correct euphemisms.

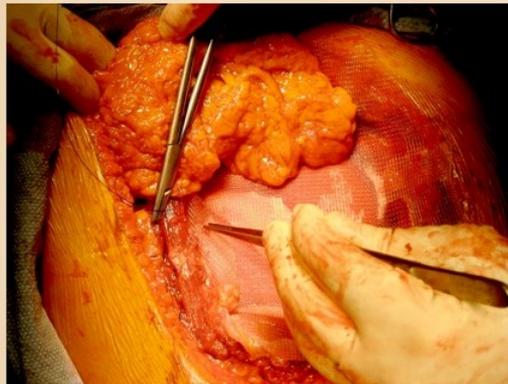
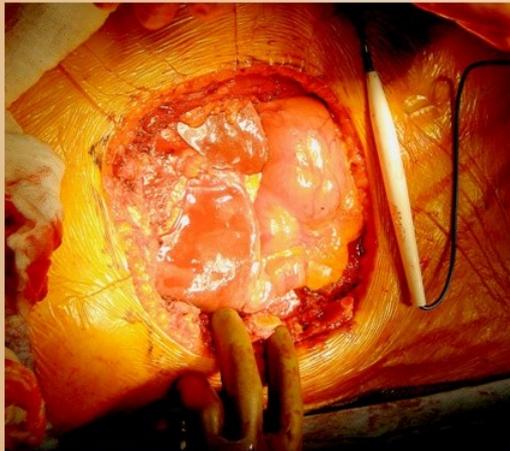
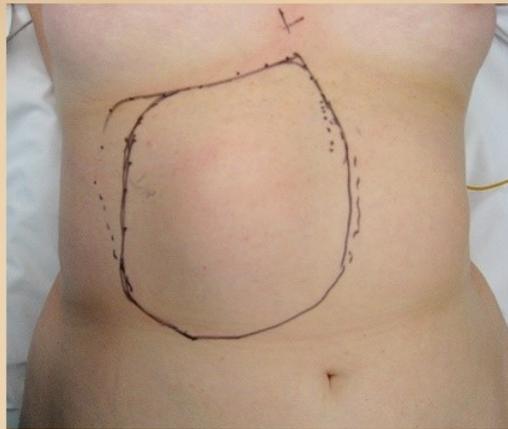
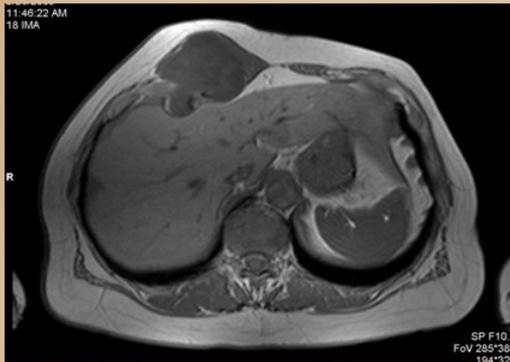
# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



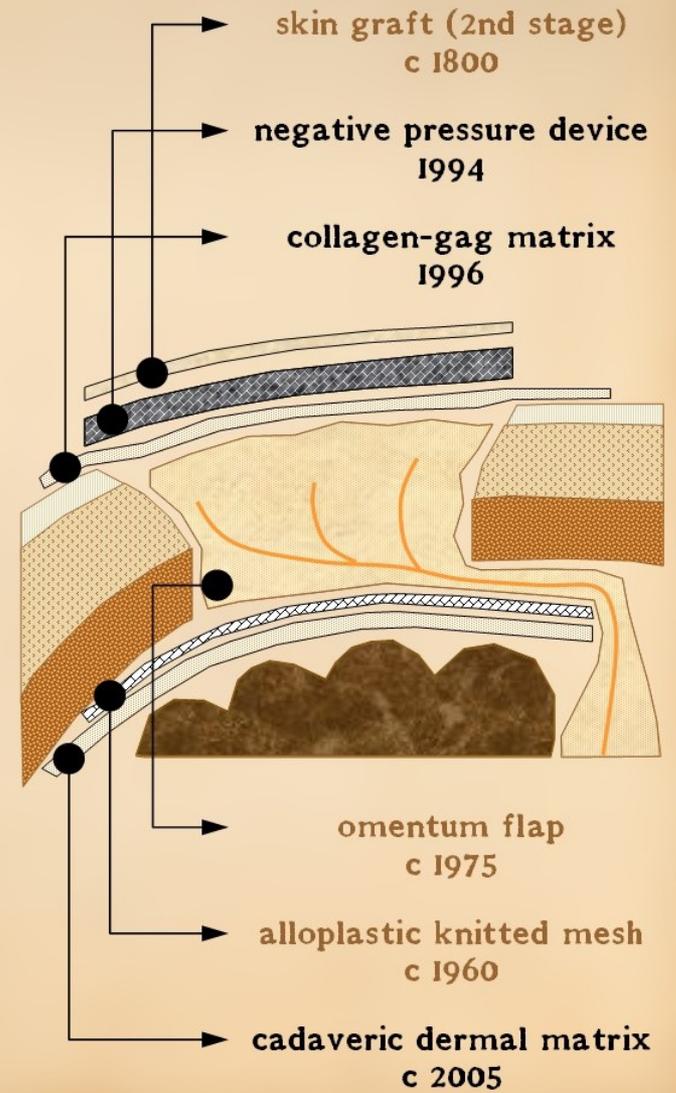
WRITING HOME ON AN ADJUSTABLE TABLE.

**“Hospital Life in New York”**  
Harper’s Monthly v57, July 1878

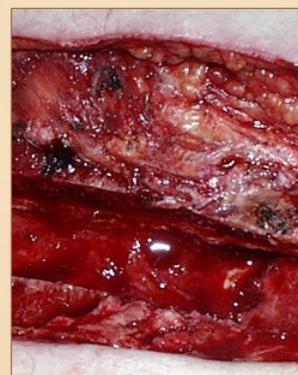
Medical arts and sciences evolve, and all practitioners will, in the course of their careers, be expected to understand the advances that support better care of the patient - new medical knowledge and also new products and their usage.



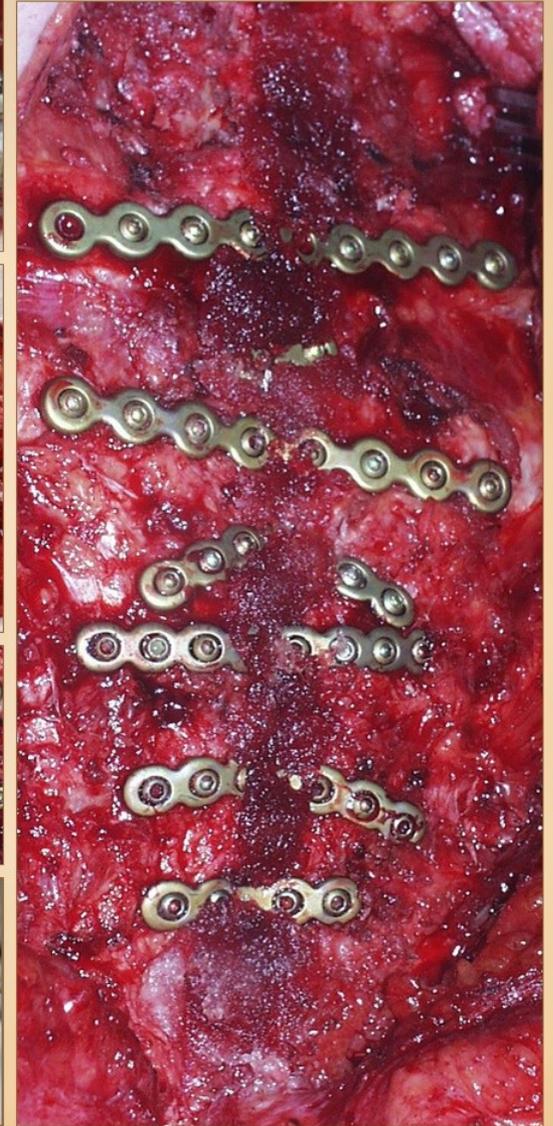
## 74 F, Chondrosarcoma of chest and abdominal wall.



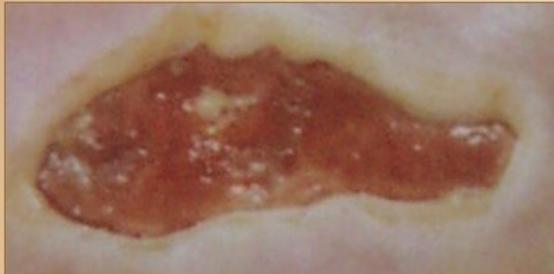
Integra collagen-gag matrix



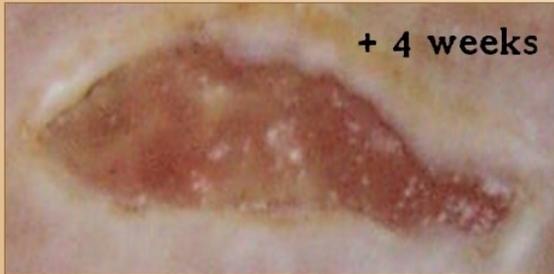
Sternal ORIF



# Apligraf - Re-engineered living skin equivalent



+ 4 weeks

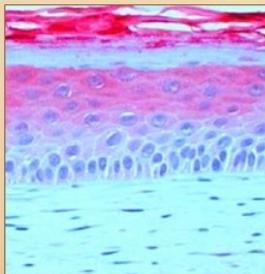


+ 4 weeks



Apligraf applied

+ 2½ weeks



# Botulinum toxin A



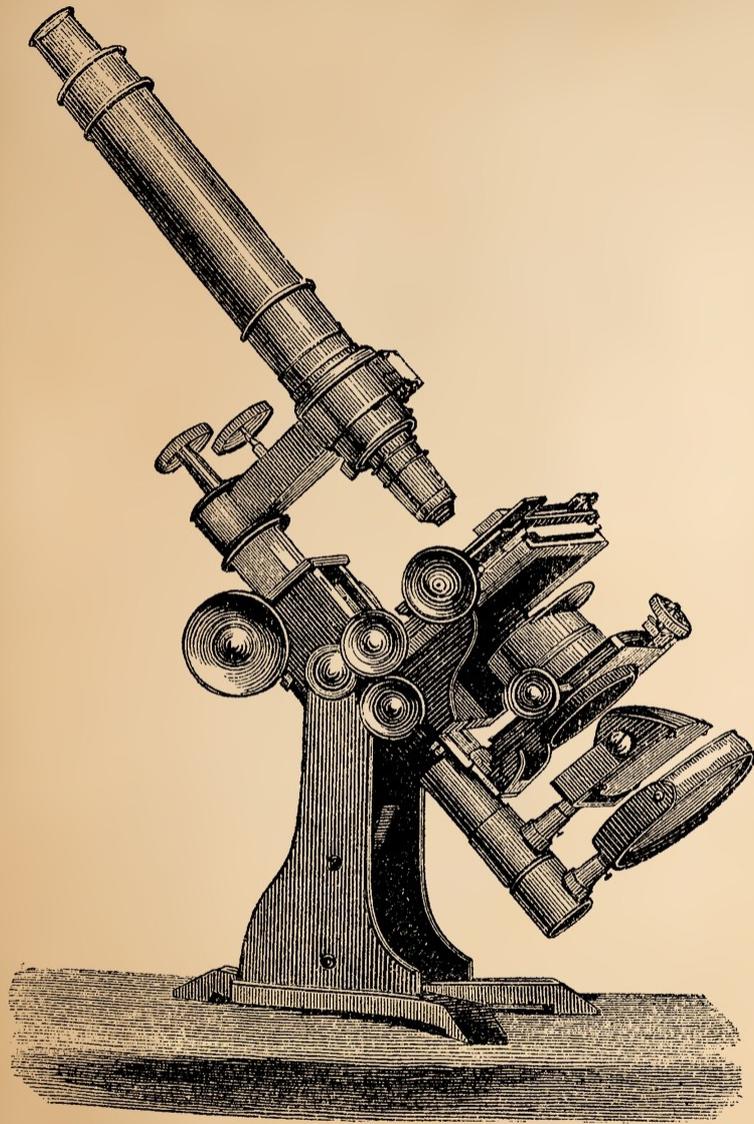
## Immunopathic ulceration



## Hypercoagulable ulceration



# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



A HIGH-CLASS MICROSCOPE.

1876

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There is an ongoing exponential rise in new medical products and devices, attributable to many factors, including:

the general advance of medical knowledge  
advances in micro-level biological science  
advances in materials & electronic technologies  
advances in computer & information technologies  
career track bioengineering and biotechnology  
changes in business finance and investment

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# MEDICAL DEVICES - RECENT STATISTICS

Figure 1. US Medical Device and In Vitro Diagnostic Spending, 1989 to 2004

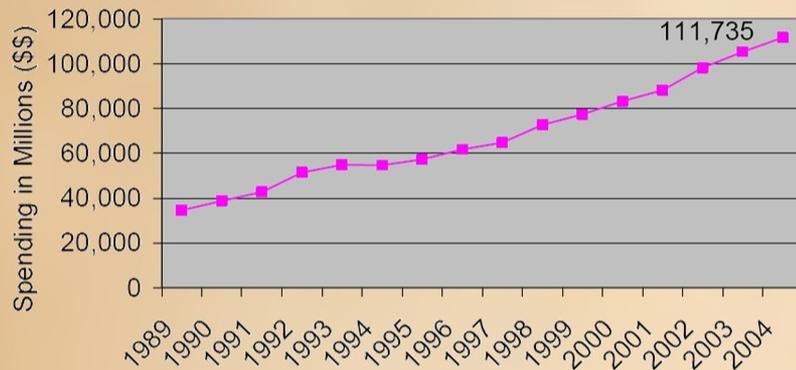


Figure 2. Medical Devices as a Percentage of National Health Expenditures



<http://www.amsa.org/business/King%20Paper%20Medical%20Device%20Spending.pdf>

## Biotechnology Industry Organization (BIO) 2006

“The biotech industry has mushroomed since 1992, with U.S. health-care biotech revenues increasing from \$8 billion in 1992 to \$39 billion in 2003.”

Medgadget, June 3, 2008

“Although the top 25 companies represent the lion’s share of sales (almost 60 percent), there are an estimated 20,000 medical devices companies around the world.”

## Wound Care Devices: Growth Amid Uncertainty

Medtech Insight, Executive Summary

January, 2009

“Over the last 15 years, a trend toward evidence-based medicine has led to a greater understanding of the science behind wound healing. This knowledge has fueled an explosion of innovation in technology and in the commercialization of a wide range of new products, generating a worldwide market estimated at \$4.5 billion annually, with double-digit growth projected over the next three to five years.”



AT  
 BEDTIME  
 I TAKE  
 A  
 PLEASANT  
 HERB  
 DRINK

THE NEXT MORNING I FEEL BRIGHT AND NEW AND MY COMPLEXION IS BETTER.

My doctor says it acts gently on the stomach, liver and kidneys, and is a pleasant laxative. This drink is made from herbs, and is prepared for use as easily as tea. It is called

**LANE'S MEDIGINE**

All druggists sell it at 50c. and \$1 a package. If you can not get it, send your address for a free sample. Lane's Family Medicine moves the bowels each day. In order to be healthy this is necessary. Address. ORATOR F. WOODWARD, LE ROY. N. Y.

**INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE**



The deluge of new products is good in principle, but the scene is muddled by a relaxation of standards, principles, and ethics, in medical practice, medical education, medical industry, medical finance, business, and government.



# DIATRIBE AGAINST A RELAXATION OF MORAL & PROFESSIONAL STANDARDS



**1**

Formal medical education has relaxed its 20th century standards of excellence. Without robust knowledge and analytical skills, new products and developments can not be critically evaluated. This leaves the door open for hucksterism and patent medicines. This is especially problematic for wounds, which is ignored in the schools.



**2**

Business has become business for its own sake (and the money), with blatant (and at times abusive) disregard for science, ethics, customers, patients, & prescribers.



**3**

Regulatory oversight has become overly politicized, arbitrary, bureaucratic, and inept. For wounds, which is ignored in schools, and the foundational knowledge is not in wide circulation, the subject is treated perversely and contradictory to science and sense.



**4**

There has been attrition of the principled "ethical drug industry" of the 20th century, and a resurgence of the no-claim-is-too-stupid-nefarious-or-disingenuous-to-be-promulgated "patent medicine era" of unproven remedies that value profit above performance.

VULNERARY DRUGS **WOUND MEDICINE** A BRIEF HISTORY

1



THE  
**PATENT MEDICINE**  
ERA

# VULNERARY DRUGS

# WOUND MEDICINE

# A BRIEF HISTORY

[A p]laster  
for [w]ondis.

Tak þe jus of plantayn & þe jus of morell & þe jus of  
ache & þe jus of walleworte & whete flour, & mak it in a  
plaster with-owtten fire & lay it to.

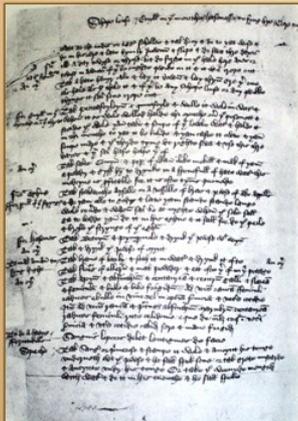
## The Thornton Manuscript, circa 1450

## The Liber de Diversis Medicinis

Tak wodbynde & stamp it & lay on þe wond & it  
wil draw owt wondirfully. /

[To] drawe  
owt broken  
[b]anes of  
woundis.  
An oper.

f. 312r. Tak violett and drynke it, for it castes owt broken  
25 banes of mannes wondis lyghtly.



sauē, betoyne, ache,  
yarow (milfoil, millfoile),  
auance, centory, tansy,  
lekes, malves, burnette,  
tomentil, herbe Robert,  
cynkefoil, marygolde,  
playntayne, waybrede,  
comfory (comfery), &c.



## OFFICIAL -VS- FOLK MEDICINE



## PRELUDE TO ACADEMIA



## A litle Her ball of the properties of Herbes.

Anthony Askham,  
1561

¶ *Consolida minor.*  
This is called Daylie or Brus-  
worte, his vertue is, if it be stam-  
ped and layde to a Botche, it shall  
heale it & breke it, for it is a spice  
of the comferie.

# VULNERARY DRUGS    WOUND MEDICINE    A BRIEF HISTORY

3

## The Age of Reason THE GREAT HERBALS

John Gerard, surgeon, 1597  
Thomas Johnson, apothecary, 1633



1 Panax Heracleum.  
Hercules All-heale.



CHAP. 389.

*Hercules Wound-wort, All-heale.*

*Chirons All-heale*

*Hercules All-heale*

*Æsculapius All-heale*

The leafe or root stamped with honey,  
and brought to the forme of an Vnguent  
or Salve, cureth wounds and vlcers of  
great difficultie, and couereth bones that  
are bare or naked without flesh.

**GORDAK'S  
HIGHLY APPROVED  
OPODELDOC,  
AN INESTIMABLE REMEDY FOR THE  
RHEUMATISM.**

For pain in the Side, Back and Limbs; it speedily cures violent Bruises; valuable in Swellings; it will remove Humours and Pimples; most efficacious for Chilblains and Stiffness in the Joints; and is also a most excellent Salve for Sores, and is well known to heal the hardest wound in forty-eight hours.

**DIRECTIONS.**

In cases of the Rheumatism, pains in the Side, Back and Limbs, Bruises, Swellings, Chilblains, and Stiffness in the Joints, one large tea-spoonful at the time will be sufficient, to be well rubbed on the part affected, before a fire, three or four times a day. In Humours or Pimples a very small quantity at the time will be sufficient, to apply every three hours to the part affected. In Sores and Wounds use it for a Salve.

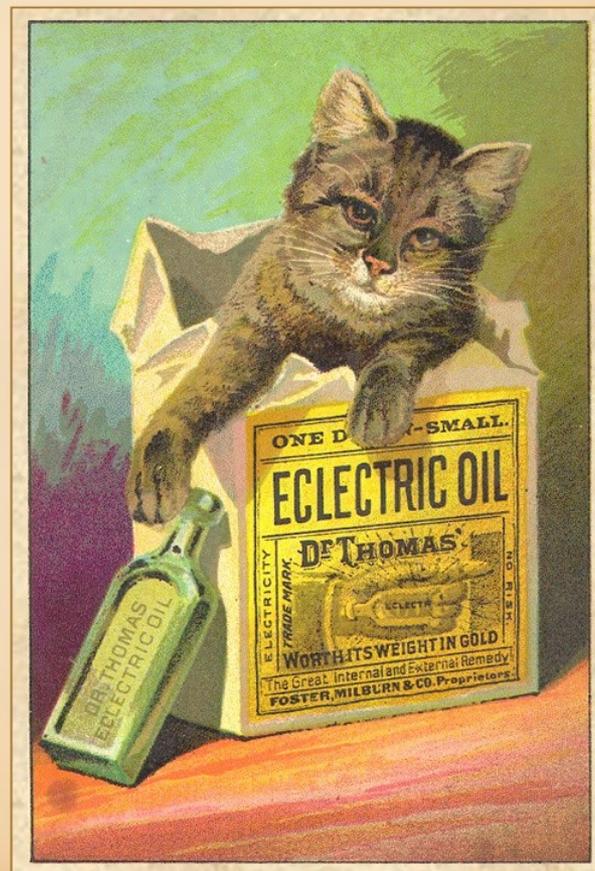
**Price 33 1-3 Cents per Bottle.**

None are genuine unless stamped on the Cork and signed on the Label

*JOHN MARSH, No. 84, Washington Street, and  
WM. C. STIMPSON & CO. south side of Faneuil  
Hall, Boston, General Sole Agents for the only Inventor  
and Proprietor.*

## PATENT MEDICINES

“... and is well known to heal the hardest wound in forty-eight hours.”



# VULNERARY DRUGS **WOUND MEDICINE**

# A BRIEF HISTORY

5

ALPHONSO & IMOGENE  
AN IDYL OF HENRY'S  
CARBOLIC SALVE.



ALPHONSO LOVED DEARLY THE BLITHE IMOGENE WHOSE FACE WAS THE FAIREST THAT EVER WAS SEEN, BUT WHEN HE PROPOSED, "ALAS", IMOGENE SAID "I WOULD GLADLY ACCEPT AND WITH THEE WOULD WED BUT WITH UGLY ERUPTIONS YOUR FACE IS SO SCARRED THAT ALL MY LIFE'S FUTURE, WITH YOU WOULD BE MARRED UNLESS YOU REMOVE THEM, SO IF ME YOU'D HAVE YOU MUST CURE THEM WITH HENRY'S CARBOLIC SALVE.

20<sup>th</sup> Century  
The Ethical  
Drug Industry

1906  
The Pure Food  
and Drug Act

1910  
The Flexner Report

ALPHONSO & IMOGENE  
AN IDYL OF HENRY'S  
CARBOLIC SALVE.



ALPHONSO THIS REMEDY TRIES — AND AGAIN POPS THE QUESTION — NOR DOES SO IN VAIN HENRY'S CARBOLIC SALVE HAS SWEEPED HIS FACE CLEAN OF EVERY UNSIGHTLY SPOT THAT WAS SEEN AS A COMPOUND FOR HEALING IT'S SPEEDY AND SURE AND FOR BURNS, CUTS AND BRUISES, READIEST CURE.

**HENRY'S  
CARBOLIC SALVE,**

The Most Powerful Healing Agent Ever Discovered.

HENRY'S CARBOLIC SALVE HEALS BURNS  
HENRY'S CARBOLIC SALVE CURES SORES.  
HENRY'S CARBOLIC SALVE ALLAYS PAIN.  
HENRY'S CARBOLIC SALVE CURES ERUPTIONS.  
HENRY'S CARBOLIC SALVE HEALS PIMPLES.  
HENRY'S CARBOLIC SALVE HEALS BRUISES.

**ASK FOR HENRY'S AND TAKE NO OTHER**  
BEWARE OF COUNTERFEITS.

LEGITIMACY

PSEUDO-  
LEGITIMACY

ABUSE

# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



While cynicism is valid because it reflects genuine problems, fortunately the good side of medical science & development is healthy as well, giving us a dizzying array of new tools that can safely treat and cure heretofore incurable problems.



**“The Four Doctors”**

William H. Welch, William Osler  
William S. Halsted, Howard A. Kelly  
The Johns Hopkins University & Medical School  
John Singer Sargent - 1906

# A SAMPLING OF MODERN MEDICAL TRIUMPHS BASED ON NEW PRODUCTS & TECHNOLOGIES OF THE PAST 25 YEARS



## General Surgery

endo surgery  
*robotics*

## Plastics & Burns

regenerative matrices  
biologics & cell-based rx

## Orthopedics

internal fixation  
prosthetic joints

## Vascular

endo surgery  
thrombolysis

## Cardiology

aicd  
rapid cardiac intervention

## Rheumatology

monoclonal antibody rx  
auto-antibody identification

## Gastroenterology

endo surgery  
control of peptic disease

## Neurology

rapid stroke intervention  
*implantable electronics*

## Rehabilitation

bio-interfaced prosthetics  
*gene therapies*  
(e.g. muscular dystrophy)

## Radiation

robotics and control  
implantable sources

## Imaging

mri & pet  
network distribution

## Laboratory

immunos  
*gene chip*

GRAND NATIONAL PRIZE of 16,600f.

**QUINA-**

**LAROCHE'S  
INVIGORATING TONIC,  
CONTAINING**



Peruvian Bark, and  
Pure Catalan Wine.

Endorsed by the Medical Faculty of  
Paris, as the Best Remedy for

**LOSS of APPETITE,  
FEVER and AGUE,  
MALARIA, NEURALGIA  
and INDIGESTION.**

An experience of 25 years in experi-  
mental analysis, together with the valu-  
able aid extended by the Academy  
of Medicine in Paris, has enabled M.  
Laroche to extract the entire active  
properties of Peruvian Bark (a result  
not before attained), and to concen-  
trate them in an elixir, which possesses in the highest  
degree its restorative and invigorating qualities, free  
from the disagreeable bitterness of other remedies.

22 rue Drouot, Paris.

**E. FOUGERA & CO., Agents for U. S.,  
30 North William street, N. Y.**

**LAROCHE**

**INTEGRATING NEW PRODUCTS  
AND TECHNOLOGIES INTO PRACTICE**



**How does the practitioner:**

**evaluate new products?**

**decide which ones to trial?**

**recognize the good & the bad?**

**integrate good therapies  
into daily practice?**

**Sort out products by type & purpose.**



# WOUND PRODUCTS & CONCEPTS - A GENERAL CATEGORIZATION



## Wound & Skin Mgmt

### GENERIC WOUND CARE

*dressings*

*non-specific topicals*

### PURPOSE-SPECIFIC TOPICALS

*pharmaceuticals*

*semi-stimulatory*

*semi-regenerative*

### SKIN CARE

*general skin care*

*stoma & peri care*

### DEVICES

*npwt*

*debridement*

## Wound Healing

### STIMULATORY THERAPIES

*platelets & releasates*

*living cell biologics*

*acellular biologics*

*growth factors*

*physical agents (e.g. rf, us, em)*

*novel pharmaceuticals*

*transfectives*

### REGENERATIVE THERAPIES

*regenerative skin substitutes*

*cadaveric skin matrices*

*miscellaneous bioparts*

*auto-cell culture technologies*

## Patient Support & Rehab

*orthotics*

*support surfaces*

*home health services*

## Diagnostics

*pressure mapping*

*O<sub>2</sub> & blood flow measures*

*immune & coag chemistries*

*proteomics and genomics*

*gene chips*

## Ancillary Therapies

*hbo*

*vascular technologies*



## Competition or Cooperation with Other Products

Products can work together for cooperative strategies of tandem or sequential therapy

*e.g. topical hygiene or npwt > then physical agents > then living cell biologics > then pdgf*

*e.g. topical hygiene or Vac > then Provant or Mist > then Apligraf > then Regranex*

# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



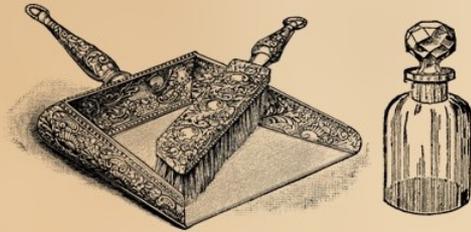
**There is both wheat and chaff among the endless new products, and sometimes some genuinely nutritious and tasty grains that will fundamentally change the way you and we all do things. All practitioners are obliged to keep an eye open for them, and hopefully participate as well in the planting and harvest.**



# NEW PRODUCTS - THE GOOD, THE BAD, THE UGLY - & EVERYTHING ELSE

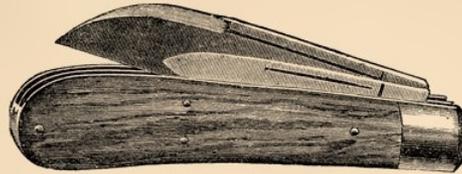
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## Trinkets



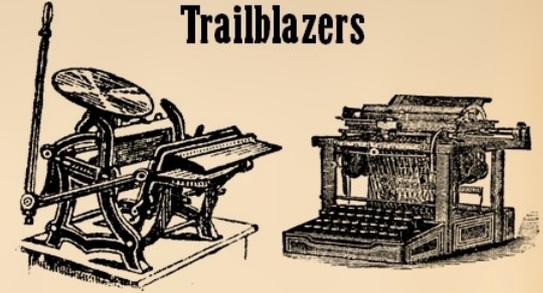
baubles & bling in the cabinet

## Toolbox toys



now and then, just in case

## Trailblazers



changing the way we do things

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## Missing Products, What-If's, & Wishlists

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Products that (1) do not exist, (2) did and died, (3) live in oblivion, (4) could or should be developed.

*e.g.*

*aminoglycan - Hyalofill (hyaluronic acid, Convatec)  
allantoin - Carrington gel (Carrington Labs) vs. maggots*

Products pending, coming soon to a store near you (maybe)

*transfectives - adenovirus + growth factors  
novel metabolites, mab's, etc.*

# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



Depending on:

your knowledge and interest  
in a particular subject,

your experience & intimacy with  
that subject in daily practice,

and your temperament,

you might be on the leading edge  
of using a new product, or you might  
wait until others have established the  
place for that product.



A STREET ACCIDENT.

“Hospital Life in New York”  
Harper’s Monthly v57, July 1878

# EVALUATING & USING NEW PRODUCTS - POINTS OF PHILOSOPHY



## **BE EDUCATED AND RESIST BOGUS CLAIMS**

Understand wounds: science, pathology, diagnosis, therapeutics, clinical arts.  
Maintain professional standards of evaluation and use.  
Don't let patent medicine practices sway your thinking.



## **INTELLIGENTLY TRY NEW THINGS**

You can only get good with and understand a few at a time.  
Outfit and become a master of YOUR toolbox.  
Don't be afraid to "pull the trigger" for potent or risky therapies.



## **SHARE KNOWLEDGE**

Share your experience & insights with others.  
Learn from others who take the same approach.



## **DO NOT ADOPT NEWNESS FOR ITS OWN SAKE**

Some new products don't work well.  
Many old products are good or better.  
Many old products are uncontestable paradigms & foundational therapies.  
**TOOLS - NOT TOYS.**



## **REMAIN IN CHARGE OF YOUR ANALYSIS**

Beware of profit motivation and inept misleading marketing materials.  
Knowledge and principles must always trump sales pitches and FUD.  
Keep total value in mind – cost, utility, effectiveness, safety.

# RHEUMATISM POSITIVELY CURED

Also Gout, Sciatica, Neuralgia, Numbness and Blood Disorders, resulting from excesses, impaired circulation or sluggish liver, by wearing

**Dr. BRIDGMAN'S**  
full power Electro-Magnetic **RING**, which is a quick and reliable remedy as thousands testify, and it **WILL CURE YOU.**

"Offices of the New York Bottling Co., N. Y.

"Dr. Bridgman's ring quickly cured me after years of intense suffering from Rheumatism. Ten thousand dollars would not buy mine if I could not obtain another. I confidently recommend it to all.

GEO. W. RAYNER, PRES."

Thousands of others offer similar testimony.

We have also supplied these rings to *Harrison, Cleveland, Blaine, Depew, Gladstone, Bismarck* and other eminent men. Their effect is marvellous. Price \$1 plain finish and \$2.50 heavy gold plated. All

sizes. For sale by **Druggists** and **Jewelers**, or we will mail it on receipt of price and size.

**There is absolutely no other ring but Dr. Bridgman's possessing real merit for the cure of Rheumatism. Beware of imitations.**

**The A. Bridgman Co., 373 Broadway, N. Y.**



## INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



Practitioners must evaluate new product claims based on several criteria:

purpose & need  
efficacy

proven or promising science

safety  
risk versus benefit

utility & cost  
comparative value

# CHECKLIST WHEN EVALUATING NEW PRODUCTS



## Concept

What is the purpose and rationale?  
Does it fulfill a need? Does it make sense?  
Does it solve problems or fulfill needs for my patients,  
because current therapies are not good enough?



## Proof

Is there valid science, proven or promising? . . . does it fit with what is known?  
Have satisfactory clinical or other real world trials and evaluations been made?  
What were the testing protocols and analysis?  
Efficacy - does it work? . . . in the lab? . . . in clinical trials? . . . is it safe?



## Principals

Who is the company? . . . who is behind the product? . . . reputable or credible?  
Who represents the company? . . . how well? . . . can they answer questions?  
How do they do business? . . . customer liaison, support, feedback, interaction?  
Is this a credible company that you can believe in?



## Principles

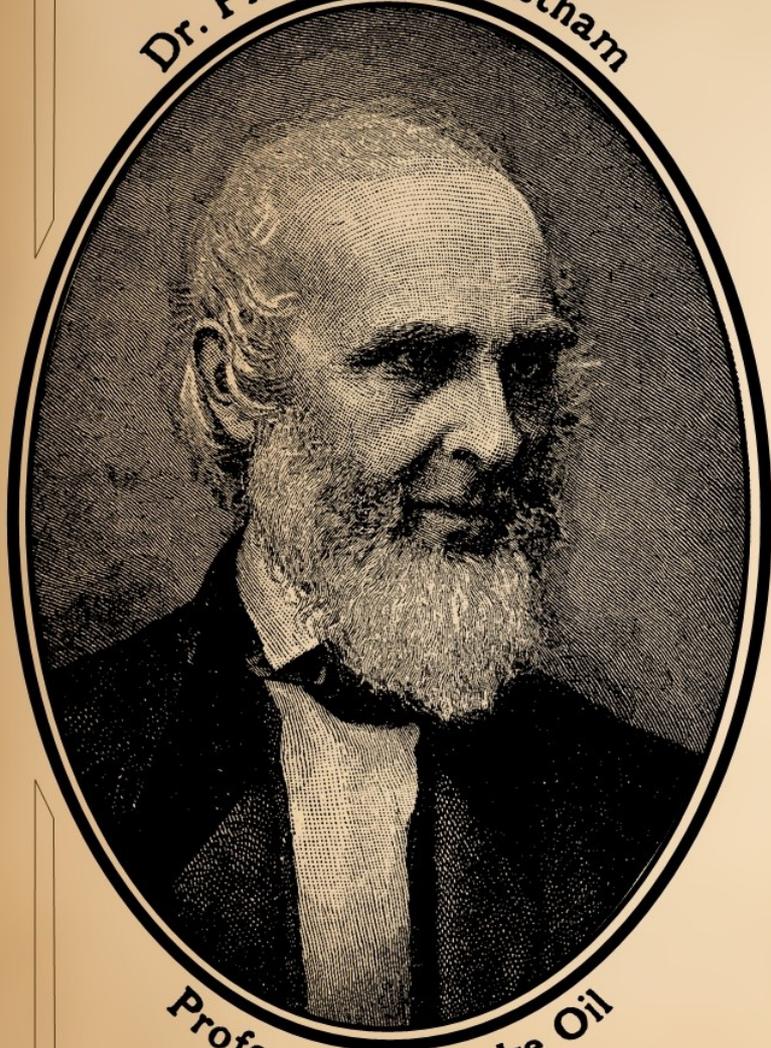
Is it driven by science-biotech, clinical-medical, or business-marketing?  
Are the marketing materials meaningful? Who is the target market?  
Are you dealing with real reps or with pitchmen? Are scientists & execs accessible?  
Are they dazzling you with legitimate brilliance, or are they muddling with manure?



## Value

efficacy & safety  
risk versus benefit  
utility & cost  
real value & comparative value

Dr. Phelonius Cheatham



Professor of Snake Oil

**DRS. DEWEY, CHEATHAM, AND HOWE**  
SPRINGFIELD

# CHECKLIST TO EVALUATE NEW PRODUCTS



## DR. CHEATHAM'S BOGOSITY MATRIX

		LEGITIMACY	
		Bogus	Real
PROOF	No data	Bogus No data	Promising Limited data
	Data	Bogus Pseudo-data	Promising Good data

ANALYSIS
False pretenses and predicates Bad engineering Corrected missteps Unforeseen horizons

# EXAMPLES - CHECKLIST WHEN EVALUATING NEW PRODUCTS



## OTHER RANDOM CONSIDERATIONS NO. 1



### Conceptual Origin of Product

#### **Biotechnology - vs - Clinical**

*supply versus demand driven*

*instigated by technology concept versus clinical need*



### Fulfilling Real, Perceived, or Contrived Needs

#### **Novel new product**

*e.g. winning new products spawn competition - good up to a point*

#### **Worthy variation**

*e.g. various narcotics, various regenerative matrices*

#### **Me-too slice of the pie**

*e.g. ssri's, cephalosporins, beta blockers; topical silvers, alginates*

# OTHER RANDOM CONSIDERATIONS NO. 2

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## Be Aware of Bogus Studies and Marketing Materials

**Slick brochures with fancy color photos showing:**

*Healed wounds that would have healed anyway.*

*Wounds that healed because of the initiation of basic hygienic care.*

*Wounds that healed slower than with natural or good care.*

*Unhealed wounds.*

**Caveat - many people do not know that wounds heal naturally.**

*There are people and companies with no concept that wound healing is normal,*

*... nor what it looks like, and how long it takes – they do not know what normal is.*

*They do not appreciate the crucial role of basic care (hygiene, debridement, bioburden and edema control, compression, &c).*

*When they see a wound heal, they attribute it to their magic poo.*

**When a patient goes from bad care to basic good care, do not attribute success to the test product.**

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## Look for Proper Wound Care Studies

**Many wounds will heal because proper basic care is started concurrent with a test agent.**

*Good wound studies control the wound in advance.*

**Ideally, a good wound study must have 3 arms:**

*agent -vs- placebo -vs- standard*

# EXAMPLES - CHECKLIST WHEN EVALUATING NEW PRODUCTS



## DR. CHEATHAM'S BOGOSITY MATRIX

		LEGITIMACY		
		Bogus	Real	
PROOF	No data	Bogus No data	Promising Limited data	Provant, Regenesis Biomedical
	Data	Bogus Pseudo-data	Promising Good data	Fibrinet, Cascade Medical

To Be Announced ●

False pretenses and predicates ● Invanz, ertapenem, Merck

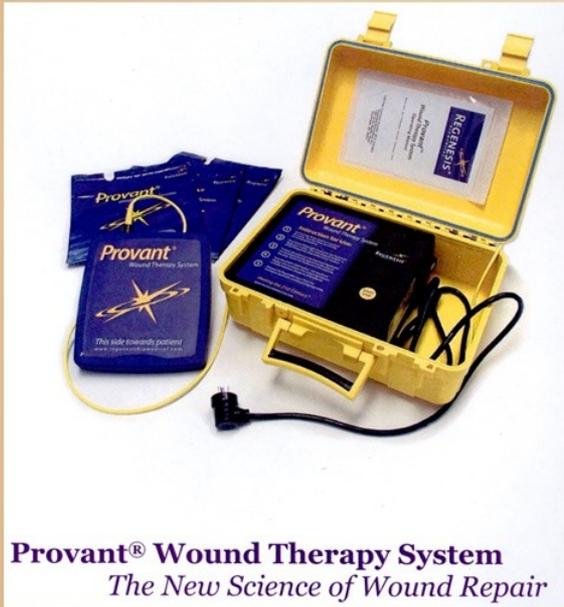
Bad engineering ● Kugel mesh, Bard

Corrected missteps ● Apligraf, Organogenesis

Unforeseen horizons ● Integra, Integra Life Sciences



Promising  
Limited data



**Recruits Dormant Cells and Optimizes Cell Proliferation**

Initiates the critical MAP kinase cascade to induce cell replication

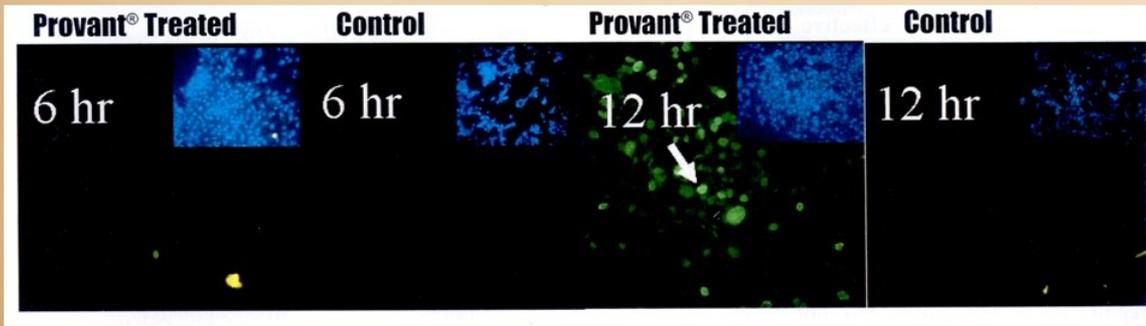
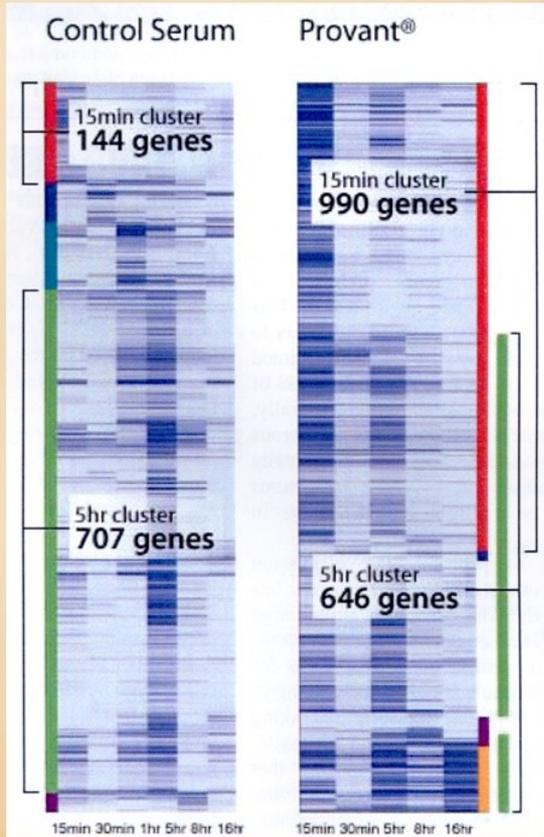
Initiates the gene expression cascade

Enhances cell replication

DNA synthesis occurs in half the time  
Cells replicate at twice (2X) their normal speed

Expressed hundreds of genes

At the right time  
In the right amount  
Throughout the entire wound healing cycle



**Cascade Medical** LLC ENTERPRISES

**FIBRINET**<sup>®</sup>  
AUTOLOGOUS FIBRIN & PLATELET SYSTEM

A point-of-care system for the isolation and concentration of a patient's fibrin and platelets, with their associated growth factors.

**FIBRINET**<sup>®</sup> Video

Watch a brief video of the FIBRINET<sup>®</sup> System

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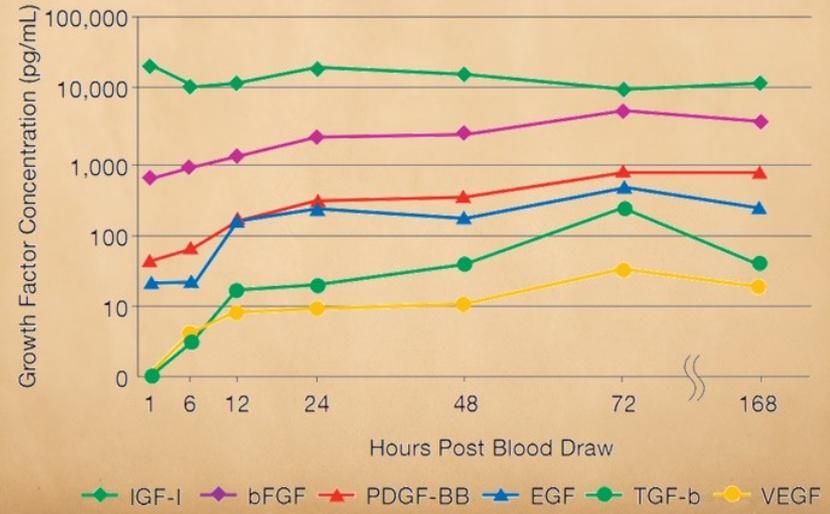
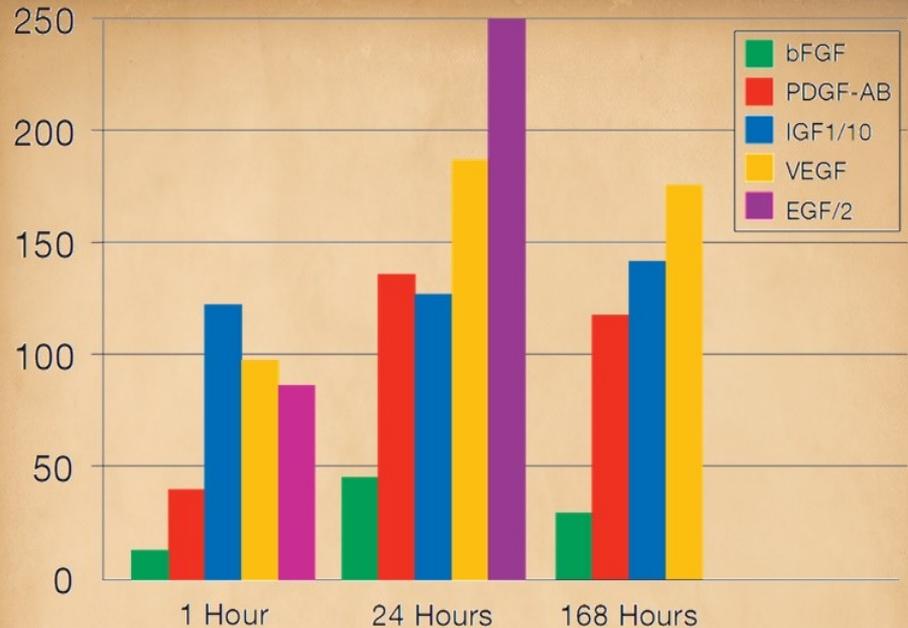
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**Promising  
Good data**

**AUTOLOGOUS PLATELET-RICH FIBRIN MATRIX AS A STIMULATOR OF HEALING OF CHRONIC LOWER EXTREMITY ULCERS**

S.M. O'Connell<sup>1,2</sup>, T. Impeduglia<sup>1</sup>, K. Hessler<sup>1</sup>, X-J. Wang<sup>1</sup>, R.J. Carroll<sup>2</sup>, H. Dardik<sup>1</sup>  
<sup>1</sup>Englewood Hospital & Medical Center/Mount Sinai School of Medicine, Englewood, NJ <sup>2</sup>Cascade Medical Enterprises, Wayne, NJ

**FIBRINET**<sup>®</sup>  
*Autologous Fibrin & Platelet System*  
**Cascade Medical**  
 prfm: platelet-rich fibrin matrix



## Bad engineering

“Kugel Hernia Repair is gaining momentum around the world as the next step in hernia repair when comparing laparoscopic versus open procedures. The benefits to the patient, surgeon, and hospital make this procedure a winning combination.” **Bard Promotion**



**Kugel Mesh Patch: 'A Terrible Ordeal'**  
 “In 2003, when Janine Ryan's (not her real name pending a lawsuit) mother, Sophia, had a Kugel Mesh hernia patch implanted, neither knew that there were any possible risks associated with the patch. But Sophia's patch broke, causing her to experience severe pain and other serious problems.” **Lawyer Site**

## RECONSTRUCTION WITH REGENERATIVE MATRICES

### Restoring Normal Anatomy With Histo-Inductive Bio-Materials



*Integra collagen - gag skin regenerant*

Cadaveric Alloskin  
 Adult Xenografts  
 Fetal Xenografts



*Alloderm - human cadaver dermis  
 Strattice - porcine dermis*



*Graft Jacket  
 human cadaver  
 dermis*



*DermaMatrix - human cadaver dermis*



*FlexHD  
 human cadaver  
 dermis*



*Surgimend  
 Primatrix  
 fetal bovine dermis*



*Veritas  
 bovine  
 pericardium*



*Unite BioMatrix  
 equine pericardium*



*Surgisis  
 porcine  
 intestine submucosa*



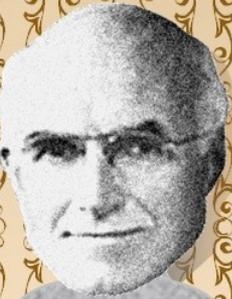
CARREL



LANDSTEINER



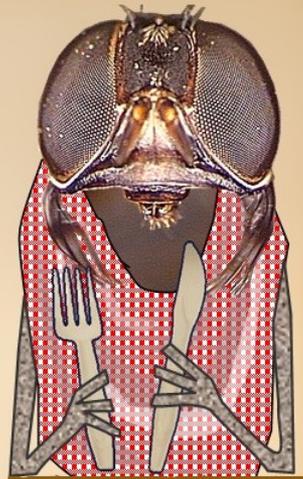
MEDAWAR



MURRAY



STARZL



# TRANSPLANTHEON

Corrected missteps

• Apligraf, Organogenesis

**BARRIERS TO ALLOGENEIC TRANSPLANTATION  
CANNOT BE SO EASILY OVERCOME**

The initial false concept was corrected by the company, based on science, experience, & user feedback.



**APLIGRAF**

**NOT**

a skin graft  
in a box

**YES**

a pharmaceutical  
packaged in a  
living material

**Integra**  
**Collagen-gag matrix**  
**Integra Life Sciences**

**Unforeseen horizons**



## False pretenses and predicates

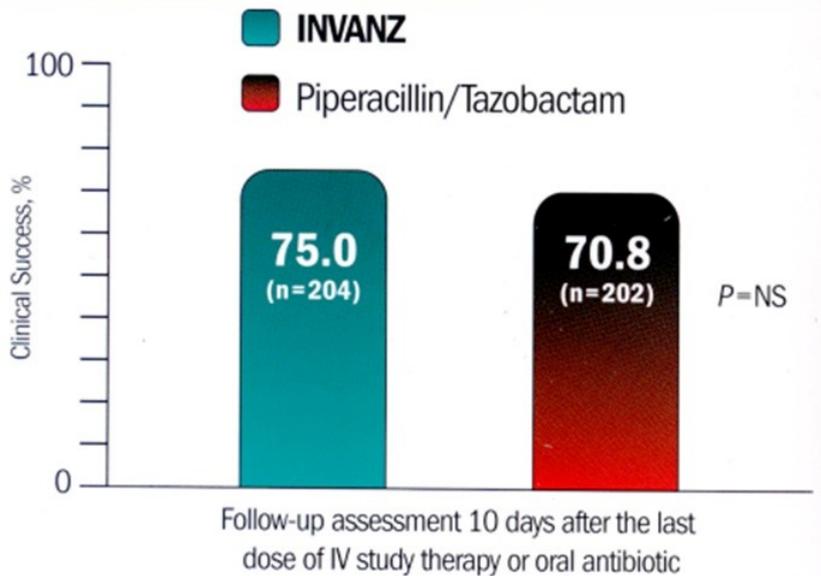
Invanz  
ertapenem  
Merck

**Bogus  
Pseudo-data**

406 clinically evaluable patients

INVANZ  
1 g IV once daily  
(n = 204)

Piperacillin/Tazobactam  
3.375 g IV q6h  
(n = 202)



Clinical success (cure or improvement) required resolution of all or most (respectively) pretherapy signs and symptoms of infection (and specifically of fever, lymphangitis, and purulent drainage), and no need for additional antibiotic therapy.<sup>1</sup>



**Axilla after hidradenitis resection -  
Topical natural remedy**

## **Bogus Pseudo-data**

**FALSE PRETENSES  
AND PREDICATES**

**Good general care**

**Placebo effect**

**Eschew normality**

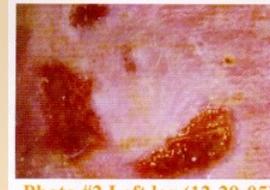
**Bogus products**

**Bogus data**

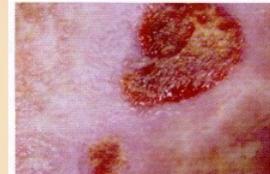
**Bogus marketing**



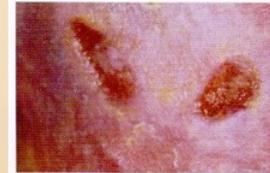
## **Topical collagen product Leg ulcers & Heel ulcer**



**Photo #2 Left leg (12-29-05)**



**Photo #2 Right (12-29-05)**



**Photo #3 Left (1-12-06)**



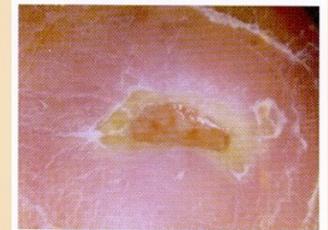
**Photo #3 Right (1-12-06)**



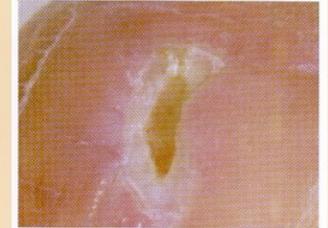
**Photo #4 Left (2-23-06)**



**Photo #2 (1-5-06)**



**Photo #3 (1-26-06)**



**Photo #4 (2-2-06)**



**Photo #5 (2-9-06)**

# Accelerates Healing.

# Controls Infection.

## VENOUS STASIS ULCER

## BURN

75 YEAR-OLD FEMALE CONFINED TO BED AND WHEELCHAIR DUE TO VENOUS STASIS ULCER ON LOWER LEG. ULCER PRESENT FOR 7 YEARS AT TIME OF TREATMENT.

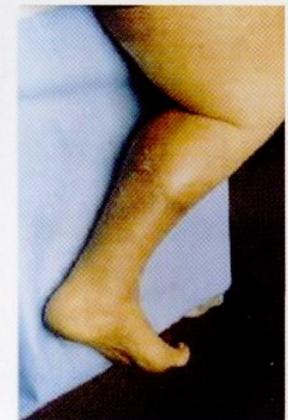
37 YEAR-OLD MALE WITH DEEP SECOND-DEGREE BURN ON LEFT CALF.



### FALSE PRETENSES AND PREDICATES

Good general care  
Placebo effect  
Eschew normality

Bogus products  
Bogus data  
Bogus marketing



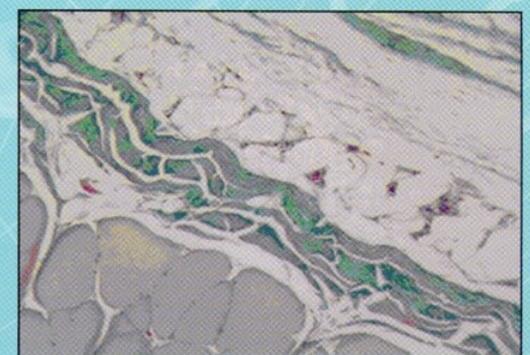
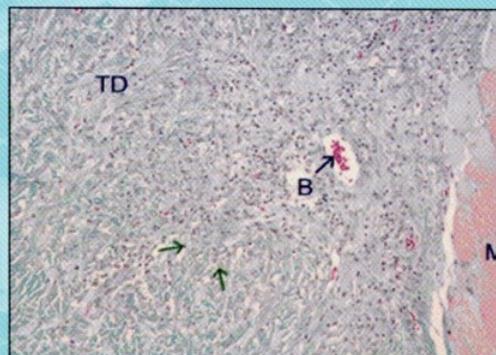
TOTAL NUMBER OF TREATMENT DAYS TO HEALING: 90 DAYS

TOTAL NUMBER OF TREATMENT DAYS TO HEALING: 12 DAYS

Venous & burn - Topical antiseptic

**Bogus Pseudo-data**

Cadaveric dermal matrix



# DO NOT GET SUCKERED IN BY BOGUS PSEUDO-DATA



## BOGUS PRODUCTS

Some products are just bad - period.

*But bogus products need to be discriminated from bogus data and bogus marketing.*



## BOGUS DATA

Data based on false misleading pretenses, a lack of knowledge, and erroneous concepts and methods is bogus.

*Do not be hoodwinked by it.*

Understand the significance of good general care and the placebo effect in wound healing.

Do not confuse normal healing and good care with a response to the product.

Some products with little to go on may be meritorious. Little data with honesty and a believable concept is okay.



## BOGUS MARKETING

Sincere good faith use of misunderstood bad data - *versus* -

Deliberate, deceptive, and disingenuous use of bad data.

*“There are three kinds of lies: lies, damn lies, and statistics.” - President Theodore Roosevelt*



Products with bogus data may be good products, but, amidst the clutter & noise of hundreds of products, claims and pitches, they need to give me something to go by to persuade me to try them.

# INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



Either way, the ultimate utility and usage of new products is established by the broad base of practitioners and prescribers working with their sick patients, and not by the inventor, the company, the market, nor the FDA.

In your quest for better care, good products **AND** the companies who make them are your allies.



The Doctor.

A DAY WITH A COUNTRY DOCTOR.

Scribner's Magazine v8, November 1890

# TRYING NEW PRODUCTS - A GENERAL PHILOSOPHY & PEP TALK

---

COMPANIES DEVELOP AND BRING NEW PRODUCTS TO MARKET, BUT

**The real usage and truth of these products is discovered by the users.**

*Do not be afraid of new products.*

*Have a plan for using and evaluating them.*

*Be responsible, scientific, professional, learned, thoughtful, analytical.*

*Learn what you can from other users.*

*Work with the company.*

---

SOLVE PROBLEMS WITH THE NEW PRODUCT.

**Look for the Novel and Frontier Uses**

*FDA “labeling” restricts a companies claims and marketing.*

*FDA “labeling” does NOT restrict practitioners uses.*

*Innovation and novel solutions are encouraged.*

**Be innovative - solve a problem with your new tool - the truth awaits the world.**

THE GREAT COUGH REMEDY.

WONDERFUL  
REMEDIAL  
IN ALL  
CASES  
WHERE THE  
ORGANS  
OF  
RESPIRATION  
ARE  
AFFECTED

# HALE'S HONEY OF HORSEHOUND AND TAR.

FOR  
COUGHS,  
COLDS,  
DIFFICULT  
Breathing

AND ALL  
AFFECTIONS  
OF THE  
LUNGS  
AND  
THROAT.

Well Known Throughout the  
United States and Canada as Having NO EQUAL  
for the Cure of  
**Coughs, Colds, Bronchitis,**  
DIFFICULT BREATHING,  
and all Affections of the Throat, Bronchial Tubes, and Lungs  
LEADING TO CONSUMPTION.

Rapid and permanent cures are effected by using HALE'S HONEY OF HORSEHOUND AND TAR, a pleasant and efficacious remedy, which does not contain anything whatever injurious to the most delicate constitution, yet exerts almost magical power in all affections of the Throat and Lungs, soothing and allaying irritation and inflammation, and strengthening the tissues, thus enabling them to endure the changes of the seasons. Invaluable in the first stages of Croup, before a physician can be had. Beware of inert and worthless imitations similar in name. Ask for HALE'S Honey of Horsehound and Tar, and take no substitute.

**KEEP IT IN READINESS.**

Three sizes—25c. 50c. and \$1; the larger proportionately cheaper.

HALE'S HONEY IS FOR SALE BY ALL DRUGGISTS. C.N.Crittenton, Propr. New York.

## INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE



Practitioners have a moral and professional obligation to evaluate new products. One must reject those that do not work and adopt those which seem promising or are confirmed to work.

One must also decide which ones to trial yourself and which ones to eye as others trial and confirm them. For the adventurous and curious, be on the front lines of figuring out how-to-make-it-work for novel products that tweak your interest.

# WORKING WITH NEW PRODUCTS - A PRACTICAL GUIDE

---



## 1 - Getting Started

---



Obviously, some product or concept has tweaked your interest.

**Read:** package insert, company website, company brochures, conference notes, papers.

**Speak to:** the company reps, company execs & scientists, other users.

---



**Plan for:** medical usage, support materials, dosing, follow-up frequency.

**Anticipate side effects, and how you will handle them.**

---



**Plan for:** usage, logistics, procurement, stocking & supply, reimbursement.

**Plan for record keeping, data review, and evaluation.**

**Educate your staff.**

---



**Plan how to educate the patients, especially if it is investigational, unusual, or risky.**

# WORKING WITH NEW PRODUCTS - A PRACTICAL GUIDE

---



## 2 - Figuring Out How to Make it Work

---



When it works as expected . . .

When at first it doesn't seem to work . . .

When it doesn't work as intended . . .

---



You have it figured out, and it exceeds expectations.

*Taking it to the next level . . .*

When it works or not for its prime use, but  
*it is effective for another need or usage . . .*

Going beyond label, nominal, or primary usage.  
*be thoughtful, wise, analytical, knowledgeable . . .*

# WORKING WITH NEW PRODUCTS - A PRACTICAL GUIDE

---



## 3 - For Problems or Perplexity

---



Preempt issues by being aware of anticipated side effects and take precautions.

Manage side effects as required.

Discontinue use - *versus* - continue & manage the side effects.

---



Read what you can about the issue.

Speak to the company reps.

Speak to the company scientists.

---



Use the lab, especially histology, immune & blood studies, vascular studies.

---



Critique & feedback to company.

File adverse reaction reports for serious events worth knowing about.

*Personally, I have done it twice: (1) drug-induced lupus due to pregabalin;  
(2) a neuroleptic malignant reaction due to risperidone, triggered by hydrocodone.*

**Cascade Medical** ENTERPRISES

Autologous Fibrin & Platelet System  
Easy-to-use Safe 100% AUTO



**FIBRINET**  
AUTOLOGOUS FIBRIN & PLATELET SYSTEM

- A proprietary technology platform to produce an autologous platelet-rich fibrin matrix (PRFM) with associated growth factors
- Proprietary centrifugation process
- Eliminates the need for bovine thrombin or exogenous activators
- Preserves functional growth factors
- Produces an easy-to-handle, suturable gel or membrane

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## FIBRINET<sup>®</sup>

*Autologous Fibrin & Platelet System*

**Cascade Medical**

**prfm: platelet-rich fibrin matrix**

**A story about initiating a new promising high tech therapy in a busy clinic.**

*equipment  
staff training  
procurement and reimbursement  
patience & reward*



## APLIGRAF<sup>®</sup>

**A set of peculiar contrary adverse events, presumed due to immune reaction.**

**Organogenesis inc.**  
LIVING TECHNOLOGY

# YOUR NETWORK & SUPPORT TEAM IN THESE ENDEAVOURS



Nurses in your practice  
Doctors in your practice



Dinner meetings  
Other wound care doctors



Wound journals  
Wound societies  
Wound meetings, symposias, workshops



Hospital and clinic administrators



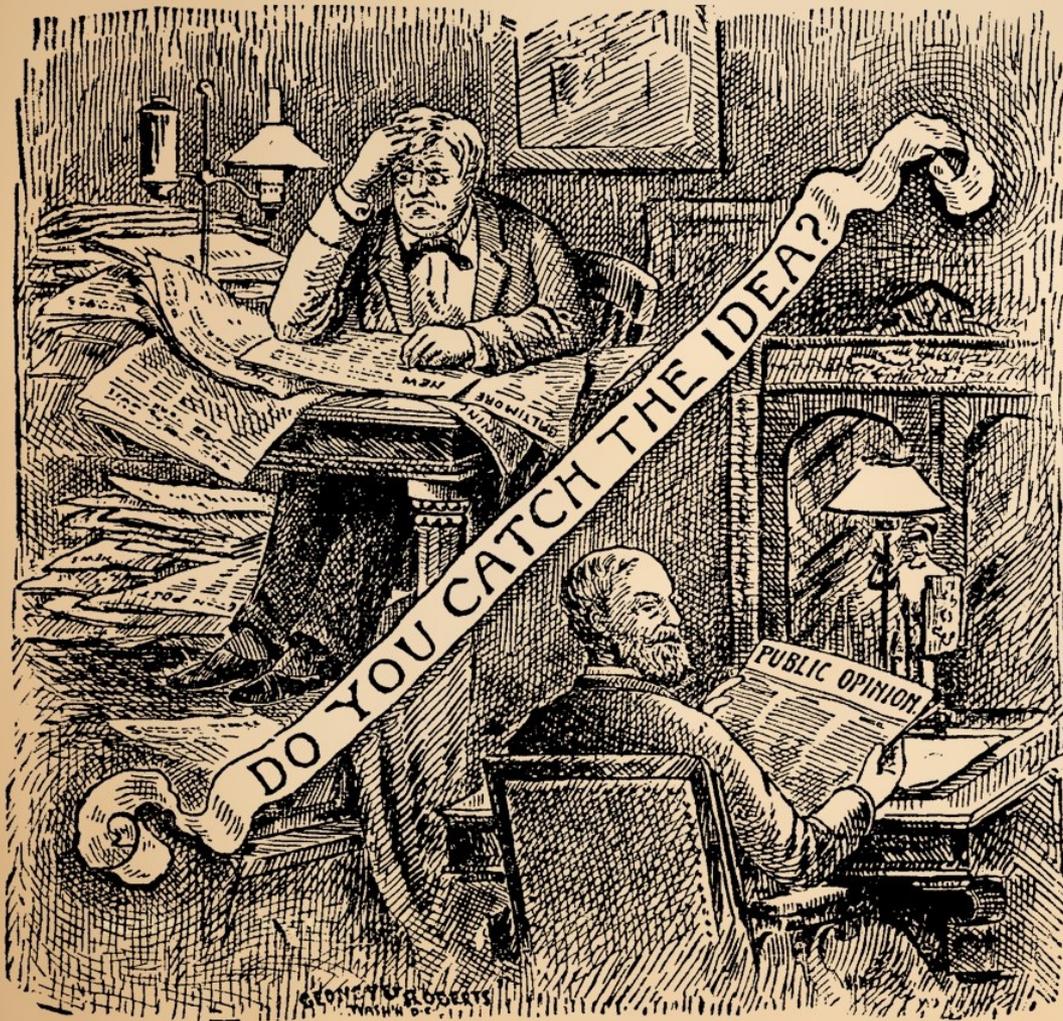
Company reps  
Company execs and scientists

*Make the reps prove themselves & their products.*

*If they are bogus – done.*

*If they are legitimate, then make them part of your professional family.*

# INTEGRATING NEW PRODUCTS, TECHNOLOGIES, & KNOWLEDGE INTO PRACTICE



Scribner's Magazine 1890

## SUMMARY

Be learned about wounds.

Understand the relative role and value of each product.

Keep an open eye to new products.

Listen to your colleagues.

Keep an open mind to trying them.

Recognize & reject the bogus.

If it seems promising, work with it until you can make it work.

Work with the company & reps.

Share your experiences.

***END***

ABSTRACT:        INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE

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Phoenix, AZ  
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arimedica.com

This is a simple conspectus of the presentation that will be given. The final presentation will be posted at the website arimedica.com. You can view the presentation and annotations there. The main concepts presented are:

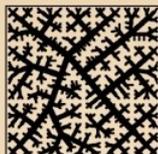
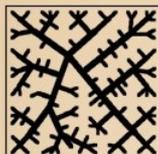
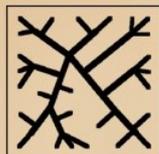
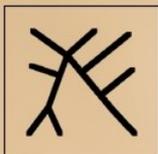
- 1 - Medical arts and sciences evolve, and all practitioners will, in the course of their careers, be expected to understand new advances in knowledge and the products that support care of the patient.
- 2 - There has been an exponential rise in new medical products and devices, attributable to: the general advance of medical knowledge, advances in micro-level biological science, advances in materials and electronic technologies, advances in computer and information technologies, career track bioengineering and biotechnology, and changes in business finance and investment.
- 3 - The deluge of new products is muddled by a relaxation of standards and principles: formal medical education has been inept in training new professionals to understand and critically evaluate new technologies; business has become business for its own sake (and the money), with disregard for science, ethics, customers, patients, and prescribers; regulatory oversight has become overly politicized, arbitrary, bureaucratic, and inept. This has led to the attrition of the principled "ethical drug industry" of the 20th century, and the resurrection of the no-claim-is-too-stupid-nefarious-or-disingenuous-to-be-promulgated "patent medicine era".
- 4 - While this sounds like an overly cynical diatribe, it does reflect one facet of the current medical landscape. Fortunately, the good side prevails as well, giving us a dizzying array of new tools that can safely treat and cure heretofore incurable problems.
- 5 - How does the practitioner evaluate new products, decide which ones to trial, recognize the good and the bad, then integrate the good therapies into daily practice?
- 6 - Practitioners must evaluate new product claims based on: Does it fulfill a need? Would it solve problems in my patients, because current therapies are not good enough? Is there valid science behind it, does it fit in with what is known and understood? Has it been adequately tested for safety? . . . for efficacy? Who is the company, and who is behind the product? . . . are they reputable or credible? Have satisfactory clinical or other real world trials and evaluations been made? Who represents the company, how well, and can they answer your questions? Are the marketing materials meaningful? Who is their target market? Are you dealing with real reps or with pitchmen? Are they trying to dazzle you with legitimate brilliance, or are they trying to muddle with manure?
- 7 - Among all the chaff of endless new products are some nutritious grains that will fundamentally change the way you and we all do things, so all practitioners are obliged to keep an eye open for them.
- 8 - Depending on your knowledge and interest in a particular subject, your experience and intimacy with that subject in daily practice, and your temperament, you might be on the leading edge of using a new product, or you might wait until others have established the place for that product.
- 9 - Either way, the ultimate utility and usage of new products is established by the broad base of practitioners and prescribers working with their sick patients, and not by the inventor, the company, the market, nor the FDA.
- 10 - All practitioners have a moral and professional obligation to evaluate new products, decide which ones to reject, which ones seem promising, which ones to trial, which ones to keep an eye on as others trial them. One must further be ready to reject those which do not work, adopt those which are confirmed to work, and, for the adventurous and curious, be on the front lines of figuring out how-to-make-it-work for novel products that tweak your interest.
- 11 - These principles will be illustrated through case examples of patients whose successful treatment was significantly enhanced by the use of new products, and then by case examples of novel therapies and companies that have come to market with good and bad products.
- 12 - The talk will conclude with a discussion of where to get information from, and how to stay abreast of contemporary developments and new products.

## Marc E. Gottlieb, MD, FACS

*A Professional Corporation*

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**Acute and chronic wounds • Diseases and defects of the soft tissues • Injuries, diseases, and defects of the hand and extremities • Defects of the head and trunk**

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### INTEGRATING NEW PRODUCTS AND TECHNOLOGIES INTO PRACTICE

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Baptist Health South Florida

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**Marc E. Gottlieb, MD, FACS**  
**Phoenix, AZ**





# YOUR NETWORK & SUPPORT TEAM IN THESE ENDEAVOURS



Nurses in your practice  
Doctors in your practice



Dinner meetings  
Other wound care doctors



Wound journals  
Wound societies  
Wound meetings, symposias, workshops



Hospital and clinic administrators



Company reps  
Company execs and scientists



*Make the reps prove themselves & their products. If they are bogus – done.  
If they are legitimate, then make them part of your professional family.*