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Hypothesis –

There exist **scientifically promising therapies** that are **not part of** mainstream medicine (nor are they being investigated to become part of mainstream medicine)





How can this be?



How do therapies reach patients?

Scientific promise



Clinical studies



Routine use in patients

- \$\$\$
- Time
- High failure rate



Pharma undertakes



Adequate ROI?






In assessing ROI, pharma looks for **three** things:

- **Patent** on the drug?
- Adequate **market** for the drug?
- Is the drug likely to **succeed in clinical trials**?





And if the estimated **ROI** is felt to be too small, you have a **scientifically promising therapy** that languishes ...and patients lose...



Examples

Generic (off-patent) FDA approved drugs that could be used for a new use

- In some cases, a new use patent **cannot be obtained** because of prior public disclosure e.g. in a scientific journal
- Even if the drug could be patented for a new use, the patent may be **hard to enforce** or the **price point** needed to make the new indication profitable may be higher than the current drug price
- **Combinations of generic drugs** for a new use especially if accompanied by a **new formulation** may be patentable






Substances **never patented** e.g.
nutraceuticals such as vitamin C

Therapies such as a **lifestyle changes** or a **special diet**





An additional quality of many of these examples is their **immediate availability** for clinical studies – so it is particularly unfortunate that these opportunities lie unexplored, especially for diseases where current therapies are inadequate





GlobalCures (GC)

Why we exist: GC's mission is to bring to patients worldwide novel, immediately implementable, scientifically promising therapies ignored by the for-profit sector because of inadequate financial reward. Its first focus is on cancer.

What we are: A non-profit organization

www.global-cures.org



Workflow/deliverables

Patient (and physician) education

Write up disease and stage specific treatment options

I-FIND

Patients as discovery partners

Design and implement a web-based clinical data collection and analysis platform

I-TOO

Patients as discovery funders

Conceive, design, write, and sponsor clinical trials

I-FUND

Collect, conceive and prioritize promising therapies that are immediately implementable and not being pursued by the for-profit sector



Perspective

- GC *values***: singularly patient centered (“Patients over patents”; “Patients helping patients”)
- GC *information***: scientifically rigorous, unbiased, up-to-date, comprehensive
- GC *therapies***: immediately implementable, affordable (in many cases); “out-of-the-box” ideas
- GC *leverages*** the power of the internet and the “wisdom of the crowds”: e.g. ideas for new therapies and patient data from around the world for promoting discovery - paradigm shifting



Legal issues

I-FIND

- GC liabilities in “providing advice”
- Protecting the physician if he/she wishes to implement I-FIND ideas
 - Current US law on off-label use

I-TOO

- Patient privacy
- Research vs patient care

I-FUND

- A model is to have patients pay for trial participation; is this acceptable as an eligibility criterion (legal, ethical)?



Legal issues (contd)

Another question...

- Is it time to reexamine the issue of access to “unproven” therapies for patients with a fatal illness (“**A terminal patient’s bill of rights**”)
 - Protecting patients from quack medicine
 - Protecting physicians from lawsuits
 - Impact on drug development

