The Emergence of Pharmaco-Electronics

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Introduction

We will define Pharmaco-Electronics.

We will highlight some of the Legal, Ethical, Social Considerations.

We will make suggestions for Recommended Action.

What is Pharmaco-Electronics

Convergence of

Electronics (science of controlling electrical energy)

+ Pharmacology (study of drug interaction)

Merging the progress of sensor, computing and telecommunication technology with in the body medical devices.

What is Pharmaco-Electronics

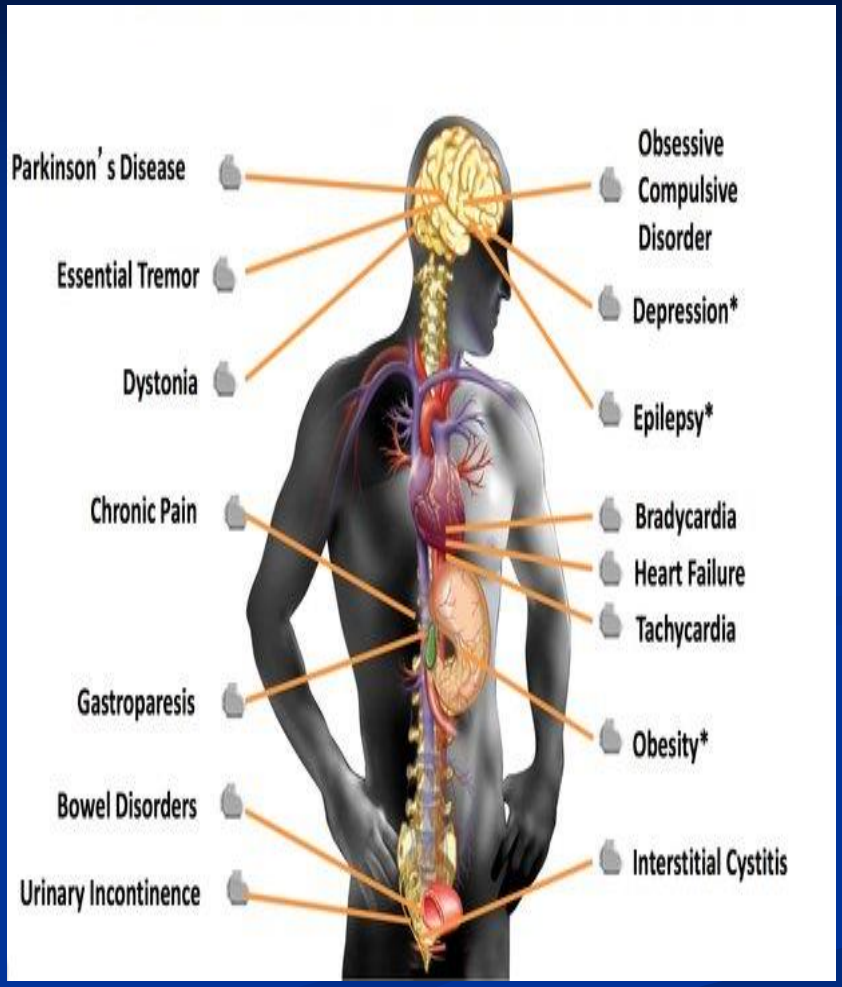
A regime whereby remedies for disabilities, diseases and bio-physiological enhancements are delivered via telemetry to and from in-the-body electronic devices to a patient and community of medical and technology providers.

MARKET FACTORS

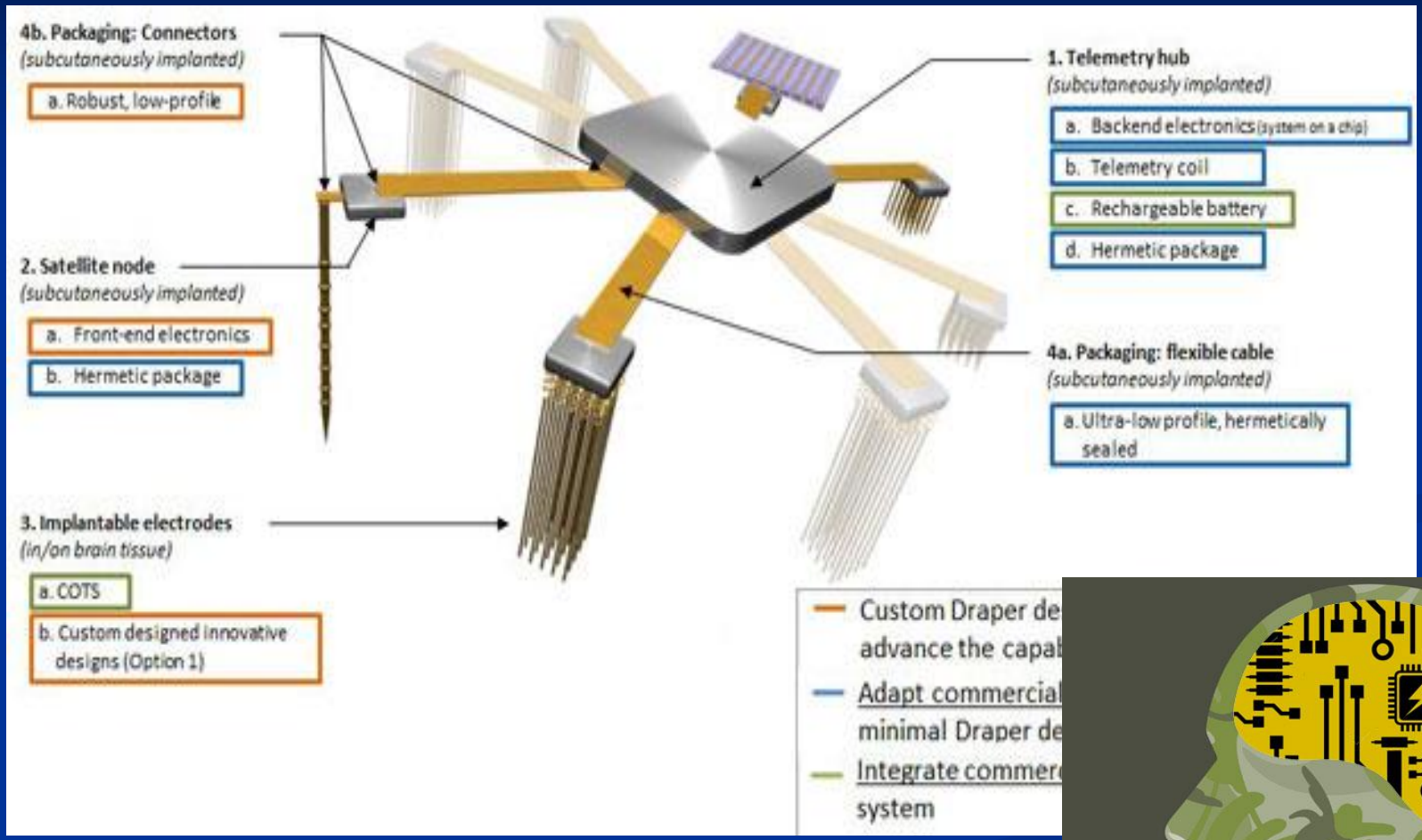
MicroBio Implanted Tech = Big Business

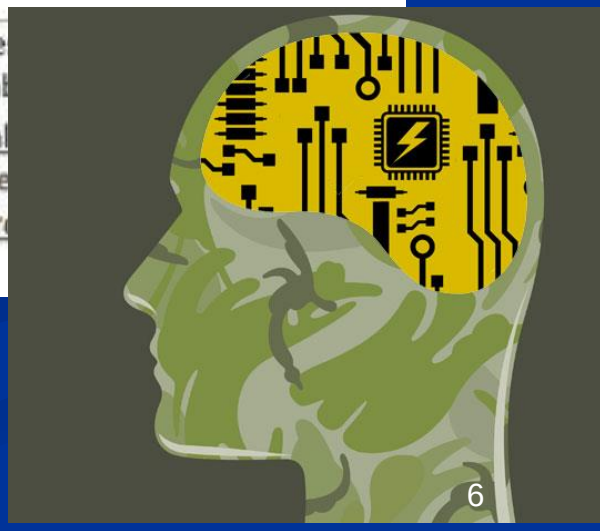
The 2010 global market for microelectronic medical implants, accessories and supplies has been estimated at $11 to $15 billion USD and by 2016 forecasted to be US $17 - $24.8 billion.

Companies are exploring new approaches to the treatment of medical conditions and ailments once thought to be either untreatable, or only treatable by drugs.



Implant for Treating Brain Injuries





IEEE Tech-talk, Biomedical devices; Military Aims for brain implants to restore wounded soldier's Memories.

The Transition To Electronically Driven Medicine

Between 2012 and 2020 processor speeds will increase from 40 billion operations/sec. to 330 billion operations/sec.;

4G communications planned successors with > gigabit (10^9)/sec., from anatomically deep seated application specific processors to the cloud;

Transistors, currently smaller than a 22 nanometer (the size of a rhinovirus) will soon transit into the 5-7 nanometers size range using materials such as wafer-thin graphene (carbon) and MoS_2 (molybdenum disulfide) that measure a few atoms wide.

Development of biological transistors.

Sources of Pharmaco-Electronics

Wearable and embedded computer/transmitters, sensors, electrodes, stimulators, actuators, and pumps that deliver therapy and make and transmit data

Device

Network architecture, including telecommunications that interconnects P-E devices within the body to/from outer world

Mechanisms to program and re-program P-E applications using an interoperability architecture

Pharmaco-Electronics Today

Jan 2016: Proteus Digital Health

Digital Medicine Platform

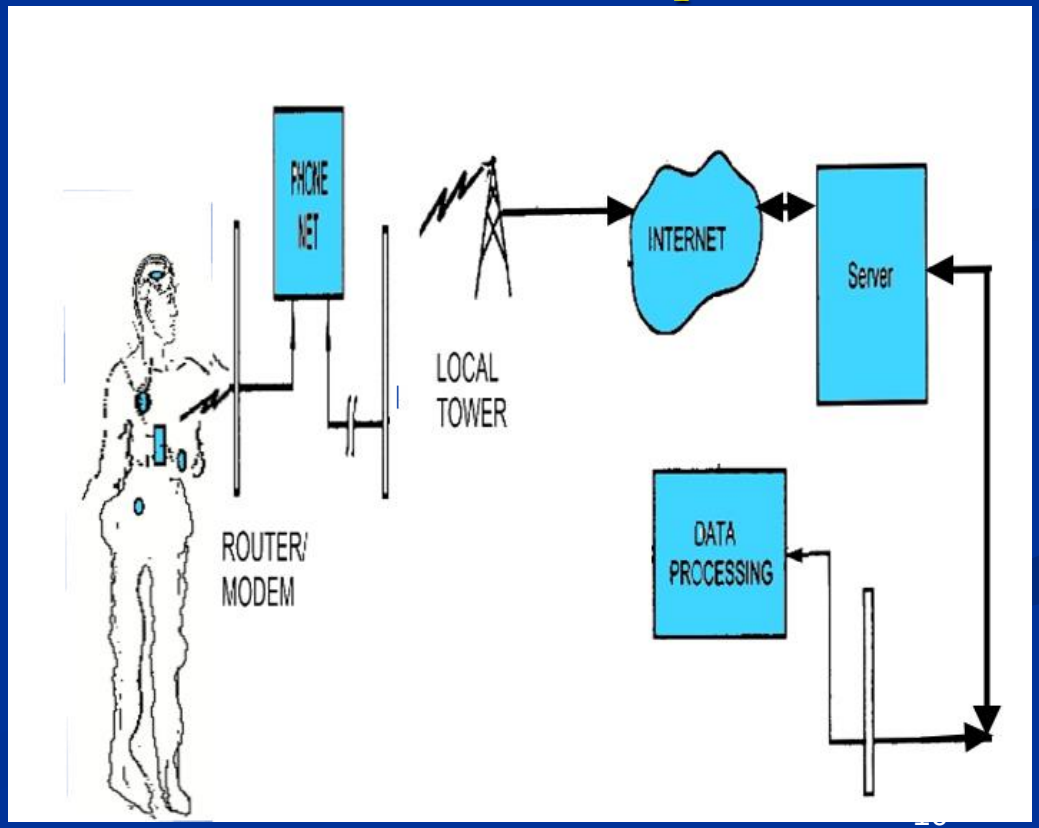
- A pill with an ingestible sensor & semiconductor the size of a grain of sand, to help with medication adherence for patients taking a certain medications for chronic conditions (i.e., co-morbidity hypertension);
- External patch collecting and transmitting data
- To another external device, and displayed and distributed to authorized users (patient, health provider, insurer, pharmacy).

WELLNESS TRANSFORMED

- Public health service will be completely "predictive, preventive, personalized, and participatory"—, in most cases without the patient being aware of data being transmitted.
- 24-Hours data accessibility.
- Data fed-back directly to imbedded technology, as a form of electronic prescription medicine.
- With the ability to modify the device and medication to achieve a particular bio-physiological result.

From a systems perspective, the person with embedded technology will become …

~The Human Peripheral

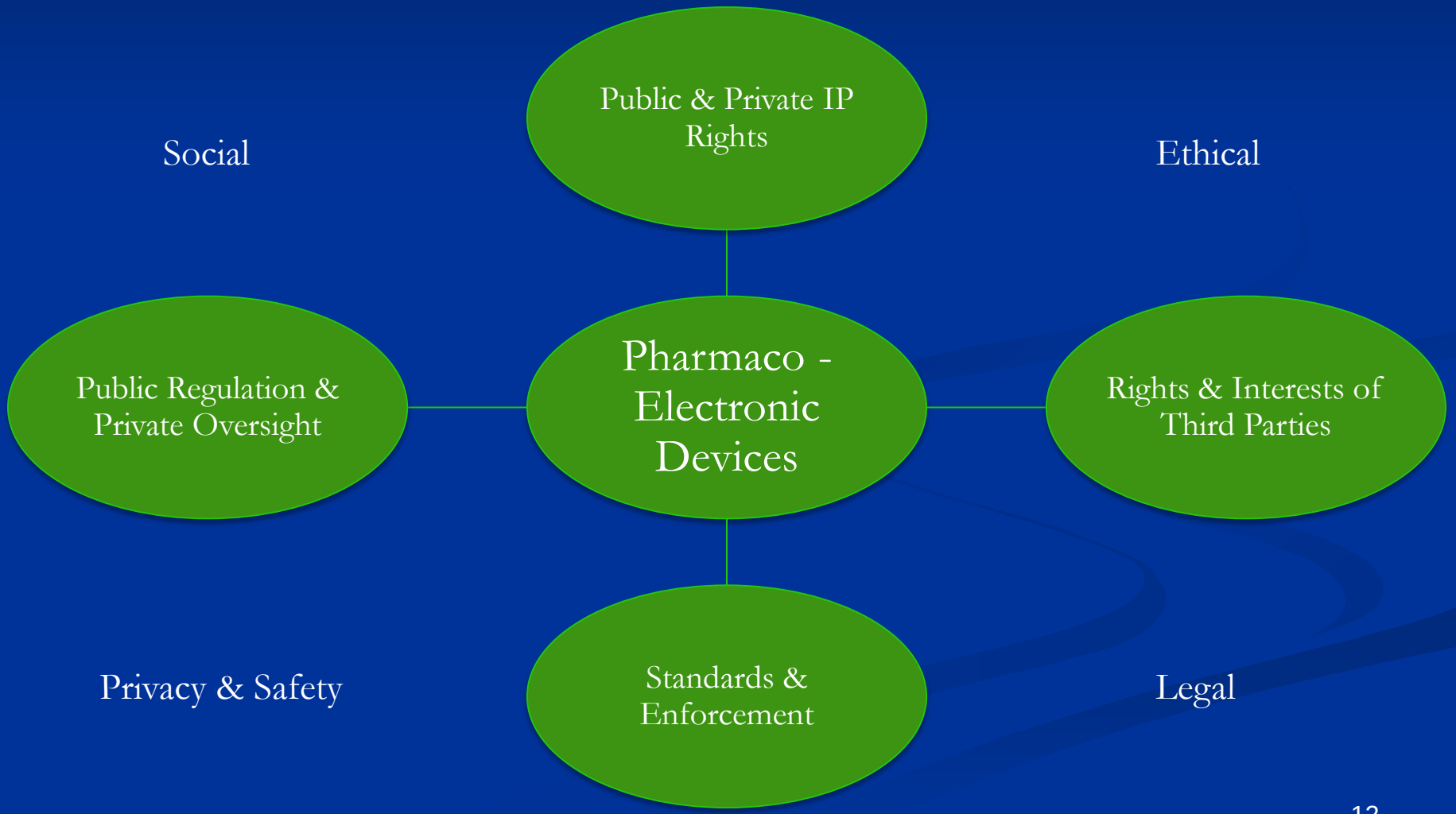


Pause to Consider. . .

So as commercial interests begin conditioning us into believing we will enjoy better health and wellness through embedded medical technology, we should pause to consider whether adequate technological controls are in place.

If not, then we must understand the role that this type of health technology might play in permitting 24 hour monitoring, tracking and accessibility.

Framework
Pharmaco-Electronics Considerations



Privacy & Safety

PROBLEM: Vulnerability to attack at all Peripheral Intersections.

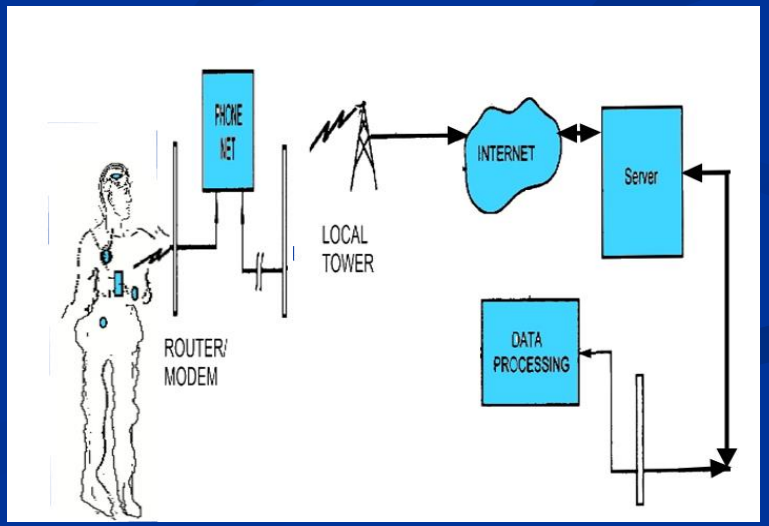
As recent at 2015, researchers and others have demonstrated their ability to hack into a variety of wireless devices, including medical equipment and heart defibrillator/pacemakers.

Device reprograming;
Data intrusion / corruption;

Sudden power activation or modulation.

Battery depletion;

Sudden power down;



Privacy & Safety

1. Better governmental coordination relating to cybersecurity policy.

2. Require that all devices have basic security requirements in place according to some industry standard.

   - standardizing system design or protocols directed to device, data and user authentication and authorization.

   - e.g., separating data from control instructions to minimize corruption that may affect the operation of the device, the content of the data or provide a window of opportunity for the insertion of malicious code or false data by bad actors.

3. Require device manufacturers be more transparent-informed consumer consent.

4. Creation of civil and criminal penalties for injuries that results from intentional acts or gross / criminal negligence with enforcement component.

Public Protection

Civil Remedies

- No enforcement mechanisms at FDA level until the matter becomes a reportable event.
- Regulatory considerations to insure efficacy and safety, through monitoring, testing and **enforcement**.
- Civil action that allow individuals and classes to seek redress for negligence, (strict) product liability, and warranty.

Criminal Punishment

- Criminal penalties to punish and deter crimes, such as hacking P-E Devices, causing some device malfunction designed to kill or cause bodily harm, or other acts similar intentional acts that that jeopardize human health or safety, as intentional murder.

Protection of Property

Society, the world over needs to decide if any corporation, institution, or individual should have the right to private ownership of certain forms of property—most notably, life saving devices and selected methods of extending life and enhancing intelligence or skills.

- Who owns the device, data during life?
- Will I be able to bequeath my device, data after death?

Whether the systems that operate large scale networks that telemeter to individuals will be subject to business method patenting.

Whether open sourcing of software that runs the internal and external software processes will become the preferred paradigm.

- Will updates, upgrades be free or pay as you go?
- Distinguishing Between Life Enhancing / Life Sustaining?
- What licensing restrictions will be allowed, internal software?
- Who will own/operate / control the servers and databases, pricing, access.
- Private industry? Government regulation?

LAW AND SOCIETY

"Humans have rights, under which they retain some measure of dominion over their bodies. Machines, meanwhile, remain slaves with uncertain masters. Our laws may, directly and indirectly, protect people's right to use certain machines—freedom of the press, the right to keep and bear arms. But our laws do not recognize the rights of machines themselves. Nor do the laws recognize cyborgs—hybrids that add machine functionalities and capabilities to human bodies and consciousness."

~ Benjamin Wittes, Jane Chong, Our Cyborg Future: Law and Policy Implications, (Sept. 2014).

At what point do we lose that which makes us essentially human.

SOCIAL & ETHICAL CONCERNS

- Future computational/telemetry processing therapies might go beyond health-related purposes to provide a greater level of intellectual quickness or greater access to commercial opportunities, who will be the beneficiaries?

- Part of what will distinguish the future human population having implanted computational devices connected to the world-wide-web from a population that does not, will be the enhancements that open vast benefits for the "haves" and consequent potential detriments for the "have-nots".

- Will AI be programmed with something that replaces "free will," according to and intelligent designer (a computer or software architect or business model)?

Anticipated Side Effects

Individuals with knowledge-based and skills-based enhancements will be the new expert class, cognoscenti and leaders that have a built-in ability for superior analysis, judgment and timely decisions.

Disease early warning systems: an anatomy under assault by viruses, bacteria, pollutants and other technology.

Physicians of the future will be versed in cyber-topics including knowledge regarding optimal software & device interfaces.

In the far future population-wide management and control will be subject to competing paradigms vying for an individual's portfolio of enhanced abilities and health related processes, not different from how today one is solicited by commercial and non commercial interests trying to recruit the best candidates.

THANK YOU

QUESTIONS?

Further information…..