

Scenario Development Workshop Report

The Future of Medical Diagnostics

November 14-15, 2007 Arizona State University

Sponsored by:

The Biodesign Institute The Consortium for Science, Policy, & Outcomes The Center for Nanotechnology in Society Arizona State University

Cynthia Selin Center for Nanotechnology in Society Arizona State University

2008

CNS-ASU and its research, education and outreach activities are supported by the National Science Foundation under cooperative agreement #0531194. Any opinions, findings and conclusions are those of the authors and do not necessarily reflect the views of the National Science Foundation.



Acknowledgements

The Center for Nanotechnology in Society would like to thank the Biodesign Institute for their support of the workshop. The development of the workshop was furthered by the insight and support of a Steering Committee composed of Stephen Johnston, Mike Tracy, and David Guston. Rebecca Hudson, Melissa Cornish, Susan Quisenberry, Tobie Milford and Regina Sanborn have ably assisted in the organization of the workshop. Thanks to Andrew Gaddis for web design and Roxanne Wheelock for producing the workshop materials and this report.

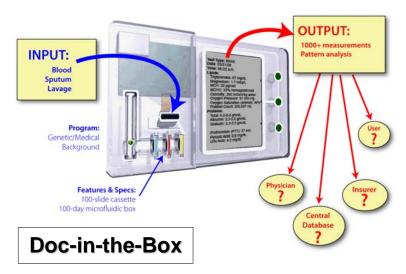
CNS-ASU and its research, education, and outreach activities are supported by the National Science Foundation under cooperative agreement #0531194. Any opinions, findings and conclusions are those of the author and do not necessarily reflect the views of the National Science Foundation.

New Frontiers in Medical Diagnostics

Doc-in-the-Box is a proposed health management tool under research and development at The Biodesign Institute at Arizona State University. It is anticipated to be a household instrument used to measure personal biosignatures of health on a regular basis, allowing more accurate, individualized accounts of health emphasizing the treatment of illness before the onset of symptoms. It signifies a **new dimension in medical diagnostics** that warrants a closer look.

By assessing biomarkers, or particular proteins, in the blood, sputum, nasal lavage or urine, Docin-the-Box could give an indication of disease before symptoms appear. Of the ~ 80 known

biomarkers in the body, 42 have been associated with disease states and usually show up in the body early on. However, the presence of the biomarker must be mapped against the usual levels of all the biomarkers for any given individual as we all have **unique biosignatures** composed of variously fluctuating biomarkers. Biomarker changes can be due to many different naturally occurring events such as puberty, pregnancy, or menopause, along



with disease changes such as getting cancer, flu, or Alzheimer's disease .The Doc-in-the-Box is imagined to be used on a daily basis and give a **real time read out of an individual's health** status.

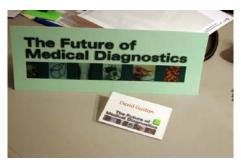
At the moment, Doc-in-the-Box is a **technological vision** that promises to benefit society and is being nurtured and supported in hopes that one day it will produce positive outcomes. How do we know if all the hard work and investment will lead to **positive social outcomes**?

The answer is that we cannot know with certainty that plans for the future will work out. **We cannot predict** whether or not the technological challenges will be overcome, much less how doctors, insurers, patients and regulators would respond to such a technology. We cannot know for sure if the clinical correlation of biomarkers to disease can be reliably established and assessed in real time. We cannot know for sure if such a device would be cost effective. There are numerous uncertainties that thwart our ability to predict what the future for Doc-in-the-Box will be.

However, it is possible to develop, through **sustained inquiry**, an appreciation of the potentials of new presymptomatic diagnostics.

By drawing together not just technology developers but also physicians, policy analysts, economists, scholars of technology and society, bioethicists, political scientists and sociologists, possible futures can be discussed, critiqued and sketched out. By **deliberating on the critical uncertainties** attending Doc-in-the-Box, a diverse group of thinkers can begin to synthesize the complex array of economics, politics, values, institutional set-ups, activism, patient behavior and emotions and sketch out consequence amidst uncertainty. "How well we understand biomarkers will determine how powerfully Doc-in-the-Box will predict disease."

In November of 2007, the Center for Nanotechnology in Society in cooperation with The Biodesign Institute held a workshop to explore **The Future of Medical Diagnostics**. The workshop was focused on the intricate social arrangements, economics, ethics, values, use, and politics of Doc-in-the-Box (in text)/presymptomatic diagnostics (in about this report).



The discussions in the workshop moved beyond thinking about Doc-in-the-Box strictly in terms of future applications, inventions and devices. Instead our primary goal was to think creatively about how such emerging diagnostic technologies might **be used**, **managed and adapted in different contexts**. We explored how the varied human and social systems that

embed such medical diagnostics might change over time and with what consequences. Our conversations yielded **four scenarios of Doc-in-the-Box** that are included in this report.

While exploring potentials, of **consequence amidst uncertainty**, is in some ways less satisfying than analyzing facts, "the future" becomes the relevant analytic category available to address the societal outcomes of technologies that, conservatively, are ten years to actualization. Assuming that the health care system, regulatory bodies, and conceptions of health and wellness stay the same over the next ten years defies all evidence of human, social and institutional change processes over time. Thus thinking long term requires not just technological advance but also advance of the **forces that embed**, **enact and shape the technology**.

Without thinking ahead in this systematic way, it is difficult to make well-informed choices today. Our visions of the future inform our decision making in the present.

With emerging technologies, the importance of anticipation is intensified in two important ways. Firstly, in terms of the gravity of the situation as the chemical, biological and physical materialities of new technologies endure into the future; and secondly, as early decisions often distinctly shape societal outcomes in a way that later stage decisions do not. From the executive management of the project to the decisions made at the bench, the imagined device of Doc-in-the-Box takes form over long stretches of time. Some of these choices can be modified. Other decisions impose lock-in where once choices are made, it is difficult to reverse them. It is these sorts of decision spaces- those that create **path dependencies**- that are crucial to think about in advance if the broader aim is to produce technologies with social benefit and to mitigate negative consequences.

The social benefit of a new technology is not automatic. Decisions about ownership, control, ethics, power and values must align in such a way that the positive effects outweigh the bad. Decisions occur all throughout the technology development phase- with or without attention to the **gravity of the longer term situation**.

Building scenarios is a way to extend and challenge perceptions and embedded assumptions. Engaging expectations is a means to become aware of probable, desirable, repulsive and possible futures and take responsibility for technological futures put in motion. Futures in the making manifest every day, with every decision, yet are poignantly evident in early stage technologies. Developing sensitivity for the array of plausible futures through studied deliberation prepares the way for **responsible and socially robust technologies**.

Researching the Future

Participants in the workshop were carefully selected in order to constitute a diverse set of individuals who collectively possess understandings of biomedical research and the social implications of new technologies. They represented bioethics, sociology, policy, political science, business, law, natural science, and journalism. Additionally, a medical doctor, a neural implant user, and a health care analyst attended.

In order to bridge the institutional, philosophical, professional and cultural perspectives that are relevant to thinking systematically about the prospects of presymptomatic diagnostic technologies, the conversation was at once open ended and highly structured.

The methodology used to create the salient, logical and inventive scenarios was the traditional deductive approach, sometimes called the *intuitive logics approach*. We followed this standard process: 1) identify general, broad, driving forces; 2) develop a variety of realistic critical uncertainties within each driving force topic; and 3) synthesize the forces into storied futures, or scenarios. "...in times of rapid change and increased complexity, mental models become a dangerously mixed bag. Enormously rich detail and deep understanding that can coexist with dubious assumptions, selective inattention to alternative ways of interpreting evidence, and projections that are a mere pretense – blind spots and dead angles. It is here that scenario approach has a leverage to make a difference."

Pierre Wack, 1984

The agenda was designed so that each discussion

built on what came before, and so that emergent ideas formed the basis for further exploration. Prior to the workshop, more than 20 interviews were conducted with workshop attendees and other relevant experts to explore the question: What are the driving forces shaping the outcomes of Doc-in-the-Box technologies?

Interviewees¹ told stories of fate, risk, care, life and death through this device and talked of novel ways to know bodies, new forms of responsibility and liability, the formulation of

¹ Non-participating experts interviewed included: Gary Marchant (Arizona State University (ASU) professor of Law; Executive Director & Faculty Fellow, Center for the Study of Law, Science, & Technology; Lincoln Professor of Emerging Technologies, Law & Ethics); Jack Horn (Executive Director/CEO of Partnership Health Plan); Robert Cook Degan (Director of Duke's IGSP's Center for Genome Ethics, Law & Policy; author of *The Gene Wars: Science, Politics, and the Human Genome* [1994]); Susan Mattson (ASU professor in the College of Nursing and Healthcare Innovation); Alex Brewis

different economic incentives, revolutions in the temporalities of medicine, and unresolved questions about acceptable levels of uncertainty. While it was not surprising that responses covered a landscape of concern, what was instructive was the framing of thoughts about the futuristic technology in terms of experiences with and lessons learned from past technologies. The following past analogies are drawn directly from the interview data, where included in the Background Material to participants, and served as a way to begin to scope the dilemmas and features of presymptomatic diagnostics.

Slade (ASU bio-cultural medical anthropologist,); Ken Noonan (ATV Technology Partner); Daniel Sarewitz (Director CSPO; author of *Frontiers of Illusion: Science, Technology, and the Politics of Progress* [1996]).

Lessons from Past Technologies

BODY SCAN: ultra-fast computer assisted topography kiosks have been popping up in public places advertising "Add years to your life in just a few minutes." One such kiosk was installed in Scottsdale's Fashion Square where an athlete was scanned and praised the technology as 'saving my life' by

athlete was scanned and praised the technology as 'saving my life' by revealing a tumor. The information gleaned from the scan is not definitive (difficulty in defining 'abnormality' and risks of false positives), requires interpretation and further testing yet cannot be ignored by physicians for liability reasons and patients due to anxiety.

Dilemmas and Features like Doc-in-the-Box:

- Clinical correlation with disease/reliability of reading
- Who interprets the data?
- Liability rests on whom, what?
- Anxiety-provoking diagnosis with potentially limited treatment options
- Evokes further more invasive diagnostics without known costs or clinical benefits
- Digitizing the body/expansion of medical gaze



GLUCOSE MONITORING: diabetics monitor their glucose levels on a daily basis, usually from home. Baselines for problematic levels are typically established against an individual baseline. Diabetics have to be able to self-administer the test and are in close collaboration with their physician. The readouts have eventually developed in such a way to give reliable diagnostic output of health status directly to the patient.

Dilemmas and Features like Doc-in-the-Box:

- Patient-driven care
- Self-administration, self-monitoring
- Individual establishment of baseline for clinical trouble
- User friendliness of device
- Negotiation of what information output is directed at patient/doctor
- New role for physician as partner (with patient and device)
- Impacts of daily monitoring



PULSE OXIMETRY: now a standard OR procedure, the device measures oxygen content in the blood. However, it was once disparaged. Though general anesthesia through the 80s was a dangerous high-risk affair, the alarm sounding clip was resisted by doctors- "a good anesthesiologist doesn't need this." Now if the clip is forgone, there are serious liability issues if there are bad outcomes from the surgical procedure.

Dilemmas and Features like Doc-in-the-Box:

- Early physician resistance to technological device
- Establishment of new standard of care/best practice
- Demand to establish clinical utility testing
- Liability issues



IN VITRO FERTILIZATION (IVF): this suite of assisted reproductive technologies has developed mostly outside of insurance reimbursement schemes and instead has been financially shouldered by private payers. Within this



domain, there are also a host of pre-symptomatic tests of embryos that while heavily regulated in most of Western Europe, remain relatively free of regulation in the States. There are also ethical issues that question the religious sanctity of 'natural' methods, how to handle embryos, and the appropriate allocation of medical resources.

Dilemmas and Features like Doc-in-the-Box:

- Payer attitudes/Reimbursement patterns
- Role of entrepreneurship in biomedical applications

- Uneven regulation across nations, states
- Equity and access
- Varied social acceptance and contested ethical issues

ELECTRONIC NURSE: the semi-conductor group at Motorola wanted to extend its technologies to address the health care issues of the elderly. They created a lazy susan device to direct the user to take pills and interact regularly ("I'm okay") yet test markets found it "unfriendly" not least because it yelled at the user if he didn't respond.

Dilemmas and Features like Doc-in-the-Box:

- Importance of user-friendly design
- Tailoring devices to users early / Extent of patient involvement in design
- Patient/User need for personal touch/care/compassion
- Technological "fix" and its match to patient and market demands





PREGNANCY TEST: In 1978 a "private little revolution" was advertised – the test to detect levels of hCG in the urine, indicating pregnancy. This "revolution" enabled women to take control over the early diagnosis of pregnancy in the privacy of their own homes. While hCG correlation with pregnancy was established in the 20s, and a lab test was developed in the 60s (though with unacceptable rates of false positives), a complicated athome lab test was not released to the market until 1978. Decades later the test is considered easy-to-use.

Dilemmas and Features like Doc-in-the-Box:

- Privacy of biomedical data
- Value of security and control of biomedical data
- Speed of commercialization (timeframes from bench to bedside)
- Patient-driven

BRCA 1/BRCA 2: a blood test to check for specific changes (mutations) in genes that help control normal cell growth. Finding changes in these genes, called BRCA1 and BRCA2, can help determine your chance of developing breast cancer and ovarian cancer. However, the resulting risk profiles display high levels of uncertainty and many institutions are ill-equipped to counsel patients.

Dilemmas and Features like Doc-in-the-Box:

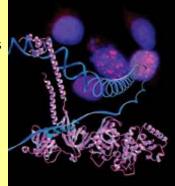
- Reliability in the interpretation of results
- Role of counseling and managing results by patients
- Risk perception of patients
- Development of the pre-symptomatic ill and pre-diseased
- Security of biomedical data
- Uncertainty in correlating biomarkers with potential disease/diagnostic definitiveness

SCALE: while a stretch to consider a diagnostic technology, the scale provides a means for individuals to gauge a measure of health on a daily basis from their home: weight. Weight and particularly obesity have been strongly correlated to an increased risk of diabetes, heart disease and cancers. Despite public campaigns and the widespread access to resources enabling individuals to monitor their weight and BMI, obesity in the US is on the rise.



Dilemmas and Features like Doc-in-the-Box:

- Patient behavior vs. medical knowledge; "Just knowing something is a risk doesn't change behavior"
- Medical knowledge versus positive health outcomes
- Role of preventative medicine in society
- Payer incentive to intervene



Looking Forward

Past technologies hold past realities and by most measures, realities are changing. The future of medicine will not look like the past and grasping the complexity of new possibilities requires novel ways of thinking. However, technologies do not arise in a vacuum and are indeed indebted to prior technological systems and devices as well as cultural norms and entrenched institutional practices. While retrospective analyses capture many dilemmas, the conversations in the workshop were purposefully extended into the future to deal more specifically with 'what's new and different about this technology?' "People who take seriously the idea that the future is both a mental construct and an achievement run into questions like this: how can studying the past prepare for the future if that future is problematic precisely because of its dissimilarity from the past?"

Weick 2005

The future oriented conversations conducted in the workshop were designed to stretch our understanding of technological change and consider what new challenges, dilemmas and contexts matter for presymptomatic diagnostics. Knitted together here are slices into the workshop discussions which covered a broad spectrum and dug into the embedded assumptions attending Doc-in-the-Box.

"I think individualizing medicine is a misnomer... instead, this type of vehicle is going to be more about informed decision-making... the real issue is: who makes these decisions? Different cultures with the same tool will make different decisions." It was quickly noticed that the paradigm of heath underlying Doc-in-the-Box implies a shift to **personalized**, **preventative medicine**. This shift is problematic in that our current "social and political infrastructure is embedded within certain assumptions about disease" that are, for instance, population based. "Doc-in-the-Box would require a complete shift in how we think about disease." "You could be diseased as soon as your protein level is shifted" thus giving rise not only to **new taxonomies of health and wellness** but also new categories of patients as "prediseased."

Doc-in-the-Box could expand categories of disease to include future disease thus "releasing pent up disease states" that

could raise health care expenditures in the short term. However, "if you could crack the diagnosis part, you could protocol treatments and **make health care affordable** over the long term. Treatment protocols are programmed easier than diagnostic protocols and could change

the way medicine is practiced." In the longer term, costs could come down. In the meantime, "if the purpose is to intervene more quickly, there are lots of companies who want to intervene quickly and they would benefit by making your presymptomic condition urgent. **We are currently over medicated and over technologized**- this would make it profoundly worse."

already approval based being blood body box certain change company comprehensive control create data decision different disease doc doc-in-a-box doctors fda happen health information insurance interested issues medical medicine particular patients people personalized political problems public Question social society technology terms testing things think tool treatment type used ways Work

Tag Cloud of Workshop Brainstorm

"Would Doc-in-the-Box be only for people on the high end of the income curve? For conventional diagnostics, 1 in 5 people don't have health coverage." Yet participants also thought beyond the have/have not categories to consider that new social divides could emerge between the responsibles /irresponsibles thus ushering in **a new form of social control**. "Past history (e.g. reproduction, contagion) demonstrates that it could be used for recipients of public assistance" where, for instance, certain biomarker readings could get you kicked out of public housing.

"What are the values that underlie Doc-in-the-Box? Speed, efficiency, detached technological precision. Not to say they are bad values, but they aren't the only values. Consider that human trust, human interactions, sympathy..." are important dimension of the doctor-patient

relationship. Physicians regularly make ethical and moral judgments as well as connect local and historical knowledge to make a diagnosis- the Box could not be programmed with this sort of tacit knowledge, intuition, and complex thinking that often addres the broader determinants of health. Will physicians then take on new roles? To what extent will physicians be liable for interpreting the data produced by Doc-in-the-Box?

Have/Have Nots? Responders/Non-Responders Responsibles/Irresponsibles

Would you want to know you have a disease without a cure?

While some noted the relief in just knowing, it was acknowledged that "there would be large cohorts of people who know they have a disease for which no treatment exists." This concern about **diagnostic capacity outstripping treatment capacity** gave rise to questions about which disease(s) the Box detects. Will the disease(s) be those that are expensive? Pervasive? Curable? Treatable? Preventable?

These issues are tightly intermingled- which diseases are programmed in the Box and liability will depend on who pays for the device which will then influence who is responsible for interpreting the result. Or as one participant noted: **"decision making capacity is often subordinate to ownership."**

All of these issues- control, economics, and clinical judgment- are related to the flow of data. Is the box designed with a readout for the user or is the information sent directly to the physicians office? Your employer? Your insurer? Is that biomedical information then stored in a larger data base where population health information can be aggregated?

"This is a tool for surveillance and diagnosis, not treatment or eradication." The collection and aggregation of data draws up issues of **privacy and security** while at the same time is mandated for the development of the Box. That is, in order to establish more clinical correlation of biomarkers to disease, large data sets of health status and protein level change must be collected and analyzed. In order for the box to learn, individuals must allow their medical histories (and futures) to be scrutinized alongside their blood. Without that learning there are profound issues as to the reliability and predictive power of the data, the **acceptable levels of uncertainty**, and the extent that one can act from the Box. "How much

of the readout will be pattern recognition vs. understanding what we are measuring?"

Adding yet another level of complexity, the aggregate data must be treated by **sophisticated bioinformatics programs**. Such program algorithms should give a patient an interpretation of the data generated by the Box. That is, the Box may detect a change in Biomarker X from .09d to 2.9k but what is the significance of such change in relation to your baseline biosignature? During the workshop, it was considered that the algorithms that make sense of the data- not the actual Box- are the valuable product.

The **potential social impacts** of the Doc-in-the-Box are varied across a range of actors and raise issues of unintended uses and consequences. Will there be new excuses: "My protein levels are

too high- I cannot go to school!" or new demands: "Your read-out is this [boss holding Doc-in-the-Box report], you can work late tonight!"

There were also concerns about the unintended social and medical consequences. One physician noted: "not all disease is bad...would there be an increase in **self-quarantine**? Immunity protects us from a lot. We could create a culture in which acquired immunity during childhood doesn't happen thus making the entire population vulnerable."

On another level, concerns about the further **medicalization of the human experience** raised: "What happens when you reinterpret the body as a data reserve?" When the body becomes a "readable" text, what other takes on what it means to be human are subsumed? "Do we all become hypochondriacs" constantly monitoring our bodies for signs of something amiss? Yet an early version of Doc-in-the-Box is offered by BioPhysical 250 which analyzes known biomarkers and other indicators of health. A market study revealed that more than just the "worried well" is interested in this kind of technology; their clients are those who are not sufficiently treated in traditional channels.

There were concerns about empowerment and one's ability to opt out of such a system of diagnosis. "Who is in charge of determining what is normal? [A person could use the Box at home] and determine for herself whether or not something was pathological. Will his increase agency on the part of the individual? Is the individual deciding on normalcy or is it something else?" Critically, "the more you regularize this kind of testing the more difficult it is to subject it to choice."

Potential Unintended Uses of Doc-in-the-Box:

- Real-time monitoring of blood doping
- Responsibility test of welfare recipients
- Insurance surveillance of drug, alcohol, tobacco use
- Personal health monitoring by a home security agency
- Screening for environmental toxins in the body (worker safety tool)
- Population level monitoring of biothreats

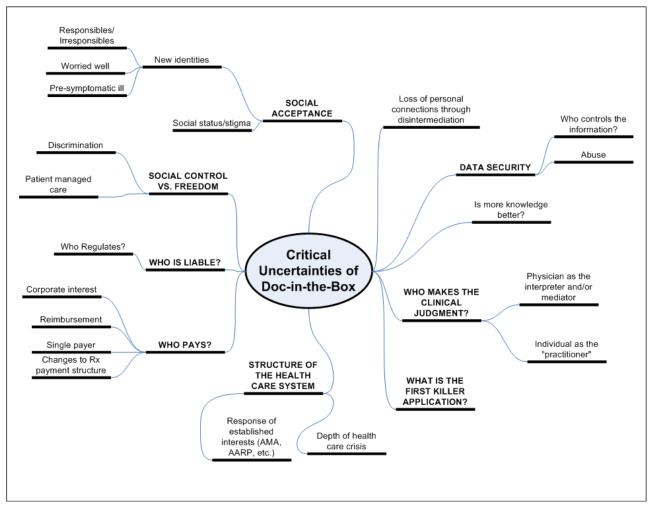
At the close of the brainstorm, we revised the focal question to:

What are the benefits, risks, implications and significance of widespread use of personalized devices for rapid, broad spectrum, presymptomatic testing in 2030?



The issues and tensions raised during the brainstorm were collectively grouped and ordered. Participants were then asked to vote for the issues that they thought were **most important** and **most uncertain**. The map (Figure 1) captures their ordering and ranking:

Figure 1: Map of Doc-in-the-Box Critical Uncertainties



Developing the Scenarios

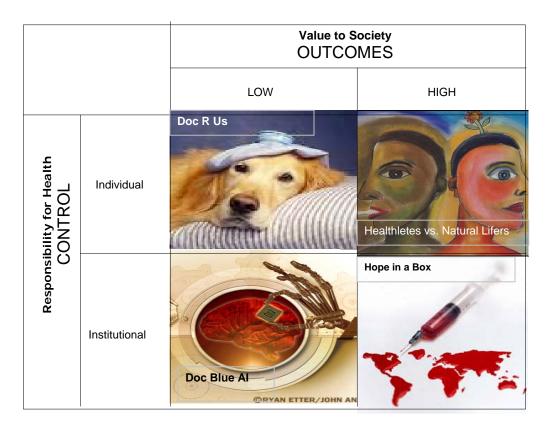
From this map, participants were guided to construct a scenarios matrix, which served to structure the main themes into four "worlds." Each world set the conditions for the scenarios along 2 axes:

• Value to Society: deals with the outcomes of the Box; presuming that the technology works, this axes explores the extent of social, institutional and political alignment thus capturing the range of other actors that may diverge or converge around the Doc-in-the-Box.



• **Responsibility for Health**: deals with the degrees and locations of control of the technology, including the control of data, and clinical interpretation.

The matrix served to provide scaffolding for the scenaric stories by synthesizing the complexity into frames broad enough to capture the rich brainstorming, yet distinctive enough to produce divergent, though equally plausible futures.



Docs R Us



<u>Summary</u>: Kody and Victor are regular users of presymptomatic devices yet are consumed by the daily read-outs, giving rise to anxiety, compounded by the lack of regulation and standardization leading to inconclusive clinical correlation or quality interpretation of the biomedical data analyzed by the box.

"...Just remember to re-input your stats next week because I have a new algorithm that will shed new light on your supplements."

"Kody, you're the best! How is Victor? Are his levels down?"

"No- the poor chap is still suffering from hypertension. We go again to the vet tomorrow"

"Good luck."

"Thanks, we sure do need it"

Kody logged off the chat with one of his regulars and looked sadly at Victor, who looked sadly back at him. Despite Kody's best efforts, the readout from the AstraZeneca vet-in-the-box (VIB) was nearly the same each morning. The puzzling array of biomarker levels seemed to indicate that Victor was on his last legs. "You'll be okay, guy" said Kody to Victor, though he worried that this wasn't the case.

Kody then began yet another search to see if there was some kind of treatment option developed for Victor's particular readout. While there was an abundance of sites that promised to correlate your Doc-in-the-Box and VIB readouts with treatment plans, there was so much inconsistency. Part of the problem was a lack of standards. One day Kody would be so lucky as to find Victor's particular level changes described and suggestions made, only to discover the following day another company suggesting another course of treatment. Kody was scared not only for Victor, but also for himself.

Kody had always been health conscious. He was diligent about getting his body scanned every time he went to the mall. He took an Omega 3 supplement for neural health, vitamin E for his heart, selenium to protect him from cancer, and St. John's Wart to ward off depression. He wore sun screen, avoided cigarettes and alcohol, and always, always sanitized his hands after spending time in public places. His subscriptions to Health, Prevention, Men's Health, and Dr. Weil all kept him informed on new ways to protect himself from the ever present risk of disease and illness. Now he is 52 and is the picture of health, save for some manageable symptoms brought on from anxiety.

He had to get ready for his weekly drive by visit with Dr. Gunush so he gently touched his Astra on his way to his supplement counter. After washing down his slew of pills with an energy drink fortified with the latest algae, he was stunned to see that his readout was different from yesterday. The dramatic spike in biomarker 394 made his knees so weak he nearly collapsed. What could this mean? Is this the end? He immediately called his school and told his co-teacher that he won't be in and that the students should proceed with their studies of the Mars colony.

Hands shaking, Kody reached for his phone and summoned Dr. Gunush only to get his automated assistant. He considered going directly to the ER like everyone else, but knew that even with the hologrammed diagnostic nurses, he would have to wait for hours in a hospital full of germs. Glancing back at his biosignature, images of long painful hours of dreadful sickness, of funeral arrangements, and of searching for a caregiver for Victor consumed Kody. Finally, he regained his composure and got to his computer station to learn more about biomarker 394. His initial search got 2,300,577 hits because in his panic he forgot to sign in with his preferred provider filter. Voice quavering, Kody tried again to search yet was still overwhelmed with tens of thousands hits. As he began to sort through what different DIB providers attribute to the spike, he realized that he was on the verge of being late for Dr. Gunush.

Approaching Dr. Gunush's window, Kody was still and quiet and numb. He vacantly inserted the Astra readout card into the automat and had no problem reading the deep concern in Dr. Gunush's eyes. "It's the end" thought Kody. Dr. Gunush spent an endless moment with his analysis, glancing at Kody with concern and then leaned out of the booth to give his interpretation of the diagnosis. "Kody, please relax. Have you eaten any fish lately?" Kody panicked. Deadly food poisoning! His stomach tightened as he replied: "Yes. Last night I had a Danish cod-herring hybrid supposedly full of Omega 3s. I knew I shouldn't have though, with the risk of contamination and all. What was I thinking?!!" "Kody", said Dr. Gunush calmly, "The fish was fine. This is a normal and expected change to your biosignature. You have nothing to fear."

Hands moist with sweat and mind spinning, Kody drove back home in a haze. He couldn't even remember how he got home. He could only sit and marvel and how this kind of near hit with death could happen again in just two short weeks. Last week, biomarker 72 *and* biomarker 987 drove up together. Could he really trust Dr. Gunush who said that that rise, like many of the others, had no real significance? Who to believe? There were many in Second Life who had experienced similarly shocking news and had found doctors who had supported their need for treatment.

Maybe it was the Astra? He decided to investigate another box. There were so many to choose from and he couldn't afford the third mortgage on his house to finance the latest, top of the line boxes. But then again, without your health, what have you got? He made a note to himself to buy insurance this time. He would not have his box stolen again, particularly since the newer models have enough memory to store his biomedical data for years.

He decided to not go to work at all today, even though his doctor said his biosignature is okay. He figured that the stress from the episode would only make him more vulnerable to the bacteria-laden children. Despite all of his measures, he knew that they were always infecting him. He knew that some of the parents ignored his pleas for them to insist that their kids use the box *every day* and *not* send them to school if the readout is strange.

Unfortunately, his blogging on the Nutra-Fit Analysis site paid him very little in advertisements (mostly from DIB and VIB distributors). Until he actually pursued some studies in medicine, he could not be paid directly for his DIB advice, even though he had 750,000 hits on any given day. His dream is to become a Biosignarologists. While he could get a foreign degree rather quickly, he was not sure he could understand all the complexities of the algorithms- his was not a mathematical mind. He sighs, prepares Victors mix of supplements and Kibbles and Bits, and logs back in to read reviews of the newest DIB from Taiwan.

Healthletes vs. Natural Lifers

<u>Summary</u>: Ray is conflicted whether or not to use the Doc-inthe-Box, torn between his parents who have very different ideas about the value and meaning of monitoring health.



Ray sat at a stoplight only two blocks from the Naturalife community center. He had hoped to visit with his father to discuss something that had been troubling him. But the black Hearse being followed by the train of cars was a sign that it was going to be difficult to talk to his dad. The funerals for Lifers were different than most. They usually took hours and all members of the community would participate even if they didn't know the person that well. Friends and relatives would relate the best times they had with the deceased as well as the difficulties the person had. The difficulties were always described with a certain honor – as though the adversities had been crucial to the development of the person's character.

Ray didn't quite understand the Lifers, but watching the dignified train of people drive by, he couldn't help but be impressed. This was part of his problem. For years he had tried to dismiss them as an anti-technology, anti-establishment fringe group – even though at least a quarter of the US population identified themselves as Lifers and there was wide suspicion that many more had Natural Life leanings and sympathies. He had difficulty comprehending why a group of otherwise intelligent people who fully understood the benefits of Doc-in-the-Box chose not to use them.

Yet he could never completely reject their way of life. As much as he wanted to resist, part of him felt drawn to it. He loved his father and wanted to better understand his decision to join them. This was difficult for Ray because his father's decision changed his life, changed his entire family.

At first the little box seemed simple enough to Ray. Every day there was a family routine. Before eating breakfast they'd take one of the swabs with their name on it, swab the inside of their cheek, and insert it in the Doc-in-the-Box. Then he'd run off to school and think nothing more of it.

As time wore on, his mother became more watchful of what he ate and began putting a bowl of nutritional supplements by his cereal each morning. At first it had all seemed innocuous enough. It seemed like just another one of his Mother's fads. She has always been extremely health conscious.

He didn't really notice the tensions around the house until one night at dinner when his mother seemed particularly agitated, all the while glowing. She announced that Ray had a 12.7% chance of getting diabetes, Ray's dad had a 64.3% chance of getting prostate cancer, and she had a 37.3% chance of getting osteoporosis. She demanded that we start on a new diet, supplement, and exercise regiment that she had read about on WebMD. She had carefully selected each regiment - approved by the AMA - to address the specific health issues that each one had. They were proven techniques that could be even more customizable once they had been on the program for a few weeks.

Ray audibly groaned. He had thus far gotten away with his Big Mac runs, but the way his mom explained it, it seemed that he might get caught for each transgression.

Ray's dad was ominously silent until he finally said: "We now spend 15% of our budget on nutritional supplements. How much do these new regimens cost?" "Well that is something we need to talk about," said his Mom. "They are not cheap. But I have a solution. I think it's time that we join one of the LEC's that we've been hearing so much about."

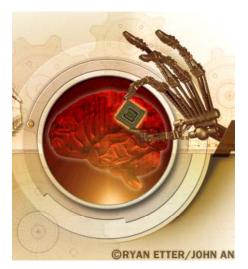
Life Extension co-ops (LEC's) had been getting a great deal of press coverage. All the vitamins, diets, exercise programs and household detoxifiers that the Box inspired people to use were expensive. And not covered by traditional insurance. Years ago, a group of runners who had long monitored their bodies banded together to create a co-op to pool resources and save money through bulk purchases. They set aside some funds for physicians and medical procedures, but the focus was primarily on prevention.

Eventually, the tensions overwhelmed the family His mother moved out the day his dad started smoking again. It was an antiquated and obvious rebellion. Though he didn't continue to smoke, his dad did begin to indulge in fine wines, fatty cheeses and had a special fondness for marshmallows- all foods that his mother wouldn't dream of touching in her new Life Extension commune.

Ray has now been shuttled back and forth between his parents, his body a battle ground where loyalty is regularly (and literally) tested. He has finally had enough, realizing that he must decide a way of life and commit to it.

After many years of mediating between his mother and father and their very different worlds Ray understood his father only slightly better than he understood the Natural Life movement. He needed to sit down with his father and figure out exactly what it was, all those years ago, that finally broke the proverbial camel's back. But this conversation wouldn't happen to day- the funeral would last into the evening and Ray will have to continue yet another day split between two worlds.

Doc Blu Al



<u>Summary</u>: This is a world in which the institutional control over the Box exceeds patient choice and individual responsibility for health.

The sharp knock on the door awoke John from his painful reverie. He was trying to figure out when he lost control...

Twenty years ago, he had completed a prototype Docin-a-Box, a device capable of in-home pre-symptomatic diagnosis and near real-time health monitoring. This represented one of those critical moments in history, he

was sure of it, which would change the very structure of human society. Clearly Doc Mart, a subsidiary of the world's largest retailer, agreed as they paid him an unbelievably large sum of money, much of which went to the university, in exchange for an exclusive and perpetual license.

If he had only been paying closer attention he might have seen signs of trouble even then. Doc Mart had immediately moved to push him out of his own research, warning him obliquely that if he didn't find a distinctly different research direction they would sue him for violating the licensure agreement.

Doc-in-a-Box vanished into the product development bowels of Doc Mart and fell off of everyone's radar screen for a while. Unknown to John and certainly to the regulators in the federal government who would have reacted to the blatant violation of both the Equal Opportunity Employment Act and the Americans with Disabilities Act, Doc Mart had mandated use of Doc-in-a-Box as a condition of employment. There was no official order, but managers at Doc Mart and its vast parent company let it be known that choosing not to participate wasn't an option and that in the interest of cutting health insurance costs a certain level of bio-metric excellence was expected. What Doc Mart was more interested in was observing a small-scale trial run of Doc-in-a-Box's public roll-out.

While Doc-in-a-Box was unsurpassed in its ability to measure more than a thousand health indicators found in a small sample of saliva, blood, or mucus and then converting those daily readings into running bio-signature; it lacked the capacity to transform that data into the sort of robust medical advice one would get from a doctor. Doc-in-a-Box could detect ill-health

better than any human in history but was entirely unable to transform that detection into a regime of treatment or a prognosis of future health.

This shortcoming was solved with the use of artificial intelligence that could in real-time adapt algorithms to assess the biomedical data. The whole device was marketed as Doc Blu and the AI for Doc Blu was nearly sentient, according to Doc Mart. there were many others who warned that Doc Blu could already pass the Turing Test and had become self-aware.

Doc Blu was so good it was able to devise pre-therapeutic interventions. It could detect illhealth far enough in advance that often through diet and exercise alone it was able to prevent the need for more radical interventions later. Needless to say the pharmaceutical industry as well as the medical establishment, represented by the AMA, was grumbling about the "potential dangers" of such a system long before a product was ready to roll out. After much political turmoil, Congress passed legislation exempting Doc Blu from FDA oversight and granting the AI prescribing privileges equal to any physician.

Doc Blu's retail introduction was one of the most successful in history and by 2014 they had sold more than 100 million units domestically, by 2020 they had sold nearly 2 billion units world wide. Doc Blu's success had been so complete, medical costs nation-wide were down almost seventy five percent by 2019 while overall health in the United States was sky rocketing as obesity and other chronic lifestyle problems plummeted.

Public perception of the traditional medical establishment had turned vicious. Doctors were reviled as charlatans and snake-oil salesmen and finally the government passed legislation that required all diagnosis and treatment in the US to involve Doc Blu, either as the first line of diagnosis or as a safety check after diagnosis by a physician. The entire US medical establishment was firmly in the hands of Doc Blu, the artificial medical intelligence.

In spring of 2025, Doc Mart contacted John with a remarkable offer. They were working on the next version of Doc Blu, D II, and they wanted John to participate as a consultant. As he was working with Doc Mart's AI scientists and going over the program parameters for both Doc Blu and D II, he realized the code was tragically flawed.

When the next software update was installed, Doc Blu and D II would prescribe a massive overdose of anti-cancer medication to millions of people world-wide who presented with an elevated level of a certain blood borne protein. The overdose was easily large enough to be fatal and the system simply did not have the human and institutional safety checks to notice.

John went to his supervisors and, ultimately, to Doc Mart's executive leadership with the flaw. Shortly thereafter his contract was cancelled and he was warned, in tones very similar to those employed nearly two decades before to warn him away from any further research in medical diagnostics, to remain quiet about the "flaw".

John struggled with his conscience and couldn't remain silent. He went to the press and tried to warn the public of the error. He was astonished when Doc Mart issued a press release minutes before his own press conference in which they admitted the flaw's existence. His astonishment doubled when they claimed to have just caught the flaw in time to save the lives of millions. His heart nearly stopped when they asserted that it was John's shoddy work which had introduced the flaw into Doc Blu's source code and that they would be pursuing legal remedies to recover the losses they would now incur from the delay in updating Doc Blu's software and releasing D II.

Congressional hearings were quickly convened and, though no hard evidence was produced, John was quickly condemned as an incompetent at best and a terrorist at worst. He was threatened with arrest and prosecution but these never materialized and they were the least of his concerns in any regard. Doc Mart served him with a succession of lawsuits. They were seeking damages both for defamation as a result of John's claim that they had tried to cover up the flaw and for the losses they had suffered as a result of his mathematical incompetence and negligence. The courts issued orders to freeze his assets and in short order he was forced to file for bankruptcy.

When he awoke this morning, replaying these turns of events, he lethargically surmised that things could not get worse. Now, with all the commotion outside his door, John realizes that yet again he was wrong.

Hope-in-a-Box

<u>Summary:</u> The world has been ripped apart by an old disease behaving in new ways. As global warming changed the distribution of people across the globe, migrating populations carry drug-resistant Cholera with them. The globe banded together to address the new health and security issues by utilizing the technology, Doc-in-a-Box.



"No hay mal que por bien no venga."

My mother used to always say this to me when I was growing up in Tierra del Fuego. In English it means "There is not bad from which good doesn't come". It never seemed to offer much comfort to me as a child but now I understand what it truly means. The global epidemic of drug-resistant Cholera brought on by global warming took a billion lives and changed the world as we knew it. Thanks to this 'bad" new approaches to medicine have evolved and I have risen to become the Chief Medical Researcher at the United Nations Organization for Bio-medical Research (UNOBR).

Before global warming started taking effect most of the world probably could not have even pointed Tierra del Fuego out on a map. We were the first region to be forced into migration due to rising water levels.

I was 17 years old when the first researchers began showing up in Argentina. An unknown disease had begun to spread among the natives. Yet everyone from Tierra del Fuego was unaffected. Within days there were more people in white coats roaming around the streets than I had ever seen. Some of these people- the *intrusos extranjeros* or foreigner intruders- were collecting plants, animals, food and samples from the water for study. I was more fascinated by the activities of the medical doctors. They were the ones who explained to me that the world was in crisis, the same thing that was happening in here in Argentina was happening in other sites of massive migrations. These places were experiencing a disease strikingly like Cholera. The natives weren't responding to traditional treatments. Most of the new migrants were sick, except for those of us from Tierra del Fuego. It was a mystery.

I was fascinated by the technology the doctors were using to learn more about our bodies. It was called Hope-in-a-Box, but we started to call it *cuadro de respuesta* or the answer box. The doctors would extract our blood, put it into the Box, and then the cuadro de respuesta would begin to unravel the mystery.

"What is it saying?" I would pester. "It gives a read of special proteins in your blood", said Pierre, the one physician who took a liking to me and put up with my persistent questioning. I took to following him around and over time, began borrowing medical books. As this disease plagued the world, I was receiving the only pre-med education I had access to.

At first, the answers from the Hope-in-a-Box were scrutinized for each separate location that was designated as 'immune'. Eventually they learned that put together, the biomedical data was more meaningful. Organizing this sharing of information was difficult, with many groups objecting on the grounds of privacy, while bureaucrats argued over who should oversee the project. The United Nations eventually created a UN Organization for Bio-medical Research (UNOBR).

The international collaborations between UNOBR scientists, doctors, and researchers started producing results immediately. Within three years the death rates from the new Cholera leveled off and hope for a cure was high. Hope-in-a-Box remained in widespread use to keep constant data streams flowing to UNOBR. As some of the doctors in Tierra del Fuego were called to the UNOBR American headquarters in Arizona, lower level researchers were asked locally collect the data for Hope-in-a-Box. Given my expertise with the answer box plus the five years of ad lib but intense education and training, I was more qualified than most to help with this effort.

When the cure was discovered in 2030 there was almost an audile sigh of relief all over the world. The vaccine was distributed, deaths from Drug-resistant Cholera were eradicated, and UNOBR was attributed with saving the world. The enclave of scientists, researchers, and doctors that came to study our immunity soon packed there bags and left, which for me was a bittersweet departure.

For me, the good of this bad was not only increased international collaboration, and novel ways to diagnosis disease, but the life that emerged from this crisis. When it was time for the scientists to leave, I wanted to go with Pierre who over the years continued to train me. A UN scholarship enabled to me to formalize my medical training. To this day, I work with UNOBR heading up the public deliberation component where we work to communicate worldwide our mission, to improve health "One Biosignature at a Time".

Outcomes

The conversations conducted during the workshop were the main outcome: bringing together a diverse array of individuals to discuss emerging technology in itself makes headway into responsible, socially robust technological development. The other practical outcomes of the conversations reverberate over time and are hard to account for. Future decisions informed or influenced by the insights gleaned from the workshop are likely but hard to track. However, a few weeks after the workshop, one of the participating graduate students took seriously the dilemmas around the problem of detecting diseases without a cure. This student changed the research orientation from designing a tool to diagnose a more exotic disease to a more common infectious disease.

The evaluations of the workshop consistently revealed a strong value to participants by expanding their thinking about technology in society. Particularly, one scientist participant gained new understandings of the "possibility of political implications and social backlash related to the choice of individuals to use or not use the technology." Another noted "how important it is to look at the impact of technology early in development." One participant noted how "the creation of stories helped me to see the connections between decisions made

early in the development process and the outcomes." Nearly all the participants valued the "unique variety of perspectives" and the way a "diversity of participants" could sustain a rich dialogue about risks and benefits.

Additionally, there were several key dilemmas and tensions that arose during the workshop that are of contemporary relevance for more attention:

- *Access:* Who owns the technology? What licensing agreements, partnerships may affect ownership and hence accessibility?
- *First Application:* How will Doc-in-the-Box make its entrance? To whom? What sorts of lasting effects in terms of institutional, social and political support? In terms of technical lock-in?

"If the first commercializable application is combating infectious disease, you create a very specific type of market, despite the fact that this is reducible to home use, it becomes a tool of surveillance of public space instead of knowledge of previate space.... This could set it on a trajectory of something which is used to attach stigma rather than something which is used to provide treatment."

- *Design:* What is the extent of customization (how tunable is the device)? How should data flow? Is this device designed as portable and private, or public?
- *Technical:* What are acceptable levels of reliability? Should the aim be towards infectious disease or chronic conditions?

For more information:

CNS's survey of the literature (from books, press releases, editorials, academic journals, government reports and industry white papers) led to an extensive collection of documents that together begin to get at the contexts in which Doc-in-the-Box will develop. You will find these documents annotated on the Future of Medical Diagnostics webpage: www.cspo.org/outreach/md The Future of Medical Diagnostics Workshop Participants:

Daniel Barben, PhD, Associate Research Professor, Consortium for Science, Policy and Outcomes, Arizona State University (ASU)

Michael Chorost, PhD, author of *Rebuilt: How Becoming Part Computer Made Me More Human*

Chris Diehnelt, PhD, Assistant Research Professor, The Biodesign Institute, ASU

Scott Endsley, MD, Vice President, System Design for Quality Improvement Organization, ASU adjunct

David Guston, PhD, Director, Center for Nanotechnology in Society-ASU; Associate Director, Consortium for Science, Policy, & Outcomes; Professor, ASU Department of Political Science

Stephen A. Johnston, PhD, Director, Center for Innovations in Medicine, The Biodesign Institute, ASU

Joel Garreau (co-facilitator), Journalist, Washington Post; author (Radical Evolution); futurist

Sean Hays, PhD fellow, Political Science, Center for Nanotechnology in Society researcher, ASU

Laurence Miller, MD, Mayo Clinic-Scottsdale

Robert J. Milligan, JD, Director, Physician Services Group, Gallagher & Kennedy P.A.

Shobita Parthasarathy, PhD, Assistant Professor, Department of Public Policy, University of Michigan; Visiting Scholar, Woodrow Wilson International Center for Scholars

Jason Robert, PhD, Assistant Professor, ASU School of Life Sciences; CNS-ASU

Michael Tracy, PhD, Deputy Director, The Biodesign Institute, ASU

Julia Trosman, Director, Center for Business Models in Healthcare

Jameson Wetmore, PhD, Assistant Professor, School of Human Evolution & Social Change; CNS-ASU **Berea Williams**, PhD fellow, Department of Chemistry and Biochemistry, Center for BioOptical Nanotechnology, The Biodesign Institute- ASU

Neal Woodbury, PhD, Director, Center for BioOptical Nanotechnology, The Biodesign Institute; Professor, ASU Department of Chemistry and Biochemistry

Organizer and co-facilitator: **Cynthia Selin**, Assistant Research Professor, Center for Nanotechnology in Society, Consortium for Science, Policy and Outcomes, ASU