

Institute for Alternative Futures
Foresight Seminars on Health and Innovation

SUMMARY

CLINICAL DEVELOPMENT IN THE 21ST CENTURY

July 18, 1997

On Friday, July 18, 1997, the Institute for Alternative Futures (IAF) conducted a Foresight Seminar entitled, "Clinical Development in the 21st Century." Our speakers were:

- Jonathan Peck, **Institute for Alternative Futures**
- Dr. William Wardell, **Covance Clinical and Periapproval Services**
- Michael Hurley, **Abbott Laboratories**
- Dr. Theodore Pincus, **Vanderbilt University**
- Dr. Judith Jones, **The Doggo Group**

The speakers described how fundamental changes to the current clinical development system would enhance development of new drugs. Jonathan Peck summarized IAF's report, *Clinical Development 2005*, raising several key points: First, we can reduce the time it takes to get medicines to market by 50%. Second, we can customize those medicines for a smarter market by delivering better information. Third, and most importantly for policy makers, we can see that beyond FDA reform a whole new system of clinical development is needed to capitalize on scientific advances.

The rapidly advancing field of genomics illustrates the fact that there is, as Dr. Wardell pointed out, a "discovery surplus" right now. New therapy candidates are being discovered so quickly that there simply are not enough resources to develop them all in a timely and cost-effective manner given today's system.

Michael Hurley demonstrated that the current system forces multiple lengthy and very expensive phases of randomized, controlled clinical trials, the final phase of which is a time-consuming process of patient and physician recruitment. Relying on this current "gold standard" for clinical development seriously limits the number of clinical trials, which in turn reduces the availability of treatments that could help patients.

Furthermore, as medicines and therapies focus on prevention or management of disease, the limited duration of clinical trials makes the current system inadequate. If new therapies are going to prevent disease, the problem of recruiting people who may be predisposed to the disease will be even greater. Additionally the current system is incompatible with some new non-traditional medicines and therapies being developed. So, what should be the new 'gold standard'?

Dr. Pincus offered us one potential solution in the form of patient questionnaires. These are short forms that patients fill out while waiting in the doctor's office. They offer four points that make them a good tool:

100 North Pitt Street, Suite 235 Alexandria, VA 22314
(703) 684-5880 (703) 684-0640 fax
<http://www.altfutures.com>

Institute for Alternative Futures

Foresight Seminars on Health and Innovation

- They are easy and inexpensive to collect in the space of a visit
- They allow The collection of data over a long term of years or decades which is more realistic for chronic diseases
- They use subjective measures, which are generally better predictors of outcome than laboratory tests or x-rays.
- They address the primary concerns of patients, such as better functioning and less pain.

One of the most important points that Dr. Pincus made about questionnaires is that if we create This infrastructure of huge questionnaire databases. "it will help us identify sub-populations that will respond differently to therapies." This accurate profiling of sub-populations allows a clearer picture of the population as a whole.

Dr. Jones described the contribution of epidemiology to the cycle of development in the smart market emerging from managed care. An accurate view of sub-populations from methods such as questionnaire databases gives us a fuller understanding of the population as a whole. Advances in genomics then allow us to apply this knowledge to predict how individuals within a given population will respond to various therapies. This information is fed back into the process, eventually allowing dosages, warnings and indications to be created for each individual. Finally, increased knowledge of the individual and the population will allow us to create drugs and therapies custom designed for each individual's unique genetic and chemical profile.

These new medicines are not the type of medicines we are familiar with. They are not mass produced chemical commodities that simply interact with the chemical processes of The body. Rather they are genetically based therapies that in fact re-program human cells and new technologies that are leaps beyond our current treatments.

The primary public policy implication, Daniel Shostak concluded, is that FDA reform which aims only at more efficiently handling today's medicines will not be enough. Policy makers need to look beyond FDA reform to an entirely new system for clinical development in the 21st century.