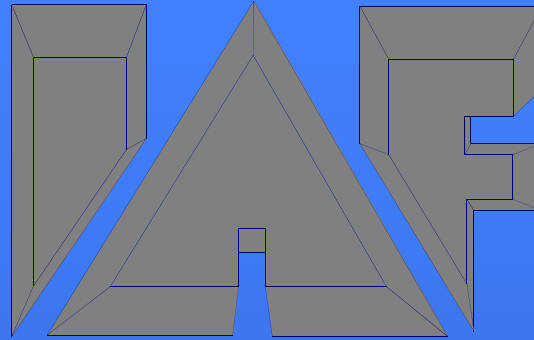




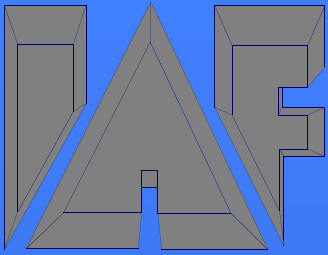
Future Challenges and Opportunities Emerging from the Mapping of The Human Genome

**The Second Annual National Congress on the Future of the Genome,
Biotechnology, and Pharmaceuticals in Medical Care**

November 16, 2000

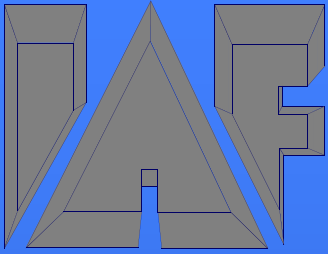
Clement Bezold, Ph.D.

**Institute for Alternative Futures
and
Alternative Futures Associates**



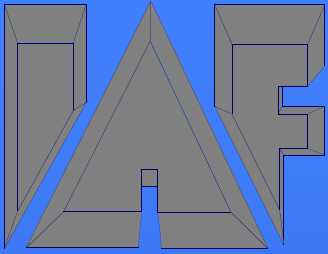
Topics

- ◆ **Opportunities and Challenges of Genomics**
- ◆ **21st Century -- Fundamental Change**
- ◆ **6 Challenges**



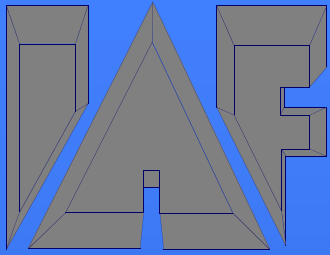
Opportunities from Genomics and Related Trends

- ◆ Predict disease likelihood
- ◆ Predict therapeutic effectiveness & safety
- ◆ Detect disease early
- ◆ Enhance therapeutics
- ◆ Improve clinical development and regulation
- ◆ “Conquering diseases”
- ◆ Design out illness, enhance humans
- ◆ Bring health and health care to all



21st Century— Fundamental Change

- ◆ **21st Century -- The Design Century**
 - ◆ **Technology and society**
 - ◆ **The environment**
 - ◆ **Health**
 - ◆ **Health care**
 - ◆ **Humans and humanity**



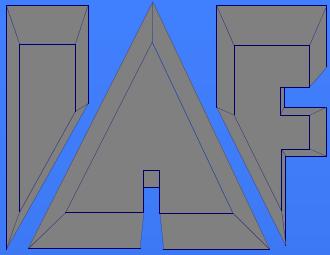
21st Century -- Fundamental Changes in Health Care

♦ Scientific and research advances

- ♦ Genomics enhancing understanding and control options**
- ♦ Additional Advances of disease and behavior**
- ♦ Biomonitoring adding specific detail**

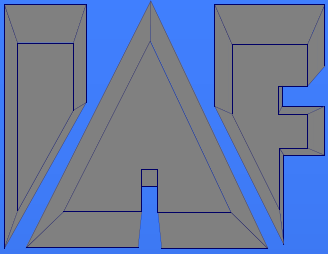
♦ Shifting paradigms in health care

- ♦ Enhanced, sophisticated self-care**
- ♦ Complementary and alternative approaches**
- ♦ Wellness and enhancement choices**
- ♦ Forecast, prevent and manage paradigm**



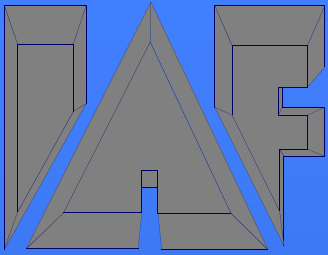
Genomics/ Pharmacogenomics

- ◆ Prediction
- ◆ Targeting and dosing
- ◆ Monitoring
- ◆ Fixing
- ◆ Preventing
- ◆ Redesign, enhancement of humans



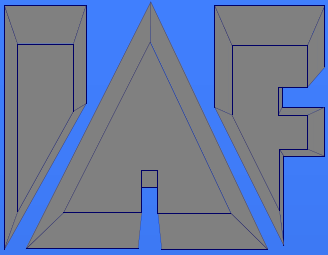
Anticipated Benefits of Pharmacogenomics (NIGMS)

- ◆ **More powerful medicines**
- ◆ **Better and safer drugs the first time**
- ◆ **More accurate methods of determining appropriate drug dosages**
- ◆ **Advanced screening for disease**
- ◆ **Better vaccines**
- ◆ **Improvements in the drug discovery and approval process**
- ◆ **Decrease overall cost of health care**



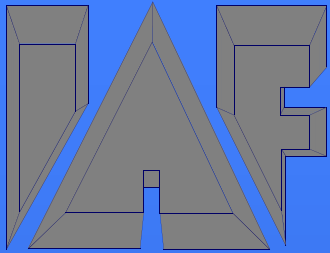
Challenges from Genomics and Related Trends

1. Pharmaceutical economics
2. Smarter markets
3. Drug Regulation
4. Public attitudes and policy
 - ◆ Privacy, discrimination, intellectual property
 - ◆ Equity
5. Governing evolution
6. Harnessing Visionary Potential



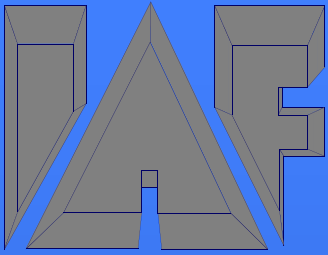
Challenge 1: Pharma Industry Economics

- ◆ Targeting shrinks many markets
 - ◆ Some blockbusters remain
- ◆ Need/demand for lower costs of R&D and FDA approval
- ◆ New pharma players, especially in discovery and development
- ◆ Marketing costs rise and fall



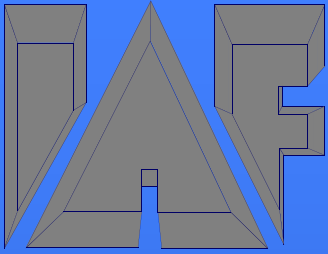
Challenge 2: Smarter Markets

- ◆ **Markets and marketplaces which give consumers more sophisticated choices and customized information for their decisions.**
- ◆ **By 2010 for most products there will be global awareness of efficacy, cost effectiveness, and price**
- ◆ **Broader criteria for choice will be included**



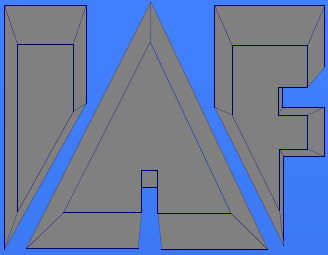
Smarter Markets in Health and Pharma

- ◆ **Buyers, large and small, will have increasing intelligence**
- ◆ **Outcome measures will be available**
 - **systems, individual health care**
 - **providers, therapy systems and components**
- ◆ **Report cards will become ubiquitous and well used**
- ◆ **Consumers will judge quality, price, and other values**



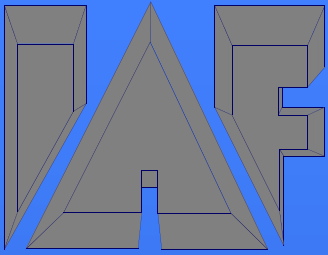
Smarter Markets: Broader Values

- ◆ **Pharma and other genomic companies will be judged by multiple bottom lines**
 - ◆ **Broader Quality measures**



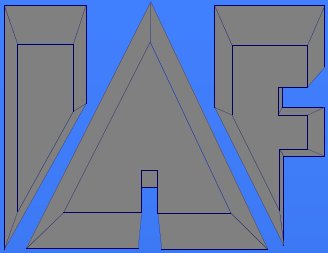
Smarter Markets: Broader Quality

- ◆ **Inherent quality**
 - ◆ Strength, purity; USP standards
- ◆ **Functional quality**
 - ◆ Safety, efficacy, cost-effectiveness
- ◆ **Contextual quality**
 - ◆ Currently: Worker safety = ISO 9000;
Environmental protection = ISO 14000
 - ◆ Emerging: Sustainability, equity
 - ◆ e.g., Social Accountability (SA) 9000; Natural Step;
WHO & Health for All



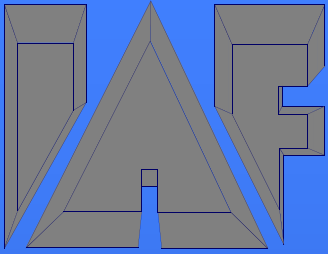
Contextual Quality: “Health For All”

- ◆ Contextual quality: What does “goodness” mean for health — what determines the right things?
 - ◆ “Health For All,” the WHO/PAHO vision as a “gold standard” — Health with these values:
 - ◆ Equity, solidarity, ethics, gender and human rights
 - ◆ US Healthy People 2010 Objectives



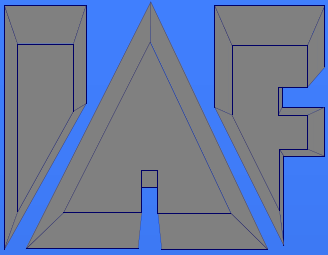
Challenge 3: Reinventing Drug Regulation

- ◆ **Current system does not guarantee “safety and efficacy” in use**
 - ◆ **1994 2 million hospitalized patients with serious reactions and 106,000 deaths (Lazarou in JAMA 1998)**
 - ◆ **6.7% of people prescribed drugs have severe adverse reactions — 5th leading Cause of death in the US in 1997 (CDC, 2000)**



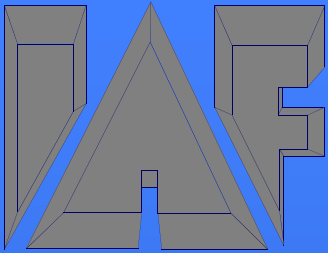
Factors Accelerating Reinventing Drug Approval

- ◆ Empowered patients
- ◆ Patient groups and disease voluntary organizations
- ◆ Lower clinical trial costs for health providers
 - ◆ Information systems, electronic medical records, low cost biomonitoring,
- ◆ Possible changes in intellectual property
- ◆ “Smarter Markets”



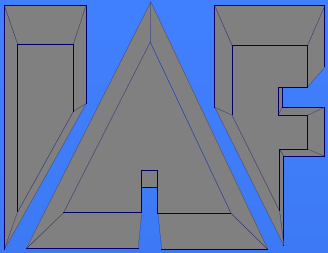
Genomics and Clinical Development

- ◆ **Virtual organs, patients and cohorts**
- ◆ **Genotype and phenotype focused studies**
 - ◆ Including phenotypes from Ayurveda, Oriental Medicine
- ◆ **Greater access to clinical trials**
 - ◆ Disease groups play active role in design and recruiting



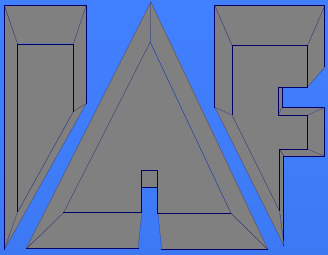
Reinventing Drug Regulation

- ◆ **Congress will need to rewrite FDA's drug process approval process**
 - ◆ **New system will need to be more:**
 - ◆ **Customized and predictive**
 - ◆ **Capable of handling multiple factors, learning from post approval data**
 - ◆ **Flexible and adjustable as options improve**
 - ◆ **Option to lower entry to market threshold, requiring greater post-market capture of efficacy, side effects; Consumers choose how much risk they want to take**



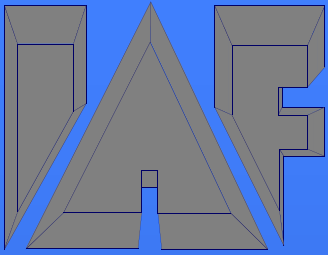
Virtual Organs, Selves and Cohorts

- ◆ Virtual organs will provide “in silico” models that embed our understanding of human physiology and that can be used to test new medicines
- ◆ Many individuals will have personalized virtual selves with their organs modeled for continuous updating and testing against new compounds
- ◆ Use of virtual cohorts will grow



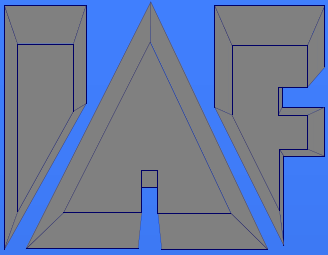
Challenge 4: Public Attitudes and Policy

- ◆ **Public reaction - depends on how well genomics is applied**
 - ◆ **GMO's in foods not a good start**
- ◆ **Policies & protections need to be resolved**
 - ◆ **Privacy**
 - ◆ **Discrimination**
 - ◆ **Intellectual Property**
 - ◆ **Equity**



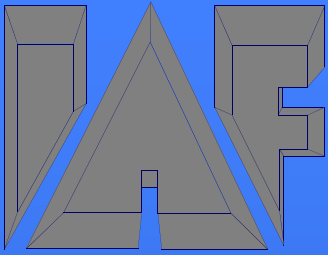
Challenge 5: Guiding Human Evolution

- ◆ **Momentous directions**
 - ◆ **Eliminate disease**
 - ◆ **Enhance human capacities**
 - ◆ **2050 - 2 Olympics**
 - ◆ **Near immortality**
 - ◆ **Designing humans and human societies**
- ◆ **Private and public decisions**
- ◆ **Corporate players are players**



Challenge 6: Harnessing Visionary Potential

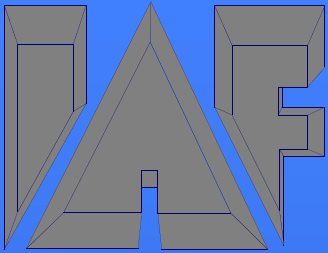
- ◆ Real opportunity for generating significant health gains
- ◆ Opportunity to use these to bring “Health For All”
- ◆ Great threats, risks, in the immediate market
- ◆ Vision needed to ensure companies provide highest value added and remain competitive.



Challenge 6: Harnessing Visionary Potential

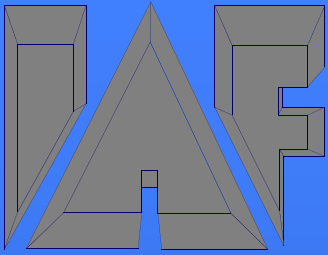
- ◆ **Genomics forces all players to consider our fundamental contribution -- what type of healthcare system, health and health gains, and society we are seeking to build.**
- ◆ **This discussion contributes to finding value added -- this discussion is occurring in several sectors**





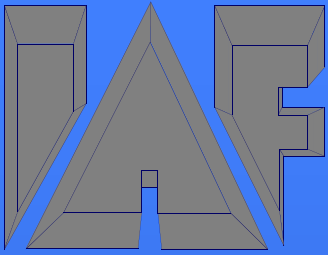
Vision & Value Added: Trends across sectors

Value-Added	Journalism	Corporate Activities	Electronic Messaging	Quality	Health Care	Military Medicine
	Civic Journalism	Visioning, Co-creation	Wisdom, Co-creation Vision	Vision	Syndrome Prevention, Community Health	Anti-War, Health/Sustainability
	providing what is significant	community services, collaboration	knowledge	strategies	disease prevention	community health
	providing what is news		information			personal prevention, fitness
	accurate facts	profits efficiency operations	data	operations	disease treatment	disease and combat casualty treatment



Challenge 6: Harnessing Visionary Potential

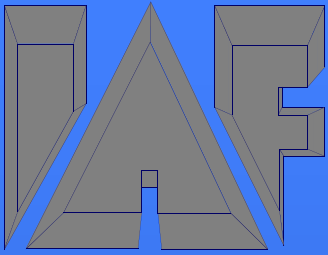
- ◆ **Harnessing visionary potential will require**
 - ◆ **All players in genomics ensuring their own vision is up to the challenges**
 - ◆ **the community as a whole (the U.S. and global communities) have a shared vision and strategies that enable genomics to make its optimal contribution to “Health For All” and to conscious evolution**



Conclusion

◆ Genomics

- ◆ gives us great power
- ◆ will make health care and pharma more complex
- ◆ can contribute to significant health gains
- ◆ invites all players to rise to the challenges, especially achieving “Health For All”



For More Information

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