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Achieving an Ethical Future for Biomedical R+D

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Sponsors: Pfizer Global Research & Development

Type: Thematic Foresight on Biomedical R+D on genomics, proteomics, nanotechnology and bioinformatics covered from a global perspective, notably through eastern and western philosophies and practices.

Organizer: The IAF - Institute for Alternative Futures in Virginia, USA

Duration: 2004-2006 **Budget:** N/A **Time Horizon:** 2029

Purpose

The 2029 Project: Achieving an Ethical Future for Biomedical R+D launched by the IAF - Institute for Alternative Futures develops forecasts on the greatest advances that will come about through biomedical R+D in the next few decades. Short, medium and long-term developments in biomedical R+D are anticipated along with related social and cultural trends. The work refers to the time-periods 2005-2010, 2011-2019 and 2020-2029. The last phase of 'The 2029 Project' focuses on the dissemination of project outputs and on recommendations as to how science and ethics will interact in the creation and discovery of new biomedical knowledge.

The Boundaries of Optimism and the Projection of the Advisable

The emergence of new fields of research, such as genomics, proteomics, nanotechnology or bioinformatics, coupled with knowledge exchanges made possible by the internet are likely to boost our fundamental knowledge of disease processes and provide biomedical R+D with a variety of new research tools.

Policy makers and the general public underestimate rather than overestimate the future contributions that biomedical R+D can make to health care. This project therefore looks at what research and development might achieve over the next 25 years and challenges the conservative view.

The 2029 Project studies the future of biomedical research and development with selected leaders across scientific disciplines that appear particularly relevant to biomedical R+D. The stated objective is to identify the most important developments

that could contribute to improving global health by 2029 as well as to draw public attention to the potential contribution of science to public health in the coming years.

The last phase of the project is focused on the dissemination of the project's findings. Information showing the potential of biomedical R+D should provide a useful framework for scientific planning as well as for public debate on research funding as well as on the cost of innovation in healthcare.

Underlying the project objectives is the idea that forecasts can influence the future path of science and catalyze cultural and societal adaptation to technological change.

A Focus on Dialogue and Flexibility

The 2029 Project is based on an interactive approach involving a project core team and a range of scientists, consultants and medical stakeholders. The project is based on



an evolutionary and flexible approach where feedback from experts is central to the projects methodology.

By scanning the literature the IAF first produced an initial mapping of thematic R+D areas to guide its research and serve as a reference throughout the project. The team has set categories in science where interdisciplinary connections are operating. It held an initial review of the research framework and identified an initial set of developments likely to foster biomedical research and global health. This map was first used to collect, update and draft fourteen forecasts for key thematic areas identified through the R+D mapping process.

These forecasts were reviewed internally and by key advisors before the preparation of a final draft. The draft formed the starting point for discussions with the designated key Advisers. IAF also organised a joint meeting with the Draper Laboratory, on the 15 November 2004 to explore the initial forecasts.

Having produced a draft report the IAF held a meeting on 11 February 2005 designed to bring leading scientists into discussions focused on future developments and their possible translation into mid-term opportunities. The focus of discussions has progressively moved from science to ethics and from the notion of disease to the notion of opportunity for health. Since this meeting the project has brought on board these expert contributions and a new section has been added to the final report entitled *Evolution of Ethics and Healthcare*.

Finally the IAF team concentrated on anticipating short-term (2005-2010), mid-term (2011-2020) and long-term (2021-2029) developments in biomedical R+D. Each of these timelines were characterised by and qualified on the basis of four themes:

- Turning data into information, knowledge and wisdom,
- The union between Eastern and Western philosophies and practices,
- Moving beyond boundaries,
- The shift from disease to health potential.

The main participants in the project were selected for their individual expertise. Interviews and meetings involved scientists from private companies and some from US public organisations. The targeted organisations include:

- Pfizer
- Draper Laboratory
- Johnson & Johnson
- Center for Integration of Medicine and Innovative Technology
- GE Healthcare
- University of California at San Francisco Centre for Drug Development
- Ohio State University
- U.S. Food and Drug Administration
- Massachusetts Institute of Technology

Biomedical R+D Changing Healthcare Practices

Futurists anticipate dramatic changes and an emerging concern with the ethical dimension of global health that will enhance biomedical R+D developments. Subsequent technological breakthroughs will have a great impact on healthcare.

Combining Eastern & Western Philosophies of Health

Researchers are progressively working with new tools which enable to quickly proceed, understand, and place into context torrents of new data and information. By 2010 the combination of open source networks and successes against some global pandemics should rapidly create and spread knowledge around the world.

As a result, a promising global traffic in ideas should bring East and West closer together in scientific understanding. China, India, Japan, Korea and Singapore are likely to generate a growing number of scientists who will take leadership in nanotechnology, stem cell research and bioinformatics. Eastern worldviews coming to biomedical R+D should also foster research into subtle effects that draw

upon areas such as chaos theory and an understanding of the body's energy fields.

On the other hand Europe and the U.S. will have an increasing number of scientists studying Asian health concepts and health improvement methods. Ongoing studies of the mind have already demonstrated that eastern meditation techniques can alter emotional states and enhance mental health. Traditional understanding of energy forces based on concepts such as 'chi' can explain physiological phenomenon such as cardiovascular rhythms. Eastern philosophies and practices will continue to be adopted by a growing number of Western educated citizens through the adoption of Yoga, Tai Chi and various other martial art and healing traditions.

Cultural and Ethical Changes

Considering the current trend for pushing cultural boundaries and for the development of global knowledge, it is argued that Western culture could move away from its historical emphasis on the individual, towards a community-based and a collective consciousness. Reciprocally, Eastern culture could move away from its traditional emphasis of cultural harmony towards a growing appeal for individual expression and accomplishment. When looking at short term ethical concerns, it first appears that self-interested national or regional policies may prevail

with hazardous global outcomes. As observed with nuclear proliferation, when technological innovations emerge, the process becomes almost impossible to stop as stakeholders in the global community hasten to occupy vacant niches. This process may already be emerging in the area of stem cell research.

Concerning in particular the development of morally debatable technologies, it can only diminish when a global agreement aims to stop the expansion of these technologies and global enforcement regimes are enacted to ensure such an agreement.

In the long-run, the close interconnection of economic and political systems in a transparent environment of knowledge exchange will encourage the development of a global ethic for biomedical activities. Complete connectivity between researchers, politics and the population who actively collaborate in science will reinforce this need for global ethic.

The project foresees that by 2029 ethical concerns will be clearly integrated in new intellectual property rules negotiated to speed innovation and diffusion. An ethical commitment will expand knowledge access so that the whole world, including the poor, benefit from biomedical R+D. Increases in the economic wellbeing of developing population centres in India and China will foster this evolution. By 2029, well established ethical conventions will frame law and economics as never before. Only then will science and technology accomplish its promise to deliver global health.

Some Potential Breakthroughs

According to the IAF team, four specific advances hold the greatest breakthrough potential, creating new hope for patients and new challenges for healthcare systems:

- **Stem Cells** hold the potential for decisively addressing heart disease, diabetes, cancer and neurological diseases such as Alzheimer's and Parkinson's.
- **Gene Therapy and Gene Silencing Therapeutics** are emerging as new delivery technologies to target specific cells. A number of Eastern countries are pursuing this promising technology. If scientists can understand the complexity of cellular systems there is great potential for the application of RNAi (ribonucleic acid interference) drugs to many diseases.
- **Nano-medicine** has achieved initial success in medical devices and diagnostic tests, but a far larger number of applications could come about within the coming decade. Nanotechnology is bringing valuable research tools and clinically useful devices. A breakthrough could come from implantable devices that diagnose, deliver therapies and monitor effects.
- **Implants and Drug Delivery** devices will improve dramatically as new advances in micro-electromechanical systems (MEMS), nanotechnology and other technologies are combined to create new ways of delivering drugs that improve patient care and mobility.

Towards a Healthcare Approach Based on Prediction and Prevention

While more diseases are overcome, interest in prevention and health potential will grow. Change is about to start with regulators accepting the validity of surrogate markers and suites of wearable biomarkers. Individuals will use these biomarkers for continuous risk monitoring. As more people learn to interpret biological signals, prevention will prevail. By the 2020s, a prognostic system will emerge and begin to replace former diagnostic systems.

The ability to continually monitor individuals and create personal risk assessments will lead to more **tailored therapies**. Risk statements are based upon cellular, tissue and organ system measurements along with behavioural assessments and environmental monitors. To fully understand health risks, research will have to shift from studies of individuals and populations to learning about communities and ecosystems.

The project plans that by 2029, an **Electronic Medical Record** that gathers all Personal Health Records (managed by individuals) from around the world will be implemented. The vast array of available genomic and phenotypic data will help characterize the diversity of populations and supports surveillance for new health threats that emerge.

In this view, IAF experts devised a knowledge interface mediating human's interactions with healthcare system: the **Health Advocate Avatar** (Avatar refers to a Sanskrit term recalling the incarnation of a Hindu God). The system uses natural language processing to present complex medical information in a clear and intuitive way and allows choosing the best possible care.

Users continuously feed data into the Avatar through monitors, used either continuously or periodically. The Health Advocate Avatar would track purchases and other evidence of lifestyle choices, while monitors would show multiple physiological parameters, such as pulse and calories expended during the day.

The interface, linked to global health records will draw upon the cumulative experience of others with similar needs, wants and values to guide decisions and provide incentives that encourage healthy behaviours. As it connects to sources of knowledge for individuals, it also contributes knowledge needed for the collective health of society. For example, the Avatar could pick up signals showing health trends, such as obesity or depression.

However, the Health Advocate Avatar would operate under ethical constraints designed to ensure that it communicates the best available knowledge back to individuals. This way, the Avatar has to be secure and discreet. It has to protect privacy and keep users interests to the fore.

Evolution of Healthcare Systems

According to the 2029 Project new biomedical technologies and preventive healthcare techniques will generate new ways of assessing risks and sharing them amongst communities.

Until now debates on healthcare have focused on the responsibility of the community in financing and delivering healthcare services. In Europe single payer systems have been implemented in order to distribute health risk across the member nations of the European Union. In the United States, the health insurance industry has evolved by distributing health risk across designated social units such as corporations.

As a shift from a disease model of healthcare to a model based on 'health potential' is likely to occur, the distribution of risk and ethical obligation will change too. Both systems need an effective ethical agreement between individuals and social units. Individuals will have a positive moral obligation to maintain their own health and prevent risks over which they have control such as lifestyle factors. For health risks over which the individual has no control, for example health risks with a genetic origin, social units will have a moral obligation to provide.

A potential evolution underlined by the project is that, without such an agreement, healthcare systems could naturally shift back to private care models because there will be no benefit, either moral or economic for the pooling of risk to create viable affordable healthcare systems.

How to Reach an Advisable Biomedical R+D

As part of the last phase of the project, the IAF proposes seven steps to promote the most ethical advances from biomedical R+D, to expand knowledge of health and disease, and to improve health for everyone. These are as follows:

- **Set a goal for adoption by the UN of a minimum health standard for all:** Such a goal could be both an ethical position and a strategy for global political and economic development.
- **Promote Individual Healthcare Responsibility:** Create personalized risk profiles that integrate the collective understanding of health and disease. Individuals and society should use these profiles to encourage individual responsibility for health and collective agreements about resource limits on healthcare.
- **Initiate a global discussion of ethical positions for intellectual property:** Ethical policies can be engineered for greater speed of diffusion while prompting innovation. Intellectual property must work so that innovation offers promise to both the rich and the poor.
- **Move from healthcare focused on the treatment of disease to healthcare that promotes health:** This needs to be accompanied by a new understanding of why people choose behaviours that they do. As a consequence, lifestyle, mental states and the environment should be recognized as integral to the health of citizens.
- **Change healthcare regulations to promote information sharing and new methods beyond clinical trials:** A partnership between research subjects and the biomedical research community should form around new methods that serve individual as well as collective interests.
- **Foster an open-source system for health research, including drug discovery:** An open source system for health research can break down the barriers between organizations and scientific disciplines to create higher quality drug candidates.
- **Create a collaboration of stakeholders to design and develop the Health Advocate Avatar:** The Avatar represents an incredible leap beyond existing strategies to empower patients, transform research and development and promote an ethical system of healthcare.

Sources and References

The 2029 Project: Achieving an Ethical Future in Biomedical R+D by the Institute for Alternative Futures, Alexandria, Virginia, 2005, © the Institute for Alternative Futures.
<http://www.altfutures.com>.

About the EFMN: Policy Professionals dealing with RTD, Innovation and Economic Development increasingly recognize a need to base decisions on broadly based participative processes of deliberation and consultation with stakeholders. One of the most important tools they apply is FORESIGHT. The EFMN or European Foresight Monitoring Network supports policy professionals by monitoring and analyzing Foresight activities in the European Union, its neighbours and the world. The EFMN helps those involved in policy development to stay up to date on current practice in Foresight. It helps them to tap into a network of know-how and experience on issues related to the day to day design, management and execution of Foresight and Foresight related processes.