National Institutes of Health Visiting Fellows Committee

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Beyond Bioethics: New Approaches to the Governance of Human Biotechnology in the United States

By Dr. Tirumalai Kamala and Dr. Hwei Ling Ong

Dr. Francis Fukuyama is the Bernard L. Schwartz Professor of International Political Economy at the Johns Hopkins University School of Advances Studies, and a well-known author of several books including the controversial book, The End of History and the Last Man, published in 1992. Dr. Franco Furger is the Director of the Science and Society Project at the Institute of Communication and Culture, University of Lucerne in Switzerland. According to Dr. Fukuyama, scientific advances in the United States have consistently outpaced regulatory efforts. At a recent lecture and discussion session on bioethics at the Embassy of Switzerland in Washington, D.C., he and Dr. Furger argued that the strong anti-regulatory bias in the U.S. is somewhat responsible for this state of affairs. They feel that the situation is further hampered by the entrenched partisan positions taken up by the many interest groups who dominate the public policy scene in this area. Even though the US remains the undisputed leader world-

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In profile: Dr. Guadalupe Reyes-Cruz (Mexico)

Dr. Guadalupe Reyes-Cruz, a Chemist from Mexico, obtained her M.Sc. at the Cell Biology Department, Center for Research and Advanced Studies, National Polytechnic Institute, and her Ph.D. in Biochemistry at the National Autonomous University of Mexico. As a Ph.D. student, under the supervision of Dr. Luis Vaca, Dr. Reyes-Cruz studied the aspects of the functional regulation of the human bradykinin B2 receptor expressed in sf21 insect cells. Her research demonstrated that

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wide in many areas of biomedical research, so far it has been largely unable to shape the regulatory aspect pertaining to human biotechnologies.

Feeling very strongly that the situation needs to be addressed urgently, Drs. Fukuyama and Furger formed the Human Biotech Governance Project (http://www.biotechgov.org), based in DC and consisting of representatives from various organizations, such as the Biotechnology Industry Organization (BIO), the American Society for Reproductive Medicine (ASRM), Federation for American Societies for Experimental Biology (FASEB) and American Association for the Advancement of Science (AAAS). The two-year research project carried out at Johns Hopkins University was aimed at exploring the creation of a suitable regulatory institution for governing human biotechnologies in the US.

During his lecture, Dr. Fukuyama concentrated on the regulation of Assisted Reproductive Technology (ART). He said that both stem cell research related to reproductive medicine and reproductive cloning need a regulatory framework to work in. He also pointed out that the British and Canadian governments had the most comprehensive regulation already in place concerning these matters.

Dr. Fukuyama then went on to expound on the several layers of regulation that already exist in the US and explained why he feels that they are either unprepared or unequipped for the task of regulating ART. While several federal agencies like the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) already exist to regulate various issues pertaining to human health, he felt that their mandates did not adequately cover the regulation of human biotechnology. The FDA sets the gold standard for pharmaceuticals establishing the safety and efficacy of drugs, whereas the regulatory powers of NIH are limited to ethical issues involved with the allocation of research funding. The CDC, as its name suggests, concentrates on infectious diseases. Examples of self-regulation include ASRM and the Society for Assisted Reproductive Technology (SART) but these are largely hortatory, i.e. they have a limited ability to enforce compliance. Every university and research institute also has its own Internal Review Board but the effectiveness of these regulatory boards has been questioned. Direct legislative interventions at state and/or federal levels are another mode of regulating human biotechnology. Presently, both reproductive and research cloning are banned in Arkansas, Iowa, North Dakota, South Dakota and Michigan. Since 2001, more than 40 bills have been proposed in the Senate to regulate human biotechnology. The Senate Bill S303, which is currently making its way through both the Congress and Senate, has a big impact on governing human biotechnology. The bill proposes banning reproductive cloning while permitting research cloning. However, it does not address the most important issue – which regulatory institution(s) will govern the progress and use of human biotechnology?

This, he felt, underscored the need to create a new federal level agency. He said that the framework of such an agency could be based on already existing ones such as the Human Fertilization and Embryology Authority (HFEA) in Britain and the Assisted Human Reproduction (AHR) agency in Canada. He proposed that the regulation should be based on a set of principles that elucidate the end purpose that biomedicine should serve in ART. A feasible first principle, he suggested, would be the well-being and health, including psychological health, of children, rather than the right of parents to have children. A primary goal of biomedicine with respect to ART would be therapeutic in purpose rather than enhancement. Thus, practices such as patenting of human embryos, fusing embryonic cells from more than one zygote, reproductive cloning and prenatal gender screening would be strictly disallowed. General ethical principles applicable to ART would include ensuring equal access to ART between infertile and fertile couples, ensuring the well-being and health of children and women, free and informed consent of participating couples and limiting the commercialization of ART.

A key element of this proposal is the pronounced emphasis that both Dr. Fukuyama and Dr. Furger place on the importance of public participation in developing the framework of this hypothetical regulatory agency. They both feel very strongly that the agency should reflect a

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centrist opinion based on a democratic model ensuring that it not be swayed by the vicissitudes of entrenched partisan interest groups. Citing the current impasse on stem cell research as an example, Dr. Fukuyama argued that the public is not as polarized as the special interest groups and that the impasse exists due to the failure of all political parties to find common ground in seeking a solution for the betterment of the public. Both Dr. Fukuyama and Dr. Furger stressed that the new regulatory body should be independent of government control, not be beholden to any special interest groups and must seek to engage the public by means of public hearings, formation of citizen panels with substantial notice and comment sessions. He cited the HFEA as an example saying that the lay people outnumbered the scientists on its board, with almost equal representation of both men and women. In this agency, the Minister of Health makes appointments for two three-year term limits and all members are held accountable to the Parliament for the decisions the board makes, via the Minister of Health.

Summing up, Dr. Fukuyama said that creating an independent regulatory body is the first of many steps that the US has to make towards governing the current status, scientific advances and future prospects of human biotechnology. Issues that remain to be addressed include harmonization between domestic and international regulations on human biotechnology and improving the scientific literacy of the public on the complexities surrounding human biotechnology. To remain on the frontlines of biomedical research, the US has to move quickly and break the current political impasse that is reflective of the inertia gripping the country where human biotechnology is concerned.

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tyrosine kinases regulate the activity of the human B2 receptor by affecting its coupling to G proteins and its phosphorylation. During her Ph.D., she acquired experience in the cellular and biochemical aspects that are important for the regulation of G-protein coupled receptors.

In October 1999, Dr. Reyes-Cruz joined Dr. Allen Spiegel's group at National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) as a Supplemental Visiting Fellow to further her research in the field of Signal Transduction. Dr. Spiegel is an internationally recognized endocrinologist with an extensive research record on signal transduction. His group has made fundamental contributions that have helped to understand the genetic basis of several endocrine diseases. Dr. Reyes-Cruz was initially supported by a Pan-American Fellowship. In 2001, she obtained the status of Visiting Fellow in the same lab. During her time in Dr. Spiegel's laboratory, Dr. Reyes-Cruz's research focused on basic aspects of the structure-function of a G-protein coupled receptor, the human Calcium Sensing Receptor (CaR), which plays a central role controlling the homeostasis of extracellular calcium by orchestrating intracellular pathways that modulate the secretion of parathyroid hormone and calcium removal or absorption in target organs such as bone and kidney.

By utilizing molecular and biochemical approaches, Dr. Reyes-Cruz studied a series of mutant CaR constructs in which discrete parts of the extracellular domain of this receptor were deleted. The study of those mutants revealed the structural requirements for the activation of the CaR in the presence of calcium, its natural agonist. A substantial portion of the largest region of the extracellular domain of the CaR, the so-called loop III, can be deleted without affecting its expression or activation. Dr. Reyes-Cruz collaborated with her colleague by generating a truncated CaR designed to obtain the extracellular domain of the CaR as a secreted protein. In addition, Dr. Reyes-Cruz also investigated the role of the

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eight acidic residues in the extracellular loops of the seven transmembrane domains of the human CaR in receptor activation by Ca^{2+} and in response to a positive allosteric modulator, NPS R-568. In recognition to her work, Dr. Reyes-Cruz received the Fellows Award for Research Excellence (FARE) in 2002, which gave Dr. Reyes-Cruz the opportunity to present her work at the National Meeting for Bone and Mineral Research that year.

Dr. Reyes-Cruz enjoyed extensive discussions with very talented colleagues on the various projects she was involved in. She considers the very creative and enthusiastic atmosphere in Dr. Spiegel's laboratory to be crucial to her success during her years at NIH. She also participated in some of the workshops and courses offered at NIH, which certainly enriched her training and helped her to become an independent scientist and to mentor graduate students that have recently joined her laboratory in Mexico. Some of the NIH training courses that Dr. Reyes-Cruz took included: Speaking about Science, Scientific Writing and Workshop for Grant Writing. Recently, Dr. Reyes-Cruz traveled from Mexico to attend the workshop for Career Development and Leadership for Women Scientists in the Developing World that was held at the Stone House on the National Institutes of Health campus and was organized by the Fogarty International Center. According to her experience, Dr. Reyes-Cruz strongly suggests that postdoctoral fellows should be aware of the different activities organized at NIH, in particular the meetings and workshops held at the Fogarty Center, which are designed to help international fellows acquire additional skills that will be needed for their future careers as independent scientific leaders.

In January of 2003 Dr. Reyes-Cruz embarked on the next stage of her career as a Principal Investigator at the Cell Biology Department, Center for Research and Advanced Studies, National Polytechnic Institute in México City, which is one of the most important centers for basic and applied research in Mexico. Dr. Reyes-Cruz group in Mexico consists of three very talented graduate students, a Research Assistant and a technician. Dr. Reyes-Cruz's studies in Mexico are focused on the molecular aspects of regulation of the calcium sensing receptor. To support her research, Dr. Reyes-Cruz successfully applied for grants from the Third World Academy of Sciences and from the Miguel Alemán Foundation. Dr. Reyes-Cruz hopes that some of her students will eventually continue their training at NIH to be part of the academic effervescence that she enjoyed during her postdoctoral training.

Calling for Contributions to the "In Profile" Segment

We are interested in hearing from Visiting Fellows and Visiting Scientists who have completed their training at NIH, and have either returned home to their home countries or have started a new job outside NIH.

If you would like to contribute or knows someone else who does, please send an email to the Newsletter Editor at ongh@mail.nih.gov

Do you know…? The NIH Work/Life Center

The NIH Work/Life Center (WLC) exists to help you balance the increasing demands of your work with your personal interests and responsibilities. Our goal is to increase employee wellbeing, thereby improving the quality of work and the quality of life at the NIH as a whole.

The WLC values a workplace in which employees are given the resources, flexibility, and trust they need to exercise personal responsibility and self-discipline in managing their careers and their personal lives. We view ourselves as change agents, and seek partnerships and collaboration that will make the National Institutes of Health a leader in quality of work life.

We believe that this emphasis on quality of work life will benefit the NIH as a whole by enhancing recruitment efforts and increasing job satisfaction, retention, and productivity in our current workforce.

For more information about the services offered by the Work/Life Center, please refer to their website at http://wlc.od.nih.gov.

The NIH Work/Life Center has a full-time onsite career consultant (in our offices in Building 31), but we also have two part-time career consultants covering other NIH locations. These include Executive Plaza North, 6001 Executive Boulevard, Rockledge II, and NIEHS in North Carolina. For information about this service, visit our website at http://wlc.od.nih.gov/careers/services.asp. Please contact the Work/Life Center at 301-435-1619 (TTY 301-480-0690) if you would like to schedule an appointment.

Temporary relocation of NIH WLC during renovations to their office in Building 31:

The NIH Work/Life Center is temporarily moving to EPN/111 while their office in Building 31 is undergoing renovation. The center anticipates being in EPN until the end of October, but want to assure you that most services will continue to be provided. Their contact information will remain the same except for the address change.

Please check their website regularly for updates on their services and contact details. New materials will be added to their website over the next few months and a new quarterly newsletter is being planned.

National Institutes of Health Visiting Fellows

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The NIHVFC is a self-governing body serving the interests of visiting fellows in their transition to life after the NIH by working to create opportunities for visiting fellows to maintain continuity in their research upon returning to their home countries.

We are on the Web!
http://felcom.nih.gov/NIHVFC