Responsible Federal Oversight of the New Human Biotechnologies

Opportunities for the New Administration

Center for Genetics and Society

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INTRODUCTION

Over the past eight years, policy efforts to address the new human biotechnologies have been stalemated by partisan polarization. The new administration has an opportunity to help put this divisive past behind us. It can work to ground the public debate on these issues in fundamental values shared by the great majority of Americans, and it can develop policies that promote new biomedical research and applications while ensuring that they support rather than compromise individual and societal well-being.

Americans support a principled, common-ground position on issues involving the new human biotechnologies. They want treatments for diseases, but they also want strong public sector oversight to make sure these are safe, affordable and accessible to all, and that research activities don't compromise deeply held values of human rights, social justice and human dignity.

The new human biotechnologies, including research and applications in the areas of genetics and assisted reproduction, have potential for both great good and great harm. If properly used they could lead to advances in medical knowledge and new ways of treating disease. If misused, however, they could harm research subjects and patients, and exacerbate societal inequities and inequality.

These technologies are being developed very rapidly. Both policy makers and the general public find it difficult to keep pace with new developments. Structures of regulatory oversight are either outmoded or lacking altogether.

This document recommends ways in which the new administration might address immediate policy opportunities, reshape the public debate about human biotechnology to more deeply reflect widely shared values, and prepare to make best use of additional policy opportunities over the coming four years.

OPPORTUNITIES FOR POLICY ACTION NOW

LIFT RESTRICTIONS ON FEDERAL FUNDING FOR STEM CELL RESEARCH

A presidential directive lifting current restrictions on federal funding for embryonic stem cell research should be issued at the earliest opportunity. It should clearly establish that federal funds will be available for work on stem cell lines that have been derived in accordance with established guidelines. Most important among these are that the stem cell lines be produced using embryos created but not needed for reproductive purposes, and that informed consent for stem cell derivation be given by those whose gametes were used in the creation of the embryos.

ENSURE COMPREHENSIVE FEDERAL OVERSIGHT OF STEM CELL RESEARCH

The new administration should work with Congress on legislation that codifies federal funding for stem cell research along the lines outlined above, and, in broad terms, requires effective regulatory oversight. The Congressional directive for stem cell research standards should inform regulations that are subsequently developed by the National Institutes of Health. These may be based on the voluntary guidelines issued by the National Academies in 2005 and amended in 2007 and 2008. Legislation should specify that stem cell research regulatory standards are enforceable rather than voluntary, and that they should apply to all research. The Stem Cell Research Oversight (SCRO) committees recommended by the National Academies should be made accountable to a federal oversight authority, as are the Institutional Review Boards that currently oversee human subjects research. Proposals for stem cell research involving somatic cell nuclear transfer should be subject to particular scrutiny, given the special risks involved and the likely availability of induced pluripotent stem cell techniques for deriving disease-specific and patient-specific stem cell lines.

PROHIBIT HUMAN REPRODUCTIVE CLONING

The new administration should work with Congress on legislation prohibiting human reproductive cloning. Opposition to reproductive cloning is nearly unanimous among scientists, health professionals and the general public. As of November 2008, 59 countries have adopted legislation banning it, including those with the most robust biomedical research sectors. Of the 30 member countries of the Organization of Economic Cooperation and Development, fully 29 have banned human reproductive cloning, with the United States as the lone holdout. Bills prohibiting reproductive cloning have been introduced by Senators Dianne Feinstein (D-CA), Edward Kennedy (D-MA) and Tom Harkin (D-IA), among others. A clear, permanent ban on reproductive cloning, including explicit sanctions for those who seek to violate it, is needed now to help build public confidence in the development of new biotechnologies to address legitimate medical needs.

OPPORTUNITIES TO RESHAPE THE DEBATE

ENCOURAGE DEEPER UNDERSTANDING OF THE INDIVIDUAL AND SOCIETAL BENEFITS AND RISKS OF THE NEW HUMAN BIOTECHNOLOGIES, GROUNDED IN WIDELY SHARED VALUES

Although Americans hold differing views on many issues involving human biotechnology and bioethics, there is common ground in the desire to safely and effectively treat disease and alleviate suffering. Similarly, while Americans are well aware of the many ways in which science and technology have enriched our lives, few believe that the development and promotion of powerful technologies that pose risks as well as benefits should be left solely to researchers and entrepreneurs.

The tendency to interpret sentiment about these issues through a simplistic "blue/red" or "liberal/conservative" framework misrepresents the true state of American opinion. The great majority of Americans want thoughtful discussion of the benefits and risks of these technologies, as well as of their wider societal implications. And the great majority are more than open to responsible middle-ground policy options.

As a case in point, many conservatives who oppose abortion are willing to support properly justified and carefully regulated embryonic stem cell research. Similarly, many liberals who affirm a woman's right to end an unwanted pregnancy are deeply concerned about genetic technologies that could lead to new forms of discrimination and inequality, violate human rights, or open the door to neo-eugenic beliefs and practices.

The new administration is uniquely positioned to reach beyond the polarized framework through which human biotechnology policies have been understood, and to formulate a new framework that more fully reflects the values and beliefs shared by the great majority of Americans.

ENGAGE A WIDER RANGE OF VOICES IN THE PUBLIC DIALOGUE ON HUMAN BIOTECHNOLOGIES AND THEIR CONSEQUENCES

If the debate over the new human biotechnologies is to be reshaped in a way that resonates deeply with the American people, it will need to involve a wider range of voices than has been heard to date. Debate on these topics has been largely driven by religious conservatives, biomedical researchers, academic bioethicists and the commercial biotechnology sector. Additional constituencies that need to be represented include women's and children's health advocates, public health leaders, advocates for civil and human rights and racial and economic justice, representatives of people with disabilities, and leaders from the full range of religious traditions.

Such constituencies should be represented in all councils, committees and task forces that deal with human biotechnologies and bioethics. Their inclusion will enrich deliberations, reflect the different ways in which biotechnology research and applications affect different communities, and bolster public acceptance of any recommendations that are made. In addition, the new administration should draw on innovative communications technologies to encourage expanded and truly inclusive public participation in dialogues about the proper development and use of human biotechnologies. Further, the administration should review proposals for establishing a high-level national panel or other body, representing all stakeholders, charged with assessing the implications of new and proposed human biotechnologies and, where appropriate, recommending courses of action.

OPPORTUNITIES OVER THE NEXT FOUR YEARS

This section highlights issues likely to figure prominently in the public debate over the coming four years. The Center for Genetics and Society is preparing a full report on these issues, including discussion of specific policies intended to address them.

HUMAN RIGHTS, CIVIL LIBERTIES AND RACIAL JUSTICE

In response to concerns about the potential for genetic discrimination in employment and health insurance, the 110th Congress passed the Genetic Information Nondiscrimination Act (GINA). This was an important and long overdue policy action.

However, the rapid growth of raw genetic data, and their often simplistic and sensationalist interpretation by some commercial interests, journalists, and researchers, has the potential to encourage further discriminatory attitudes and practices. In particular, claims to have identified causal links among genetic variations, purported categories of racial identity, and particular behaviors and traits, are fraught with risk. The Food and Drug Administration has already approved one drug as a race-specific treatment for African Americans with heart failure, despite flawed scientific evidence for its racial specificity.

DNA forensics has become an important tool of law enforcement. But the inclusion and permanent retention of DNA samples from those arrested but never convicted raises concerns about civil liberties and, because of the disproportionate representation of minority communities in the criminal justice system, about racial justice. Such considerations recently led the European Court of Human Rights to rule against similar practices in the United Kingdom.

If we are to fulfill the promise of human biotechnologies, we cannot forget the sordid history of their past misuse. In the United States the first half of the last century was marked by the promotion of eugenic practices, including forced sterilization of people with “undesirable” traits and covert medical experimentation on vulnerable populations. New and strengthened US federal policies will be needed to ensure that human biotechnologies are not used, intentionally or otherwise, to undermine civil liberties or reinforce racial discrimination or inequity.

CONSUMER PROTECTION AND COMMERCIAL REGULATION

Markets play a necessary and vital role in realizing the promise of human biotechnologies, but aspects of commercialization and market dynamics raise serious concerns. Changes in patent policies and other intellectual property law, and career practices among scientists, have led to a steady growth in the extent to which market mechanisms determine the course of human biotechnology research and applications.

Today a large number of biotechnology researchers, including many working at public universities and receiving federal funding, are closely involved with private companies as founders, directors, shareholders and consultants. Many observers have noted the dangers to both the public interest and research outcomes that are posed by conflicts of interest and the dearth of disinterested scientists that now mark the life sciences, and have called for federal policies to address this.

In response to the rapidly expanding market in direct-to-consumer genetic tests, health professionals, genetic counselors, regulators and others have questioned the tests' accuracy and clinical validity, and have expressed concerns about misinterpretation. Dozens of companies are also marketing even more problematic direct-to-consumer genetic tests for non-medical traits.

Many Americans question patents on genetic sequences on the grounds that these are not inventions but discoveries. A bipartisan bill introduced during the 110th Congress would end the issuance of new human gene patents, and let existing ones gradually expire.

The role that inadequate regulation and oversight played in the current financial crisis provides a cautionary lesson for human biotechnology policy. Responsible public policies can prevent or minimize harmful outcomes caused by market excesses.

OVERSIGHT OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Over the past three decades assisted reproductive technologies (ARTs) have helped millions of people fulfill their desires to have biologically-related children. But federal regulatory oversight of these activities in the United States is widely acknowledged to be inadequate, and ethical and medical guidelines provided by trade organizations are regularly flouted. Basic data are lacking on health outcomes for women using many ARTs, children that result from them, and third parties involved in gamete donation and the practice of carrying and giving birth to children for others. Policies are needed to ensure that safe and ethically acceptable fertility treatments are widely available regardless of marital status or sexual orientation.

Several ART practices raise concerns about their broader societal impacts. Among these are the expanding use of embryo screening for non-medical sex selection and its proposed use for other non-medical purposes; the lack of adequate protections and consistent regulation for commercial surrogacy and egg retrieval; and the growing practice of "reproductive tourism," in which people cross borders in search of looser rules and lower prices. In India, where brokers recruit poor women from rural villages to serve as surrogates for Americans and Europeans, reproductive tourism has grown rapidly into a half-billion dollar a year business.

In the United States the current economic downturn has produced an increase in the number of young women trying to earn money by carrying a pregnancy for or providing eggs to others. Campus newspaper and subway ads offering tens of thousands of dollars for egg providers are routine. Many observers are concerned about the commercialization of human reproduction, and worry that these payments constitute undue inducements to put one's health at risk.

The United States is known as the "Wild West" of assisted reproductive technologies. In this era of globalization, regulation and oversight of what many call the "baby business" is urgently needed.

OVERSIGHT OF BIOMEDICAL RESEARCH AND APPLICATIONS

The need for the highest standards of ethical conduct and oversight in research that involves human subjects is widely recognized. The increasingly common sponsorship of clinical trials by pharmaceutical companies and contractors rather than by academic health centers or teaching hospitals, and the fact that researchers are increasingly hiring commercial firms to assess their own compliance with ethical guidelines, raise concerns about conflicts of interest and inappropriate commercial pressures.

Technologies that involve manipulation of the human genome raise profound questions about the proper limits of research and applications. New methods to produce stem cells for valuable medical research by reprogramming ordinary body cells could also be used in efforts to alter the genetic makeup of human eggs and sperm for the production of "designer babies." Sports professionals are concerned that genetic procedures developed to address medical conditions could be misused to allow athletic gene-doping. The creation of human-animal chimeras that may be useful for research purposes raises strong concerns when researchers propose creating animals that might exhibit what appear to be human cognitive traits.

Non-genetic biomedical research and applications also raise important societal questions, as evidenced in recent controversy about whether to sanction the use of cognitive-enhancing pharmaceuticals by healthy individuals, including college students.

The inherent blurriness of the line between therapeutic and non-therapeutic uses of biotechnology makes regulation and oversight of many biomedical applications challenging. Considered public policy, along with a robust public dialogue, will be needed to effectively address this challenge.

OTHER EMERGING BIOTECHNOLOGY CHALLENGES

Many additional new biotechnologies have great implications for the health and well-being of individuals and society. Synthetic biology and nano-biotechnology are still in their early developmental stages but could dramatically transform the ability of humans to manipulate the fundamental processes of the natural world. While beneficial applications can easily be imagined, the development and widespread availability of these technologies could at the same time pose real risks to human health, biosecurity, and environmental safety.

Despite the desire of many Americans to avoid eating food derived from genetically modified and cloned animals, commercial firms are proceeding with plans to market food derived from these sources, while opposing federal legislation that would require such foods to be labeled.

Other scientists and commercial firms are trying to create markets for cloned and genetically modified pets, despite widespread public opposition. Proposals to save endangered species and resurrect extinct species through cloning have been widely rejected by environmental, animal welfare and wildlife conservation organizations, yet continue to be promoted.

Rapid developments in neuroscience have spawned scientific and commercial initiatives to develop and promote pharmaceuticals, devices and procedures that could be used to profoundly alter the nature of human thought, memory, sensation and identity.

Many applications of these emerging technologies raise concerns that are new to the human experience, let alone to policy makers. Good decisions about whether and how they should be used require meaningful involvement by broad sectors of society, well upstream of their full development and use.

INTERNATIONAL COOPERATION

Policies adopted by national governments and intergovernmental organizations worldwide point to an emerging consensus regarding the most consequential new human biotechnologies. There is widespread support for stem cell research involving embryos created but not used in the course of assisted reproduction procedures, for the use of embryo screening to avoid passing serious diseases to offspring, and for new biotechnology-based therapies and medicines to prevent, treat and cure disease.

At the same time there is widespread opposition to human reproductive cloning, inheritable genetic modification, and embryo screening for non-medical purposes. There is also widespread concern about the use of genetic and reproductive technologies for so-called "enhancement" purposes and about the commercialization of human reproductive activities. Many countries, including the United Kingdom, Canada, France, Germany, and Japan, have successfully established oversight and regulatory structures to address the sorts of concerns noted in this document.

Further, there is widespread agreement that global biosecurity requires, at a minimum, that the 1972 Biological and Toxins Weapons Convention be modified to include effective inspection and verification measures.

The new administration has an opportunity to develop policies for the United States that reflect both our own values and the emerging international consensus, and to begin working with other countries to ensure that new human biotechnologies further rather than undermine health and safety, human rights, social and economic equity, and human dignity, individuality and diversity.

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ABOUT THE CENTER FOR GENETICS AND SOCIETY

The Center for Genetics and Society is a nonprofit public affairs organization working to encourage responsible uses and effective societal governance of the new human genetic and reproductive technologies. The Center works in a context of support for the equitable provision of health technologies domestically and internationally; for women's health and reproductive rights; for the protection of our children; for the rights of the disabled; and for precaution in the use of powerful new technologies.

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