

The Human Genome Project and ELSI

The Imperative of Technology and the Reduction of the Public Ethics Debate

by

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ABSTRACT

In the past century, a number of technological projects have been undertaken as grand solutions to social problems. In the so called century of biology, this technological world view focuses on biomedical advances. The President of the United States, who once called for nuclear weapons and space exploration, now calls for new biotechnologies, such as genomics, individualized medicine, and nanotechnology, which will improve the world by improving our biological lives.

Portrayed as the Manhattan Project of the late 20th Century, the Human Genome Project (HGP) not only undertook the science of sequencing the human genome but also the ethics of it. For this thesis I ask how the HGP did this; what was the range of possibilities of goods and evils imagined by the HGP; and what, if anything, was left out. I show that the Ethical, Legal, and Social Implications (ELSI) research program of the HGP was inscribed with the competencies of the professional field of bioethics, which had lent itself useful for governing biomedical science and technology earlier in the 20th century.

Drawing on a sociological framework for understanding the development of professional bioethics, I describe the development of ELSI, and I note how the given-in-advance boundaries between authorized/unauthorized questions shaped its formation and biased technologically based conceptualizations of social problems and potential solutions. In this sense, the HGP and ELSI served both as the ends of policy and as instruments of self-legitimation, thus re-inscribing and enacting the structures for these powerful sociotechnical imaginaries.

I engage the HGP and ELSI through historical, sociological, and political philosophical analysis, by examining their immediate context of the NIH, the meso level of professional/disciplinary bioethics, and the larger context of American democracy and modernity. My argument is simultaneously a claim about how questions are asked and how knowledge and expertise are made, exposing the relationship between the HGP and ELSI as a mutually constitutive and reciprocally related form of coproduction of knowledge and social structures.

I finish by arguing that ELSI is in a better position than bioethics to carry out the original project of that field, i.e., to provide a space to elucidate certain institutionally authorized questions about science and technology. Finally, I venture into making a prophecy about the future of ELSI and bioethics: that the former will replace the latter as a locus for only formally rational and thin ethical debates.

DEDICATION

To Molly and my family, without whom...

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TABLE OF CONTENTS

	Page
LIST OF FIGURES.....	vii
CHAPTER	
INTRODUCTION	8
1. FORMAL AND SUBSTANTIVE RATIONALITY AND BIOETHICS	16
2. MAPPING THE HUMAN GENOME: A BRIEF HISTORY OF THE HGP AND THE EMERGENCE OF THE ELSI PROGRAM	18
3. FUNDAMENTAL CHALLENGES FOR THE HGP: FROM THE PHILOSOPHY OF BIOLOGY TO EUGENICS.....	25
4. COMMON CRITIQUES MADE ABOUT ELSI: JAMES WATSON’S POLITICS AND PUBLIC RELATIONS	34
5. COMMON CRITIQUES MADE ABOUT ELSI CONT.: POLICY OUTCOMES VS. CULTURAL RELEVANCE	37
6. SUBSTANTIVE RATIONALITY IN DOUBLE JEOPARDY: BOTTLENECKING THE ELSI AGENDA	40
7. PROGRESSING WITH THE ELSI PROGRAM: THE VICTORY OF FORMAL RATIONALITY.....	50
8. BIOETHICS AND PARTISAN POLITICS: WHAT ELSI CAN DO THAT BIOETHICS CANNOT	54
9. CONTRIBUTING TO THE THINNING OF THE PUBLIC DEBATE	59
REFERENCES	63
BIOGRAPHICAL SKETCH	67

LIST OF FIGURES

Figure		Page
1.	The formal structure of ELSI	23
2.	Policy development	28
3.	The professional association of ELSI researchers	36
4.	The methods of ELSI	43
5.	List of ELSI planning moments and evaluation reports	51

Introduction

In the past century, a number of technological projects have been undertaken as grand solutions to social problems. The stories are all too familiar. Conflicting political ideologies that could result in a full scale world war were kept in check by the development of the atomic bomb, sparing the world of the same fate of the first and second wars. Space exploration was another frontier of technological advance rationalized in terms of social progress. Somehow looking up to the skies was supposed to teach us something about things down here in the world.

These stories are embedded in our imaginations in a number of ways. In the realms of art and fiction, perhaps most famously, Stanley Kubrick's masterpieces share a common theme: man designs machinery that functions with perfect logic to bring about a disastrous outcome. But things are more subtle in real life. The year 2001 has come and gone, and there is no super computer like Hal 9000. There is no literal doomsday machine either. For that matter, there has not been annihilation of the earth, evidently. But this does not mean that Kubrick's imaginations are simply fictional. As a caricature which accentuates real life's features, Kubrick's films highlight real though subtle technologically centered social processes.

The bad news is that the subtlety of reality is more treacherous than the explicit dangers of fictional scenarios. After all, Dr. Dave Bowman could always look over his shoulder to make sure that Hal was not behind him. To escape from Hal, Bowman simply had to find the master controls of the spaceship and push the

“off” button of the computer. I could go on to describe how one ought to deal with the Soviets’ doomsday machine in *Dr. Strangelove*, but I think one gets the picture. In reality, though, it is not clear what one ought to do. The imperative of technology is not reduced to a machine located in a building or in some other physical space. The imperative of technology is located in the collective imagination, and in the systems of abstract knowledge employed by our institutions of power and governance. It is as much about making the world in which we live in as it is a product of the world. As Michel Foucault points out: like it or not, we are a part of it. There is no looking over one’s shoulder.

It is also not clear if this technological imperative is good or bad, or in between –only complicating things a bit more. As it turns out, it is often the case that science and technology actually get things done. Countless are the devices, treatments, and bits of knowledge that improve, if not save, human lives. Yet, the world is in many ways still a place full of suffering and violence (broadly understood). And it is not obvious, though some disagree, that things are better in the age of science and technology than they have been before. However, regardless of how things compare with the past, it is clear indeed that the world is not a perfect place. In the age of modernity, science and technology, why is that? One way to think about this question is quantitatively, positivistically, and optimistically. Give science and technology more time, more science, and more technology, and we will get there.

The approach mentioned above misses the opportunity to ask more fundamental questions about the nature of the problem – which might just be

related to a technological world view – and how to frame it. A more fundamental critique ought to point out that how we ask such questions (e.g., “is tech good or bad?”) matters. What goods and evils are imaginable within a technological imperative? How do we think of goods and evils in the space of technological imaginations? And, in the case of this thesis, how are the Human Genome Project (HGP) and ELSI noteworthy expressions of such imaginations?

Since the Manhattan Project, the United States has invested more in research and technology than any other country in history. In the so called century of biology, the technological world view has focused on biomedical advances. The most challenging problems are now the important problems of human health and wellbeing. The Manhattan Project of the late 20th Century was the HGP¹. The President of the United States, who once called for nuclear weapons and space exploration, now calls for new biotechnologies, such as genomics, individualized medicine, and nanotechnology, which will improve the world by improving our biological lives. Most strikingly, ethics became bioethics.

Focusing on the HGP’s experience with the Ethical, Legal, and Social Implications (ELSI) research program of the National Institutes of Health (NIH), I will argue that by reducing social and ethical concerns to narrowly defined downstream problems of technological endeavors, such as in the case of ELSI, the technocratic framework to understand and address social problems attempts to remain unchallenged. Furthermore, I will point to how this framework is a self-perpetuating world making enterprise with roots directly traced back to the

¹ The HGP was the outcome efforts to study DNA changes of atomic bomb survivors.

recombinant DNA technology controversies of the 1970's; additionally, this framework is connected in both directions to a more subtle underlying social process of the thinning of social debates on the ultimate goods for society –a process pointed out and lamented by such thinkers as Max Weber and Jürgen Habermas.

Just like its physical science counterparts, the HGP's promises were of revolutionary caliber. After the completion of the HGP, its proponents argued, medicine would be completely revitalized as the path for individualized health care and tailored life plans would be paved, and a great number of human diseases would be treated at their root causes: the genes. In some ways, the HGP has been fairly well documented. The physician Robert Cook-Deegan, for example, provides an accurate account of the history behind the HGP in the acclaimed book *The Gene Wars*. Special issues of *Science* and *Nature* have been dedicated to reviewing and reflecting on the HGP, usually marking important landmarks, such as the completion of the human genome in 2001, and the ten year anniversary of this accomplishment in 2011.

However, as I alluded to above, another important dimension of projects like the HGP has to do with how they relate with the ways in which modern, technocentric societies perceive and address complicated social and ethical problems. As I will argue, the HGP, through ELSI, not independently of a socio-cultural context, helped pave the way for imaginations of social problems and solutions as technological imperatives. In this sense, the HGP and ELSI served both as the ends of policy and as an instrument of self-legitimation; while these

powerful sociotechnical imaginaries (i.e., collective visions of good and attainable futures produced by science and technology) carry tacit, though rich prior normative commitments as the ends of the policies that enacted the HGP, social and ethical considerations were, on the other hand, reduced to a set of narrowly defined downstream problems, legitimizing the HGP through ELSI.

As the ELSI program evidences, one way that scientists, policymakers, and bioethicists, imagine and address social and ethical considerations relating to grand technological projects is by incorporating a social and ethical research component to address the downstream implications of the technology. Though a number of important studies have brought to the surface the tacit ways in which genomic paradigms of scientific and social research describe and characterize the self and society², in the following pages I examine ELSI – both as a research component of the HGP, as well as a concept of a research category, or quasi field of inquiry in science and technology – as a productive and important case for understanding the forces that re-inscribe and enact the structures for these powerful sociotechnical imaginaries.

Drawing on the sociological framework for understanding the history of bioethics developed by John Evans³, I describe the development of ELSI as a research community, and I note how the given-in-advance boundaries between authorized/unauthorized questions – which derive from the institutional position of ELSI within HGP – shaped the formation of this community. In other words,

² See, for example, Jenny Reardon's *Race to the Finish: Identity and Governance in the Age of Genomics*.

³ John Evans explores the social forces that have shaped bioethics in his book *Playing God? Human Genetic Engineering and the Rationalization of the Public Bioethical Debate*.

HGP ELSI is an institutional space for articulating and inscribing the questions and the community that could answer them, and these question framings persisted beyond the HGP because they were built into the competencies for the community it produced. Thus the preoccupations and discourses that were made off limits to critique the HGP (specifically as a genome research program, and more broadly as a technological solution to not necessarily technological problems) remain so because they were boxed out of ELSI as a research community.

With this in mind, I engage the HGP and ELSI through historical, sociological, and political philosophical analysis, by examining them in their immediate context of the NIH, the meso level of professional/disciplinary bioethics, and the larger context of American liberal democracy and modernity. While the questions addressed here are about the development of ELSI from a specific research program into a quasi field of inquiry in science and technology, the answers illuminate the ways in which technocentric societies understand and address social and ethical problems.

In my view, the ELSI program of the HGP helped establish a framework of genomic research and developed techniques for imagining particular kinds of futures within this framework, by defining the problems, principles and discourses within genomic research. Furthermore, and most importantly, the very ways in which ELSI is set up as a system of governance furthers the thinning of ethical debates on scientific research – providing a pathway for the original project of bioethics – while, at the same time, necessarily carrying tacitly inscribed imaginations of social problems and solutions. In this way ELSI

transcends the HGP, or any one technological project for that matter, simultaneously exposing that in another way social and ethical considerations are reduced to being sub-components of technological projects, focused on narrowly defined downstream problems. This is simultaneously a claim about how questions are asked and how knowledge is made, and a claim about how ELSI became a “machine” for “doing” ethical considerations. These modalities of ordering the work of ELSI (e.g. through agenda-setting) and of how to think about ethics are mutually constitutive and reciprocally related in a form of coproduction of knowledge and social structures.

While I situate ELSI within the larger field of bioethics, using Evans’s work as a foundation, I also offer a detailed account of the institutional history of ELSI within the NIH and the American scientific community to add an additional layer to Evans’s professional jurisdictional analysis. This, I believe, will be crucial for making full sense of ELSI as an intellectual, institutional and social enterprise, and for understanding its place in the larger field of bioethics, with its professional norms, shared views of the ends to be pursued, and prior normative commitments.

Finally, based on the professional jurisdictional forces that shaped bioethics to become a locus of formally rational deliberations in the life sciences (see section 1 below), combined with ELSI’s administrative shape as a formal research program, with accountability structures, gate-keeping, and the obligation to produce deliverables, I also argue that ELSI is in a better position than bioethics to carry out the original project of that field – i.e., to provide a space to

elucidate certain institutionally authorized questions in science and technology.

With this rationale, and based on the evidence I have identified in the course of my research and argument, I will venture into making a prophecy about the future of ELSI and bioethics, that ELSI, as a quasi field of inquiry in science and technology, will replace bioethics as a locus for formally rational and thin debates, while bioethics will become an arena for popular and substantially rational debates.

1. Formal and substantive rationality and bioethics

Because my argument relies heavily on the concepts of formal and substantive rationality used by Evans in explaining the development of the field of bioethics, it is appropriate that I spend some lines elucidating these modes of rationality, and how they relate to bioethics.

Referring to the work of the social theorist Max Weber, Evans explains that “a pattern of action is substantively rational if it implies ‘the criteria of ultimate ends’ or ‘ultimate values’ [Weberian terms] to acts or means” (Evans, 2002). Hence, a substantive debate would be on deciding what ultimate ends should be pursued, or, when in relation to the possible means to accepted ends, whether or not the means are consistent with the ends. In contrast to substantive rationality, formal rationality relates to rationality employed in figuring out what is the most effective means to a given end. Here the ultimate ends are not subjected to debate, and possible means to a previously committed end are debated in terms of their effectiveness in leading to that end. Formal rationality is, for Weber, an expression of the bureaucratization of reasoning, with rule commensuration as the modality for tethering mid-level decision-making to predefined rules and norms. This is important for Evans’ assessment of bioethics, and its relation to democratic pluralism.

As Evans points out, the field of bioethics was developed by a shift from substantively rational to formally rational social debates relating to science and technology. Evans does a lot of heavy lifting work to analyze this changing debate in relation to the pursued ends, means, and relationship between means and ends.

For now, however, it is enough to know that because of their place in American pluralist democracy (i.e., unelected individuals making normative judgments about science and technology), bioethicists found formal rationality the most appropriate and useful way to address social and ethical problems in science and technology. Hence, they adopted the ultimate ends (i.e., the principles of bioethics of autonomy, beneficence, non-maleficence, and justice) that they argued were universal principles they derived from the public.

With this brief background on formal and substantive rationality, and on how they relate to the development of the bioethics profession, we can proceed to see how the HGP formed its ELSI program, and how this initially narrowly defined program transcended into a larger field of inquiry in science and technology.

2. *Mapping the human genome: A brief history of the HGP and the emergence of the ELSI program*

The Human Genome Project (HGP) was an international scientific collaboration initiated in 1990. Its original goals were to analyze the structure of human DNA, determine the location of all human genes in the human chromosomes, and make the mapped human genome available for further specialized studies. Twenty years later, many countries have established human genome research programs.

The conceptual foundations for the HGP surfaced in the U.S. in 1985 when the Office of Health and Environmental Research (OHER) at the Department of Energy (DOE) proposed the Human Genome Initiative – an interest that grew out of an effort to study DNA changes of atomic bomb survivors in Hiroshima and Nagasaki. While there was strong resistance to a “mindless sequencing project” in the beginning (Cook-Deegan, 1995), the feasibility of the initiative was established through a number of conferences and meetings in the following years, and in 1990 the DOE and the National Institutes of Health (NIH) presented a joint HGP proposal to Congress. In fact, they pledged just the opposite of a mindless sequence of human DNA base pairs; the HGP promised nothing less than to revitalize medicine. Through the HGP, its proponents argued, the path for individualized medicine and genetically tailored life plans would be paved, with a great number of human diseases been treated at their root causes: the genes.

In that bid, the director of the National Center for Human Genome Research (NCHGR)⁴ of the NIH, the scientist James Watson, proposed ELSI on the basis that the promised scientific revolution caused by the HGP would precipitate a social revolution, and, with this in mind, the ethical, legal, and social implications of the HGP deserved to be paid attention with a special effort, and should be funded by the HGP itself (Watson, 2000). In this way, ELSI was a program reactive to a possible future, which it actually contributed to constructing. ELSI was supposed to help create a future, but one which was already constrained by a technologically based imagination, which was out of boundaries for ELSI to question.

Ratified by the United States Senate Subcommittee on Science and Space, during its hearings on the HGP in 1989⁵, the rationale for funding ELSI in the course of and within the HGP was just that early ethical, social and legal insight would predict and prevent – rather than respond post hoc – the ethical, social and legal problems that the research, technologies, and treatments coming out of mapping the human genome would encounter. ELSI, then, was expected to provide policy options to deal with narrowly defined, downstream problems.⁶

Watson's initiative to incorporate the ELSI program in the structure of the NCHGR can also be read in a more cynical light. It anticipated Congressional reservations about the HGP, including pressure for an ethics component to the

⁴ With a growing interest in genomic research, the NCHGR gained status of full institute within the NIH in 1997, becoming the National Human Genome Research Institute (NHGRI).

⁵ Senate Committee on Commerce S and Transportation. Human Genome Initiative. Hearing T. Subcommittee on Science, and Space; 1989.

⁶ Wolfe A. Federal policy making for biotechnology, executive branch, ELSI. In: Murray TH, Mehlman MJ, editors. Encyclopedia of ethical, legal and policy issues in biotechnology, vol. 1. New York: Wiley; 2000. p.234–40.

research from then Senator Albert Gore. Watson bluntly advised the DOE that if research on ethics was not a part of that department's genome program, "Congress will chop your head off!" (Cook-Deegan, 1995). In fact, Watson assumed a Godfather-like stance: "keep your friends close, but keep your enemies closer"; that is, if the HGP was going to be the object of ethical, social and legal scrutiny, the HGP itself should make efforts to manage that. But the politics of HGP funding, including Watson's cynicism, are not sufficient to explain the form that ELSI ultimately took, let alone why ELSI is important, and why it has become a model for incorporating ethical considerations in subsequent technoscientific projects.

The first draft of the human genome was published ahead of schedule, on 16 February 2001, simultaneously by the NIH and Celera Genomics in the journals *Nature* and *Science* respectively. Francis Collins, of the National Human Genome Research Institute, and Craig Venter, of Celera, appeared alongside President Bill Clinton and British Prime Minister Tony Blair to announce the completion of a preliminary draft of the human genome. Later that year, Venter and Collins also discussed their findings at the American Association for the Advancement of Science's annual meeting. One question that was also outside the boundaries of ELSI was just how did genomics come to have such a gigantic public presence? (Maienschein, 2003).

The concept of merging ethical deliberation into the research agenda of a large technological initiative was not completely new. As the bioethicist John Fletcher has pointed out in a brief history of bioethics at the NIH, bioethical

commissions have been involved in reviewing and drafting scientific investigations in the NIH for a relatively long time when compared to the development of the ELSI program (Fletcher, 1995). The earliest example of this was the Clinical Research Committee (CRC) which reviewed all studies with volunteers as early as 1953. Since the principles that were been used by the CRC, as well as the professionals involved in that committee (virtually all physicians effectively asking medical questions), were very much different than what bioethical bodies use today, the CRC was not the sort of thing that we would recognize today as bioethics. Nevertheless, Fletcher points to, in a sense, the institutional structure for governing bioethical already taking shape.

Besides the CRC, the Recombinant DNA Advisory Committee (RAC), initiated in 1974, is among the most studied cases of ethics bodies in the NIH. This is so in part because it has become a widely used model for incorporation of ethical and social concerns in the very research that is meant to come under critical view, and it has actually been directly compared with the ELSI program. In many ways, like I will explore below, the RAC, including the Asilomar meeting of 1975, has important similarities (e.g., anticipatory governance) and differences (e.g., regulatory restraints reduced to technical risk assessment) with the ELSI program of the HGP.

Though ELSI was not the first ethics program embedded in its correspondent scientific project, it is a special and important case in the history of American science governance in many ways. Thus, the question of whether ELSI was the first (nominal) ethics program is irrelevant. ELSI is very different from

the CRC and the RAC, despite also being an attempt by the NIH to rationally contend with ethical questions surrounding medical science and technology. First, it is the largest and most well-funded⁷ research program of its kind. But most importantly: second, its structure (see Figure 1 below) is different from the previous programs in relevant ways. For example, it involves both intramural and extramural research projects, and it includes a wide variety of researchers, including from the humanities and social sciences; and third, it addresses questions in clinical bioethics, research bioethics, and wider policy issues. The other NIH initiatives tend to be intramural programs, smaller in the scope of their questions and funding, and they tend to involve mostly scientists. Thus, the implementation of the ELSI program represents, in my view, an important moment in American science governance. It was a way to respond to a wide range of concerns involving a big scientific project. Extramural research involving ethical, social, and legal concerns would all come under the umbrella of the NIH. The rationalization of the public bioethical debate, i.e., the professionalization of bioethics, was not enough. Ethical questions had to be boxed-in more concretely than they were in the abstract system of knowledge of the bioethics profession. In the following pages I will attempt to explain why.

Furthermore, the HGP's ELSI program effectively became a widely used model for integrating ethical, social, and legal research into technological

⁷ Between 3% and 5% of the total budget of the HGP (roughly US\$150 million from 1989 to 2003) was allocated to ELSI.

projects. In some cases (e.g., the Environmental Genome Project⁸), subsequent ELSI programs reproduced virtually the same kinds of questions, discourses, and communities. Interestingly, in other cases the new versions of the ELSI program were pointedly contrasted with the HGP's ELSI program's focus on the downstream consequences of technological change, (e.g., NSF's nanotechnology initiative⁹).

Fig. 1: The formal structure of ELSI: ELSI program announcements:

- First Broad ELSI PA (1990)
- ELSI R01 and R25 PA (1996)
- ELSI R01, R25 and R03 separate PAs (2000)
- ELSI R01 and R03 separate PAs (2004 and 2008)
 - No new Education grants (R25) accepted after 7/1/04
- ELSI R01, R03 and R21 separate PAs (2011)

Program Announcements solicit investigator initiated research. The priorities outlined in the PAs have been derived from the Institute's regular strategic planning process (see sections 5, 6 & 7 below), which incorporates input from external advisors.

2000 PA was based on goals from 1998 Strategic Plan, "New Goals for the US Human Genome Project: 1998-2003," (*Science* (1998) 282:682-689).

2004 and 2008 PAs based on goals from 2003 plan, "A Vision for the Future of Genomics Research," (*Nature* (2003) 422:835-847).

2011 PA based on Genomics & Society section of latest Strategic Plan, "Charting a course for genomic medicine from Base pairs to bedside," (*Nature* (2011) 470:205-213).

R01 Regular Research Grants

R03 Small Research Grant, less than 50K each year for two years

R21 Exploratory, higher risk research, no more than \$275K over two years, with no more than \$200K in a single year

R25 Education grants

⁸See, for example, the National Institute of Environmental Health Sciences' ELSI grantees webpage, at <http://www.niehs.nih.gov/research/supported/programs/egp/elsi/grantees/index.cfm>, as of March, 26, 2012.

⁹ See, for example, Fisher, Erik. "Lessons learned from the Ethical, Legal and Social Implications program (ELSI): planning societal implications research for the National Nanotechnology Program." *Technology in Society* (2005): 27, 321-328.

The ELSI case has been studied and criticized many times and in many ways. From the beginning, questions were raised about the capacity of ELSI researchers to address the larger, conceptual questions that could potentially present fundamental challenges to the HGP. That is, ELSI was a question for the HGP, as opposed to the HGP being a question for ELSI. Additionally, the lack of critical distance needed to thoughtfully engage with the HGP was noted by a number of observers, as, obviously, ELSI insiders would be criticizing the very program that paid for their salaries. Furthermore, as Watson's motivations for setting up ELSI were, at best, suspicious and political, the ELSI concept is haunted to this day by the notion that it is just window-dressing.

I will argue, on the other hand, that the driving social forces that have and continue to shape ELSI are more profound than the mere lack of critical distance, or a political move by a savvy scientist. In my view, a more profound critique of ELSI, the one to which my investigation contributes, is the argument that what this form of funding has done "is to promote the distressing general tendency to divide the project into 'science' and the 'implications' of that science" (Lindee, 1994), especially while simultaneously carrying certain normative social and ethical commitments from the get go of the technological project. I will point to how the NIH expanded the breadth of its claim to technocratic authority by claiming that the public need not worry about the societal aspects of genome research either. After all, the NIH took on the responsibility to figure this out, and it would be guided by the findings of its ELSI experts. But who counts as ELSI experts? Who gets to say? And what (who) is left out?

3. *Fundamental challenges for the HGP: From the philosophy of biology to eugenics*

In some ways what is left out of the ELSI agenda was obvious from the beginning. While the HGP presented many fundamental challenges and shortcomings, especially in light of the grand promises to revolutionize medicine made in its name, it was never a question for ELSI to consider whether focusing on mapping the human genome was something worth doing in the first place. In fact, the first director of the ELSI program, Eric Juengst, told me during an interview that that's basically right; everybody knew that ELSI was not meant to ask questions about the worthiness of the HGP endeavor in terms of the investment (financial, social, cultural) that was been made in it (Juengst, 2011). This would be what I call “fundamentally challenging the HGP”, versus predicting problems that the HGP might encounter downstream, hoping to prevent these problems so that the HGP can go on more smoothly.

Themes from which to fundamentally challenge HGP, whether ethically or epistemically (or interesting combinations of what it meant for knowledge and human self-understanding), are not uncommon. Consider, for instance, what the philosopher of biology and bioethicist, Jason Robert, has argued. Robert writes that even the realization that it is in the post-genomic era that the real work starts – i.e., to transverse between a genome sequence and a complex, functional organism, as well as complex determinants of health – is not enough¹⁰. In

¹⁰ Many have comprehended that the early promises of the HGP are far from being realized – if they will ever be able to be fully realized – from simply mapping all nucleotide bases in a given

Robert's words, "taking development into account is not the same as taking development seriously":

To take development seriously is not to hide behind metaphors of the magical powers of genes – they 'instruct' or 'program' the future organism. To take development seriously is rather to explore in detail the processes and mechanism of differentiation, morphogenesis, and growth, and the actual (not ideologically or perhaps technologically inflated) roles of genes in these organismal activities. Despite the existence of what has come to be known as the 'interactionist consensus', according to which everyone agrees that both genes and environments 'interact' in the generation of organismal traits, my claim is that those swept up in genomania have nonetheless failed to take development seriously. (Robert, 2004)

This line of criticism exemplified here by Robert, however, has never made into the ELSI program. Placing so much attention and collective hope onto the HGP is at the core of Robert's criticism, as well as that of many other scholars who criticize the genetic determinism discourse fundamental to the grandiose promises made by the early proponents of the HGP. It is also notable that similar criticisms have come after the fact (i.e., the completion of the human genome map) from a number of scientists who now point to proteomics¹¹, epigenomics¹², etc.

Additionally, in discussing the age of genetic determinism, culminating with and perpetuated by the HGP, the bioethicist Inmaculada De Melo-Martin

human being, let alone an abstract human genome. The discourse along the lines of "the real work has just began" is now widely used by the NHGRI.

¹¹ Like genomics, proteomics refers to large scale, whole-genome study, only in this case of proteins (not DNA base pairs), as the main components of metabolic pathways.

¹² Also like genomics, epigenomics refers to a large scale, whole-genome study, only this time about the set of epigenetic modifications on the genetic material.

underscores the famous point made by the French social theorist Michel Foucault in regards to “biopower”, and more broadly to “power”. By calling into attention widely used but nevertheless unrepresentative (e.g., Huntington’s disease) and over simplified (e.g., simplified discussions of testing for BRCA1 and 2 mutations for breast cancer) cases of genetic diseases to discuss bioethical concepts, De Melo-Martin points out how, “bioethicists might inadvertently be promoting genetic determinism: the idea that genes alone determine human traits and behaviors” (De Melo-Martin, 2005). Here it is important to highlight that not only are bioethicists reflecting an institutionally predetermined discourse by focusing on these unrepresentative and over simplified cases, it is also true that in order to even criticize the perceived problem one has to engage with that discourse; thus, in a way, joining the paradigm. Genetic determinism becomes, at least in some way, a preoccupation for everyone, whether by worrying about what one’s genes have in store for that person, or worrying about the detrimental effects of the erroneous notion of genetic determinism. Referring back to Foucault, the debate among these different actors, shaped by a particular discourse, forms a field in which renegotiations of power and authority are always already constrained.

The German sociologist and philosopher, Jürgen Habermas, has also considered the advances of genetic and genomic science and technology in relation to more fundamental questions of human self-understanding and nature, and its impact on our species-ethics¹³. Though Habermas was probably not interested in applying for ELSI grants (and probably too ineligible for ELSI grant

¹³ See, for example, Habermas’s *The Future of Human Nature*.

reviewers), the fact that his influential voice picked up on fundamental challenges for the HGP is additional evidence that there was indeed an interest in engaging the HGP with more upstream based considerations. Though, jokes aside, Habermas' approach and preoccupations were indeed ineligible for ELSI grant reviewers not because of the usual density of his writing; but because they were out of boundaries for the competencies built into ELSI, thus effectively rendering Habermas approach to ethics effectively invisible as far as ELSI goes.

As with Robert's critique, criticizing the HGP in terms of the problematic implications that the ideology of genetic determinism might have for individuals' wellbeing and for our public policies, as well as the power dynamics created by the HGP, are not themes encountered in the abstracts of ELSI funded projects. ELSI's goal was to identify specific, narrow and practical problems, and prevent them by developing policy solutions (see Figure 2). Furthermore, it was also not part of the ELSI task, in light of these critiques, to attempt to introspect in what ways genetic/genomic paradigms are actually useful however imperfect.

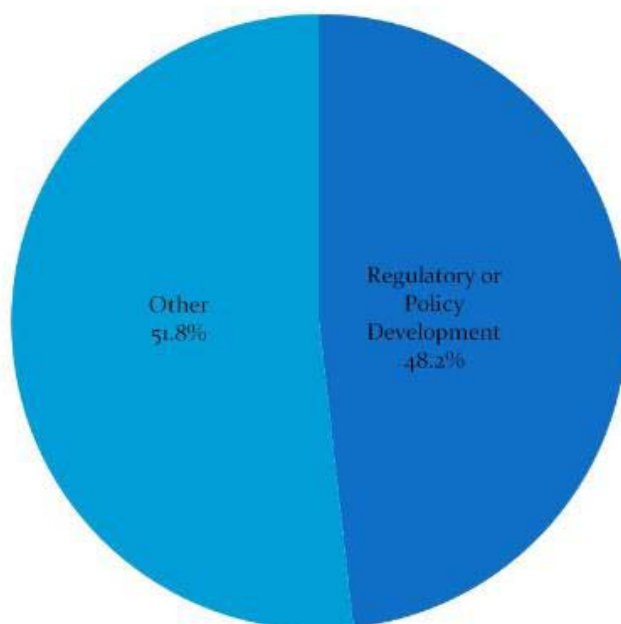


Figure 2: An analysis of 141 ELSI projects from 2005 - 2010 Fiscal Year (proportional to each year), in which only the abstract and specific aims components of the text were taken into consideration, shows that nearly half of the grants during this time period were awarded to projects that included a regulatory and/or policy development focus. This is a very narrow definition of policy. If we take a broad view on ELSI research most of it is intended to ultimately inform the evolution of policy.

On the other hand, one line of critique that had the potential to fundamentally challenge the HGP, and that indeed received ELSI funding in the early years of the program, was the challenge of whether or not the HGP was a socially appropriate scientific priority in the context of race, class, genetic discrimination, and eugenics. Here two themes can be made distinct: 1) always in very narrowly defined and immediate ways, questions of justice and fairness in relation to the distribution of the burdens and benefits of the HGP were common topics funded by ELSI; and 2) the selection of particular genotypes for future generations with renewed anxiety about eugenics.

Questions of justice and fairness continue to be discussed by the ELSI program. As I write this, for example, the controversy involving the genetic testing of the Havasupai tribe by researchers at Arizona State University¹⁴ is fresh and sparking many ethical assessments by ELSI researchers and bioethicists¹⁵. As I will argue below, questions of justice and fairness are commonly found in the HGP's ELSI literature because ELSI borrows much from professional bioethical discourse, and the principle of justice – understood in particular ways – is one of the principles of bioethics. Furthermore, addressing questions of justice and

¹⁴ The Havasupai tribe, who live on the floor of the western Grand Canyon, provided blood samples in the early 1990s for what ASU researchers said might help solve the tribe's diabetes epidemic. Instead, the samples were used for other research, including attempts to prove that tribal ancestors had crossed the frozen Bering Straits into North America. This, the tribe argued, not only went against what was agreed by the research subjects who provided the samples, it also caused distress in the community who have particular beliefs about the origins of the tribe.

¹⁵ In April of 2011 the congress *Exploring the ELSI Universe*, of the NHGRI, counted with a number of sessions and poster presentations on the Havasupai case. Also, the *American Society for Bioethics and Humanities 13th Annual meeting*, in October 2011, also counted with sessions and posters on this case. See, for example, Fullerton, Stephanie M., and Lee, Sandra S-J. "Secondary Uses and the Governance of De-identified Data: Lessons from the Human Genome Diversity Panel." *BMC Medical Ethics* (2011): 16–22.

fairness understood in these particular ways does not involve a fundamental challenge for the HGP, as the ends of genomic research can be nevertheless advanced with technological solutions and/or policy changes to ensure just distributions of the burdens and benefits of genomic research and technology.

Questions relating to eugenics enjoyed a brief window of ELSI support in the early 1990's. However, what ends up being notable is how these discussions made into the ELSI program. That is, the questions here were along the lines of "is this eugenics or not?" Most strikingly, the relationship between eugenics and genetic/genomic research is an issue thought to have been resolved, at least within the context of American bioethics¹⁶.

A number of influential scientists in the early years of the twentieth century (e.g., Julian Huxley) proposed to use knowledge of genetics to free humankind from what they called the "genetic load", i.e., genetic burdens accumulating over generations. They argued, furthermore, that improving humans over generations (their concern had to do with germline cells that were responsible for genetic inheritance) would provide meaning to human existence. As Evans shows, scientists' arguments of providing meaning to human existence moved beyond the traditional professional jurisdiction of science (i.e., improving human health and wellbeing), entering the professional jurisdiction of theologians and philosophers. To defend their jurisdiction from this intrusion of science, theologians counter-attacked by engaging scientists in the sorts of substantially rational debates common in their profession. The result up to that point was that a

¹⁶ See, for example, Buchanan, Alan, Dan W. Brock, Norman Daniels, and Daniel Wikler. *From Chance to Choice*. Cambridge, UK: Cambridge University Press, 2000.

wider number of research areas and practices of the scientists was called into question now that discussing the ends for humanity was fair game. Fearing a net loss of professional jurisdictional ground, scientists abandoned the idea of giving meaning to human existence via genetically “perfecting” the species (Evans, 2002).

However, and Evans fills in the details, scientists were able to come back to the business of genetic selection via metaphors of treatment and health – much different from discussions of giving meaning to human existence via perfecting the species. Now the selection for or against specific genotypes is thought of as a means to the health and wellbeing of future individuals (e.g., pre-implantation genetic diagnosis). An unequivocal good that is not in need of further justification, genetic selection is now very much within the well-established professional jurisdiction of scientists. Also, the new way to frame genetic selection actually promotes the ends of bioethics, such as the advancement of beneficence (i.e., genetic selection as therapy and the promotion of individual’s health/wellbeing), as well as the end of autonomy (i.e., individual patients have new choices). Furthermore, in a context in which patients are imagined as rational, autonomous consumers of healthcare, it is up to these individuals to make decisions about their future children. All that is left for scientists to do it to make sure the process is safe.

Keeping in mind that much of the historical baggage that eugenics carries has to do with the megalomiacal dreams of authoritarian states, the shift to a

liberating, individualistic, and health oriented discourse did the trick¹⁷. In fact, the early 1990's works of ELSI researchers and bioethicists on this matter concluded just that the commonsense notions of eugenics are different in these relevant ways from what geneticists are now doing¹⁸. Of course this leaves open questions of justice, but as I mentioned above, these can be dealt with technological advances and policy fixes (e.g., making technologies cheaper and more accessible, and implementing policies that regulate the use and distribution of the technologies), thus not presenting a fundamental threat to the HGP.

In sum, the kinds of critiques that could fundamentally challenge the HGP have been either ignored by the ELSI program, as in the case of misleading and in other ways problematic notions of genetic determinism; or they have been assimilated and reformulated by the ELSI program so as not to present fundamental challenges to the HGP, as in the case of questions of justice and fairness in the burdens and benefits of genomic research.

As a clarification, I should point out that when I argue that the ELSI program ignored one line of criticism of the HGP, or incorporated another to the extent that it did not fundamentally challenge the HGP, what I have in mind are not full blown conspiracies, but more subtle social forces. As I will argue below, the ELSI program now transcends the HGP ELSI research of the NIH. "ELSI" has come to refer to category of problems that attach to large techno-scientific projects, and to a community that self-identifies as "ELSI researchers". For this

¹⁷ See, *From Chance to Choice: Genetics and Justice*, by Allen Buchanan, Dan Brock, Norman Daniels, and Daniel Wikler.

¹⁸ See, for example, Robert N. Proctor, *Genomics and Eugenics: How Fair Is the Comparison?*

community to exist, it must engage in boundary work by defining the values, questions, skills, and discourses shared by its members. Now, keeping in mind that ELSI is closely related to bioethics, some of its values are the set ends of (and are inherited from) bioethics, i.e., autonomy, non-maleficence, beneficence, and justice. Indeed, many ELSI researchers are also bioethicists. In addition, the ELSI program has an added principle, i.e., moving outcomes of genomic research to society (though, as ELSI has transcended genomics, *genomic research* is interchangeable with many other areas of research, such as *nanotechnology research*).

In so far as the shared values, questions, discourses and system of abstract knowledge of the ELSI community can lead it to certain places it will go there. Likewise, to the extent that these common features shared by ELSI researchers cannot lead them to other places they won't go there. In other words, the bioethical competencies that were inscribed into HGP ELSI only answered the questions that were visible to it, while a number of other questions were rendered invisible because they were out of the boundaries of the competencies for the community it produced. Thus the more substantive preoccupations were placed off the limits to critique the HGP and they remained so after ELSI took off as a new area/community of research. Much of what is coming below is dedicated to understanding what are the sets of values, discourses, intellectual abilities, and questions that make up the ELSI community; how they came into being; what purpose they serve; and at what costs.

4. *Common critiques made about ELSI: James Watson's politics and public relations*

As I alluded to above, one of the low-hanging fruits from which to criticize ELSI is its colorful creator, the Nobel laureate scientist James Watson. One of the co-discoverers of the double helix structure of DNA in 1953 – for which he won the Nobel Prize in physiology or medicine with Francis Crick in 1962 – Watson later claimed that the biggest accomplishment of his career was the development of the ELSI program (Watson, 2000).

Watson's vision for ELSI included questions of applied ethics in the conduct and outcomes of the HGP, with expectations that ELSI would develop policy options and guidelines to address narrowly defined, downstream concerns. He was mainly concerned with questions of privacy, writing that "[w]e need to explore the social implications of human genome research and figure out some protection for people's privacy so that these fears do not sabotage the project" (Watson, 1992). Additionally, writing together with the Juengst, Watson said, "doing the Genome Project in the real world means thinking about social impacts from the start, so that science and society can pull together to optimize the benefits of this new knowledge for human welfare and opportunity" (Watson and Juengst, 1992). Though Watson's concerns were very narrowly defined, asking for nothing more than a policy proposal that could fix the problem, he seemed to see an important role for ELSI. However, other times Watson appeared to think of the role of ELSI in explicitly cynical terms. He has been quoted as saying, "I wanted a group that would talk and talk and never get anything done" (Andrews

1999, p. 206). Aware of statements like this, as well as the political background of the HGP, a number of observers have voiced the critique that ELSI merely served as the public relations branch or political cover for the HGP¹⁹.

Framing the “problem” of ELSI in terms of mere window-dressing misses more important questions. How is it that ethical and social concerns are, in one way, reduced to narrowly defined, downstream research components within technological projects, while, in another way, these technological endeavors carry prior, tacitly inscribed normative commitments to imaginations of social problems and solutions?

ELSI has a rich history of connectedness with other important events in American science governance. Its unique structure within scientific institutions such as the NIH also offers the possibilities for interesting insights about its role in science governance, and its possibilities for the future. The very progression of the ELSI research agenda alone shows a noteworthy dynamic between different actors, as it was basically carved up through persistent (re)negotiations between philosophers, sociologists, law professors, historians, and theologians (who were interested in more substantive debates about genomic research), and mainstream bioethicists and scientists who became the gatekeepers of ELSI due to prior commitments to formal rationality which lent themselves to the in-built constraints of ELSI’s scope. Understanding these negotiations in their historical contexts powerfully challenges the notion that ELSI merely serves as the public relations

¹⁹ See, for example, Fisher, Erik. “Lessons learned from the Ethical, Legal and Social Implications program (ELSI): planning societal implications research for the National Nanotechnology Program.” *Technology in Society* (2005): 27, 321–328.

branch of the HGP. Reducing ELSI to window-dressing misses these many points
ipso facto.

Figure 3: The professional association of ELSI researchers:
LAW =111; ETHICS =65; MEDICINE =65; GENETICS =63;
PSYCHOLOGY/PSYCHIATRY =56; PHILOSOPHY=51; ANTHROPOLOGY =43;
SOCIOLOGY =35; POLICY =33; EPIDEMIOLOGY=30; GENETIC COUNSELING
=24; BIOLOGY =23; NURSING =22; PUBLIC HEALTH =21; BEHAVIOR=15;
EDUCATION =15; RELIGION/THEOLOGY =15; HISTORY =14; COMMUNICATION
=12; ECONOMICS =12; PHARMACOLOGY =11; POLITICAL SCIENCE =10;
HUMANITIES=9; MOLECULAR BIOLOGY =9; NEUROLOGY/NEUROSCIENCE=9;
ENGINEERING=7; ONCOLOGY=6; SOCIAL WORK=6; PARKS & RECREATION =4;
PEDIATRICS =4; SCIENCE & TECHNOLOGY STUDIES =4; INFORMATICS &
COMPUTER SCIENCE =3; LITERATURE =3; PUBLIC AFFAIRS =2; DRAMA =1

Figure 3 shows the sheer diversity of ELSI applicants, and the general distribution. It includes information on all PIs of all applications considered for funding in FY 2005-2011. If a PI put in multiple applications, they are counted for each application they submitted.

5. *Common critiques made about ELSI, continued: Policy outcomes vs. cultural relevance*

By the mid 1990's ELSI was criticized for being structured in a way that facilitated all but the identification of narrowly defined problems with the attachment of policy solutions²⁰. According to these critics, ELSI was not narrow and applied enough, and it was unable to generate policy options. In regards, for example, to one of ELSI's pointed successes, the extension of the American with Disabilities Act of 1990, critics called it ELSI's one single success.

After leaving his post as the director of the ELSI program in 1994, Juengst wrote about ELSI's struggle to balance the inclusion of researchers from a number of fields, ranging from the humanities to the social and natural sciences. The ultimate goal was for ELSI to be an effective agent of change, capable of practical accomplishments. In Juengst's view, the best way for ELSI to be effective in its imperative to predict and prevent problems that the HGP might encounter was indeed by creating a larger community of committed, expert genomics-watchers, who would be multidisciplinary, thus being able to identify a broader range of issues the HGP might run in to. On the other hand, critics were calling for the creation of more traditional, task-specific commissions, with said tasks limited to the identification of problems and the development of policy options. The suggested approach was that the NIH leadership would give these commissions specific problems/topics to work on (e.g., genetic privacy). This was

²⁰ See, for example, Kitcher, Philip. *Science, Truth, and Democracy*. New York, NY: Oxford University Press, 2001.

pointedly contrasted with the larger ELSI research community working on identifying the many possible problems the HGP might encounter.

Ultimately the critics won. The line of criticism that the ELSI structure was more suited to stimulate discussion across a wide spectrum of scholars than to implement policy decisions triggered, in April of 1996, the appointment of an eleven member Committee to Evaluate the ELSI Program of the HGP. The committee issued its final report in December of that year. It concluded that the charge of the ELSI program was so broad and complex that it was confusing to its various participants and observers. This confusion led to uncertainty about ELSI's primary functions, meaning that appropriate public and professional interactions in health policy development could not be achieved under the current structure. From these conclusions, the evaluation committee proceeded to make a number of recommendations, including the creation of the ELSI Research, Planning, and Evaluation Group (ERPEG), which would be able to evaluate ELSI in real time.

In 1997 the National Advisory Council for Human Genome Research (NACHGR) endorsed these recommendations, and the ERPEG was established in July of that year. The report was seen as an important, redefining moment for ELSI. It initially caused a shift in the agenda making process for ELSI, with a more top-down approach –the agenda being determined by the leadership of the HGP and ELSI within the NIH and the DOE. This was clearly contrasted with the set of negotiations that took place between these more clinically and policy-oriented directors of the HGP and professional bioethicists in the leadership of the ELSI program, with the scholars who were considered to be politically

appropriate to be included as non professional bioethicist participants in the early agenda setting conferences for ELSI.

The ERPEG, which was chaired by bioethicist and then director of the Kennedy Institute of Ethics at Georgetown University, LeRoy Walters, effectively took on the role of arbiter in regards to the ELSI agenda and structure, drawing authority from its given mission to provide ELSI with expert guidance on matters relating to its extramural research portfolios. Specifically, the ERPEG provided expertise on current and future research methods or approaches for studying ELSI issues, suggesting new topics, issues, and priorities, providing input on the use of funding mechanisms, and proposing methods for obtaining input from the public, scientific and other communities about research priorities. Finally, these were coupled with including ways of disseminating information back to these communities.

Undoubtedly, the critique that the ELSI format was not suited for the development of policy options was heard by the NIH, as it triggered major changes in the ELSI program. Nevertheless, this line of criticism was so clearly pointed at a particular outcome that it also missed on many important and more profound points about ELSI and its relation to science governance. Again, the questions persist: who gets to say who counts as an ELSI expert? Who gets to say what counts as the role of ELSI? Why? And what (who) is left out?

6. *Substantive rationality in double jeopardy: Bottlenecking the ELSI agenda*

Let's now consider some possible explanations, or genealogies, for the shape that the ELSI program took, and what the consequences of taking these routes are.

Some of the earlier calls for projects by the ELSI program (as early as 1989) involved agenda-setting conferences, workshops, and speaker series²¹. This included a mix of scholars from different fields with a broad overview of the issues at hand (Juengst, 2011). The 1992 edited volume, *The Code of Codes: Scientific and Social Issues in the Human Genome Project*, was a direct product of those early years of speaker series and agenda setting seminars. It documents a rich agenda for ELSI. In it one finds materials diverse in both subject and scope. It included pieces on the integration of new genetic tests into medical practice, training, counseling and education, and accessibility of genetic tests by third parties, as well as a number of pieces on the historical²² and conceptual²³ origins of the HGP, and critiques of the HGP's conceptual approach²⁴.

Yet in 1991, following these early-stage activities and even before *The Code of Codes* had been published, Juengst produced the first document setting the agenda for ELSI. He identified three areas of interest for ELSI projects: 1) issues involving the integration of new genetic tests into medical practice; 2) issues involving education and counseling of individuals about genetic tests; and

²¹ E.g., California Institute of Technology, 1989-1990 academic year

²² Daniel J. Kelves. *Out of Eugenics: The Historical Politics of the Human Genome*

²³ Horace Freeland Judson. *A History of the Science and Technology Behind Gene Mapping and Sequencing*

²⁴ Evelyn Fox Keller. *Nature, Nurture, and the Human Genome Project*

3) issues of access to, and use of, genetic test results by third parties, including insurance providers, researchers and employers (Juengst, 1991).

Contrasting Juengst's agenda with *The Code of Codes* shows a disconnection between the official agenda of the ELSI program (the former) with a direct product of the early agenda setting years of ELSI (the latter): the absence of the historical and conceptual critiques of the HGP project.

To understand this disconnect between two different pieces basically addressing the same agenda setting period, one has to place this situation in the context of human genetic engineering discussions pre-dating the HGP. As Evans documents, it was not only out of moral scandals in scientific research, such as Tuskegee, that the field of bioethics became a new locus of ethical deliberation on science and medicine. Preoccupations about basic scientific research also profoundly contributed to the professional development of bioethics. Among these, the area of genetic engineering stirred strong responses from the public and scholars from the field of theology. It was justly in response to worries about genetic engineering that much of the bioethics profession was consolidated, with its forms of discourse and ethical deliberation becoming the norm for engaging in ethical discussions about the life sciences. Evans cites Juengst as one of the most

influential²⁵ authors in the rationalization/thinning of bioethics, and even as giving it an explicit theorization²⁶. As Evans puts it:

For Juengst, the debate during the 1960s and 1970s on germline Human Genetic Engineering, as conducted by such substantively rational authors as Paul Ramsey and Joseph Fletcher, was “primitive”. [...] While other topics discussed during the 1960s and 1970s, such as organ transplantation and psychosurgery, have “been assimilated quite productively into bioethics, evolution toward clinical ethics and health policy, the subject of human germ-line engineering resists *civilization*.” [...] Juengst points out that “it is difficult to translate this literature into practical policies for scientific research beyond the cautionary moratoria it has already inspired.” (Evans, 2002).

Using the writings of Juengst, Evans illustrates the process of consolidation of the professional field of bioethics, which involved consensus on certain forms of inquiry and discourse. That is, moving ethical deliberation on the life sciences to the stages of “precision” and “generalization”, which was possible by the acceptance of the principles of autonomy, non-maleficence, beneficence, and justice as the ends to be pursued in scientific research and bioethics. My argument about the agenda announcement for the beginning of the ELSI program is based on this context of “precision” and “generalization” having the principles of bioethics as the foundation. And my argument is very much facilitated by the fact that Juengst himself was the director of the ELSI program at the time – a

²⁵ Evans’ citation analysis in *Playing God* shows that Eric Juengst was one of the most often cited bioethicists in the early 1990’s. See Figure 5: Clustering of most influential authors, 1992-1995. Pg. 156.

²⁶ Juengst makes an analogy with the development of the professional field of bioethics over time by using Alfred North Whitehead’s concept of the three stages of inquiry: romantic, precision, and generalizing.

position of influence, to say the least, in defining the agenda for ELSI²⁷. In other words, via the formalization of the rational discourses on bioethics in general, and the figure of Juengst in particular as director of the new ELSI program, bioethics became the foundation for ELSI, with ELSI crystallizing and formalizing these debates as subsidiary to the technological project itself.

Sharing the consensus on the professional ends and discourses of bioethics (i.e., clinical and policy orientation, and based on the principles of bioethics), Juengst naturally tried to shape the ethical and social debates on the HGP in that direction. Hence what was outside of this scope did not make the cut into ELSI’s agenda. Additionally, as I will argue below, ELSI is in an exceptional position to house formally rational debates. This is because ELSI is situated in the clinically oriented NIH, and, as a formal research program, it has a system of accountability and predefined goals that give gate keeping authority to a handful of specific

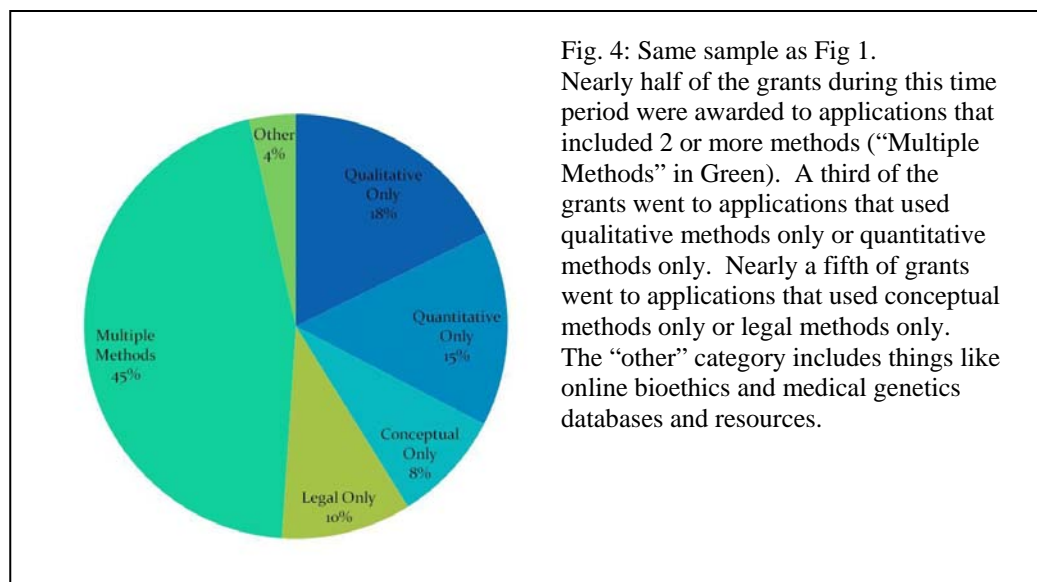


Fig. 4: Same sample as Fig 1. Nearly half of the grants during this time period were awarded to applications that included 2 or more methods (“Multiple Methods” in Green). A third of the grants went to applications that used qualitative methods only or quantitative methods only. Nearly a fifth of grants went to applications that used conceptual methods only or legal methods only. The “other” category includes things like online bioethics and medical genetics databases and resources.

²⁷ Though it did not have to be Juengst. The point is that once bioethics becomes a profession that is boxed-in by shared values and modes of discourse, any other bioethicist at the time, almost by definition, would probably have acted in the same way Juengst did.

individuals. Finally, as I explored above, discussions relating the HGP to eugenics, a relatively common subject of inquiry in the early days of ELSI, were addressed and resolved within the ELSI program and bioethics in the context of formal rationality, through advancing autonomy and beneficence, and without having negative implications along the lines of malfeasance and injustice. This explanation for the bottleneck process of the early ELSI research agenda is one level in which one can understand the ELSI program in the context of the NIH and professional/disciplinary bioethics.

As an institutional structure, ELSI produced forms of “bottlenecking” in agenda setting moments, where the range of possible questions was defined in advance by the historical events that shaped the field of bioethics. The proliferation of new concerns and forms of argumentation was always already constrained by these prior commitments which were built into the disciplinary structures of the enterprise itself, via accountability measures, grant review, merit criteria, policy-relevance, appointment of influential bioethicists to leadership positions, etc.

As is to be expected, ELSI’s agenda has been revisited a number of times since its first announcement in 1991. What is notable, however, is that these subsequent revisions, such as a piece that Juengst published for the ELSI agenda in 1993, stresses just the same kinds of concerns from the previous agenda, showing that ELSI was untouched by the more substantive interests that surfaced in the agenda setting moments a few years before. The points Juengst identified for the new agenda were virtually the same as the previous agenda: 1) helping

genetics services providers develop guide-lines for the introduction of genetic tests into clinical practice; 2) recognize the very personal nature of genetic information and taking steps to ensure its privacy and confidentiality; 3) identifying policy options to ensure the fair use of genetic information by parties outside of the clinical context, such as employers and insurers; and 4) improving professional and public education in the area of genetics and its implications for society (Juengst, 1993).

Just as the institutional position of ELSI remained the same, the larger community of science studies scholars also remained true to their more substantive interests. Similar to the preceding events of the previous announcement, a number of conferences took place yet again to discuss the agenda for ELSI going in to the future. As a result of these conferences some new edited volumes were published shortly thereafter, they were: *Gene Mapping* (1992); *Justice and the Human Genome Project* (1994); *Genes and Human Self Knowledge* (1994).

In *Gene Mapping*, which was a result of the January, 1991, extramural workshop in Bethesda, Maryland, a forward by Watson and Juengst is included; it reads: “the goal [of ELSI] is to be in a position by FY 1995 to complement the completion of the genetic reference map of the human genome with a slate of policy options addressing the highest priority challenges the uses of that map will pose” (Watson and Juengst, 1995). However, similar to *The Code of Codes*, *Gene Mapping* also counts with a considerable number of articles on the history of genetic and genomic research, as well as broad philosophical issues raised by the

HGP, such as reductionism and determinism, and the complexity of the determinants of health and disease and its implications for gene therapy. The volume counts with contributors such as the historians of science Judith Swazey and Robert Proctor, and the historian and philosopher of science and bioethicist Arthur Caplan – whose piece is titled, *If Gene Therapy Is the Cure, What Is the Disease?*

Similarly, *Justice and the Human Genome Project* is a collection of essays presented in an extramural conference held in late 1991 in Chicago. This book is certainly more in line with addressing narrowly defined problems the HGP is likely to encounter downstream. There is a small overlap of contributors between this volume and *Gene Mapping* (e.g., George Annas and Arthur Caplan write on both) and notably one piece, *Justice and the Limitation of Genetic Knowledge*²⁸, scrutinizes the value of paradigms of genomic research. *Genes and Human Self-Knowledge*, on the other hand, is a collection of essays presented in the 1992 University of Iowa's Humanities Symposium which counted with scholars from history, philosophy, religious studies, among other disciplines – some of the specific contributors were the philosophers Evan Fales and Michael Ruse, who raised ontological and epistemological questions about genetic and genomic research, and the philosopher and bioethicist Dan Brock. In opposition to *Justice and the Human Genome Project*, *Genes and Human Self-Knowledge* addresses much broader philosophical and historical issues facing the HGP, providing little immediate policy relevance.

²⁸ Marc A. Lappe (1994).

One way in which volumes like these are especially interesting is in regards to how they complicate Evans's big picture framework for understanding the development of bioethics. Here it is important to remember that while Evans's theory does much to help provide a clear and concise understanding of bioethics and ELSI, the actual dynamic on the ground is messier and more complicated. The evidence contained in these edited volumes offers further insight into the particular institutional spaces in which ELSI was molded, including challenges, negotiations, and re-negotiations between different stakeholders. But certainly while bioethicists and assorted others will challenge what other bioethicists say, I agree that over time boundary work will be accomplished, with specific values and modes of discourse and investigation predominating the field. Thus, more detailed accounts of the specific dynamics that happened in the making of the ELSI program builds on, thus comporting with, Evans's framework. What is notable from this evidence for the bottlenecking process which produced the ELSI agenda announcements is that the more formalized and tangible ways in which ELSI is structured acts as a powerful catalyst for the consolidation of certain values and modes of discourse and investigation when compared to the more loosely defined professional field of bioethics.

At the same time that ELSI, as a proper locus for ethical and social preoccupations in the HGP, can be seen as a catalyst for the consolidation of the characteristics of bioethics, it must be the case that the earlier normative work in bioethics (e.g., on human genetic engineering, the definition of autonomy,

beneficence, non-maleficence, and justice) was inscribed into ELSI. With this in mind, those who were boxed-out of bioethics in the earlier ethical and social discussions in the life sciences experienced a sort of ‘double jeopardy’ when it came to ELSI; that is, in virtue of particular values and modes of discourse and deliberation having become predominant in bioethics, bioethicists like Eric Juengst became the gatekeepers of ELSI research. As a result, those who were boxed-out of ethical and social discussions in the life sciences, or otherwise were interested in more substantive debates, had a still harder time having their voices heard in the context of ELSI, as ELSI was more tightly controlled and more narrowly defined than bioethics by virtue of its structure as a formal research program, with funding criteria, mandate accountability structures, etc. Despite of the fact that some individuals outside of bioethics did participate in the early agenda setting conferences for ELSI research – because, in the words of Juengst, they were the “usual suspects to be invited to these conferences” (Juengst, 2011) – their interests did not make the final cut into the subsequent official announcements for the ELSI research agenda.

Boxing out certain interests and approaches to social and ethical questions about science and technology had obvious impacts on ELSI’s allocation of resources. But more importantly, and also contributing to resource allocation, it had impacts on the (de)legitimization of certain questions, approaches and methods in social and ethical research on science and technology. As a public project, ELSI is, in a sense, a barer of the public interest. And its control of public resources is itself a reflection of a prioritization/agenda setting authority.

The victory of formally rational modes of discourse produced the discipline of bioethics. Since to the victor belongs the spoils, formally rational bioethicists were in a position to become the gatekeepers of ELSI. However, since many of the more substantively rational authors were still around during the formative years for ELSI – justly because the professional jurisdictional forces that shaped bioethics were not conspiracies but social processes – it was deemed politically appropriate to include non-professional-bioethicist participants in the early agenda setting conferences for ELSI. As Juegnst put it, they were “the usual suspects”. But when the time came to actually put pen on paper for what the ELSI agenda would look like, those holding the pen (e.g., Juegnst) naturally shifted the discourse towards formal rationality.

But, as I will argue in the last section of this paper, besides supporting Evans’s theorization of the development of bioethics, this account of ELSI also illuminates a larger question regarding of why many social problems are imagined in terms of technological imperatives.

7. *Progressing with the ELSI program: The victory of formal rationality*

One curious observation about the critique of ELSI contained in this work in comparison with critiques of ELSI by a number of other authors is the following: While I am coming from the perspective that technological projects like the HGP carry tacitly inscribed but rather powerful technological imaginations of what constitutes social problems and solutions, ELSI's focus on rather narrowly defined, downstream problems for the HGP (with a policy mandate). On the other hand, a number of authors have voiced just the concern that the way in which ELSI is structured facilitates all but the identification of narrowly defined problems with the attachment of specific policy solutions²⁹. As I have noted, one of ELSI's pointed successes, the extension of the American with Disabilities Act of 1990, has been called by critics ELSI's single success (though this was mostly before the passing of the Genetic Information Nondiscrimination Act (GINA) of 2008, also credited to the ELSI program).

The line of critique that the "ELSI's grant structure was more suited to stimulate discussion across a wide spectrum of scholars than to implement policy decisions" (Wolfe, 2000), however different from my critique at first glance, is also accurate in some ways. Furthermore, however narrow it is, it points to an interesting fact. Given the predefined ELSI framework, ELSI was able to engage

²⁹ See, for example, P. Kitcher, *Science, truth, and democracy*, Oxford University Press, New York (2001), and/or L. McCain, *A policy appraisal of the US human genome project*, University of Colorado at Boulder, Boulder (2003), Chapter 6.

with and respond to certain critiques but not others. At this point, I turn back to EPERG group put together to evaluate the ELSI program from 1997 onward.

As we have seen, the eleven-member EPERG ELSI-watchdog was appointed by the ELSI evaluative committee in response to criticisms that the ELSI charge was so broad and complex as to be confusing to various participants and observers. Similar planning moments and evaluation reports also attempted to keep the ELSI mandate quite narrowly defined (see Figure 5).

Fig. 5: List of ELSI planning moments and evaluation reports:

- 1990: ELSI Working Group (Wexler)
- 1995: Joint NIH/DOE Committee to Evaluate the ELSI Program (Spence/Rothstein)
- 1996: Review of ELSI 1990-1995 (Thomson)
- 2000: NIH and DOE ELSI Research Planning and Evaluation Group Final Report (Walters)
- 2003: ERA/EPPG Planning Report (Burke)
- 2005: ERA Report to Council (Burke/Juengst)
- 2008: ELSI Assessment Panel (Shapiro)

The mission of the ERPEG, chaired by LeRoy Waters, was to provide ELSI with expert guidance on matters relating to its extramural research portfolios, and expertise on current and future research methods or approaches for studying ELSI issues. The choice of Waters - coming from the birthplace of traditional American bioethics, Georgetown University, and with a longstanding role in public bioethics - for chair of the ERPEG once again highlights just the kinds of leadership positions that traditional bioethicists were able to get after the

triumph of formal rationality in the field.³⁰ But going back to the common critique that ELSI was poorly equipped to identify and address narrowly defined downstream problems, this was picked up as a valid critique because it was made in the same terms used in the system of abstract knowledge of bioethics.

The criticism of ELSI's inefficient format could resonate with the ELSI leadership because it was made within the boundaries of formal rationality. In fact, it was meant to be assimilated quite productively as a step towards clinical ethics and health policy. In a context where many critics are questioning the value of formal rationality and the downstream orientation of ELSI, the criticism that ELSI was not constrained enough as to be able to generate policy options begged the question.

Ironically powered by this lack-of-tangible-outcomes criticism, the institutional response was to implement even more concrete ways to control for ELSI's narrowly defined and policy oriented mandate.

This is especially interesting because this is a manifestation of a way in which the ELSI program was in a better position than the field of bioethics to advance the very original project of bioethics. Because of its formal structure as a research program, the ELSI program can more easily select what criticisms it will respond to, and then respond to them. Bioethics, for being more loosely defined, does not have the capability of forming a centralized, top-down plan for its future. As I will discuss in the next section, this difference between ELSI and bioethics

³⁰ Evans documents that LeRoy Waters, like Eric Juengst, is one of the proponents of formal rationality in bioethics, including the use of the so called principles of bioethics.

will probably lead to the selection of ELSI as the default system of governance in science and technology.

Additionally, in the case of ELSI, different forces from, but not at odds with (and indeed complementary with), those that drove the development of the bioethics profession, gave ELSI a life of its own. The ELSI program which originated as a specific research program with the HGP has already been selected for becoming more than a specific research endeavor. ELSI has become a research concept that is applied in many other scientific endeavors (e.g., NSF's nanotechnology initiative, the Environmental Genome Project, and more).

While bioethics is under the influence of the subtle, abstract, and soft forces of professionalization, ELSI counts with formal means of control. Though this may seem like an obvious observation at first, it was due to this fact that ELSI was selected for transcending the HGP, and now it is present in other technological projects, thus creating a community of researchers who identify themselves as ELSI researchers³¹. In other words, the formal characteristics of ELSI caused it to be selected for and a catalyst of a quasi-professional field to advance certain institutionally authorized questions in science and technology.

Though ELSI and bioethics share a lot of the same commitments to formal rationality and principles to be advanced, the differences in structure are significant enough that it is productive to examine not only how they are similar, but also how they are different, and what these differences might have in store for them.

³¹ For example, in April of 2011 I was in a meeting called, *Exploring the ELSI Universe*, in which there was a strong sense of shared questions and discourses among the participants.

8. *Bioethics and partisan politics: What ELSI can do that bioethics cannot*

One of the topics discussed in the American Society for Bioethics and Humanities (ASBH) 13th annual meeting, in October of 2011 in Minneapolis, Minnesota, was the infiltration of partisan politics in the field of bioethics. This topic yielded a few sessions in the meeting, including a plenary session with the keynote speakers Jonathan Moreno and John Arras, both senior level bioethicists. Moreno has recently published a book, *The Body Politic: The Battle Over Science in America*, which, among other things, addresses this topic.

The palpable consensus formed during the ASBH meeting was that, despite its certainly political beginnings, bioethics used to be a locus of normative considerations in the biosciences that was marked by the characteristic cordiality of academia, in which people with different ideologies were free to disagree, but it was nothing personal at the end of the day. In an almost melancholic tone, a large group of sexagenarian bioethicists (though I suspect that I am being generous in estimating their ages) spent a couple of hours thinking about, in the words of a member of the audience, “what went wrong with bioethics.” Examples given of what has gone wrong with bioethics included partisan bioethics groups that would not attend each other’s meetings and that would publish inflammatory papers. Part of the session was also dedicated to discussing how bioethics would proceed into the future, now that it found itself in the mix of this hyper-polarized political landscape.

The question of how bioethics will proceed into the future now that vicious, partisan politics has found its way in the field is especially interesting to me in light of what I have identified as the characteristics of the ELSI program.

Though remembered in very warm ways by the ASBH attendees, the good old days of bioethics, free from partisan politics, can be explained by the acceptance of formal rationality as the *modus operandi* of bioethics. In tacit ways, substantively rational authors, many of whom were conservative thinkers such as Leon Kass³², were boxed out of bioethics proper, because their questions and answers about the life sciences simply did not make sense in the context of the thinned discourse of bioethics. These tacit but powerful forces may have shifted bioethical discussions one way along the political spectrum, while simultaneously avoiding more explicitly heated confrontations. That is, overt politics were excluded by rationalizing out the discursive conflicts that would have made the political cleavages visible.

As the present political moment makes clear, the United States has become, for reasons that are better left aside, particularly socially and politically divided than in previous moments in recent American history. Now, because bioethics is a locus of deliberation of complicated moral issues, and because its professional boundaries are somewhat porous (many people can label themselves as bioethicists), it is only to be expected that political battles would enter the

³² It is noteworthy that Leon Kass, who headed a national bioethics body for 5 years, and who is arguably one of the most famous bioethicists in the country, can still be considered an “outsider/not-mainstream” bioethicist. This highlights the power of the system of abstract knowledge (i.e. formal rationality) of the field.

bioethics arena. In this sense, bioethics risks losing the formal rationality characteristics that were the basis of its jurisdictional authority in the past and that made it possible to do what it does – i.e., to apply pre-determined ethical principles (such as autonomy, non-maleficence, beneficence, and justice) to morally contentious issues.

Again, to the extent that partisan politics is infiltrating, or arguably being uncovered, in the context of bioethical bodies, this field seems to be losing some of the characteristics that have allowed it to successfully define and rule some of the normative dimensions of the life sciences. ELSI, however, is in a more secure position to do this work. In the ways I have described above (i.e., being formally boxed in governmental agencies, with a number of concrete gate keepers), ELSI becomes a locus of investigating science and technology via formal rationality and by applying the pre-determined principles of bioethics. Because the questions addressed by ELSI can be more easily determined by the single stroke of a pen, and because membership to the ELSI community can be better controlled by ELSI grants, the social forces that mold these professional fields have a smaller risk of being overmatched by other forces such as partisan political ideology. Recent developments in ELSI, such as the creation of the Centers for Excellence in ELSI Research (CEERs) add even more levels of circumscription of the ELSI community³³.

³³ To date, six CEERs have been installed: at the University of Washington, Center for Genomics and Health Care Equality; Stanford University School of Medicine, Center for Integration of Research on Genetics and Ethics; The Duke Center for the Study of Public Genomics; Case Western Reserve University, Center for Genetic Research Ethics and Law; Center for Genomics

However, since ELSI directly counts on Congressional authorization I suppose that the argument can be made that ELSI is more, not less, subject to partisan politics than bioethics. But here two points should be made, which I believe make this argument short lived. One, this characteristic of ELSI, that it counts on political authorization (from Congress) is similar to some of the spaces of bioethics, such as Presidential commissions since they are, in ways, depended on Presidential authorization (i.e., the President forms the commission). So, political authorization is something that both ELSI and at least the President's Commission on bioethics have in common. If anything, the President's Commission would be more vulnerable to partisan politics than ELSI research programs because, in so far as the President's Commission is linked to the given president of the time, the President's Commission is more likely to be significantly changed with new parties coming into the White House. ELSI, on the other hand, is linked to Congress in more indirect ways than the President's Commission is to the President. For ELSI, there are many layers of authorization and bureaucracy between itself and Congress, thus diluting overt partisan issues to the point that they are virtually not present in ELSI grant announcements.

But, of course, the President's Commission is only one of the many spaces of bioethics. Some additional spaces that are not formally linked to any governmental body are places like research institutes (e.g., The Hastings Center, the Kennedy Institute of Ethics, etc.) and professional societies (e.g., ASBH).

and Society at University of North Carolina-Chapel Hill; and the University of Pennsylvania, Center for the Integration of Genetic Healthcare Technology.

However, and as it was discussed in the ASBH meeting in 2011, it is out of political agendas that many new research institutes and professional societies come into being. With this in mind, the lack of a formal link with governmental branches, departments, or agencies does not mean the lack of political motivation. If anything, just the opposite may be true in some cases.

The institutional structures in which ELSI is set up, combined with the early influence of bioethics into the formation of ELSI's intellectual commitments, make it such that ELSI is better equipped than bioethics to advance the principles of bioethics in the context of formal rationality. With this in mind, I believe that, over time, bioethics will become a locus of more popular and substantively rational debates in the life sciences, while ELSI will go on to do the work that the field of bioethics was originally designed to do.

9. *Contributing to the thinning of the public debate*

The development of loci of governance in science and technology that primarily use formally rational means of discourse (e.g., ELSI and bioethics) is at the same time symptomatic of and explains why it is the case that social problems and solutions in modern societies tend to be imagined in the context of technological challenges.

The lack of engagement in substantive rationality – which effectively debates what a good society would look like, as opposed to what are the best means for getting to a preconceived notion of the good – does nothing to facilitate the rise of alternative imaginations of how social problems and potential solutions are imagined; in anything, alternative imaginations are discouraged by the acceptance of formal rationality as *the* legitimate mode of discourse and authorized set of questions. Though this does not identify the roots of imaginations of social concerns as technological challenges – something that has maintained social theorists occupied for a long time – it is important to note that these governance structures that are supposed to be concerned with social and ethical problems incentivize the thinning of social and ethical debates. This advances imaginations of problems as technological challenges by given-in-advance boundaries between authorized and unauthorized questions, as well as the research communities to deal with these questions. With this in mind, something that both ELSI and bioethics cannot accomplish is justly to challenge these powerful sociotechnical imaginaries. That, I think, is better left to more substantively rational fields, which are also preoccupied with identifying and

bringing into critical view these problems in the first place, such as science and technology studies, and biology and society.

A number of observers consider the RAC, and especially the Asilomar meeting of 1975, as a great achievement for the ways in which regulatory restraints allow science to express itself via the market and produce public goods³⁴. This is the case because such regulatory restraints are reduced to technical risk assessment, leaving all other aspects of the technology (e.g., social goals, human self-understanding, and cultural values) to be sorted out after the fact in the free market. In other words, the market is expected to mediate between technologies and their social meaning. Here a couple of points should be made about this general approach to science and technology governance, and about how the specific case of how ELSI fits (or fails to fit) into this picture.

Surely it is not the case that regulation *à la* Asilomar is really only constrained to technical risk assessment. That would be impossible because the risk assessment is not happening in a vacuum. Dividing science and technology in terms of risk assessment and its conformity to social goals is just too artificial, for the technology itself, as well as what is understood as risk, are themselves part of social goals.

Publics are often deemed in some way incapable of “productively” engaging with the situation, either because they are deemed to be ignorant, unscientific, ideological, religiously motivated, etc. This was indeed the case with the recombinant DNA technologies and more broadly genetic engineering

³⁴ See, for example, Sharp et al. 2004.

controversies of the 1970's. Public criticism in terms of the unnatural aspects of these genetic technologies, or for that matter of the scientists position to "play God", were considered to be non-sense, primitive, and incapable of being assimilated productively into bioethics and health policy. When taken at face-value, criticisms put in these terms (i.e., "playing God") might indeed sound unreasonable. But if these analogies carry deeper meaning to them, it would not be clear that they are unreasonable after all. Whichever is the case, those who find themselves in a position to regulate science and technology end up dictating their social meaning regardless of how minimalistic or conservative their positions are.

The case of development of the professional field of bioethics is a great example of this. In "having" to fill in the position of arbiters of scientific research, bioethicists had to judge research in some terms. Facing the difficult situation of "having" to judge for a public, while at the same time not having the democratically given authority to do so, bioethicists had to make the most minimal/conservative judgments possible. These were in terms of the bioethical principles that were argued to be universal and not controversial. This approach is in a sense a form of risk assessment in terms of harm to individuals' autonomies, health and wellbeing, and a predefined sense of justice. The rest will be sorted out in the market. What is failed to be considered is that these scientific investigations and technologies are already a response to social problems understood in particular ways. By governing these things simply in terms of risk assessments, governance structures legitimize the scientific/technological approach to social problems, especially when they are deemed safe (i.e., from a narrowly defined

risk-assessment perspective). The problem is not the legitimization of this understanding of social problems as such. It might indeed be the case that this is the most productive way to go about it. The problem, as I see it, is the lack of robust justification, debate, and public engagement in arriving at this conclusion.

ELSI, as a structure of governance like bioethics, furthers this thinning of the social debate in a number of ways. Most obviously, it is inscribed with a lot of the values, mechanisms, and methods of bioethics. Additionally, ELSI attempts to ask more questions than just about autonomy, beneficence, malfeasance and justice. But, counter intuitively, in doing so it promotes the thinning of the public engagement even more because it effectively sends out the message that the public need not worry about the ethical, legal and social implications of research because these have already been addressed by ELSI. In other words, ELSI is effectively an expansion of the power or jurisdiction of a particular approach to science governance.

It is up to us, literally thinkers about science and society, not to serve as experts to those in power who define the problem. We should redefine and question the problems themselves. Is this the right perception of the problem? Is this really the problem? Who gets to say? And what is been left out? We should ask much more fundamental questions. I think that the real task in a society such as ours is to criticize the workings of institutions that appear to be both neutral and independent; to criticize and challenge them in such a manner that the political violence which has been exercised obscurely through them will be unmasked and made vulnerable.

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BIOGRAPHICAL SKETCH

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