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The ELSI Experiment:
ethics watching science waiving ethics?

Sheldon Krimsky has written a thoughtful book that explicates several themes that are relevant not only to biotechnology, but also to the rise of bioethics as a practice and profession. When did the ethical, legal, and social implications of doing science assume its current high profile? Was there a point at which science ceased to be "…viewed as both inherently virtuous and as the engine of human progress"? (Krimsky, 1991). This essay will consider how concern by the public at the direction science was taking - especially in light of genetics and recombinant DNA - set in motion a movement to build ethical accountability into research. Although only briefly mentioned by Krimsky in his book, I have chosen to examine the ELSI Program of the Human Genome Project as a vehicle to study how social concern over genetic and related technologies was neutralized by adopting a "…curious science-ethics hybrid" (Marshall, 1996). I will follow the history of ELSI as a deliberate policy from its beginnings in 1990 up until the present day. What kind of impact has ELSI had on the direction of research or on the selection of applications/products that has resulted from the sequencing of the human genome? Does this kind of model go far enough in providing the kind of social governance of technology that Krimsky advocates?

Some historical perspective

Krimsky noted that the moral responsibility of science became a prominent theme that "… evolved from the scientists' role in developing the atomic bomb, and was applied to human experiments, war research, and subsequently to genetic technology" (p. 15). Other writers have situated the rise of biomedical ethics in the decade of the 1950's, when moral theologians like Joseph Fletcher first attempted to bring awareness of the ethical dimension of medicine

(Callahan, 1988, Toulmin, 1988). Toulmin, in particular, presents an interesting survey of the development of *medical* ethics in the United States. He argues that even the language and terminology used in professional ethics reflects a philosophical division of moral problems into, "…Aristotle's emphasis, in the *Nicomachean Ethics*, on the practical and circumstantial character of moral problems, and on the difference between a theoretical grasp of general principles (*episteme*) and the practical wisdom needed in handling particular cases *(phronesis)*" [italics are Toulmin's] (p.13). For a variety of reasons, he sees the resurgence of 'case-based' ethics as opposed to an ethics that rests on theory. This has encouraged the growth of applied ethics courses in medical training and widened the field of potential commentators in ethical discussions. Medical professionals, he says,

> "..no longer seek to restore their monopoly, or to keep the lay public at arm's length. They view medical practice as uniting technical skill with moral insight, and recognize (if sometimes grudgingly) that they cannot always - and may not be well advised to - take decisions about the moral issues of clinical practice single handed" (p. 12).

Although Toulmin is speaking specifically of physicians and clinicians, I believe that a similar case can be made for scientists and science in general. The same historical forces that challenged the "Doctor knows best" mentality may have also worked to question the inviolability of Science and allow access by lay people into ethical discussions.

This direction can be seen in fields related to medicine and science as well. In a thoughtfully written article from 1978, Catherine C. Sammons, a social worker, reflected on what many of her colleagues in social work were already grappling with: interventions such as amniocentesis, "selective abortion," and the privacy issue associated with genetic information. Writing about selective abortion (due to genetic defects in the fetus) she noted that the "…trend in modern medicine is to include the family and even the community within the area of the

physician's immediate interest and commitment. Selective abortion presents a situation in which the interests of individual, parent, and community must be weighed" (p. 239). Sammons adds a quote from L. Gardner (1970), that "...there are scientists who are seriously interested in changing man's germ plasm toward the common good of a better life. There are counselors who function as artisans in the field of human relations, who act as advocates for the parents and the fetus." It was in this atmosphere of questioning medical and scientific priorities and practices that the Human Genome Project had its start.

The ELSI component of the Human Genome Project

There are several accounts in the literature on how it came about that a fixed portion of the budget for the HGP was to be set aside for the ethical, legal and social implications of the research into the human genome. Almost acquiring the status of a science urban legend, the anecdote about the origins of the [initial] 3% set-aside by James Watson has variously been called an off-the-cuff remark, a political masterstroke, and a seminal contribution to the HGP (Marshall, 1996, Billings, 1994, and Patrinos, 1997). Although quite a lengthy quote, the story is very interesting for what it reveals about how science is never quite divorced from personality:

> … Back in 1988 and early 1989 when Jim Watson was going to Congress and, as a distinguished scientist, lobbying Congress for additional NIH support for the Human Genome Project, he was very visible in the press. At one press conference there was a somewhat aggressive reporter who said to Watson, "Are you concerned with the fact that we'll be able to test for all sorts of things in the not-so-distant future, for diseases like Huntington's disease, for which there is no effective cure or interventional strategy? So we'll know that people are going to get these terrible genetic diseases, but we won't really have anything that we can do for them." Now Watson, if you've ever seen him on television or have had the opportunity to hear him speak, is a very self-confident scientist and he said something like, "Oh, of course we've given a lot of thought to these issues and as part of this new program we're planning to address those sort of ethical and policy matters." This reporter, on that particular day, was again particularly aggressive and said to Watson, "Does that mean that you'll support research on ethical issues and in the area of the social sciences?" And Watson again, quite self-confident, said, "Indeed, that's exactly what I had in mind when I responded your question." Well, this reporter didn't let it

> go at that and said, "Does that mean that you'll have a set-aside of the overall budget for the Human Genome Project that will address issues of that sort?" And you can imagine the circumstances here, and Watson being somewhat less assertive in responding to that question, but at that point he indicated that this was part of his overall plan - that the Human Genome Project would dedicate a percentage of its overall budget to address ethical, legal, and social issues. And with that was born what has now become known as the "ELSI" program, the Ethical, Legal, and Social Issues program.
> (Sharp, 2005, ¶ 5)

It is also reported in the literature that the DOE set-aside of 3% had a similar genesis. Edward J. Larson (1993) tells the story that in 1989, then-Senator Al Gore (as chairman of a subcommittee on Science, Technology, and Space) grilled a DOE official in a Senate hearing at which the official followed the appearance of James Watson: "Noting that DOE had not created an ELSI set-aside from its genome funds, the senator declared, 'I think that whether you set aside the money or not will be a signal of whether you are really taken seriously or not. I would like to see not so much a duplicate of the NIH effort as I would like to see in the joint plan that you develop a comparable commitment of money.' … DOE promptly complied by earmarking 3 percent of its genome funds for ELSI grants and by forming a joint working group with NIH, chaired by [Nancy] Wexler, to coordinate the distribution of grants by both agencies" (Larson, 1993).

The official Genome.gov web site of the National Human Genome Research Institute (NHGRI) has an account that gives no indication of the tinge of provocation indicated in the two preceding quotations. It states plainly that "ELSI provides a new approach to scientific research by identifying, analyzing, and addressing the ethical, legal, and social implications of human genetics research at the same time that the basic science is being studied. In this way, problem areas can be identified and solutions developed before scientific information is integrated into health care practice." It will be shown later that the last sentence has, in fact, not been the case at all.

[Sidebar: there are many interesting issues with regard to the ELSI Program that I will not discuss in this paper. They include the history and circumstances that lead to TWO government departments funding and pursuing the Human Genome Project as well as its ELSI components; the history of the acronym-loaded jigsaw puzzle that was the various working groups, task forces, advisory committees, and other bureaucratic units related to ELSI that attempted at times to direct, and at other times to evaluate, the ELSI program; or a analysis of the actual projects that were funded as they relate to the articulated goals for ELSI]

In 1991, when Krimsky was writing his book, the Human Genome Project was only a couple of years old (which may account for the brevity with which he mentions it in his book). At that time, four goals had been identified by the NIH for the ELSI program:

- To anticipate and address the implications for individuals and society of mapping and sequencing the human genome.
- To examine the ethical, legal, and social consequences of mapping and sequencing the human genome.
- To stimulate public discussion of the issues.
- To develop policy options that would assure that the information be used to benefit individuals and society. (NHGRI, 2004a).

The DOE, in 1991, narrowed its ELSI scope to concentrate on genetic education, the privacy and fair use of personal genetic information, and genetics and the workplace. During its first two years, the ELSI Program dispensed over $6 million in grants that supported 18 research projects, 8 educational programs, and 10 conferences (Larson, 1993). Its twin goals of funding research by scholars to study the ethical, legal, and social implications of human genetics and educating the public about the promises and risks of genetically-based applications and products opened a virtual cornucopia of grants opportunities.

[Sidebar: The amounts spent on ELSI projects vary with who is doing the reporting and what periods of time they are aggregating. The NHGRI has comprehensive information on its web site, along with tools to search and retrieve grants by a number of parameters (e.g. principal investigator, funding mechanism, area of research, etc.) It also provides complete

budget information; however, ELSI projects are not a line item, so that it is difficult to ascertain what proportion of the funding mechanisms - Research Project Grants, Research Centers, and Other Research - were actually earmarked ELSI funding. That being said, a number of writers have done the math at various times and although their accounts differ, they do offer insight into how the direction and priorities of the program changed over time.]

At the close of 1993, over $20 million had been spent on ELSI programs, and that year may be regarded as a watershed in terms of the evolution of the program. By then, James Watson had resigned as Director of the HGP and its present director, Francis Collins, had taken the helm. A rash of critical commentary appeared, questioning the effectiveness of the ELSI Program and questioning its fundamental underlying assumption - that it is possible for a scientific enterprise to evaluate the implications coming out of its research at the same time it is conducting it.

1993 - 1996

This time period yielded a number of insightful articles and at least one major report (by the Office of Technology Assessment) that strove to justify where the ELSI money had been spent and to what effect. Interestingly, a report published in 1992 by the House Committee on Government Operations - whose sub-committee had held hearings on ELSI - received a measure of attention and commentary in the press. Leslie Roberts reported for *Science* that ELSI was drawing criticism for its series of academic meetings, where "often the same cast of characters debate the same issues" (1993). She quoted from so-called bench scientists who said that "we've had enough of this Hastings Center stuff." Three years later, *Science* writer Eliot Marshall was also airing quotes from disgruntled NIH officials: "I still don't understand why you want to spend all this money subsidizing the vacuous pronunciamentos of self-styled 'ethicists'" (1996b). Indeed, he quotes James Watson himself as saying that he (Watson), "…saw ELSI initially as a

shield and a sounding board. 'It kept us from being attacked' by those who were concerned about the consequences of genetic research" (p.490).

A major structural problem with the ELSI program was identified: it was too low in the hierarchy and did not have the clout required to adequately represent and push through policy recommendations. In another article published in the Hastings Center Report, Roberts included a quote from a Capitol Hill staffer who said that, "ELSI is so low in the agency structure that even if it did make some policy recommendations, they would have to wend their way up through "97 levels of bureaucracy," and all the substance would be "sucked out of them" in the process" (1993). The 1993 OTA Report echoes the previous sentiments completely. While acknowledging some valuable work being done in the area of cystic fibrosis screening and in health insurance, the report flatly stated that "...no formal mechanism exists for ELSI-funded research findings to directly make their way back into the policy process. And although the ELSI programs have a large funding base for grants, they lack resources for in-house policy analysis" (box p.8). With reference to the genetic information and health insurance project, the Hill staffer referred to above stated: "The ELSI report on insurance just disappeared without a trace. Low level policy people with no particular charter issued a mandate and nothing happened" (Roberts, 1993, p.5).

As if these problems were not enough, in March of 1996 ELSI again made press in the science journals. Lori Andrews, the chair of the Working Group set up jointly by the NIH and the DOE to provide advice on ELSI, resigned. At issue was her belief that the autonomy of the Working Group (composed of outside experts in the fields of bioethics, law, the social sciences, basic and applied genetics, as well as representatives of professional societies and the public) was compromised. The specific "trigger" for the disagreement and departure by Andrews, as reported in *Nature* by Sally Lehrman, was the denial by Francis Collins of a plan by the Working

Group to develop a collection of papers on the non-medical uses of genetics (1996a). According to the vice-chair of the Working Group at the time, the plan, "…may have been squashed partly because of concern among geneticists working on behavioural issues that the working group would put together a general attack on their area of research" (p.96). In an article two months later, Lehrman followed up with a quote from Dorothy Nelkin (a New York University sociologist and member of the working group's executive committee) to the effect that the working group members "…feel that they are sometimes being used to legitimate the genome project, rather than to explore critically issues relating to its social impact" (1996b, p.357).

It would require far more time and research, but an interesting issue to pursue might be the timing of "major program reviews" instigated by agencies that find themselves under the glare of public scrutiny. This is what happened with the ELSI Working Group. The NIH, through Francis Collins, launched a review of the ELSI program. The leaders of the 7-month review were attorney Mark A. Rothstein and geneticist M. Anne Spence. Sally Lehrman, in the article referenced above, quotes Rothstein as saying that "…the goal is not to develop a "report card" on the ELSI panel, but to suggest how it might operate most effectively" (p. 357). The official wording of the committee's charge was that it would "…evaluate the appropriate scope of ELSI activities and the role of external advisers in the ELSI program. The committee will assess how, in the near term, it would be best to structure input on ELSI issues raised by and as a consequence of the Human Genome Project. The Committee also will assess how, in the longer term, it would be best to structure input on ELSI issues raised more generally by research involving human genetics" (Report, 1997, ¶ 5).

1997 - 2000

The Evaluation Committee took advice from many stakeholders and performed its own analysis of the function and operation of the ELSI Program. It appears to have taken seriously the issues of autonomy and lack of clout by observing that oversight of the ELSI research program by external advisers was essential. The Committee also found that the importance to public accountability of providing an independent evaluation and review of ELSI issues could "not be overstated" (Report, 1997, Essential Elements, #7). Three recommendations were made: 1) that the existing Working Group should be restructured and designated the ELSI Research Evaluation Committee, housed within NHGRI as an advisory committee to the Director and the Council and within DOE advisory to HERAC and the HGP (it had previously been a subcommittee at both NHGRI and the DOE); 2) that a process be established for ongoing coordination and communication with respect to ELSI issues throughout all the institutes of the NIH; 3) that a federal advisory committee on genetics and public policy be formed which would report to the Secretary of DHHS. These recommendations effectively separated the research function of ELSI from policy-making. It was intended to elevate the policy function to advisory committee status so that it could:

> …advise the secretary of DHHS and other government officials on matters concerning: genetic policies and practice, legislative and regulatory policy, professional education, public education, access to and quality of genetic services, privacy and confidentiality, and discrimination based on genetic information. (Report, 1997, Recommendation 3, bullet 4)

In addition, such an advisory committee would:

> … be independent and look to the future. It should identify emerging ELSI issues and, as necessary, form task forces to address them. The task force approach already has been effectively used, as illustrated by the current Task Force on Genetic Testing. However, the experience of this Task Force has also clearly shown the problems that arise for a group situated in an inappropriate governmental location. (The Task Force is technically a subcommittee of a subcommittee of an advisory council within a center at NIH and a subcommittee of a subcommittee of an advisory committee of an office at DOE.) Professional societies and government

> agencies whose participation is vital to successful policy development also will find working with a group at the level of the Secretary much simpler and more effective. (Report, 1997, Recommendation 3, bullet 5).

The stage was thus set for a revitalized and refocused ELSI Program.

The first recommendation came to fruition by the establishment of ERPEG (ELSI Research, Planning, & Evaluation Group), whose mission was to review and analyze the portfolio of ELSI research grants at both NHGRI and DOE; to participate in the development of the ELSI component of the new 5 Year Plan for the HGP; and, of course, to prepare a report that summarized its findings and make recommendations. ERPEG performed its initial analysis, which was followed by the development of five new goals to coincide with the new goals for the HGP; then followed up with a more extensive analysis of the ELSI portfolio. The five new goals were to:

1. Examine the issues surrounding the completion of the human DNA sequence and the study of human genetic variation.
2. Examine issues raised by the integration of genetic technologies and information into health care and public health activities.
3. Examine issues raised by the integration of knowledge about genomics and gene/environment interactions into non-clinical settings.
4. Explore ways in which new genetic knowledge may interact with a variety of philosophical, theological, and ethical perspectives.
5. Explore how socioeconomic factors, gender, and concepts of race and ethnicity influence the use and interpretation of genetic information, the utilization of genetic services, and the development of policy. (ERPEG Report, 2000).

From its extended analysis, the ERPEG report noted that there were emerging issues - such as behavioral genetics, genetic enhancement techniques, and other emerging technologies (such as fetal cell sorting, preimplantation genetic diagnosis, and the ability to test for adult onset disorders in children or even in the prenatal period) that would require additional ELSI attention in the coming years. It also found that while the large number of empirical and applied studies funded had been successful and should be continued, there was a need for more studies that took

a theoretical or analytical approach - and it specifically mentioned legal, historical, and philosophical analyses. The under-representation of minority principal investigators and investigators from disciplines outside of science (economics, cultural and physical anthropology, religious and moral philosophy) rounded out the ERPEG findings. Having concluded its mission by the publication of its report and recommendations, ERPEG as an entity expired in February 2000. Before it departed, however, it recommended that the NHGRI and the DOE should continue with a joint planning and evaluation group.

2001 - present

In spite of the recommendation from ERPEG that a joint group continue to oversee ELSI projects, with no explanation that I could find, the NHGRI and DOE decided that the ELSI advisory function would again be administered independently by each agency. The NHGRI established the ELSI Research Advisors (ERA) group. The DOE ELSI program continued to be staffed by one person, who is also responsible for overseeing other DOE programs.

There was a drop off of articles relating to ELSI in the early 2000's. Certainly ELSI grants were being funded, and a recent search of the active grants in the database results in 66 different projects at various stages of completion. They run the gamut of ELSI program areas and address all five of the goals previously mentioned; e.g. from "Parents' Interpretation and Use of Genetic Information," "Effects of gene patents on genetic testing and research," to "Indian and Hindu Perspectives on Genetic Variation," and "Distrust, Race/Ethnicity, and Predictive Genetic Testing," to name only a few.

In early 2004, ELSI invited proposals for the development of "Centers of Excellence in ELSI Research" (CEER). This new initiative was aimed at research groups that will "…bring investigators from multiple disciplines together to address new ELSI issues resulting in the

advances of genetics and genomics" (NHGRI, 2004b). In August, 2004, an NIH News Release announced that:

> "The initiative, the Centers for Excellence in Ethical, Legal and Social Implications Research, is being led by NHGRI, with significant contributions from the U.S. Department of Energy (DOE) and the National Institute of Child Health and Human Development (NICHD). About $20 million in grants will be awarded over the next five years with DOE contributing $500,000 and NICHD, $450,000. The first four Centers are being established at Case Western Reserve University, Cleveland; Duke University, Durham, N.C.; Stanford University, Palo Alto, Calif.; and the University of Washington, Seattle."

As always, the news release pointed out that, "the centers' output will be critical in formulating and implementing effective and equitable health and social policies related to genomic research" (NHGRI, 2004c).

Discussion

ELSI was, and is, an experiment in trying to balance the scientific work being done in the Human Genome Project in particular, and in genetics in general, with the consequences of that basic research -- new technologies, new applications, new products that have ethical, legal and social implications for all of us. Although its basic mission remained the same from 1990 to the present, its structure, composition, and goals changed over time. Although not always the most interesting aspect to read about (or write about!), the ELSI organizational structure was an important factor how well it was able - and perceived to be able - to make the kind of contribution for which it was intended. My research has shown me that there is a culture and hierarchy that exists in probably all government departments - but most definitely in the NIH and to a lesser extent in the DOE - and that where a program fits in that hierarchy will have a great influence on how seriously its work is taken.

Aside from administrative or functional issues, there are also philosophical issues associated with ELSI. Looking back at the historical environment that existed at the time ELSI

emerged, it is notable that a basic division existed between theory and practice in ethics. In its early years, the ELSI program seemed to be establishing a scholarly or philosophical space in which to study these profound and troublesome implications of research. That strategy and direction eventually led to criticism by many that it was "all talk and no substance." It also revealed a division between those scientists at the bench and the social scientists, ethicists, and legal experts who were critiquing the results and implications of the scientists' work. M. Susan Lindee made a very insightful observation with regard to this 'quality control' function of the ELSI program. She observed that "what the funding has done…is to promote the distressing general tendency to divide the project into "science" and the "implications" of that science. Officially outside the ELSI territory is the most important question of all: Is mapping the human genome a meaningful scientific priority?" (1994). A cynic would have said that this may, in fact, have been its intention.

ELSI is not without its accomplishments. It has funded many projects in the areas of privacy and fairness in the use and interpretation of genetic information (the U.S. Senate passed the Genetic Information Nondiscrimination Act of 2005 in February, although it has not yet become law); genetic testing and counseling (especially cystic fibrosis and breast cancer); issues of informed consent; and numerous projects, publications, and interactive media pieces in public and professional education about the issues surrounding genetics research. [In fact, several of the books we are reading for this course were funded by ELSI - the Daniel Kevles and the Lily Kay.] The NHGRI and the DOE both have extensive lists on their respective web sites that attest to the quantity and quality of the work undertaken in the ELSI program.

Nevertheless, there is a widespread belief that as worthy as the grants, books, and projects might be, they were never going to affect <u>policy</u> in these areas. This goes back to how

the ELSI program is structured. In its present iteration, policy work is undertaken in the Policy and Program Analysis Branch of the Office of Policy, Communications and Education, which is a part of the Office of the Director (Francis Collins). The branch includes a chief, a science policy analyst, a health policy analyst, and a program assistant. The official purpose of the PPAB is to analyze and track federal and state public policy that may have an impact on the mission of the National Human Genome Research Institute; work at the national level to identify, coordinate and develop genetics education activities for the public and for health professionals; and establish outreach activities with voluntary health organizations and consumer groups with a shared interest in human genetics and genome research.(NHGRI, Policy & Program Analysis Branch, 2005). Far from being the advisory body that reports to the Secretary of the Department of Health & Human Services, as recommended by ERPEG, it would appear that this branch is an in-house organ to disseminate official NHGRI statements and positions.

Another critique that has been made very eloquently by a number of writers has to do with the very existence of an ELSI program. It has been alleged that because of its influence (limited though that may be) and because of the dollars that the program brings into the field of bioethics, it may have skewed the research agenda (Sharp, 2005). Leigh Turner writes somewhat acidly that:

> "The availability of funding for genethics research is attracting researchers who - in the absence of this cornucopia of financial resources - would likely never consider pursuing scholarship in this area. It is hard to believe that pure intellectual fascination or a sense of civic duty are the only factors prompting so many scholars from anthropology, sociology, media studies and bioethics to pursue genethics-related research" (2003).

R.R. Sharp makes a related critique to the effect that ELSI failed to address controversial issues that might interfere with the pace of science; for example, in forensic science, genetic technologies are already being used routinely to "type" certain individuals in ways

that may be morally troublesome (Slide 5, 2005). This surely goes to the heart of the of the dilemma - thinking, studying, writing, researching, and publishing about the ethical, legal, and social implications of human genome research has not generated solutions to these problem areas.

Conclusion

It could be argued that the ELSI program was established merely to provide the conscience for the Human Genome Project. Such a characterization de-values the work of hundreds of well-intentioned and worthy scholars who participated in the program and believed in its core mission. Whether through ELSI's direct efforts or not, public awareness of issues surrounding genetic information and research has greatly increased. Nevertheless, as a science policy that proposes that 'problem areas can be identified and solutions developed before scientific information is integrated into health care practice,' it may not have succeeded. I will give Ruth Hubbard the last word: "The ELSI program gives the illusion that the social problems raised by the Genome Project will be handled, but the way it has been set up virtually guarantees that such concerns will not get in the way of the science" (1999).

References

Billings, P. (1994). *Genetic information in the health care reform era*. In D. Macer (Ed.), Bioethics for the people by the people (pp.51-56). Eubios Ethics Institute. Retrieved on March 25, 2005, from http://zobell.biol.tsukuba.ac.jp/~macer/

Callahan, D. (1988). The Development of biomedical ethics in the United States. *Annals New York Academy of Sciences*, 530:1-3.

Cottingham, K. (2001). A Decade of ELSI research: embracing the past and gazing into the future. *Science Next Wave*. Retrieved on March 24, 2005, from http://nextwave.sciencemag.org/cgi/content/full/2001/01/25/9?ck=nck

Department of Energy. Human Genome Project Information. (2001). *DOE ELSI Program emphasizes education, privacy: A retrospective 1990-2000.* Retrieved on April 2, 2005, from http://www.ornl.gov/sci/techresources/Human_Genome/resource/elsiprog.shtml

Hubbard, Ruth. (1999). *Exploding the gene myth*. Boston: Beacon Press, p. 159.

Krimsky, S. (1991). *Biotechnics and society*. Westport, CT: Praeger.

Larson, E.J. (1993). Half a tithe for ELSI. *National Forum*, 73 (2):15-17.

Lehrman, S. (1996a). Genome ethics chair resigns amid worries over autonomy. *Nature*, 380, March 14, p.96.

Lehrman, S. (1996b). Genome ethics panel comes under the microscope at NIH. *Nature*, 381, May 30, p.357.

Lindee, M.S. (1994).The ELSI hypothesis. *Isis*, 85:293-296.

Marshall, E. (1996a). ELSI's cystic fibrosis experiment. *Science*, 274 (5287):489.

Marshall, E. (1996b). The Genome Project's conscience. *Science*, 274 (5287):488.

Marshall, E. (1997). Panel urges cloning ethics board: Human Genome Project.

Science, 275 (5296): 22.

National Human Genome Research Institute. (2004a). ELSI Research Program. *About ELSI*. Retrieved on March 22, 2005, from http://www.genome.gov/10001754

National Human Genome Research Institute. (2004b). Budget and Financial Information. *NHGRI FY 2005 Justification of Estimates for Congressional Appropriations Committees.* Retrieved on March 29, 2005 from p.14, http://www.genome.gov/Pages/About/Budget/FY05justification.pdf

National Human Genome Research Institute. (2004c). *"NHGRI Launches Centers for Excellence in Ethical, Legal and Social Implications Research."* NIH News Release. Retrieved on April 3, 2005, from http://www.genome.gov/12512375

National Human Genome Research Institute. (2005). Policy and Program Analysis Branch. Retrieved on April 2, 2005 from http://www.genome.gov/10001087

National Human Genome Research Institute. (1997*). Report on the Joint NIH/DOE Committee to Evaluate the Ethical, Legal, and Social Implications Program of the Human Genome Project.* Retrieved on April 2, 2005 from http://www.genome.gov/10001745#top

National Human Genome Institute. (2003). *A Review & analysis of the ELSI Research Programs at NIH and DOE.* (ERPEG Report). Retrieved on March 28, 2005, from http://www.genome.gov/10001727

Patrinos, A. (1997). Introducing the Human Genome Project: its relevance, triumphs,

and challenges. *The Judges' Journal*, 36(6). Retrieved on March 25, 2005, from http://ftp.ornl.gov/sci/techresources/Human_Genome/publicat/judges/drell.html

Roberts, L. (1993). Whither the ELSI program? *Hastings Center Report*, 23 (6):5.

Roberts, L. (1993).Taking stock of the Genome Project. *Science*, 262 (5130):20-22.

Sammons, C. (1978). Ethical issues in genetic intervention. *Social Work*, May, 237.

Sharp, R.R. (2005*). Ethical issues in predictive genetic testing: BRCA1 and beyond.* Online CME presentation of Strategies for meeting the needs of today's women during menopause. Baylor College of Medicine. Retrieved on April 1, 2005 from http://www.baylorcme.org/needs/presentations/sharp/presentation_text.cfm

Toulmin, S. (1988). Medical ethics in its American context: an historical survey. *Annals New York Academy of Sciences*, 530:7-15.

Turner, Leigh. (2003). The tyranny of 'genethics'. *Nature Biotechnology*, 21 (11):1282.