

HUMAN GENOME ORGANISATION

ETHICAL, LEGAL AND SOCIAL ISSUES COMMITTEE

STRUCTURES & FUNCTIONS SUBCOMMITTEE

ENHANCING THE ROLE OF THE HUGO-ELSI COMMITTEE

BETHESDA MEETING OCTOBER 1995

1. MEETING: A meeting of the HUGO-ELSI Committee was held on 14-15 October 1995 at Bethesda, USA. It was co-chaired by Dr Nancy S Wexler (USA) and Professor Alain Pompidou (France). Members participating were Professor Kåre Berg (Norway), Professor Alexander Capron (USA), Professor Ruth Chadwick (UK), Justice Michael Kirby (Australia), Professor Bartha Knoppers (Canada), Dr Victor A McKusick (USA), Professor Stefano Rodotà (Italy) and Dr Hiraku Takebe (Japan). Attending by invitation at various times were Dr Jessica Davis, Professor Henry Greely, Dr Kenneth Kidd, Dr Robert Murray and Dr Elizabeth Thomson (all of the USA). The Committee was assisted by Ms Susan Wallace of HUGO Americas.

2. COMMITTEE DOCUMENTATION: The Committee had before it a number of documents including:

2.1 A short statement on the purposes and functions of HUGO;

- 2.2 The HUGO statement on patenting of DNA sequences;
- 2.3 The HUGO summary document on the Human Genome Diversity (HGDP);
- 2.4 Paper prepared for the Committee on Ethical Issues in International Collaborative Research on the Human Genome: the HGP and the HGDP (Professor Knoppers);
- 2.5 Proposed Model Ethical Protocol for Collecting DNA Samples - North American Regional Committee Human Genome Diversity Project (Professor Greely);
- 2.6 Working document: Position of France About Patentability of the Human Genome (10 October 1995);
- 2.7 French Ministry of Higher Education and Research: Report of the Study Group on the Intellectual Protection of the Results of Research on the Human Genome, Cell Collections and DNA Sequence Data (10 June 1994); and
- 2.8 Order of the President of the Peoples' Republic of China, *Law of the Peoples' Republic of China on Maternal and Infant Healthcare*.

Also tabled at the meeting were various other documents including some emanating from WHO, the UNESCO International Bioethics Committee and by individual members of the Committee.

3. Although some members of the Committee have had a virtually continuous association with HUGO since its foundation (Dr McKusick being the

Foundation President), it is inevitable that new members will not have a close knowledge of the institutional history of HUGO and the preceding and parallel history of general DNA sequencing. Some useful information on such historical matters is contained in R Cook-Deegan, *The Gene Wars*, Norton and Co, New York, 1994. It was agreed that a short institutional history of HUGO would be useful to this and other HUGO Committees and would become indispensable as time went on. Obviously, Dr McKusick, Professor Capron and Dr Wexler should be most closely involved in the preparation of this document which should issue under the authority of the HUGO Council.

4 WORK OF COMMITTEE: In particular, no institutional history of the ELSI Committee of HUGO was available to new members. What was available was a report of Workshop on the "Ethical Implications of the Human Genome Project - International Issues". But this Workshop was held as long ago as October 1992. It recorded the then defined role of the Committee as being:

- 4.1 "Identifying and analysing the ethical, social and legal issues of Human Genome Project;
- 4.2 Promoting the international exchange of information and concerted action amongst regional, national, professional and lay bodies concerned with these issues;
- 4.3 Disseminating reports or analyses which promote public understanding of these issues; and
- 4.4 Advising the HUGO Council on how it can fulfil its stated purpose: to encourage public debate and provide information and

advice on the scientific, ethical, social , legal (and commercial) implications of Human Genome Projects”

To the Amsterdam meeting were offered reports and recommendations by representatives of various bodies which attended (French National Ethics Committee, CABHI, WHO, CIOMS, UNESCO, Japan ELSI Group, ECWP and USDOE/NIH Ethics Committee, EC Group of Advisors, ISENB and others).

The major proposal emerging from the Amsterdam meeting was for HUGO-ELSI to convene an ongoing international forum on the ethical, legal, cultural and social implications of the Human Genome Project. Various activities were foreshadowed from the forum including the collation of reports, exchange of information and promotion of public debate. It has to be said that these proposals have not been diligently followed up. It does not appear that very much at all has been done between 1992 and 1995, despite the rapid advance of the Human Genome Project, the advent of and debates surrounding the Human Genome Diversity Project and the multiple ethical, legal and social issues which each has produced. The achievements of HUGO-ELSI to date have been limited. Upon one view, the main achievement is the existence of a Committee which can give the appearance that serious attention is being given to ethical, legal and social issues by HUGO when the reality is that HUGO-ELSI appears to have been the orphan child of HUGO.

5. COMMITTEE STRUCTURE: The HUGO-ELSI Committee is one of six existing Committees under HUGO's organisation. The others are Human Genome Mapping; Mouse; Human Genome Diversity; Informatics; and

Intellectual Property. Each Committee reports to the HUGO Council which is made up of eighteen elected persons, including the President. Membership of the Council is limited to three years with a possibility of one additional term. Each year six members of HUGO Council rotate off the Council. The general membership (currently numbering 824) elects four Council members. The other two members are co-opted by the Council. The latter facility is designed to ensure good international representation. The Council meets approximately twice a year. The procedures for running the Committees is quite loose. No written protocol for HUGO-ELSI exists. Such a protocol does exist as "Operating Rules and Procedures" of the Human Genome Mapping Committee. It would be desirable if appropriate protocols, suitable to each Committee, were settled and approved by HUGO Council. This would establish the mandate of the Committee and a procedure for systematic Council review and consideration of the Committee's recommendations as made from time to time.

6. SUBCOMMITTEES: At the HUGO-ELSI meeting in October 1995, the following sub-committees were established:

- 6.1 Human Genome Diversity Project;
- 6.2 Gene Therapy and Screening;
- 6.3 Patents and Commercialisation; and
- 6.4 Structures and functions.

It is hoped that each of these sub-committees will, before the next meeting of the Committee, prepare papers with proposals for the better organisation of the work of HUGO-ELSI and to ensure that there is, between meetings of the Committee

(which necessarily are rare) an ongoing programme of activities necessary to discharge the Committee's functions between meetings.

7. LIAISON: The Committee also decided to establish liaison with various international and regional bodies concerned with concerns overlapping the mandate of the Committee. Particular members of the Committee were assigned, because of their contacts, as points of liaison with these bodies. It may be expected that they will report on the work of the HUGO-ELSI Committee. But it will be necessary for them to have something to report on. It may also be expected that they will circulate other members of the Committee about the activities of international and regional bodies having relevance to the ethical, legal and social issues connected with HGP and HGDP. An effective protocol within the Committee will be needed to establish modes of communication and procedures for follow-up action where that is suggested and agreed to.

8. NEXT MEETING: It was agreed that the next meeting of the Committee should take place in association with the meeting of the International Association of Bioethics. This will be held in San Francisco 22-26 November 1996. It was contemplated that the meeting of the Committee should occur within a framework of a forum at that conference, possibly in the two days following the conference. This could provide opportunities for the discussion of working documents to be produced by the first three (substantive) sub-committees established at the meeting. It was particularly emphasised that it would be imperative to have present at any such forum participants from (a) a wider range of countries than are represented on the HUGO-ELSI Committee; (b) younger

bioethicists and scientists, possibly under schemes available in North America for that purpose; and (c) critics of HGP and HGDP in order to permit discussion and to encourage mutual understanding.

9. COMMITTEE STATEMENT: The substantive work done by the Committee at its October 1995 meeting involved the examination of the two papers addressed to the Human Genome Diversity Project, respectively by Professors Knoppers and Greely. The Committee spent considerable time examining these papers and the ethical protocols which they propose. At the end of the meeting, the Committee approved a consensus document which is to be forwarded to HUGO Council. This will be a provisional *Statement on the Principled Conduct of HGP and HGDP*. The statement records the origins of both projects; acknowledges the concerns that have been expressed about each; identifies certain principles which have guided the Committee's approach to the expression of essential ethical rules to guide each project, and then lists ten rules put forward as prerequisites for principled conduct. Although the rules stated were elicited from documents prepared on the context of HGDP, they apply, in the opinion of the Committee, equally to HGP and are so expressed. If this document receives provisional approval by the HUGO Council, it may be circulated for comment and criticism. The results can then be discussed at the San Francisco forum, as proposed above.

CRITIQUE OF THE COMMITTEE

10. CRITICISM: From the foregoing description of the October 1995 meeting of HUGO-ELSI, the following critique can be offered:

- 10.1 Its meetings are not regular and an undue interval has elapsed since the last meeting;
- 10.2 Its membership is unrepresentative of a body which is concerned with ethical, legal and social issues of a global organisation concerned, in turn, with matters pertaining to the entire human species. All members come from advanced, developed countries. All but Dr Takebe are members of countries whose ethical and legal traditions are derived from Western Europe and the Judeo-Christian tradition. This monochrome quality was not altered by the distinguished invited guests. Nor were the members of the Committee who were unable to attend the October meeting such as would have altered this composition. They come respectively from Japan via the United States, Germany and The Netherlands. A need for diversity in membership is patently obvious;
- 10.3 The resources of the Committee are also inadequate. Although various proposals have been made from time to time to levy five, three or two percent of the budget for Ethical, Legal and Social Issues, the funding attributed to HUGO-ELSI is clearly much less than this. The fact that no meeting of the Committee has been held between 1992 and 1995 is indicative of an apparent lack of

between 1992 and 1995 is indicative of an apparent lack of encouragement from, and concern of, the Council about the activities of the Committee. If the Council had deemed it imperative, the Committee would have convened much earlier to offer the Council advice;

10.4 The methodology of the Committee is also imprecise. Although at the last meeting in Amsterdam numerous ideas and proposals were put for an international forum, these do not appear to have been pursued with the attention that their importance deserves. The lack of methodological guidelines and even a provisional protocol for the conduct of the work of the Committee is painfully obvious; and

10.5 Indeed, there seems to be some uncertainty as to what the Committee is expected to do and what weight will be assigned to its recommendations with what sanctions (if any) imposed by the HUGO Council to their breach.

11 DIAGNOSIS: In much discussion of the history of HGP, mention is made of the ambivalence in some scientific quarters, about ethics etc committees working in the area of HGP. In Robert Cook-Deegan's book, he described James Watson's support for study of such questions. *Ibid*, 237:

"Some very real dilemmas exist already about the privacy of DNA. The problems are with us now, independent of the Genome Program, but they will be associated with it. We should devote real money to discussing these issues.

Watson considered that NIH should set aside 3% or so of its Genome funds for this purpose. He was completely candid about how the information could be abused. It was in this context that he suggested the necessity for laws and for candour with legislators, specifically the Congress of the United States of America. *Id.* Dr McKusick and Dr Wexler have established an undoubted personal commitment to ELSI activities of HUGO. Professor Capron has, virtually from the start, played an important part in these issues and explained their importance.

12. On the other hand, there are different attitudes:

- 12.1 That Ethics Committees merely waste scarce funds which should be devoted to scientific research;
- 12.2 That such Committees direct attention, promote controversy and impede the work of science;
- 12.3 That such Committees are ultimately powerless because of the lack of sanctions to prevent scientific research going ahead, if not in developed countries then in undeveloped countries eager for technological industries; and
- 12.4 Such Committees merely propose the drawing of lines congenial to their members, agitate political intrusion and can rarely, if ever, understand fully the scientific and technological issues that are at stake.

A dispassionate examination of the activities of the HUGO-ELSI Committee would suggest that the Council of HUGO is content to have the Committee perform occasional functions but not able, or willing, to provide the resources and backup that will ensure that it can perform those functions effectively as the controversy, importance and potential dangers of the issues within its mandate suggest are needed. The future activities of the HUGO-ELSI Committee must be directed towards remedying the defects in the previous organisation of the Committee and addressing, with candour, the fundamental question: Does HUGO simply wish to be an organisation of scientists completely unconcerned with ethical, legal or social issues until disasters, scientific or political, occur? Or does the HUGO Council embrace the opinion expressed so eloquently by James Watson, with a consequence that it is willing to devote a significant part of its budget to ensure that the Committee can function as a reality, with a real programme and with significant ongoing activities. The kinds of persons whom the HUGO Council would wish to have associated with the HUGO-ELSI Committee, with appropriate expertise and credibility, are unlikely to offer their services if it becomes obvious that their function is to perform a palliative role - providing the appearance of legitimacy and concern without the substantive backing that the proper discharge of the mandate of the Committee demands.

RECOMMENDATIONS

13. COMMITTEE PROTOCOL: The HUGO Council should give consideration to the above critique and diagnosis. It should decide whether it wishes the ELSI Committee to have an active function or to be no more than an occasionally

meeting body, with very small resources, providing a talk-shop from time to time giving the appearance of activities and providing occasional statements which few scientists, actually engaged at the workplace, will read, fewer still will be concerned with and even fewer will feel bound by. To this end the HUGO Council should:

- 13.1 Identify the goals which it sets for the ELSI Committee;
- 13.2 Specify the protocol by which the Committee is to operate and priority areas for its concern and report to the Council;
- 13.3 Follow-up the work of the Committee with endorsement, with or without modification, of statements issued by the Committee and encouragement of public and scientific debate about ethical, legal and social issues;
- 13.4 Address the issue of the sanctions, if any, that will be provided for breach of ethical guidelines set by HUGO, both institutional and individual;
- 13.5 Promote in all scientific meetings a component of the activities addressed to the ELSI issues raised by the scientific meeting. A good model in this respect would be the international scientific meetings on HIV/AIDS. It is rare indeed for such meetings now to be held without the participation of People living with HIV/AIDS and without a component addressed to ethical and social issues;
- 13.6 The HUGO Council should recognise that ethical, legal and social issues are not separate from, but must be intimately integrated

with, the scientific advance of HGP and HGDP. Without this recognition, it is likely, before long, that political and popular concerns will provide serious impediments to the beneficial advance of both projects.

14. BUDGET The HUGO Council should identify a fixed proportion of the total HUGO budget for ELSI activities, just as James Watson urged. This proportion should be earmarked and available for economical use in meetings, fora, publications, exchange of information and other activities within the specified mandate of the Committee. A large discretion should be given to the co-chairs of the Committee to organise activities. Such activities should be much more regular and certainly more frequent than once every triennium.

15. MEMBERSHIP: It is inevitable that the membership of the HUGO-ELSI Committee cannot be representative of all interests, ethical, legal and social. However, the present Committee is quite ill-balanced as it recognised itself. The overwhelming majority of humanity is simply not reflected in its membership. The need for better gender, racial and cultural diversity is clear. But, in addition to the foregoing, the following interests should be reflected in a broader based Committee:

- 15.1 Representation from the Council in order to afford feedback;
- 15.2 Representation of skilled scientists with good knowledge of the empirical data concerning the advance of the HGP and HGDP to which ethical etc issues can be addressed;
- 15.3 Some continuity of membership; and

15.4 Greater membership from outside the United States of America. It should be possible, at meetings, to invite observers from interested groups and experts who could participate with the utility offered by the invited guests who attended in October 1995.

16. METHODOLOGY: The Committee itself should establish its own methodology. It should set its objectives and targets and report these to the HUGO Council. The Committee should accept the obligation to present an *Annual Report* to the HUGO Council detailing its activities. Indeed each of the Committees of HUGO should provide *Annual Reports* and their content should be publicised in order to promote the transparency of the Organisation.

17. PUBLICATIONS: There is a need for the Committee to undertake the task of coordinating, collating and distributing ELSI material. A number of newsletters already exist such as *Human Genome News*, the *European Biotechnology Information Service Newsletter* and *Eubos Journal of Asian and International Bioethics*. There would be no point in duplicating them. Bibliographies are also produced by M Yesley at Los Alamos Laboratory (reportedly about to go on the Internet) and D Karajala at Center for the Study of Law, Science and Technology of Arizona State University, both in the United States. However, there is a need for a comprehensive service. The HUGO-ELSI Committee should be exploring ways of meeting that need effectively. Its role at the centre of the HUGO organisation should give it an authority and legitimacy to perform or at least organise such a task.

18. BIOETHICS COMMITTEES: A large number of national bioethics committees have now been established, connected with HGP. Some have become involved in HGDP. This national consultative process should also be integrated into the thinking of HUGO and a synthesis of material provided to HUGO Council. This would seem to be a natural task for the HUGO-ELSI Committee. At the moment it is not being done. Only slow progress appears to be being made in the preparation of a *Year Book* as proposed at the Amsterdam meeting in 1992. There is little point in the preparation of formal statements by the HUGO-ELSI Committee if they are not given widespread publicity, attention and promote the kind of public debate which encourages appreciation of the importance of these issues, particularly by scientists.

19. SANCTIONS: The Council of HUGO should give some consideration to attaching some consequences to a breach of ethical rules which HUGO has adopted. Unless HUGO can itself demonstrate the effectiveness of self-regulation, it is likely that governments and legislatures will step in with more heavy-handed and inappropriate legislative regulation that could set back either HGP or HGDP or both.

20. INTERNATIONAL GUIDELINES HUGO should contribute to the development of international statements or guidelines eg by the European Union, UNESCO, IBC and other bodies. This cannot be done unless there is true liaison between the Committee and those bodies and a principled approach to the consideration of their proposals.

21. INSTITUTIONAL HISTORY: There should be prepared, under the auspices of HUGO Council, an institutional history describing the origins of HUGO, of HGP and HGDP, current activities and some of the personalities that have been involved. Consideration might also be given of the preparation of a glossary which would be available beyond the Committee to explain to the public the scientific terms and some of the chief scientific and technological issues being addressed by the two projects.

22. ADMINISTRATIVE ASSISTANCE: If a budget of HUGO devotes an adequate resource to the Committee, consideration should be given to the appointment of an executive officer (even part-time) who could service the Committee and help it to perform its tasks. In scientific committees it might be possible to rely on scientific institutions to do this. This is likely to be less viable in the case of the HUGO-ELSI Committee.

23. TRANSLATIONS: Statements by the HUGO-ELSI Committee should be provided to international journals for debate, consideration and criticism. The translation of such statements into at least major international languages should be contemplated. Where papers are prepared for the HUGO-ELSI Committee, eg the paper by Professor Knoppers, such papers should be printed by HUGO and made available through appropriate channels, especially to scientists. Only in this way will their understanding of the ethical, social and legal issues be enlivened. Paper-writers in this area should be invited to HUGO scientific meetings. Such interface between bioethicists and scientists would be good for both.

24. TRANSPARENCY: To promote transparency of the organisation of the HUGO-ELSI Committee, to deflect criticism which is partly justified and to meet objections, consideration should be given to the widest possible distribution of discussion papers produced by the sub-committees of the Committee, including discussion papers on the objectives, structure, and methodology of the HUGO-ELSI Committee. Unless there is a genuine attention to the activities of the Committee on the part of the HUGO Council, the members of the Committee and others in the international community are likely to lose faith in the commitment of HUGO Council to serious injection of these issues into the two projects.

25. EDUCATION: It will be essential to establish a sophisticated educational strategy. Indeed, this should be under preparation at the moment. Otherwise, there is a real danger that commercial interests may run ahead of national health budgets, realistic capacities and public tolerance of gene therapy and screening in particular but also of HGDP. If the HUGO-ELSI Committee is not to do this, it must be done by the HUGO Council itself. No evidence of an active educational programme by HUGO Council was presented to the Committee meeting.

26. FUTURE PROGRAMMES: The HUGO Council should endorse the decision of the HUGO-ELSI Committee to meet, if not before, in conjunction with the conference in San Francisco in 1996. But it should support, with appropriate funding, at least some consultative measures, particularly in

countries likely to be concerned by the HGDP. China, India and countries of the Pacific spring to mind.

27. COMMITMENT: The fundamental issue is the commitment of HUGO Council to real attention to ethical, legal and social issues of HGP and HGDP. If there is a fundamental commitment, resources must be provided and institutional support given. Otherwise, there is a danger that the Committee will be seen as more active than its resources permit it to be, more representative than its membership really justifies and more defensive of HUGO's projects than reality allows.

28. THIS PAPER: This paper represents the views of one member only of the HUGO-ELSI Committee. It has not been discussed with the other members of the Committee who take no responsibility for the opinions expressed. It derives from a reflection upon the October 1995 meeting and a consideration of the ways in which the Committee's activities can in the future be channelled to maximise its utility to the furtherance of HGP and HGDP, each of which the author accepts as vital for humanity.

18 October 1995

MDK