

ABSTRACT

WHOSE DNA?

TONGA & ICELAND, BIOTECH, OWNERSHIP AND CONSENT

Co-presented by Lopeti Senituli and Margaret Boyes
Australasian Bioethics Association Annual Conference
Adelaide, February 14-16 2002

In November 2000, Australian biotech company Autogen announced it had secured the exclusive rights to the entire gene pool of the Tongan people through a contract signed with Tonga's Ministry of Health. Due to adverse public reaction in Tonga, Autogen is supposed to have withdrawn its interest in August 2001. However, other biotech companies are interested in the Tongan people because they are genetically isolated. If Autogen has indeed withdrawn its interest, it is one battle won in the ongoing struggle by indigenous peoples to assert their sovereignty over their own resources.

The agreement was originally negotiated without any publicity or public debate in Tonga. By comparison, the consent given by Icelandic people to their agreement with the commercial firm de-Code, was achieved after being hotly debated in the parliament and the media, and was described variously as "democratic" and "acrimonious, polarised and pitting laymen against experts". When informed consent becomes a political activity, which questions take priority? Will biotech take "no" for an answer, if that is the decision?

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WHOSE DNA? TONGA AND ICELAND,
BIOTECH, OWNERSHIP AND CONSENT

Let me begin by acknowledging the Kaurna people, and that we have the privilege of conducting discussion on their land. Thank you.

In Western medicine and research, dissent and controversy are not usually elements of reaching informed consent at the bedside. The individual usually gives consent or doesn't, although the path to reaching the decision may be a complex one. When the process involves the parliament or families and traditional community decision-making processes, it looks quite different. Add to this biotechnology, venture capital and a new kind of commodity, bioinformation,¹ the chance of a new clinic for each village, collaboration with geneticists who specialize in an illness familiar to the community, international media attention, employment opportunities, health strategies, a share in profits, complex debate about privacy, a dissenting status for those who opt out, acrimonious and polarized debate in the parliament as well as the medical and research communities and cultural differences on basic concepts such as personhood² and autonomy³. Genomic research has brought some of these elements to Iceland, Estonia, a remote Italian village⁴, Tonga, Norfolk Island⁵ and other places.

I will touch briefly on what has happened in Iceland around its agreement with deCODE Genetics, and mention some of the concerns raised by indigenous peoples around culturally appropriate informed consent and ownership of DNA. Then LS will speak about events in Tonga.

¹ Rose, Hilary (2000) The Commodification of Bioinformation: the Icelandic Health Sector Database The Wellcome Trust, London p5.

² Christakis, Nicholas (1992) "Ethics are Local: Engaging in Cross-cultural Variation in the Ethics for Clinical Research" Social Science and Medicine V35 #9, pp1079-1091 @ p1086.

³ Levine, Robert J (1991) "Informed Consent: Some Challenges to the Universal Validity of the Western Model" Law, Medicine and Health Care V19: 3-4 Fall-Winter, pp207-213 @ p210.

⁴ Follain, John (2001) "Sample People" The Weekend Australian Magazine Sep 8-9

⁵ Hinde, Julia (2000) "Genetic Bounty: An Island Lifestyle is helping the Hunt for Disease Genes" New Scientist 6 May p23.

Population genetics is of interest to two broad areas of scholarship: human evolution and the global history of human migration and differentiation⁶ (geneticists working with anthropologists, linguists, biologists, social scientists) and secondly to medical research (geneticists working with pharmaceutical researchers, bioprospectors, doctors and epidemiologists). Of course both groups will have lawyers.

Population based genetic research is being carried out under the auspices of the HGDP as well as being linked to biotechnology companies and government projects, sometimes as hybrid structures between state and market⁷. Genomics is distinguished by the strong interest of venture capital, major pharmaceutical firms, new biotech companies and governments. Some of the people from whom DNA is taken or sought are indigenous peoples. The issues that have been identified by them as being of concern include:

- The dissonance between the concept of "genetic property" and the shared nature of economic and cultural assets, which is integral to most indigenous societies⁸.
- That human bodies are being treated with disrespect⁹ and located as sites of exploitation¹⁰.
- That the scientific community in wealthy nations will acquire and use genetic samples and information about indigenous peoples that will create wealth in which they will not share.¹¹

Genomic projects are also being undertaken with populations which do not identify themselves as indigenous peoples, such as the UK¹², Norfolk Island, Mormons¹³ and in

⁶ Committee on Human Genome Diversity, National Research Council (1997) Evaluating Human Genetic Diversity National Academy Press, Washington DC p2.

⁷ Rose, Hilary (The Wellcome Trust) op cit, p 31.

⁸ Dodson, Micheal and Williamson, Robert (1999) "Indigenous Peoples and the Morality of the Human Genome Diversity Project" Journal of Medical Ethics v25 pp204-208 @ p205.

⁹ Liloqula, Ruth (1996) "Value of Life: Saving Genes versus Saving Indigenous Peoples" Cultural Survival Quarterly Summer, v20, Issue 2; pp42-45 @ p44.

¹⁰ Dodson Michael (2000) "Human Genetics: Control of Research and Sharing of Benefits" Australian Aboriginal Studies 1&2 Pp56-64 @ p57.

¹¹ Dodson, (2000) op cit p57.

Iceland. Such populations are sometimes targeted because they are (arguably)¹⁴ genetically isolated, and have well documented genealogical histories, making them valuable for tracing inherited diseases.

ICELAND

In the case of Iceland, the availability of genealogies which date back for centuries contributed significantly. The Iceland government's agreement with the commercial firm deCODE has been one of the most studied and controversial cases of the new pharmacogenetics, and is an example of the hybridising of research paradigms.

The way in which informed consent was claimed on behalf of the people of Iceland was through an act of parliament. The agreement with deCODE was achieved after being hotly debated in the parliament and media and was argued by some to be "the most fully informed-consent population-wide debate about biotechnology that's ever taken place"^{15, 16} and by others to have appropriated democracy to deCODE's advantage¹⁷. The first Bill proposed that the medical records of the entire Icelandic population were to be entered into the database on the basis of universal presumed consent. The scientific, medical and legal communities immediately entered into intense public debate which has continued internationally to the present. Many of the opinion polls have been paid for by deCODE, including the setting of questions, and in this context, Stefansson, the geneticist who set up deCODE, says that 90% of Icelanders are in favour of the database¹⁸. Mannvernd,¹⁹ however, (which is the association of Icelanders for ethics in science and medicine) argues persuasively that this is far from accurate and that there has been no reliable assessment of public opinion²⁰.

¹² Rose (Wellcome Trust) op cit p7.

¹³ Rose (Wellcome Trust) op cit p8.

¹⁴ Iceland's "genetic homogeneity" is increasingly being questioned, eg: Sigurdsson Skuli (2001) "Yin-yang Genetics, or the HSE deCODE Controversy" New Genetics and Society v20 #2 pp103-117 @ 107.

¹⁵ Rabinow, Paul quoted in Sigurdsson, op cit @ p110.

¹⁶ Gulcher, Jeffrey & Stefansson, Kari (2000) "The Icelandic Healthcare Database and Informed Consent" New England Journal of Medicine v342 #24, June 15 pp1827-1830 @ p1827.

¹⁷ Sigurdsson, op cit, p111.

¹⁸ Masood, Ehsan (2000) "Gene Warrior: Opinion Interview" New Scientist 15 July pp42-45 @p44.

¹⁹ www.mannvernd.is/english

²⁰ Arnason, Einar (2002) personal communication.

Subsequently, the “opt-out” system was adopted, requiring citizens to register if they do not want to be on the database. By November of last year (2001) slightly more than 20,000 citizens had done so, roughly 9-10% of the population. The Mannverndt website includes a 4 page list of doctors who have gone on record to say that they will not hand over data on their patients unless the patient requests to participate in writing. Sigurdsson²¹ notes the irony of legislation requiring these people to be on a database by the Office of the Director General of Public Health in Reykjavik (Iceland’s capital) while the database of participants remains empty for six months, thus giving the “opt-outers” a socially deviant status.

A few facts:

- Rose’s research revealed that the HSD controversy, which bitterly divided the intellectual community and media, did not mobilize much interest among women.²²
- Annas argues that the commercial nature of the linked databank and its for-profit research agenda means that individual consent should be sought, even though records are non-identifiable.²³
- The Iceland Psychiatric Human Rights Group maintains concerns about the consent process on its website.

Informed consent thus becomes a question of public consultation and how political will is mobilised, as much as it is about the components familiar to western bioethics of disclosure, comprehension, voluntariness, competence and consent or refusal

²¹ Sigurdsson, op cit, 113.

²² Rose, Hilary (2001) “Gendered Genetics in Iceland” *New Genetics and Society* v20 #2 pp119-138 @p128.

²³ Annas, George (2000) “Rules for Research on Human Genetic Variation—Lessons from Iceland” *New England Journal of Medicine* v342 #24 pp1830-1833 @p1831.

INFORMED CONSENT

The Council for International Organisation for Medical Sciences (CIOMS) recognizes that what is meaningful consent changes with the prevailing cultural norms.²⁴ In 1991 the CIOMS asked Robert Levine to provide a definition of informed consent which is widely applicable to different countries and cultures. He deliberated at length and said that he could not, in recognition of the vastly differing perspectives on the nature of the concept of “persons”²⁵. Part of the difficulty lies in the differing cultural understandings between collective and individualist oriented societies. The practice of seeking consent from individual research subjects may be at variance with cultural norms. In Australia, research involving Aboriginal people requires the researcher to approach the Aboriginal organisation (such as the Land Council or umbrella organization) representing the group prior to approaching individuals.²⁶

Dodson argues that consent ought to be approached as negotiation rather than consultation, because “consultation” is inadequate for what is required. Along with Williamson, he states that “the first fundamental ethical imperative is that (researchers) must begin by making an effort to understand (indigenous peoples’) situation and culture and by respecting their concept of autonomy and their belief system”²⁷. Thus they turn informed consent on its head. The western disclosure model of bioethics focuses on researchers informing subjects about the research. But Dodson and Williamson advise that much onus is on the researchers to be informed by those whom they seek as subjects about their culture.

Each element of informed consent poses potential difficulties for some non-western cultures:²⁸ full, truthful disclosure may be at variance with cultural beliefs about hope, wellness and thriving of individuals; autonomous decision-making may counter

²⁴ Knoppers, Bartha Maria; Hirtle, Marie; and Lormeau, Sebastian (1996) “Ethical Issues in International Collaborative Research on the Human Genome: the HGP and the HGDP” Genomics v34 pp272-282 @ p274.

²⁵ Levine, op cit p210.

²⁶ Australian Institute of Aboriginal and Torres Strait Islander Studies Research Grants: Information for Applicants and Ethical Guidelines

²⁷ Dodson and Williamson, op cit p32.

²⁸ Gostin, Lawrence O (1995) "Informed Consent, Cultural Sensitivity, and Respect for Persons" JAMA v274 #10, Sep pp844-845 @ p844.

family-centred values and the social meaning of competency; uncoerced choices may contradict cultural norms about, for example, obedience to the wishes of spouses or family elders

The isolated and self-governing subject thus presents an important challenge to research involving groups. Additionally, some research is focused on the nature of the group, not on its composite individuals, making consent by groups an important consideration. Anthropology has well-defined methods for the study of collective decision making, but bioethics is only beginning to articulate the mismatch between individualistic disclosure models of informed consent and population genetic research. The model represented by "I inform, you consent" presumes a rational researcher informing a rational subject. A fuller view of the communication act would situate informed consent in a particular historical and socio-cultural context which would transmit certain worldviews and value systems about persons, illnesses and relationships.²⁹ This view recognises the speaker's social status and power.

Informed consent is an imperfect instrument, but it is also an essential standard and a safeguard of the rights and dignities of subjects. As it evolves to take account of collectivities and of non-western cultures it is doing so by preserving some elements of the ethics and values of the individualist and ownership oriented market economy. The commodification of body parts through patents and the commercialization of molecular genetics challenges the Kantian imperative against using human beings merely as a means. It does this through knowledge production and a discourse of meaning, the beneficiaries of which are not those from whom DNA is taken or sought.³⁰

Models to guide the conduct of trans-cultural research are also problematic and deficient³¹. Race has a well documented past and present in genetics discourse, and

²⁹ Marta, Jan (1996) "A Linguistic Model of Informed Consent" *Journal of Medicine and Philosophy* v21 pp41-60 @ p49.

³⁰ Boyes, Margaret (2000) "Population Specific Genetic Research, Indigenous Peoples and Culturally Appropriate Informed Consent: Who Decides?" Paper presented to ABA Annual Conference Sydney 5-9 July.

³¹ Christakis op cit

when George Annas³² says that gene-ism could eclipse racism as the most destructive force on the planet, the politics of informed consent beckon greater attention.

To Conclude

Tonga has a certain amount in common with Iceland although they are globally opposite. Iceland has a small population which, in Sigurdsson's words, has 'neither vocabulary nor tradition to discuss biotechnology, bioinformatics or the regulation of biomedical research and certainly had no international models with which to discuss novel genomic database issues'.³³ Iceland has a high quality health care and good medical record system and a well-educated populace. Tonga also has a healthy and well educated populace, the size of which is considerably smaller if you exclude those living (legally or otherwise) in Australia, New Zealand and in the USA³⁴.

Tonga has a certain amount in common with Iceland although they are globally opposite. Iceland has a small population which, in Sigurdsson's words, has 'neither vocabulary nor tradition to discuss biotechnology, bioinformatics or the regulation of biomedical research and certainly had no international models with which to discuss novel genomic database issues'³⁰. Iceland has a high quality health care and good medical record system and a well-educated populace.

Tonga also has a healthy and well educated populace³¹ the size of which is considerably smaller than that of Iceland if you exclude those living (legally or otherwise) in Australia, New Zealand and the United States of America³².

At this point I'll hand over to LS to discuss the situation in Tonga.

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³² Genetic Crossroads #20. 4/10/01 geneticcrossroads@genetics-and-society.org

³³ Sigurdsson, op cit p106.

³⁴ Life expectancy for Tongans is 69 years and the adult literacy rate is 99%.

³⁰ Sigurdsson, op cit p106

³¹ Life expectancy for Tongans is 69 years and an adult literacy rate of 99%.

³² The population of Tonga in 1996 was 97,784 and according to the Autogen the population in 2000 was 108,000. There is easily another 100,000 Tongans living overseas.

Tonga's health care system needs a major boost. According to the Hon. Minister of Finance, "most of the health facilities in the Kingdom of Tonga are between 20 and 30 years old and while they have served their function well over the period, in many ways they no longer reflect the needs of a modern health system"³³. This need obviously did not go unnoticed with Autogen Ltd for included in their research proposal was the offer to build a genetics based research facility and the provision of annual research funding to Tonga's Ministry of Health. But of course the poor state of Tonga's health care system was not the main attraction for Autogen Ltd. Rather it was ... "the unique family structure and isolation of this population together with the high prevalence of a variety of diseases represents a major resource for geneticists to identify genes that predispose people to those diseases"³⁴

BACKGROUND TO AUTOGEN PROPOSAL

In October 1999, Autogen Ltd announced an agreement in principle to form a strategic alliance with Merck Lipha a subsidiary of Merck Kga A of Darmstadt, Germany the manufacturer of metformin the world's top selling drug for the treatment of diabetes³⁵. Metformin which holds over 50% of the market for the treatment of Type 2 diabetes in Australia, was only introduced into the US market in 1996 where it has become the number one best seller with sales of US\$1.3 billion per year.

The agreement provided amongst other things for the acquisition by Merck Lipha of 15% of Autogen shares and for Merck Lipha to fund Autogen's Human Genetics Project conducted by the International Diabetes Institute (located in Melbourne) for US\$1 million per annum for six years. This is in addition to an already existing arrangement under which Merck Lipha funds Autogen's obesity and diabetes research project based on animal genes at Deakin University (also located in Melbourne). The objectives of the Human Genetics Project is the discovery of human genes involved in weight imbalance, Type 2 diabetes and insulin resistance. It is under the guidance of

³³ Hon. Minister of Finance Siosua 'Utoikamanu in a speech to Civil Society organisations in Tonga on 20 December 2001.

³⁴ Media announcement from Autogen Ltd, 17 Nov. 2000 signed by J. I. Gutnick, Chairman & Managing Director.

³⁵ "Autogen Lipha Cooperation Announcement" on
<<http://www.egoli.com.au/forum/archives/9666.html>>

Professor Paul Zimmet³⁶ who said, "The funding that comes to the laboratories at the IDI will keep Australia at the forefront of world research with the possibility of not only defining the genes that cause the major form of diabetes, that is Type 2 diabetes, but also the possibility of developing the diagnostic tests to predict future sufferers and also developing drugs that will significantly target the abnormalities causing the diabetes".³⁷ The International Diabetes Institute houses a database and sera established over decades through Professor Zimmet's international contacts and is described as one of the most comprehensive available world-wide comprising cross-sectional samples from Europid, Asian, Indian, Chinese, Creole, Polynesian, Melanesian and Micronesian populations"³⁸.

In October 2000, a year after the announcement of its strategic alliance with Merck Lipha and about a month before the announcement of Autogen's contract with Tonga's Ministry of Health, scientists involved in Autogen's obesity and diabetes research in Deakin University announced they had discovered a gene (which they called TANIS) they hoped would lead to the treatment of diabetes. According to research team leader, Dr. Greg Collier, researchers working with Israeli sand rats discovered that the TANIS gene was responsible for coding receptors that appear on the outside of cells found mostly in the liver and fat tissue. They found that while the number of receptors on the outside of the cell increased when a non-diabetic animal fasted overnight, the number of receptors went up tenfold when a diabetic animal fasted overnight. Under its alliance with Merck Lipha, Autogen was to receive a "milestone" payment of more than \$700,000 for the discovery. Dr. Greg Collier also agreed to enter into a joint venture with Autogen to take the research through to clinical trials costing up to A\$10 million.³⁹ Dr. Collier is now the Chief Scientific Officer at Autogen and Director of R & D.

³⁶ Professor and Director of International Diabetes Institute Professor of Diabetes at Monash University and Professor of the Graduate School of Public Health at University of Pittsburgh, He is actively involved in WHO's Diabetes and Obesity Study Groups and member of Australian Federal Government Task Force on Diabetes, the Victorian Ministerial Advisory Committee for Diabetes and National Obesity Strategic Committee.

³⁷ Autogen-Lipha Cooperation Announcement

³⁸ *ibid.*

³⁹ <http://www.theage.com.au/news/20001010/A40729-2000oct9.html>

THE AUTOGEN PROPOSAL

On 17 November 2000, Autogen announced through the Australian Stock Exchange Limited Office in Sydney, "the signing of an agreement with Tonga's Ministry of Health to establish a major research initiative aimed at identifying genes that cause common diseases using the unique population resources in the Kingdom of Tonga".⁴⁰ Under the terms of the agreement, according to the announcement, any serum or DNA samples collected in Tonga shall remain the property of Tonga and the collection of DNA and medical information will be in accordance with the highest ethical standards. In return for access to these samples and data, Autogen will provide annual research funding to Tonga's Ministry of Health in addition to paying net royalties on revenues generated from any discoveries that are commercialised.

For ordinary Tongans this was the first we heard of an agreement to conduct research on our genes. We in the Tonga Human Rights and Democracy Movement condemned the agreement in the strongest possible terms. In our media release of 24 November we said, "The Minister of Health's intentions may be noble, but the main reason for our condemnation is the fact that the implications of the Agreement has never been discussed publicly either through the media or in Tonga's Legislative Assembly ... What is involved is the sanctified blood of human beings and not the genetic make-up of our pigs (with all due respect) so there should have been prior public discussions before the Minister signed."⁴¹

Since the Prime Minister's Office denied any knowledge of the agreement our attention was focussed on the Hon. Minister of Health, Dr. Viliami Tangi. In an appointment with him on 23 January 2001, he denied that he had signed an agreement with Autogen. But he admitted that discussions had been going on with Dr. Greg Collier about a genetic research project on the Tongan people along the lines of the Autogen announcement of 17 November 2000.

⁴⁰ Media Announcement from Autogen Ltd 17 November 2000 op. cit.

⁴¹ "THRDM Condemns Agreement for Genetic Research on Tongans", THRDM Media Release 24 November 2000.

The Hon. Minister of Health's denial of an agreement with Autogen was repeated by the Chief Superintendent of Tonga's main referral hospital (Vaiola Hospital) Dr. Taniela Palu in a presentation at the "Bio-ethics Consultation in the Pacific" on 13 March 2001. This Consultation, which was organised by the Tonga National Council of Churches and in partnership with the World Council of Churches in Geneva, brought together Church and community leaders from all over the Pacific Islands to discuss how to deal with genetic research proposals such as Autogen's. Dr Taniela Palu stated that any genetic research conducted on the Tongan people should have the prior approval of the Tonga Government and people. He also stated that his Ministry had set up a National Health Ethics and Research Committee to review and scrutinise all medical research conducted in Tonga.

In a chance conversation on 28 August 2001 with the Secretary of the National Health Ethics and Research Committee, Dr. Sunia Foliaki, informed me that Autogen had withdrawn its initial genetic research proposal. He said that Dr. Greg Collier had been in Tonga recently and he made no reference to their original research proposal, instead he lodged a totally new and unrelated research proposal. (He did not give me for details of the new Autogen proposal.)

In a meeting with German television documentary producer Karl George Peschke on 26 November 2001 in Nuku'alofa he told me that Dr. Greg Collier had informed him in Melbourne the previous week that Autogen was no longer interested in conducting genetic research in Tonga.

Despite these repeated denials by Ministry of Health and Autogen personnel of an agreement, Autogen has not seen fit to amend its web-page on the "Ethics Policy for Genetics Research Involving the Use of Biological Materials Collected from the people of Tonga".⁴² In fact, at the end of November 2001, according to Dr. Kirsten Brodde of Greenpeace (Germany), Merck of Darmstadt (Merck Lipha's mother) is... "still convinced that there will be a treaty between the Tongan government and ...

⁴² http://www.autogenlimited.com.au/f-ethics_p2-6.hotmail

Autogen Ltd. Autogen confirmed this information and furthermore they told us that there is only one last step necessary to start".⁴³

We in the Tonga Human Rights and Democracy Movement are giving our Ministry of Health the benefit of the doubt and are assuming that there is no agreement for genetic research between Autogen and the Tongan Government. At the same time we are assuming that Autogen and other biotech companies will make genetic research proposals of a similar nature to Pacific island countries including Tonga in the future. As such we are concerned about the substance of the "Ethics Policy for Genetics Research Involving the Use of Biological Material collected from the People of Tonga" as posted on Autogen's website as it could very well be the template for future research proposals in the Pacific Islands.

CRITIQUE OF AUTOGEN'S ETHICS POLICY

Dr. George Annas has described Autogen's Ethics Policy as "an unacceptably vague "ethics" statement that simply recites the "Georgetown mantra", has no substantive requirements, contains only the vaguest hint of a procedure for ethical review (whatever that means) and no enforcement mechanism whatsoever. At least since deCODE in Iceland (and the death of Framingham Genomics in Massachusetts) there is no excuse not to do a much better job in detailing issues of consent, community consultation, ownership, privacy, benefit, oversight and enforcement"⁴⁴.

Another major weakness is that it fails to address the unique processes for group decision making in a tightly knit but acutely status-conscious Tongan society. The Ethics Policy provides for voluntary and prior informed consent from individual volunteers but fails to acknowledge that in the tightly knit Tongan society the extended family grouping (ha'a or matakali) will definitely have a say on whether its individual members be permitted to give prior informed consent in the full knowledge that the serum and genetic material donated is reflective of the extended family's genetic make up. In other words genetic research such as Autogen's is in fact group research but the

⁴³ Personal Correspondence from Dr. Kirsten Brodde 20 November 2001.

⁴⁴ Utley Professor and Chair, Health Law Department, Boston University School of Public Health, in personal correspondence 16 Feb. 2001.

Ethics Policy is not equipped to address group rights, but only caters for individual members' rights.

In addition, although Autogen makes very clear that the research will not involve the whole population of Tonga but instead only focus on individual patients and volunteers, the database that they will accumulate will in effect be pretty close to complete given the limited size of the population and the intermarriage over the centuries. So there should be provision in the Policy for the Collective rights of the total Tongan population.

The Ethics Policy makes very clear that participants may elect how their samples and data can be used and that samples will be securely stored and will be discarded once the purpose for which the sample was collected has been achieved. But scientists often share their collections with their colleagues as a matter of course or for a price, and as Dr. George Annas says there is no enforcement mechanism spelled out in the Ethics Policy. In addition there is no existing national legislation in Tonga or a Pacific regional mechanism to regulate not only the transfer of samples and data but also to regulate biological genetic research in the region.

In 1999, a Forum Secretariat study found that in the absence of appropriate laws in the Forum Island Countries (Cook Islands, Fiji, Kiribati, Marshall Islands, Federateral States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Solomon Islands, Samoa, Tonga, Tuvalu and Vanuatu) to govern access to biological resources and to protect traditional knowledge, the Forum Island countries will not derive any economic benefit but will continue to become easy targets for the exploitation of this knowledge, and genetic materials which are patented overseas. The Forum Trade Ministers (from the 14 FIC's and Australia and New Zealand) while discussing the WTO Millenium Round in June 1999 recommended that Pacific Forum Leaders "recognise the need to work towards the development of appropriate national, regional and multilateral rules and legislations to protect the intellectual property rights of the indigenous people"⁴⁵.

⁴⁵ "Intellectual Property Rights" Briefing Paper Prepared by Forum Island Secretariat for Forum Economic Ministers Meeting 25-26 July 2000, Alofi, Niue.

The biggest carrot being dangled before the Tongan government is the benefit from any royalties or profits arising from new therapeutics and the provision of these therapeutics free of charge to the Tongan people. Apart from this promise the direct benefit to the donors and the government and people through a research laboratory and research funding is a literal drop in the Ocean. There should be in the agreement the provision of "milestone payments" to the donors and Tongan government for any significant discovery during the research similar to the milestone payment of \$700,000 made by Merck Lipla to Autogen on the discovery of the TANIS gene in October 2000. The terms being offered by Autogen for its genetic research proposal follows the pattern of other bioprospecting proposals in the Pacific region, be it for mineral resources or for marine life. That is to say that the Autogens of the world have the capital, the technology and the expertise. All we have is the raw material in this case, our genes. Historically the owners of the raw material have never ever got a good deal. But this should not necessarily be the way forward in the 21st century.

In the Final Statement⁴⁶ of the Bioethics Consultation in the Pacific, held in Nuku'alofa in March 2001, Church and community leaders stated, "In the context of the proposed agreement between Autogen Ltd (Aust) and the Government of Tonga regarding genetic research on the people of Tonga we are concerned as Christians about the requirements of prior informed consent and the right of people to information regarding any negotiations in the field of genetic research in the Pacific". In addition the Pacific Church and community leaders went on to state, "We believe,

- ◆ in God as the supreme creator of all living things
- ◆ all lifeforms should be treated in a way that respects their intrinsic value as living generational manifestations of creation.
- ◆ the quality of life is based on the development of human relationships, spiritual fulfillment and reverence for life and the natural world

⁴⁶ Statement of Bio-ethics Consultation, Tonga National Council of Churches Center, Nuku'alofa, Tonga 12-14 March 2001. Note that Dr. Greg Collier at one stage was going to make a presentation at this Consultation but this did not eventuate.

- ◆ commitment to the quality of life of future generations is fundamental to the world view of the peoples of the Pacific
- ◆ the peoples of the Pacific are guardians of their heritage and have the right to protect and control dissemination of this heritage
- ◆ the peoples of the Pacific have the right to manage their own biological resources, to preserve their traditional knowledge and to protect these from expropriation and exploitation by scientific, corporate or governmental interests
- ◆ no person should be subjected to medical or scientific, experimentation without that person's freely given prior informed consent
- ◆ that cloning of human beings is wrong
- ◆ the conversion of lifeforms, their molecules or parts into corporate property through patent monopolies is counter-productive to the interests of the [people] of the Pacific.
- ◆ that scientific and commercial advances should not be allowed to proceed past the deliberations necessary to provide for their social, moral and ethical control
- ◆ that national laws and provisions in international agreements which encourage and patenting of lifeforms - such as the Trade Related Aspects of Intellectual Property Rights (TRIPS) of the General Agreement on Trade and Tariffs (GATT), should be repealed.
- ◆ all forms of genetic engineering of human genes should be rejected
- ◆ and confirm our stand against the unauthorised collection and commercialisation of genetic resources from the Pacific.

The Church and community leaders, recommended to the Churches, Pacific Council of Churches and the World Council of Churches, to amongst other thing "continue to be at the forefront in the promotion of human dignity, defending human rights, and protecting the environment which supports all of our lives. They must make sure that our human, animal, plant and micro-organism species, and their genetic and other biological inheritance be safeguarded from exploitation and manipulation...."

To the Pacific Island Governments and Councils of Chiefs the Church and community leaders recommended

- ◆ that when any genetic research, project is proposed, there should be full public discussion and absolutely all relevant information disclosed by all parties involved, including financial interests and assessments of environmental, health and socio-economic risks.

- ◆ that independent experts should be fully accessible to aid the public discourse, and to evaluate proposed research protocols in order to insure the full protection of the individual human and collective rights of the Pacific peoples, and to ensure that all research is sound, valid and beneficial to the people and environment.

- ◆ that the people should be consulted before any government signs any agreement impacting people's rights.

CONCLUSION

In 1993 the US Department of Health and Human Services and the National Institutes of Health filed patent applications on the human T-cell line of a Papua New Guinean. According to the application, blood samples were taken from 24 people who belong to the Hagahai people of Madang Province in May 1989. The cell line, the first of its kind from an individual from Papua New Guinea is potentially useful in treating or diagnosing individual affected with a Human T-lymphotrophic virus type 1 (HTLV-1). This virus is associated with adult leukaemia and with a chronic degenerative

neurologic disease. The novel cell line is of potential value in understanding the enhancement or suppression of an immune response to this virus.

A second patent application was filed by the US Department of Commerce on the human T-cell line of a 40 year old woman from Maravo lagoon in Western Province and a 58 year old man in Guadalcanal Province of the Solomon Islands. The blood samples were taken in March and August 1990. Similar to the patent on the Hagahai cell line, the Solomon Islanders' T-cell line may be useful in producing vaccines and/or diagnosing human T-lymphotropic virus type 1.³⁵

As a result of official protests by the Papua New Guinea and Solomon Island Governments these patent applications were withdrawn in 1999. What is of continuing concern is the ability of bioprospectors to collect and expatriate human genetic material from the Pacific Islands under the guise of say a WHO sponsored disease eradication programme or say an AusAID funded public health programme. This brings us back to our assumption that Tonga's Ministry of Health has been telling us the truth about the Autogen proposal.

On 17 January 2002 the regional news service PACNEWS carried an article that is supposed to have originated from Radio Australia.³⁶ Key paragraphs from the article read:

“Australian authorities are helping to tackle a growing health crisis in Tonga. The Government of the island country admits it is in the middle of a national health disaster caused by years of overeating and a taste for junk food...”

“According to health experts, Tongans are slowly eating themselves to death. Diabetes related disease is one of the countries biggest killers. The diabetes rate in Tonga is close to 14 percent, almost twice the rate seen in countries such as Australia and it's expected to get higher at an alarming speed...”

³⁵ RAFI Communique #21 The Patenting of Human Genetic Material Jan Feb 1994. Rural Advancement Foundation International, Ottawa Canada.

³⁶ “Australian Clinic a Small Step in Tonga's Diabetes Battle” Pacnews 17 Jan 2002

“But AusAID, supported by Sydney’s Prince of Wales Hospital has responded to the situation by opening a diabetes clinic in the capital Nuku’alofa and providing ongoing treatment on diabetes treatment for local medical staff...

“Ironically, the country’s best chance of tackling diabetes is one they are almost certain to refuse. The company called Autogen has been attempting for more than a year to persuade the Tonga government to allow it to construct a DNA database of the country’s 108,000 residents. One company source says the data they want to collect would be vital in tackling diabetes and related illnesses. Officially, the proposal is being considered by a special government health, ethics and research committee but few believe it would ever go ahead.”

The article does not quote any identifiable human resource for the article and PACNEWS could not help either. My email enquiries to Radio Australia (Melbourne) has remained unanswered. But according to an AusAID official at the Australian High Commission in Nuku’alofa, the diabetes clinic has been in existence for over two years already and that further AusAID funding for it in 2002 is doubtful. Asked whether it is possible that Autogen will take over the funding of the clinic, the official said she needs to check with the High Commissioner as she didn’t know. No further information has been received.

We in the Tonga Human Rights and Democracy Movement would like to think that the PACNEWS article was not planted by Autogen and that they are not planning to circumvent the scrutiny of the Tongan public by collecting the human genetic material they crave under the guise of an already approved aid project. Instead we would like to think that Autogen is willing and able to dialogue directly with Church, community leaders and organisations of civil society in Tonga and the Pacific islands including Australia. Instead we must build on the new foundations which in the Mabo and Wik decisions the Australian High Court handed down in the early 1990s. That is the way forward.

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