Report to General Assembly 2001

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GM Animals, Humans and the Future of Genetics

Society Religion and Technology Project

SRT General Report to 2001 General Assembly
1. Introduction

While the controversy of GM foods has been so much in the news, the genetic engineering of animals has been comparatively ignored. It was one of the main themes of the SRT Project study "Engineering Genesis",1 in which context it was mentioned briefly in SRT's 1998 Assembly report as well as in the 1997 National Mission report on Animal and Human Cloning.2 The recent genetic engineering of a monkey in the USA has now brought to the fore some important issues about the research on animals for human benefits. The dramatic developments in cloning and embryonic human stem cells are raising another basic question of the increasingly blurred borderline between animal and human research. Research done on animals today, like cloned sheep and mouse stem cells, can rapidly become applied for use in humans. Insights from human examples feed back into animal research. In this report, we wish to examine how far we may use and modify animals for human uses, and the relationship between biotechnology in animals and in humans. By way of example, we discuss the latest developments in xenotransplantation, animal models of human disease, and cloning and stem cell technology.

The genetic engineering of animals has stimulated much public discussion, and raises a number of important questions about human intervention in animals. Despite much research, it has not found significant application in animal production for meat, milk, eggs, wool or hides. So far it seems to offer few advantages over conventional breeding and the promising field of genetic marker assisted selection. Genetic engineering in animals has primarily been in novel applications in medicine, and in particular making pharmaceuticals in the milk of farm animals, pig organs in humans, and use of mice and other animals as models of human disease.

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2. Theological Reflection on the Human Use of Animals

The universe is created by God. It is not merely "nature". It belongs to God, not human beings. Because God created them, animals have intrinsic value. They exist first of all in relation to God, before any considerations of their value and use to humans. Humans, however, have a special place, being both a part of creation and also over it. Humans are uniquely the bearers of God's image. Two expressions of the relationship are found in the opening chapters of Genesis. For centuries the emphasis was in strong terms of dominion or subduing from Genesis 1. 3 In recent years belated recognition of the environmental damage we have caused has led to a recovery of second picture, in the gentler language of working and caring for a garden. 4

The relationship of humans to God's creation has been expressed most often in Calvin's notion of the steward. God gives humans a special duty both to develop the natural world - and hence the use of technology - but also to take care of it - which puts limits on our activities. Stewardship means that humankind is answerable not merely to future human generations, but to God, the divine owner, for how we have looked after his estate. Alongside this Ruth Page introduced the notion of companionship, to reflect that we are also fellow creatures in a shared creation.5 Thus while God puts animals under human subjugation for a wide variety of uses, they are still God's creatures first, and humans will have to give an account to God for their care of them. Old Testament injunctions such as "Do not muzzle an ox when it is treading out the grain", "Do not boil a kid goat in its mother's milk." (Deuteronomy 25:4 and 14:21) imply that wider principles of relationship set restraints on human uses.

This contrasts with historical views of animals as merely there for human purposes,6 or the view that they are not radically different from us scientifically or morally.7 Aspects and characteristics which human and animal hold in common, like both being creatures, being "subjects of a life",8 or being sentient,9 do not mean that humans cannot eat animals or use them for traction and carriage. The notion of animal "rights" is criticised because in a Christian understanding there are no rights without corresponding responsibilities, and animals do not have responsibilities towards humans it is meaningless to give them rights.10 Rather we would stress our duties towards them under God.

Commercial animal production by selective breeding would be allowed, but not to every degree possible. Limits are exceeded when this is taken as an end in itself, or if it becomes so dominated by a functional view of the animal under pressures of economic efficiency that wider principles of God's creation are overridden. The case of poultry production has shown that when taken to such degrees that harms, distortions, disablement or impairment of function begin to emerge, a good end would have been taken too far.11

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3. GM Animals

Genetic engineering opens up an even wider range of technical possibilities. As we have seen most of these relate to medical applications. How far are we justified in manipulating our fellow creatures, or indeed any part of God's creation, even in the cause of human medicine? How do we balance the ethical dilemma which this poses? First we must ask a more fundamental question.
Is genetic engineering inherently wrong, irrespective of its application or its consequences?

Some Christians may consider that to change a single gene in an animal would be attempting to change God's best design, upsetting the wisdom inherent in the natural order by humans who did not know the full extent of the unprecedented changes they were making. Some would say we should not genetically engineer animals in any way we would not do in humans. The SRT report to the 1999 Assembly on genetically modified food and crops established grounds that manipulating genes and transferring

them amongst widely varying species did not in itself violate a fundamental limit in the nature of things. The same would apply to animals, but, as with GM crops, there are important caveats. The nature of an animal, like plants and humans, is more than the mere sum of its genes but lies in the wider essence of the creature as a whole. Animals are also in constant genetic variation. To change one or two genes is not like changing a fixed blueprint, which would irretrievably violate the animal, unless the result brought about a severe impairment or suffering to the animal. We must therefore ask whether a particular genetic change poses special problems in relation to the nature of the animal, and also what regard we give to different types of animals, for example, primates, pigs, mice, frogs and midges.

A "No, unless" approach might allow uses where the prime benefit was to the animal, such as increased disease resistance, or in cases where a major human benefit could be achieved with minimal interference in the animal. It would be more critical about increased growth rate in animal production, whether the level or nature of intervention was permissible, and what motives were driving it. It would ask if there were better ways to the same end without manipulating the animal.

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4. Pharmaceuticals in GM Sheep Milk.

The ability to genetically modify animals in order to produce valuable proteins such as pharmaceuticals in their milk has been one of the most innovative applications of the genetic engineering techniques. Pioneered at the Roslin Institute and PPL Therapeutics, it has now been applied to cattle, sheep and goats in order to produce a variety of different proteins. The leading example, now in the last phase of clinical trials, is alpha-1-antitrypsin (AAT) for treating lung diseases emphysema and cystic fibrosis. It is produced in the milk of sheep by adding the human gene which codes for the protein in humans. A related area of research is in genetically modifying poultry to produce pharmaceuticals in the eggs.
The 1997 Assembly report on cloning acknowledged that this did not raise undue ethical problems. The use of sheep milk is traditional and therefore to produce a particular protein in the milk would not seem an undue departure from the current situation, particularly since the sheep version of AAT is produced by the animal, albeit in the liver rather than in milk. The intervention in the animal is judged to be small, the human medical need being addressed is considerable, and other routes to the protein are much more difficult. Indeed, it could be argued as a genuine partnership, in which humans give especial husbandry and care of the sheep in exchange for a valuable product in the sheep's milk. No welfare concerns have arisen from this particular example.12 In general this is an area where we would say "Yes, provided." One such proviso arose in research to produce a more active protein erythropoietin showed unacceptable welfare effects for the animals, which led to the trials rightly being terminated.

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5. GM Pigs for Xenotransplantation

A much more serious intervention in farm animals is xenotransplantation. Various pig organs have potential for transplantation into human beings, including hearts and kidneys. Research in this area has been carried out for many years, prompted by hope that this would meet the shortfall in supply for human organs, where people are currently dying while on the waiting list. There are immense technical problems, however, which in turn pose major issues of ethics. This is discussed in more detail in our pages on the Ethics of Xenotransplantation.
The first is the rapid rejection by the human immune system of organs from another species. Pigs have to be genetically modified to try to overcome this. Several human genes have to be added to the pig to send "human" signals that would prevent the human immune system not to reject the organ. There are as many as four genes involved. This requires multiple gene changes, something which has never been done before in a large animal, and is hard to achieve even in plants. It also requires knocking out genes in the pig which would trigger the rejection. So far most genetic engineering has only added genes. The nuclear transfer cloning of piglets by PPL in 2000 has opened a potential way to do this, if gene deletion were done in vitro in cells, and if pigs could be "grown" from these genetically altered cells. This is uncharted scientific territory. No one knows if this can be done to overcome rejection to a sufficient degree for a viable medical procedure.

The second technical barrier is the remote risk of the transfer of a pig retrovirus to humans, to which humans might not be immune. The concern is less for the patient, who is probably terminally ill anyway, but about the possibility that such a virus might be transmitted to the family and then out into the wider human population. This is an extremely remote risk, in terms of probability, but it could have epidemic consequences were such a chain of events to occur. The origins of HIV and the trans-species aspect of BSE both present scenarios sufficient for the government to have a moratorium on clinical trials. Its advisory body on xenotransplantation has recommended draconian restrictions on the patient and family, were clinical trials ever to begin. The implications and evaluation of this lie beyond the scope of the present report, but it clearly indicates the delicacy and complexity of the animal - human interface.

For the present report our main ethical concern is to review the use of animals in this way. To breed and genetically engineer an animal solely to remove an entire live organ represents a different use of animals from anything humans have done before. It is a large leap from using pig heart valves, which are merely dead tissue with convenient elastic properties. The "yuk reaction", which the idea of xenotransplantation often prompts, suggests that having a complete animal heart inside oneself poses underlying questions beyond mere unfamiliarity. Some respond by contending that if we accept eating pigs, it is even more justified to use them this way to save human life. This purely consequential way of framing the issue is shallow, however. Logically it would justify doing literally anything to a pig in order to save human life. It is at odds with any ethical perspective based on the notion that animals have intrinsic value, and the implication from the biblical examples that animal use eventually has limits. The landmark Banner Report on animal ethics established that there are some things we should never do to animals, no matter what the reason.13 This "ham sandwich argument" also side steps other issues. Unlike eating animals, there is no parallel to xenotransplantation in nature. The fact that xenotransplantation is unnatural, in that sense, may not necessarily make it wrong, but

it prompts a question whether this is an acceptable extension of human use of animals from traditional suppliers of food, clothing, traction, transport and manure?

For some, even if the genetic change is not an objection, the interspecies mixing of whole organs violates a wisdom in God's natural order, of which the retrovirus risk is a physical indication, indeed a warning that this is quite different from eating pigs. For our working group the majority did not feel they would draw an absolute line here, but expressed some serious reservations. We noted that creating pigs to kill them to obtain transplant organs is different from taking the same organ from someone already dead. It constitutes a serious intervention in highly intelligent animals with some close physiological similarities, and for whom many humans have a special fondness. There are also animal welfare questions about the quality of life for the pigs kept, of necessity, in a highly sterile environment.

We suggested a "no, unless" approach. It would only be justified in exceptional circumstances. Does the mismatch in supply and demand for a surgical procedure which has become resource limited - the "shortage" of transplant organs - might meet the case? A few months of life extension, with immunosuppressant drugs merely delaying the inevitable death would not be reason enough. A long, high quality life might well be, if the technology could work well enough. It is justified to conduct research while this remains a realistic prospect. Given the complexity of the multiple genetic modifications that are now likely to be needed, it is not a foregone conclusion that there will come a point where that ethical balance would be reached for it to become an accepted therapy.

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6. GM Animals as Models of Human Disease

The largest application of transgenic animals by far is the use of mice as models of human disease and tests for potential therapies. The first example was the Harvard oncomouse, with an added human gene which gave it a form of human cancer. The certainty of giving such mice cancer, compared with a statistical probability of a population of mice, was claimed to lead to less mice being needed in research. The opposite has been the case. The applications in mice have increased enormously to the point where GM mice are used in a wide range of experiments. Once a gene is identified in the human genome project, it has become almost routine to seek to "knock out" the equivalent gene in a mouse and to try and identify the function of the gene.
In "Engineering Genesis" we pointed the anomaly of the vast increase in model mice against the general European trend in animal research of the "3 R's" - reduce, refine and replace. We suggested that the use had become too automatic, and steps needed to be taken to make researchers think twice before using mice.14 The fear is that mice have ceased to be seen as animals at all, in this context, and are merely items in a research catalogue.

This poses a deep ethical dilemma for Christians. No one could justify wilfully genetically changing a mouse to give it cancer, or one of a range of fatal and painful human diseases, were it not for the awfulness of those diseases in humans, and the immense difficulties of the medical profession in understanding and treating them. There are almost two cultures, depending on what one's exposure has been to the issue. For the medical research community, the imperative of relieving human suffering is overwhelming in this area of disease. For the animal welfare lobby, there is the sense of outrage at what we are doing to defenceless animals.

Here we reach a generic issue about the use of animals in human medical research. Christians may be torn both ways. There is a deep sense of concern for the human suffering that might be alleviated, but a deep reluctance to treat another of God's creatures merely as a source of spare parts, or to programme them genetically to have dreadful diseases. While we would find it difficult to say an absolute "no" to xenotransplantation or GM mouse models, there would be individual experiments and uses which would not necessarily be justified.

Motion on GM Mice as Disease Models

There are also be types of animals whose use might not be justified. It has been suggested that sheep would be a better model for studying cystic fibrosis than mice, because mice do not develop the corresponding symptoms in the lung. For farm animals it is becoming more difficult to justify. To satisfy a "No, unless" policy, it is even more important to ask how necessary would the intervention be and how good the model. In the case of GM primates, however, utility to human medicine has surely reached a limit.

How do we decide amongst animal species? Most people value large mammals and primates higher than small mammals like mice and rats, because of more human-like characteristics. Primates possess much higher levels of sentience, consciousness and socialisation. The Home Office regulates UK animal research but seldom grants licenses for primate research, requiring "exceptional and specific justification". It is not enough to argue in this case that we need to use monkeys because they model human disease better, because the closer the animal models the disease the more likely the animal is unfortunately to suffer. Whatever animal is used, moreover, a gulf always exists between disease in humans and in another species. It is unlikely that genetically modifying primates would ever provide that one vital difference between a treatment and none. Unless this were so, this use has no justification.

Animals are God's creations and have intrinsic value in themselves, regardless of any human value we attach to them or use we may put to them. While the Bible endorses some use of animals, it also sets restraints. Although there is no hard and fast line across the range of animals, the closer they are to humans, the more this should hold us back from intervening. In 1996 the Nuffield Council on Bioethics questioned the potential use of genetically modified primates as sources of human transplant organs, recommending that non-primates like pigs should be used instead. 15

While there is undoubtedly a great concern to find treatments for serious human diseases, the ethical imperative for medical research should never be seen as an

absolute. Other ethical factors must also be taken into account. These include our respect for higher animals and especially those closest to humans and of high degrees of sentience and consciousness. GM primates should in general be a line we should not cross over. We should be content to use lower animals and accept any limitations this imposes.

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7. Cloning and Stem Cells : the Animal - Human Crossover

See SRT's General Report for SRT's involvement with MP's, government and public debate on stem cells and cloning

In 1997, SRT reported to the General Assembly on human and animal cloning. At that point, and since, cloning research was almost entirely confined to animals. The human interest in cloning was in the possibilities that reproductive human cloning might be attempted, despite the declared intention of the UK government never to allow it, and the unlikelihood that this would ever be safe. The persistent question in the media is that somewhere, someone will attempt it in the USA where private sector research is essentially unregulated, or in an "offshore" situation outside any restrictive jurisdiction. It began in animals to help in genetically engineering sheep more effectively to produce pharmaceuticals in their milk, but for some sections of the media, it is still all about who would clone the first human baby, however dangerous and unethical this would be. Motion on Reproductive Cloning Legislation
In 1998, the isolation of human embryonic stem cells was announced in the USA, extending from many years of work in mouse stem cells. These are special cells in the early embryo before it begins to differentiate. At this point, they can turn into any type of cell in the human body. Two years ago, US scientists found a way to isolate them. Using special chemical treatments, they believe they can direct them into becoming any type of human cell they choose - skin, heart muscle, nerve cells, etc. This opens up a possibility to create replacement cells to inject into patients suffering from a wide range of diseases which cause irreversible cell degeneration, like Parkinson's, some heart conditions and diabetes. In December 2000, the UK Parliament gave its approval to research using these techniques to produce replacement cells for a range of human diseases where cell degeneration is crucial. Thus far, most of the research is however done in animals, for example into the ways in which early embryonic cells go through the strange process of differentiation. Mice have been genetically engineered to induce a form of Parkinson's disease and tests have been done on replacement cells as a possible mimic of a human therapeutic technique. Research in human stem cells will now proceed, but many of the discoveries may also feed back into other mammalian stem cells, and the spiral of development will continue.

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8. Cloning for Human Therapeutic Purposes

We welcome the focus away from the cloning of human beings, about which the Church of Scotland was the first to give a clear ethical basis for what is now a near

universal rejection. The use of nuclear transfer cloning to create embryos of the right genetic type to produce replacement cells presents further ethical dilemmas, however, in addition to those discussed above for human embryos in general.
The vote in Parliament extended the uses of embryos to include making embryonic stem cells for serious human disease. Most of cells needed would be taken from existing "spare" embryos from IVF treatments. The careless use of the word cloning to describe this caused much confusion, but it does point to an issue of concern. MP's did not have any chance to vote on the cloning of embryos, because it was technically legal due to a loophole in the Act. The present Human Fertilisation and Embryology Act (1990) allows the creation of embryos for limited research purposes, mainly to do with infertility. On these grounds, the creation of cloned embryos has been forbidden, because this would be seen as reproductive cloning. By creating a new legal use for creating embryos for a non-reproductive use - to create stem cells - the Commons vote automatically allowed the cloning of embryos for this purpose, without ever voting on it. The influential European Commission ethical advisory panel reported on these issues in November 2000 and drew an ethical line at cloning embryos, as did a vote in the European Parliament. The UK vote should not be seen as a mandate to allow cloned embryos also, because this has not been put to a proper democratic test. We need early primary legislation on therapeutic as well as reproductive uses of cloning.

Cloned human embryos present several ethical problems. Firstly, it seems illogical to allow the creation of a cloned human embryo knowing full well one would have to destroy it on ethical grounds, because it was unethical to allow it to go to term to produce a cloned baby. The second objection is that this involves the deliberate creation of an embryo for other than reproductive purposes, although this is not specific to cloning. The use of "spare" embryos from fertility treatments would be a use of an embryo that would be destroyed anyway.

Thirdly, there is a gradualism argument. Once cloned human embryos were created, it would be much easier for someone misguided enough to go the next step and allow them to be implanted, or for someone rich enough to seek a clandestine "off-shore" treatment. This underlines the need for clear national laws, in those states which do not currently have them, to outlaw the practice of human cloning worldwide.

The creation and use of cloned human embryos should not be allowed as a general therapeutic procedure. We urge, however, that a priority should be put on nuclear transfer research which aims at avoiding use of embryos, by direct programming from one adult body tissue type to another. One could take, perhaps, a blood sample and reprogramme directly into becoming, say, a set of nerve cells. This is of course even more speculative than the methods discussed above, but several routes have recently been suggested. Ethically this would remove most of the above objections.

There is also a further reason. The ethics committee of Roslin's collaborators, the Geron Biomed company, has urged that the technique should have the widest applicability and not be simply a treatment for the rich. It is very unlikely that enough human donor eggs could ever be provided to treat the millions of potential patients across Europe. It would therefore probably be essential to find a method of producing replacement cells without using embryos. On present evidence, however, this would probably be impossible without some human embryo research to work out the method. This poses a deep ethical dilemma whether a very limited and fixed number

of experiments should be allowed to obtain the data necessary to avoid any such use of embryos in future. Some would reluctantly argue for very limited research for this sole purpose, but if it seemed unlikely to succeed, then it should stop, and not proceed to use embryos routinely for cell therapies.

Motion on Therapeutic Uses of Cloning
Some exaggerated claims have recently been made for alternative sources of stem cells, for example from human adult cells or placental material. While recent advances in these areas are indeed encouraging, scientists are urging great caution over assuming universal therapeutic success with any one method, when these are still very early stages in research. One speculative means to produce stem cells may already be rejected on ethical grounds, however. This is the production of non-viable human embryos within cow's eggs. The idea would be to take a human cell and perform a nuclear transfer into a denucleated cow's egg. Passing an electric current would fuse the two and stimulate the human cell to divide as though it were a human embryo, but one which was not viable. At the blastocyst stage of division, the stem cells would be removed and cultured as human somatic cells. This raises many serious uncertainties and risks, not least whether the use of a cow's egg as a host for the human cell had no adverse effect on the eventual human cell lines. It would raise immense ethical problems. Even though it would avoid the creation of a human embryo, the mixing of human and animal genetic material at such a profound level would raise a major intrinsic ethical objection for many people.

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9. Conclusions

This report has set out several key areas involving genetic engineering in animals for human medical research and examined the complex crossover point, scientifically and ethically. The use of animals by humans is accepted in general, but our duty also to respect them as God's creatures sets limits to what we may do. Animal selective breeding is acceptable, but not where this becomes dominated by a merely functional view of the animal, without regard for any harms caused. Good ends can be pursued too far. GM applications in animals are not seen as wrong in themselves, but require a significant justification. Genetic intervention should not be done to the impairment of the animal without very good reason; some interventions may be unacceptable for any reason. A range of applications was considered in this respect :

Pharmaceutical production in the milk and eggs of farm animals was acceptable except in cases where it would harm the animal significantly.
Xenotransplantation is more problematical. Using live pig organs in humans represents a new and serious human intervention in intelligent animals. For some this is fundamentally unacceptable ethically; others have less reservations. A "no, unless" approach is suggested. It would not be justified unless it was realistically likely to deliver substantial human benefit. This is at present uncertain, but it warrants further research.
The use of GM mouse as disease models poses a serious ethical dilemma between seeking treatments of fatal and painful human disease and the suffering caused in the animal. The great increase in the use of GM mouse models and "knockout mice"

arouses concern. The established “3 R’s” principle of refining, reducing and replacing animal research use points to the need for greater restraint on the part of medical researchers in GM mouse use.
The ethical imperative for medical research should not be seen as an absolute. Respect for higher animals suggests that we should not GM primates to model human disease.
The areas of cloning and stem cells illustrate how research begun in animals quickly passes into humans and back again, raising new and complex issues on both sides.
The ethical problems of therapeutic applications of human embryo cloning have been briefly reviewed. Because of a legal loophole, the vote in the UK Parliament to extend the use of embryos to stem cells has automatically allowed the creation of cloned embryos for this purpose. This aspect is proving highly controversial, especially as it is only one step from cloning human beings. It would only be justified under very limited circumstances, if at all. The changes in legislation allow too much latitude on this particular point, and primary legislation is urgently needed. Developments in alternative sources of stem cells without using embryos are encouraging, but at this very early stage in this new science, we should not raise premature expectations by claiming this will necessarily supersede any need for embryonic stem cells. The use of human-animal hybrid embryo constructions are ethically unacceptable.

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Deliverance (i.e. Motions)

That the General Assembly ...
1. Receive the Appendix on GM Animals, Humans and the Future of Genetics

2. Affirm that there are limits to how far we may genetically engineer animals for medical benefit, on the grounds of animal welfare, and because animals have inherent value as God’s creatures.

3. Affirm that genetic engineering of farm animals to produce pharmaceuticals in milk and eggs is ethically acceptable, subject to welfare considerations in each case.

4. Recognise that the use of genetically modified pigs as a source of human organ transplants is justified only if there is a realistic chance of substantial human benefit.

5. Express concern at the large increase in the use of genetically modified mice in human genetic research, and urge the Home Office to adopt tighter controls in the purposes for which it issues licenses in this area.

6. Urge the Home Office not to allow the genetic modification of primates for medical research.

7. Urge HM Government to bring forward with urgency primary legislation to ban human reproductive cloning, to press for such a ban internationally, and to impose tight restrictions on the use of nuclear transfer cloning methods in stem cell research in the UK.

8. Oppose the use of nuclear transfer to create hybrid human-animal embryos.
Additional Deliverances from SRT's General Report for 2001

9. Urge HM Government to increase its efforts to combat climate change and to ring fence fuel tax revenues for environmental remediation, promoting energy saving and renewable energy use, public transport and rural infrastructure.

10. Welcome the launch of the Eco-Congregation initiative in Scotland and urge all congregations to take part in the scheme.

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2 Church of Scotland (1997), Cloning Animals and Humans, Supplementary Reports to the Church of Scotland General Assembly, May 1997, p. 36/22, and Board of National Mission deliverances 35 and 36, p.16.

3 Gen. 1:26-28

4 Gen. 2:15

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