

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

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**Consultation Paper:  
Give and Take?  
Human bodies in medicine and research**

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**Q 1. Are there any additional types of bodily material that could raise ethical concerns?**

The list provided in the consultation paper is adequate and has taken care of the most essential bodily materials that could raise ethical concerns.

**Q. 2 Should any particular types(s) of human bodily material be singled out as 'special' in some way?**

The answer to this question is both 'yes' and 'no'. It is yes because the human body materials such as sperms, eggs and foetus (embryo) are the means of continuation of life by being connected with the progeny. It is not to be considered as 'special' in any way because human body is a system. In a systems' approach each and every organ-sub-system is important. In the absence of a part of a few sub-systems like the whole organ subsystems like kidney or liver, the main system is able to make some vital re-adjustments with a single kidney or a part of the liver

In any case the following human body material may be considered 'special'

- Yes! (i) Sperm for use in infertility treatment or research  
(ii) Eggs, for use in infertility treatment or research  
(iii) Embryos for use in infertility treatment for example where neither partner can produce viable gametes or research  
(iv) Products of conception such as aborted foetal material and embryonic stem cells for research and potentially treatment in the future.

The wide gulf between life and death is becoming narrower and narrower due to the advancement of Science and Technology in the field of stem cell research. During a recent deliberations of the Annual Meeting of the International Society for

Stem Cell Research Ben-Num and Jeanne Loring reported that they have “created induced pluripotent stem (iPS) cells from the frozen skin cells of a deceased male drill monkey *Mandrillus leucophaeus*.” Results of their experiment indicated that a frozen cell from a dead animal is reprogrammable to become sperm and egg (Aldhous, 2010). At the present it may appear that taking an organ or a body part from a dead person may be objectionable but in the future it is possible to reap life from death. Hence, at the present due education may be given to persons to donate organs in the event of their death and other persons in need to accept such a reprogrammed cell/tissue system with out any inhibition.

The 51 year old Michigan, Kirk Maxey was in medical school and has been a sperm donor since 1980 till 1994. His rough estimate is that he has fathered 400 children by his sperm donation to an IVF clinic. “He's looked at the records of his donations, multiplied by the number of individual vials each donation produced, and estimated the success of each vial resulting in a pregnancy. By his own calculations, he concluded that he is the biological father of nearly 400 children, spread across the state and possibly the country” (Lehmann-Haupt, 2010). Another California Cryobank now sells an average of 30,000 vials of sperms a year. “Now, mindful of the dangers of passing on serious genetic defects or of incestuous relationships amongst his offspring, he has some regrets... and has become a forceful lobbyist for government regulation of the sperm-donor industry.” (Cook, 2010). The bioethical issues are that Government regulations supervising the records of successful creation of ‘donor children’ are weak and poor. The gift of life has been commercialized by IVF clinics so as to make it ‘a sperm donor industry’.

Some where I have read that one in five Indian men is infertile and hence the Indian environment for commercial surrogacy and letting the wombs to babies for infertile men all over the world has been considered as a prospective “pot of Gold”. While a foreigner can have baby, the Indian surrogate mothers will earn in dollars. Indian IVF clinics are sprouting like mushrooms. In order to combat infertility, in Mumbai, a group of well cultured boys who call themselves as “breeding boys” have made themselves available to fertilize the females of an infertile couples. Under these circumstances the Indian Government aims to bring all the Assisted Reproductive Technology (ART) clinics under its regulatory control by introducing legal measures. A draft bill entitled “**The Assisted Reproductive Technology (ART) [Regulation] Bill 2010** is in the offing which will legalize commercial surrogacy and will permit unmarried women to provide their womb-services to serve as commercial surrogates for both couples, singles including homosexuals (Hindustan times, Newspaper, June 21, 2010). India cultural milieu is conservative and it remains to be seen how legislative measures will keep social and family values intact. It may be recalled that Government had to cancel the license of thirteen hospitals for engaging in illegal activities in organ (kidney) transplantation. India has splendid

legal environment in terms of laws and it is a different story when it comes to the question of implementation.

**Q 4. What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them of providing bodily material)?**

Although the impotent individual/couple may be benefited with a baby in hand there are many social and family values and structure at great risks. In an Indian cultural climate to have a baby in the family enhances one's family status and also in society.

In a global scenario the picture that emerges about the upcoming educated community is disappointing. In a recent survey it has been recorded that honesty among the students in USA is on the decline. The survey indicted "The extent of student cheating, difficult to measure precisely, appears widespread at colleges. In surveys of 14,000 undergraduates over the last four years, an average of 61 percent admitted to cheating on assignments and exams" (Gabriel 2010). A measure of 61% is well above the average. These intellectuals will, in future, occupy positions of power. Will they be honest and transparent in their dealings? If an IVF clinic can not maintain honest records of its commercial activities in terms of impregnating a women with donor sperms how difficult it is going to be to have a dishonest student in positions of power? Their commercial deals may not be transparent also. The technology employed by the students to trick the regulatory mechanism is far superior to the surveillance technological gadgets.

**Q 5 What do you consider the costs, risks or benefits (to the individual concerned, their relatives, or other close to them) of participating in a first-in-human clinical trials?**

All the precautionary measures in bioethical practices must be followed such as obtaining written informed consent, approval of an IRB of well standing and an assurance to provide medical assistance or provide financial support to any injury or harm caused to the human participants during the clinical trial or due to the administration of the test materials.

**Q 6 Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?**

In the informed consent document the purpose for which the human bodily material is collected must be stated in plain terms. If, at a later stage, if the same bodily material is used for a different purpose then a fresh informed consent must be obtained.

**Q 7 & 8**

Difficult to answer

**Q 9- 13**

Prioritizing moral values is a difficult exercise. This may depend on various factors. To generalize that it a "moral duty" of a human to provide bodily material is misleading since in the western world the word "moral" is being used very scarcely. In one of the meetings which considered the ethics of science and technology I was told by a very distinguished panel that it is very difficult to define the word "moral" since it means different thing to different people and varies from region to region and from one religion to another. In the western world which is dominated by evolutionary philosophy of Darwinism what type of morals would be practiced by men and women in authority?

**Q 14 Is it right always to try to meet demand? Are some 'needs or demands' more pressing than others?**

Food security always looms at our doorstep. In order to meet the demand for food many other types of pesticides were used to boost food grain production.

Theodore A. Slotkin, professor of pharmacology and cancer biology, Duke University Medical Center reacts by saying "'I'm not in blanket opposition to the use of pesticides, but **methyl iodide alarms me**. When we come across a compound that is *known to be neurotoxic, as well as developmentally toxic and an endocrine disruptor it would seem prudent to err on the side of caution, instead of putting it into (human) use*". Secondly, Genetically Modified (living) Organism was introduced to meet the challenges of food shortage. There is both a demand and need for enhanced production of food grains. But the side effects are more and offers more risks like infertility. Feminization of males is caused due to environmental mimics of estrogen. Accumulation of environmental mimics of estrogen can result in reduced production of sperms so as to make a person infertile.

Personally, I think that it is a wrong policy to try to meet demand if it leads to unethical practices. Which is a greater need -Food security or climate change? Modern civilization is geared to produce many food products that will upset hormonal balance i.e. *an endocrine disruptor* and hence it would seem prudent to err on the side of caution,

In the case of blood donation, it is likely that it is right to meet the demand, Blood donation may be enhanced so as to meet the demand because it is renewable. In the case of close relatives, demand and for organ transplantation, say kidney may be permissible to meet the demand of a close relative. The donor may function well even with one kidney.

**Q 15 Should different forms of incentive, compensation recognition be used to encourage people to provide different forms of bodily material or to participate in a first- in-human trails?**

In the case of blood donations it may be right to provide compensation may be considered for recuperation.

**Q 16 -19**

Incentives must be given to meet the cost of transportation and loss of time as well as lost earnings. Some respondents may be offered free air travel ticket for donating their body-parts to a person overseas. Such an incentive in terms of meeting air travel cost may be unethical. Payment in terms of cash for travel time and the amount of time spent in being a human clinical trials candidate may be considered. In the case of discomfort and inconveniences high quality medical care should be given besides payment of money. All the ethical issues raised in this section must have the approval of a qualified Institutional Review Board (IRB).

**Q 20 Are you aware of any developments (scientific or policy) which may replace or significantly reduce the current demand or any particular form of bodily material?**

With out any governmental regulation unethical practices are bound to happen. A draft bill entitled “**The Assisted Reproductive Technology (ART) [Regulation] Bill 2010**” may regulate the donation of human egg and sperms. How far it is going to be an effective measure only time will tell?

**Q 21- 22**

Getting a written consent and approval of an IRB are essential. Assurance with regard to confidentiality is essential. In an Indian climate, it is usually the parents take the decision and in a village situation it is head of village who generally takes the decision. Economic vulnerability is one of the main causes which invite cash incentives. In the case of kidney harvesting and subsequent transplantation there is always that ‘middle man’ who is monetarily benefited. The donor who is poor may not get substantial cash incentive because of the middle men and other greedy medical doctors.

**Q 23 Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?**

No. The human bodily material should be used only to that purpose for which a written consent was obtained. A fresh informed consent is to be obtained. It is ethically wrong to send blood sample of respondent overseas or to any other advance hospitals.

**Q 24 Is there a difference between making a decision on behalf of yourself.....?**

As I mentioned earlier it is the parents who take decision on behalf of their child. In the case of an adult who lacks the capacity to make the decision, a close relative can take the decision but it should be obtained in the presence of a witness.

**Q 25 What part should family members play in deciding whether bodily materials may be used after death?**

Since hospitalization in India is costly for a middle class society, children will not be able to give consent. An unmarried son or daughter may be advised by the parent. Usually an educated middle class person writes a living will in which case family members can't veto it,

## **General Comments on life and living: The process of "give & take" of human bodily materials!**

### **With what we are dealing with?**

In the area of 'Give and Take' with special reference to human bodily materials the commonality between the two aspects - i.e. give and take - is life itself. Life is resident in all living cells or tissues or organs. However, without any exception, all humanity has no knowledge of what life is! Still the word 'life' remains as an undefined term just like its close associate i.e. death. Various opinions of scientists and philosophers were summarized in earlier papers (Azariah, 1995, Azariah, 2006). A gist of the summary on the know-how of life is that "life is a Black Box". We know its attributes; but not its basic 'ingredients' or 'the composite mixture of the ingredients' or is it one "single entity". It is unfortunate that one is compelled to use the word 'it' when describing about life. Similarly, the word 'it' has to be used in describing a living foetus! The famous bio-philosopher Prof E. Mayr has opined "Attempts have been made again and again to define life. These endeavors are rather futile since it is now quite clear that there is no special substance, objects or force that can be identified with life"(Vide Azariah, 2006). Therefore, in dealing with an unknown and unknowable entity, it has always inbuilt risks. Hence, adequate precautionary principles must be enforced.

### **Are their varieties in life *per se*? : Variability and Vagaries of life**

With the present knowledge it is very difficult to find an answer or answer the above question straight away! We can philosophize the topic to arrive at some point. The position of Nuffield (2005) is that animals have "a life". Such a non committal statement is safe both scientifically and philosophically. But Christianity's position is based on the emphatic declaration of Jesus Christ "I am **the** life" (Azariah, 2006). These two positions are the two extremes of the continuum of life. But are there different 'forms' or 'types' of life between these two extremes? There must be! But we do not know for certain.

### **Living cells are immortal**

The creation account, as recorded in Genesis 1 & 2, would categorize different life forms as 'kinds'. Logically there must be some or many difference(s) in life present in the biosphere! If anyone asks Prof. James Lovelock the question: does the earth as a biosphere has 'life'? As per his Gaia hypothesis he would emphatically say that the abiotic component of biosphere has 'life' since it responds to intemperate human actions. If so, then what is the nature of that abiotic-life? A contradiction

of terms – a non living with life! Secondly, the offer of Jesus Christ is interesting. Jesus Christ claimed that He is able to give the “eternal life”, which makes the topic more interesting because ‘ordinary’ or ‘natural’ life which is the one every human is bestowed with at the time of conception, is by itself is ‘eternal’. In the text book entitled **Bioenergetics** written by Broady, results of an interesting experiment has been cited (currently I understand that this book is out of print. A copy of the book that was available in the university of Madras library is now in tatters and so discarded as unrecoverable item). The experimental results reported in the book referred to above, relates to the tissue-culture of living cells taken from a living human. A few body cells were cultured on a nutrient medium and soon the cells grew and divided by binary fission. The process went on. The research scientist kept changing the tissue culture medium and sub cultured the cells by transferring the growing and dividing cells of the isolated cells of a human body. In the meantime the donor died of old age but his cells, kept in tissue culture, continued to live on. There were no signs of death and hence it was concluded that this isolated human bodily materials (cells) are “*potentially immortal*”.

The only current-living proof for the claim that human life is potentially immortal is found in animal kingdom. The *Amoeba* is a remarkable animal because it has no mechanism to die. It has no senescence period. It does not grow senile. It grows and divides and grows. At seasons of environmental stress Amoebae become a cyst and then a cyst comes back to life once the external stress is over. It is immortal. The human cells in culture behave exactly in a similar way. An Amoeba can not die but it can be killed. Similarly a/the life in the cells of a tissue culture can not die but it can be killed (Azariah 2005).

#### **In a ‘body’ living cells differ in behaviour**

Interestingly these cells when they form a body, as in the case of humans, they show aging and death. In Tamil language human body is called a “*sair-eer-um*”. In Tamil “*saireev-u*” means a downward slope and “*eerum*” means wet-ability or water content. It simply means that a human body as soon as it is born it is on a downward slope with reference to its water content. It also means that there is a “biological clock” which does the function of water regulation. I presume that this neonatal chronometer is different from that of the one which modulates the night-day cycle and other bio-cycles. The logical inference is that in each and different human body such a soma-chronometer must be in various stages of operation. It is like saying that two watches never agree!

The relevance of this conclusion is that of the compatibility of human bodily materials of the giver with that of the other person who takes. Logically two different clocks with two different (time) chrono-regime must be running in the same living body of the taker. Human body is so versatile that it accommodates such cells or tissues with variable time cycles. The scientific basis for this argument is that of the proven results of the classical new life form – the cloned

dolly. The donor sheep bodily materials (cells) to be cloned were taken from a six year old sheep. Cloning scientists expected that Dolly will live its full life of 12 years. When the cloned Dolly was in the prime of youth i.e. six years old, Dolly showed signs of senility and suffered the symptoms of advanced old age. No one wanted Dolly to suffer as a young animal with the sufferings of old age symptoms and so Dolly was euthanized.

### **Is there a different chronometer in blood cells/germ cells?**

I think that such variability does not apply to both sperm and blood cells since both are renewable bodily resources of biological materials. In all human beings, blood cells are renewed once in about 100 days. Since all blood cells are similar to one another it is logically inferred that their time duration for renewal may also be similar. But it is not so in the case of human stem cells (hSC) responsible for such renewal. "It was originally believed that all hSC were alike in their self-renewal and differentiation abilities. This view was first challenged by the 2002 discovery by the Muller-Sieburg group in San Diego that different stem cells can show distinct repopulation patterns that are epigenetically predetermined intrinsic properties..." (Wiki, 2010). It is likely that in blood cell replenishment also there could be variations. And that no two person's pattern of self renewal of the blood is the same!

In the consultation paper on "Give and Take" both blood donation and sperm donations are permissible since they are renewable resource. In the light of the above discussion in the case of blood transfusion it is likely that in the blood of the taker, there may be two patterns of multipotency and self renewal patterns in blood.

### **Two points for consideration: Variation and Vagaries**

Between "a" form of life and "the" form of life are there various other categories of life? Are there inter species and intra species variation in life? Scientifically there is no affirmative answer. It is a scientific fact that no two fingerprints and no two irises of human beings agree. Each human body has its distinctive 'watermark'! It stands to reason that similar specificity with reference to life must also exist with reference to life itself. Hence, the life of Human being A must be different from that of human B since each human is an individual. Just like there is no copy of DNA of given human being, his/her life also does not have 'copy' of life or in other words each human life is distinct.

We generally do not mention that humans have "the" life! If there are variations in human life-categories then there will be inbuilt compatibility problems in the process of "give and take." In the Christian position the free offer of Jesus Christ (eternal life) makes no problem with compatibility. It appears that both naturally received human-life at conception which is "*potentially immortal*" can coexist in human body along with "eternal life". Is human life in Human A different from that of Human B? Logically the answer is 'yes' but there is no scientific proof! If there



are such intra-species variations also in the case of humans-life as an entity, then it will complicate the matter more, philosophically. This is one of the vagaries of life on earth. Human life in many occasions is linked with water. In the Martian probe the main idea to find alien life is to identify life by locating the presence of liquid water in Mars. It appeals to logic that life, like water which exhibits its own specific "watermark" signatures can mix with water from a different region and can become one in nature.

In the case of Japanese culture I was educated by a Japanese medical expert that each organ in human body is resident shrine of a demigod. The number of demigods in Japanese culture is more than the number of gods in Hinduism. As a result such a notion makes the process of 'give and take' in human body parts more difficult for a traditional-religious Japanese person from the view point of spirituality. The gods must match and agree! It may be a religious safeguard to wade off more physiological complications and to reduce pain and suffering. But I know a specific case in Chennai where kidney from a sister was transplanted to her brother thirty years ago. Such a kidney transplant candidate is living a successful and purposeful life of a Government servant as well as a famous Christian preacher. If there are inter personal differences in life as an entity among unrelated person then the success rate may be less!

Secondly, the variability in each cell chronometer, if any, does it make any difference or complicate the giver and the taker? Since such transplant-candidates are administered with immuno- suppression drugs if there are any variation and vagaries these may have been obliterated by the drug effect.

### **Variability does it lend itself to divisibility of life?**

The number of chromosomes had to be maintained in all progeny like that of its two parents who have  $2n$  chromosomes. A reduction division at the time of gamogenesis makes this possible by reducing the number of chromosome by half ( $n$ ). When male and female gametes unite in fertilization the parental condition of  $2n$  is restored. It is to be emphasized that each gametocyte is a living entity. Since each gametocyte has life in its cell then two points need to be considered.

When there is a reduction division in the number of chromosomes is there a similar reduction in the entity which we call "life"? The answer is 'No' because life is indivisible. If life is indivisible then does it mean life can be fractionized? The answer is 'yes' it can be fractionized in the sense that each cell has the full life in the gametocyte. It is a situation of antimony. Both positions are true! Secondly, in the event of fertilization, the process does not obey simple mathematics! Generally it construes to reason that one male sperm with life when it unites with an oocyte with its own distinctive life does not make double/two lives. In this case  $1 + 1$  is always equal to  $= 1$  and not 2. This means that, at the gametocyte level, lives derived from two parents are merge-able (can merge).

Azariah (1994 a) enumerated that in a systems approach there are three components. Component A (oxygen) when it combines with another component Hydrogen (B) gives rise to a new component (C) which is a newly emerging entity namely water. Component C is in no way comparable to either components - A or B. In a similar manner when sperm with its distinctive life (Component A) unites with an egg with its own distinguishing features (Component B) a totally new emerging property is witnessed in the birth of a new life (child) (C). This child is an individual while sharing the genome of his/her father and mother, bears a totally different life. Further such an analogy can only be applied to the gametocytes of male and females are concerned. But is it true at the somatic level? No! It appears that at the somatic level it is not true.

In the context of give and take of human bodily materials, in the donor body will have two lives-i.e. one life of the recipient and the other of the donor. This case is not similar to the situation projected in the movie "Face Off". It is a special condition of a human body harboring two different lives (cells) in one body.

### **Use of the phrase "Human Bodily *material*"**

With the advent of the strong evolutionary paradigm there was a quantum change in descriptive vocabulary of the biota. The phrase "living being" or living organisms' was replaced with the phrase "living things" (Azariah, 1994, b). How can a dog be a 'thing'? But a dog is a living thing! If the phrase 'living thing' is applied to all biota then logically it is right to say 'human thing'. But how can a human being be a thing? In the present civilization many cultures adopt the policy of "use and throw" even in the case of humans. The phrase 'human thing' strips off the human dignity of a person. But in practice the usage of a human thing has come to stay! Currently, literature is rampant with the phrase living things. These two words – human and thing - are uneasy bedmates and breaks relationships as it is underscored by the use and throw concept!

If we accept the phrase 'human thing' then the combination of words to arrive at the phrase 'Human Bodily *material*' is perfectly right. The usage of the word 'material' leads to the idea of 'commodities'. Such a view imposes a 'market value' on human body components and emphasizes a materialistic way of life. Commodification of a bodily material is unethical. In which case, making the sperm donation for IVF or surrogacy as **an industry** is justified. In this context the human womb is rightly considered as a future "pot of gold" and surrogacy as business which can spin money in dollars. But it is not bioethical in its approach. In a system's approach words such as body parts, or units or components instead of 'materials' would have been much better!

### **Voyage of life: End of life-issues of life itself!**

The current concept of cosmos is that of “multiverses”- multiple universes. A universe has roughly about 120 billion galaxies. Each galaxy has about 200 to 400 billion stars. Planets teem beyond calculation. Multiverses mean the existence of many such universes! The total number of universes amount to a staggering number i.e.  $10^{10}$  is raised to the power of 10 which is again raised to  $10^{10,000,000}$ . In such an extensive cosmos, presence of life only on earth is a fact and *so far* science has not found the presence of intelligent beings like humans in any other plants of the cosmos. Therefore, it is a scientific fact that life is found only on planet earth. Are we alone? If so Why? Secondly, Does life has end-of-life-issues just like humans? If there is none then there is no problem. If yes! then we need to pay some attention to it.

When a human dies his/her life leaves the body. But where does his/her life go? The Greeks philosophers of 3-5 BC recognized the immortality of human life. The Greeks took shelter in the concept of eternal soul. On the other hand, the contemporary way of life of Hindu culture incorporated this notion into their religious practices. Vedic philosophers of that age devised the concept of “cycles of rebirth” to accommodate the permanency of life. Such a religious view emphasizes that life is immortal. But the question ‘is there a cycles of rebirth?’ is a different discussion point. Culturally also there is proof to sustain the claim that life is immortal. Moreover, the Vedic Culture, way back in 3500 BC, Rig Vedic time, was in search of a plant-derived-drink (The nearest approximation of plant name - *Ephedra sinica?*), called the *Soma* (variously called *Nectar*, *Amrita*, *Living drops*, *Elixir of life*) which would impart immortality to them. It appears that Immortality was a basic human property or rights. Hindu religious texts point to the possibility of usage of two different elixirs for immortality; one for the body and the other for the soul!

### **Views on life beyond cosmos**

According to world famous evolutionist like Prof. Richard Dawkins there is no life after death. In such a revolutionary idea, life becomes non-existent since there is nothing after death. But such a final assumption stands in total contradiction with the proven scientific facts as well as religious and cultural beliefs of ancient Vedic, Greek and Persian records. Prof Dawkins notion appears to be unscientific and not based on proven scientific facts. Scientific experimental results postulate that bodily cells are “potentially immortal” (Vide Broady’s book entitled “Bioenergetics”) and life just does not become non existent. Body can die but life will live! Anything that dies is not life! Therefore, necessity is laid upon humanity to look for another stream of thought which is spiritual. According to religious doctrines God is immortal so also His creations.

### **Life’s voyage through cosmic holes**

There are at least three holes in the cosmos: (i) Black holes (deadly) (ii) White holes (creative giving birth to stars) and (iii) Worm holes (WHs). Einstein’s theory of

relativity predicted the possible existence of a worm hole which is a theoretical 'tunnel' or a shortcut to connect two universes separated by space-time. Hawking (2010) visualized that WHs are "way too small for a human to pass through". Because of their size - they are "just a billion-trillion-trillionths of a centimetre across – a living human cannot pass through. But what about human's immortal life/ spirit (soul)? Can it pass through? If human life can not pass through then there is a problem!

### **In for a big surprises**

In the realm of metaphysics it is better to err on the right side. There lived in Tamil Nadu, an agnostic philosopher and social reformer by the name of late E.V. Ramaswamy Periyar. He once said "if you believe on earth that there is life after death and when you go there and if you find that there is no God or life after death then there is no problem. But when you believe here on earth that there is no God or life after death and when you go there and if you find God or life after death then there is definitely a very big problem"! In either position humanity is in for big surprises!

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