Answers to Emerging Biotechnologies Questions

New technologies emerge from scientific advances that allow existing problems to be tackled in innovative ways, or that reveal new avenues of progress that were not previously seen. Technology development is one of the key hallmarks of human activity that distinguishes us in a major way from all other animal species. Biotechnologies allow humans to better control their living standards, their environment and their own health and welfare.
Every new biotechnology will have potential risks as well as benefits. How these are widely perceived and balanced will be largely determined by the flow of information that is provided to the public. The 'media' have a crucial role in public education that is too often typified by sensationalism, over stressing risks or over promising benefits. Politicians are mostly scientifically illiterate and are therefore not equipped to play the role that they should in debating new biotechnologies. Council has a crucial role in providing excellent source material for politicians and the media. In this role it is important that Council tries to anticipate emerging biotechnologies and provide ethical insight relating to the potential impacts of those advances.

Humans have been developing new technologies since the dawn of the stone-age. The domestication of animals and the cultivation of crops were the earliest examples of biotechnology, although they are not recognized as such nowadays. Never the less, we should acknowledge that the huge benefits accruing from agriculture have come with several downsides. Most of our infectious diseases are zoonotic. From cattle we have acquired. measles and various pox viruses (and possibly tuberculosis although it may be that we have transmitted that disease to cattle), horses are the source of rhinoviruses and influenza came from pigs and ducks, with new variants continuing to be transferred there from. Dogs, which as companion animals are very close to humans, are the source of at least 60 diseases. Agriculture allowed, and required a much denser human mode of dwelling and this in turn encouraged the rodent population to cohabit with us. Rats gave us the bubonic plague that decimated many populations. All of these many adverse effects of domestication of wild animals and of agriculture are clear in retrospect. Would we, with this knowledge, now wish that these early forms of biotechnology had been restricted?

Biotechnologies that are based on a scientific understanding of biology are somewhat more recent. Vaccination (immunization) was one of the earlier biotechnologies (based initially on a very limited knowledge of the immune system) and it has proven immensely effective. Smallpox is the only major lethal human disease to have been eliminated completely as a result of extensive vaccination. Many other immunization programs have been very effective, with polio being almost eliminated. However, vaccination has also

had to face many criticisms (see below for a recent example) and undoubtedly can have adverse side effects in some cases.

The newer biotechnologies are firmly based on our understanding of molecular biology. However, this understanding is imperfect and the broader ramifications of the exposure on a new biotechnology on a large scale cannot be predicted with certainty. The impact of a new biotechnology can be first or second order. First order effects are exemplified by the introduction of GM crops into the environment. An example of second order effect are the longer term implications of rapid DNA sequencing technologies that raise major questions about applications to sequencing human genomes as well as to other species.

It is generally the case that some people may '*believe that an emerging biotechnology could cause harm*' but such beliefs are often irrational and should only be given credence where empirical evidence shows that there is a real possibility of harm and that this out-weighs the potential benefits that can accrue from the particular biotechnology. Even established biotechnologies are subjected to 'scare-mongering' concerning their safety, as shown by the recent MMR myths that have resulted in a drop –off in immunization rates and a rise in the number of cases of measles. In finding a balance between the precautionary and the proactive approaches we should require reasonable safety studies to be performed before widespread application, and ensure that surveillance continues after the introduction of the biotechnology with reporting of any suspected adverse effects. This balance will ensure that new biotechnologies are not stifled at birth by a negative precautionary approach.
The dangers of being over cautious are exemplified by the current approach of the FDA in the USA. Over the past 5 years the number of new drug approvals has fallen dramatically due to an overemphasis on potential adverse effects versus the clear therapeutic benefits of the New Chemical Entities (NCE's) being reviewed. Under the current regime we would most likely not have in clinical use many of the most efficacious and beneficial drugs including all of the NSAID's. Many of the recent new drug applications have been for therapeutic antibodies that are products of a new biotechnology. These biological therapeutic agents are often targeted selectively at low numbers of patients and are therefore priced at a high level. This is an important ethical issue since treating a few patients with a costly medicine may limit the use of other medicines for a wider population. How are these to be balanced?

The precautionary approach to GM crops has severely restricted the development and application of this technology to make a beneficial impact on world food needs. The European restrictions on GM crops have limited investment in R & D that could have provided major assistance to developing countries. Those restrictions have also limited the export market for produce from developing countries and therefore had a deleterious economic effect. Thus, it is the lack of globalization of policy that is hurting the development of new biotechnologies. A balance must be struck between precautions and progress in an ethical manner.

The production of biofuels, (e.g. bioethanol or biodiesel) is an example of a new biotechnology that has been introduced without due consideration of the ethical impact on food supply and food prices. The recent Council report is an admirable document that provides a much-needed set of ethical guidelines. One wonders whether commercial interests are already too strong the full acceptance of these guidelines on a global scale.

You ask "Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?"

Public engagement is a difficult issue. For democracy to work properly one needs an educated electorate. If we are to have any meaningful democratic involvement in decision making concerning new biotechnologies then we need a scientifically educated public and more importantly scientifically educated policy makers. It is currently a major problem that our government and senior civil service are woefully lacking in their knowledge and understanding of science; that is the first issue to tackle in order to achieve better political decisions on new biotechnologies. Once our politicians are scientifically literate then we can hope to move closer to better public involvement in science policy. The media also need to improve their reporting on science of all kinds and particularly on biotechnology. The promise of a new biotechnology is often over-played only to be shot down to quickly thereafter with scare stories of adverse effects that are greatly exaggerated. The problem is how to educate our politicians in science and to produce high quality scientific reporters and commentators. In both of these endeavors there needs to be a basic understanding of the science and importantly a solid grounding in the ethical considerations that apply to the introduction of new technology. Expert advisors can only contribute effectively if those being advised understand the issues.

In choosing where to focus, Council needs to look as far forward as possible. I think that Council was too slow in grasping the importance and ethical implications of the new rapid DNA sequencing technologies. It would have been helpful to undertake an ethical analysis before the beginning of the commercial impact of this technology. The application of DNA sequencing to Biobanks could make a huge impact on the practice of medicine with molecular genetic diagnosis replacing current symptom-based diagnosis. There could also be a big impact on forensics if the ethics of collecting DNA samples across the population can be resolved in a way that would leave the majority of people comfortable.

One area that should be on Council's agenda now is synthetic biology. It is not too early to look into the potential uses and the ethical implications thereof.

Regenerative medicine may also be worth examining since the field has developed rapidly (and continues to do so) since the Council report on Stem Cell Therapy over a decade ago.

One possibility for future Council action would be to tackle the issues surrounding risk-benefit analysis across the whole of biotechnology. Several of the examples quoted above show that the ethical issues usually involve a

balance of real or potential risks against overall benefits. It would be extremely useful to government, the media and the wider public audience to have Council look broadly at the ethics of the balance of risk-benefit analysis taking examples from a wide range of current and future biotechnologies.

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