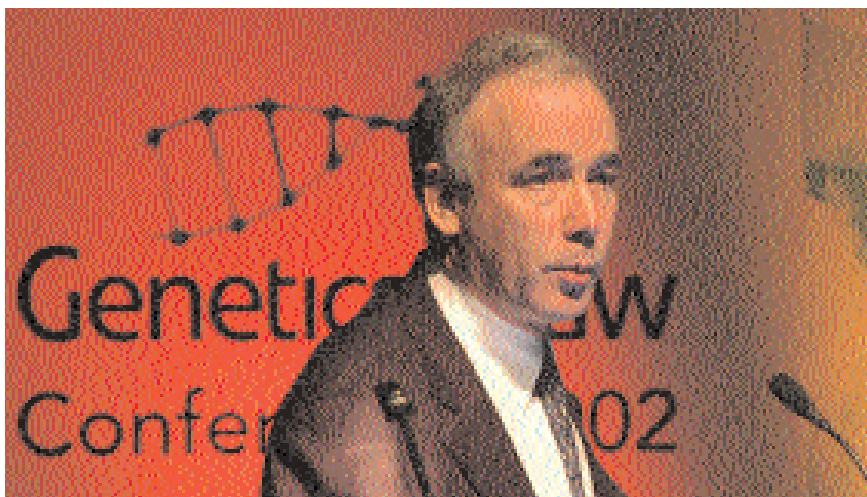


How genetics affects pharmacy

The aim of the first Genetics and Law conference held in London on 19 and 20 November was to look at the facts, the future and the fallacies of genetics. Speakers at the conference included experts from the insurance industry and legal profession as well as representatives from health care



Kevin Cheeseman: *in terms of the sheer number of DNA samples alone, the pharmaceutical industry is probably the major stakeholder in the field of genetics*

Thousands of DNA samples are banked and analysed by drug companies each day and genetic data are used in new drug applications and to find new drug targets. According to Dr KEVIN CHEESEMAN, director of development pharmacogenetics at AstraZeneca, the collection and use of genetic data "presents the pharmaceutical industry with a whole load of new challenges".

In genetics research there are five areas of constraint that need to be considered by industry: ethics, national law, good clinical practice and regulatory bodies, public opinion and confidentiality. Although these constraints also apply to other areas of drug research, they are amplified in genetics, Dr Cheeseman said, and AstraZeneca has adopted an "AZ policy for genetics research" taking these into consideration.

Genetics is perceived as being a particularly sensitive area of research for a number of reasons. For example, it is associated with the diagnosis of serious heritable diseases and unlike other types of clinical data (eg, blood pressure) an individual's genotype cannot be changed. It may also affect a person's ability to obtain life insurance or his or her employability, he explained. But care is needed not to make a categorical distinction — genetic data are not always sensitive. In terms of using genetic information to predict an individual's response to a particular drug, in most instances, this is unlikely to be considered as sensitive. However, if there is only one drug available and tests say that the patient will not respond to it, that would be a different matter, he said.

Genetics research has to be approved by ethics committees and one of the problems facing major pharmaceutical companies is

that they perform research in many countries and so have to be aware of the different ethical opinions, guidelines and laws that prevail, Dr Cheeseman says.

Moreover, ethical issues vary with time. There is a cycle, said Dr Cheeseman: "Things go from complete ignorance from ethical committees about an area and as a consequence it is easy to do something. Then there is an increased level of awareness and sensitivity and suddenly, it becomes more difficult to do something. Then generally, the next stage is that they become more familiar and it becomes easier again."

It is still common for ethics committees to "bounce back" study applications Dr Cheeseman said. Typical reasons include an unacceptable or undescribed process to ensure confidentiality, an unacceptable or unspecified duration of storage of samples and no mention of disclosure of genetic data. Genetics "is a new area for everybody, and we are still learning how to do things," he explained.

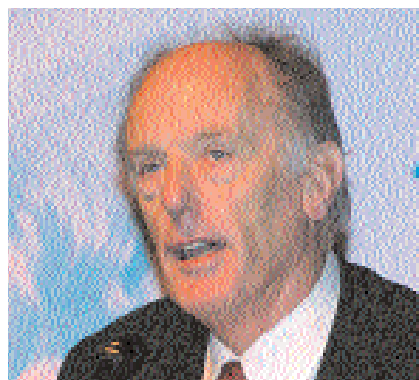
With respect to confidentiality, "you might think that you can remove all problems by anonymising data, but the best you can do is to increase the level of confidentiality," said Dr Cheeseman. This is because good clinical practice means retaining an audit trail. As for disclosure, it is not usual for drug companies to disclose genetic information, and in most cases this would only be done with informed consent, he said.

"Everybody has an opinion about what it is we are and are not allowed to do," Dr Cheeseman said, and he called for education and debate. "If people understand what it is we do in genetics research then they will be generally accepting of it. We do not want to

be in the same position as [those working with] genetically modified organisms where we are not allowed to do anything because there is a huge public outcry."

Most countries do not have specific legislation for genetics research, but there are other areas of law that impinge on genetics, for example, personal data law, said Dr Cheeseman. In the United Kingdom, bodies involved in the regulation of new genetics include the Human Fertilisation and Embryology Authority, the Human Genetics Commission, the National Institute for Biological Standards and Control and the Medical Devices Agency, and it is time to look at the overall shape of the regulatory framework, said Dr IAN GIBSON MP, chairman of the science and technology select committee, House of Commons. For example, the HFEA works with law which is more than 10 years old — out of date, considering recent advances in technology.

However, "frequently, policy makers do not know enough about science and scientists' work in order to regulate effectively. And just as frequently, we find that scientists and their institutions are unaware of political processes, of the need to take into account so-called 'lay opinions' and to reach out to the wider community," he said.



Ian Gibson: *"should DNA tests be available in pharmacies?"*

Dr Gibson agreed that further debate is needed. In the future, pharmacy may not only be affected by pharmacogenetics (predicting the response to a drug), but also by clinical genetics (diagnosis and prognosis). For example, "should DNA tests be available in pharmacies?" he asked.

Research presented by Dr DARREN SHICKLE, clinical senior lecturer at the University of Sheffield, suggests that people are more keen to be told about the various risks of different diseases where their risk of having a gene and of developing that illness is high and where the illness is treatable.