## Americans For Medical Advancement &

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To: Department of Health re: DE00000905720

I am writing regarding a response from Malcolm Jones of Ministerial Correspondence and Public Enquiries of the Department of Health to a letter from Ms Minns and Ms Irving.

I appreciate the fact that the UK government has made a commitment to "reduce the numbers of animals in scientific research." However, this has nothing to do with the issue of the scientific efficacy of using animals as models to predict human response to drugs and disease. The issue Ms Minns and Ms Irving are concerned about is one of science not ethics. If there is overwhelming scientific evidence that animal models fail as predictive models for human response to drugs and disease then the use of such models should not be minimized but rather abandoned. Physicians do not continue the practice of trephination (drilling a hole in the skull to release evil humors) because it has no merit. They did not reduce the number of cases where trephination was used; they abandoned it.

Neither do animal experiments need to be refined if there is scientifically no chance that such studies will predict human response to drugs and disease. Almost every study involving animal models explicitly states that the model is, or will be, of predictive value or implies it.(1-3) Likewise, almost every study that has examined the predictive value of animal models has revealed that they lack it.(4-33) The use of animals in other forms of science or research (that is use outside their claims as predictive models) continues despite viable alternatives, because of the unquestioned claim that animal models have predictive value for human response to drugs and disease.

The notion that "Animal research still plays an important role in providing vital safety information for potential new medicines," is verifiably false (see references above). Indeed, scientists acknowledge that society has lost cures because of misleading studies in animals.(7, 24, 34-39) The only people that think "Animal research and testing is a small but vital part of this effort, and is essential for understanding physical and disease processes for the non-clinical development of new medicines, and for detecting unforeseen toxic effects," are the people with a vested interest in animal models or their representatives.

As to the comment that "Approximately 99 per cent of new drugs are eliminated during testing, most during early research phases, but this is a necessary part of the process of demonstrating efficacy as well as safety," this is indeed the main reason why animal models are still used in drug development and has been shown to be about as good as random chance in predicting human responses. (See references above.)

The comment that "less than one per cent [of medications], are subsequently withdrawn as a result of serious side effects," is disingenuous as a vast majority of these drugs are me-too drugs or different formulations of old drugs. The fact that the Department of Health would voice such errors in medical science is disheartening and is perhaps, sadly, representative of a position favoring vested interest groups over patients.

The correspondence from Jones also stated: "Most studies investigating the value of animal studies in drug development have methodological shortcomings, and datasets are often limited in size or scope. It is therefore challenging to make an unbiased and comprehensive analysis of whether animal studies are of value in predicting short- and long-term clinical safety." As the above references prove, this is not the case. Animal models have been shown to lack predictive value and a theory now exists explain why this is currently the case and will always be the case. (40) As monozygotic twins do not always respond the same to drugs and disease the notion that animal models will have predictive value for human response to drugs and disease belongs in the same category of ideas as the tooth fairy" and "the oil industry can police itself." (3, 14)

Moreover, the word *concordance* is not used by scientists when describing predictive value. It is a weasel word used to obfuscate.(1) No project whether funded by the EU or anyone else can change the facts presented in the above references. Politics is not the same as biomedical science.

Finally, the statement that "it is important to remember that without the judicious use of animal studies we would have no modern drugs," is as vacuous as it is disingenuous. Apparently the Department of Health really does not care about patients, only about maintaining the status quo so vested interest groups can continue to fleece taxpayers and those who donate to charities out of money that could be used in productive research modalities that would result in cures. In reality, abandoning animal models would not take money out of the UK, it would allow the UK to increase productivity with a healthier population and increase gross national product because it would be on the cutting edge of science.

Yours sincerely, Ray Greek, MD

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