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Legislation, social licence and primate research

"The end of monkey research?" ask Melissa Suran and Howard Wolinsky (2009) against a background of growing concern over the use of primates in research. Indeed, the one factor that might have the biggest impact on primate research in Europe is the revision of Directive 86/609, which will greatly affect the work of many scientists. It is therefore in the interest of all researchers to get an unbiased picture of what is happening in the legislative realm; something that the article unfortunately does not provide.

The far-reaching measures for regulating primate research that Suran and Wolinsky outline in their article come from the European Commission's proposal to revise the Directive on the protection of animals used for scientific purposes (86/609/EEC), which was presented in November 2008 (EC, 2008). This proposal has since progressed to the next entity in the legislative procedure, the European Parliament (EP), which published its First Reading Report in May 2009 (EP, 2009). The EP report introduced amendments that changed the original text on a number of points—including the principal points regarding primate use. It removed the limitation on the use of non-human primates for research into life-threatening or debilitating diseases (Amendment 10) and replaced the demand for the rapid phasing out of F2-animal use with a requirement for studying the feasibility of limiting the animals used to those from self-sustaining colonies (Amendments 11 and 65). This change certainly increases the pressure to make primate research independent of wild-caught animals, but does not present insurmountable obstacles to research. Of the points mentioned by Suran and Wolinsky in regard to the revision, the only one that is left unchanged by the EP report is the ban on research with great apes—but there is no such research in Europe anyway.

At the time of writing, the final Directive text is not yet established. It has progressed to the next stage, the so-called trilogue between the Commission, the Council of Ministers and the Parliament, in which these three entities will work out the final legislative document, which will be a compromise between their respective views. It is clear that the future Directive will not look exactly as originally proposed and, therefore, Suran and Wolinsky's reliance on the Commission's original proposal to illustrate the future of European primate research is obviously misleading.

What is particularly unfortunate about the article is that portraying matters so negatively plays into the hands of researchers who see legislation primarily as an obstacle to research; a view that alienates them from efforts to ensure both the quality of life of experimental animals, and quality of the experimental data.

The view of legislation as a burden is widespread among biomedical researchers —and not only among those using animals (Dixon-Woods & Ashcroft, 2008). But is there any evidence that legislation will threaten animal research? The examples cited by Suran and Wolinsky are unique in that research with those monkeys was actually stopped. But, it is important to note here that the instrument used to achieve this was not animal research legislation, but rather a legal appeal to animal dignity as inscribed in the constitution of Switzerland, a non-European Union country (Abbott, 2008). Typically, however, legislation does not stop projects. Rather, quantitative analyses of the decisions of ethics committees show that the majority of projects are approved, most without revision and a few after changes (Hagelin *et al*, 2003).

In a wider sense, legislation and other instruments of research governance are probably largely beneficial for researchers, because they secure a social licence for research (Dixon-Woods & Ashcroft, 2008). Researchers using animals need this social licence more than most biomedical researchers if they want to be able to defend their work. It is clear that primate research is particularly controversial—indeed, as Bernard Rollin commented in the article, "people have a special thing about primates". Thus, more than any other scientists, researchers using primates need public confidence. Societal trust and acceptance of primate research can only be founded on clear communication between the stakeholders involved, and complaints about legislation are unlikely to help achieve this.

The Commission's proposal to revise the Directive as presented in November 2008 was heavily criticized by the biomedical research community on a number of points (EBRA, 2008). All of these concerns—of which primate research is only one—are essentially taken into account in the EP's First Reading Report. With the EP as one key player in the legislative process, there is little reason to expect that the revised Directive will pose insurmountable difficulties for primate research in Europe, or for any kind of research for that matter. Rather, the revision is to be welcomed for seeking to introduce the much-needed level playing field for animal research within the European Union.

CONFLICT OF INTEREST
The authors have no conflict of interest.

REFERENCES
Abbott A (2008) *Nature* **453:** 833
Dixon-Woods M, Ashcroft RP (2008) *Med Health Care Philos* **11:** 381–391
EBRA (2008) *EBRA Bulletin* [online] Nov
EC (2008) *Proposal for a Directive of the European Parliament and of the Council on the Protection of Animals Used for Scientific Purposes*. Brussels, Belgium: European Commission
EP (2009) *European Parliament Legislative Resolution of 5 May 2009 on the Proposal for a Directive of the European Parliament and of the Council on the Protection of Animals Used for Scientific Purposes*. Brussels, Belgium: European Parliament
Hagelin J *et al* (2003) *Lab Anim* **37:** 10–18
Suran M, Wolinsky H (2009) *EMBO Rep* **10:** 1080–1082

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