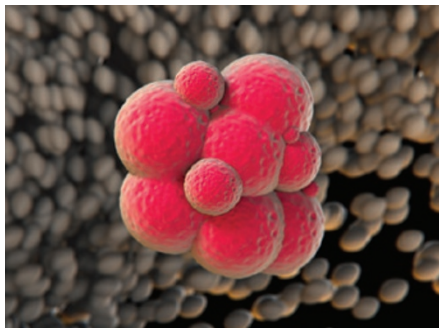
Compromise is in sight for new embryo research rules in France

PARIS — In 2004, France made a radical reversal by lifting its total ban on human embryonic stem cell research. But the law governing approval to conduct these types of studies remains convoluted, and scientists worry that the current system is dissuading companies from setting up research outfits in France. Proposals to update the French bioethics law will finally be presented to Parliament in early February, and a compromise may be on its way to help satisfy all partisans on this score.

Scientists are virtually unanimous in the opinion that the current ban with exemptions should be dropped, but politicians remain divided over the question. "The opposition comes mainly from the Roman Catholics and crosses party lines," says Jean-Sébastien Vialatte, a parliamentarian and vice president of a special all-party National Assembly committee for the new law. Although France has been a staunchly secular country since 1905, "there has been strong pressure from the Church," he adds.

The draft bill adopted by the cabinet of ministers last October still includes a ban on work involving human embryonic stem cells (hESCs) and embryos but has special exemptions for research that could lead to "major medical progress." This is aimed to ease the current requirement in the 2004 French law that any approved research must have the prospect to bring "major therapeutic progress."



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Embryonic development: New ethics rules.

"This is a very important improvement," says biologist Marc Peschanski, whose team at France's Institute for Stem Cell Therapy and Exploration of Monogenic Diseases (I-STEM) was the first to generate whole skin grafts from stem cells. "It will allow for studies on diagnostics and pathology mechanisms, which could open the way to new therapies," he adds. Research for cosmetic purposes, for example, would still be illegal.

As *Nature Medicine* was going to press, the *ad hoc* committee was hashing out amendments to be added to the bill, but a compromise was starting to take shape. Some people speculate that the ban with exemptions will probably be kept for *in vitro* embryos. But it looks as though the partial ban on hESCs will be lifted and replaced by a general authorization, with restrictions.

A general authorization to work with stem cells might still require scientists to get approval from the Biomedical Agency, which oversees such projects, for their research endeavors with hESCs. "Whatever Parliament decides [on the ban], it will not make much difference in practice, because researchers will probably still have to seek authorization from the Biomedical Agency before embarking on any embryonic stem cell or *in vitro* embryo research," director general Emmanuelle Prada-Bordenave says.

But, according to Peschanski, continuing the system would be "a catastrophe," especially now that stem cell research is moving from the basic to the applied stage. This means "we need new industrial and hospital partners and investments involving millions of euros," and these partners are spooked away by heavy-handed restrictions, he explains.

Barbara Casassus

New regulations urged for UK health research

Complex regulation and governance of clinical research in the UK has held back research with no evidence of improved patient safety, concludes a report by the country's Academy of Medical Sciences (AMS).

The AMS was commissioned by the UK government in March 2010 to review the regulation of clinical and health research. The review, released on 10 January, recommends the establishment of an independent Health Research Agency (HRA) to simplify approval processes that currently differ across the UK. The authors also recommend the establishment of a National Research Governance Service within the HRA to accelerate approval of multicenter studies. The branch would take responsibility for certain approvals of multicenter trials; the current system requires multiple approvals carried out by different units within the country's National Health Service.

According to the report, "nearly a quarter of the world's top 100 medicines" were developed in the UK. Antibody therapies, first developed in the UK, constitute a third of all new drugs for major diseases, including cancer and arthritis, and this sector of the market is projected to grow to over $43 billion by 2012. But whereas 46% of EU products in clinical trials were developed in the UK in 2002, this fell to 24% by 2007.

The report's authors say that even though the country's Medicines and Healthcare Products Regulatory Agency (MHRA) provides timely authorization of clinical trials, the EU Clinical Trials Directive is hampering scientific work and discouraging academic and commercial health research sponsors in the UK.

"The European Clinical Trials directive has been a disaster," the chair of the AMS working group that prepared the report, Sir Michael Rawlins, told *Nature Medicine*. "Within Europe the number of patients on clinical trials has dropped by about a third in the last nine years which, considering that elsewhere in the world it's increasing, is not good." The bureaucracy is "horrid," he added, "the time taken in countries like Britain makes it just completely unattractive."

The UK government welcomed the recommendations, but organizations including the BioIndustry Association (BIA) voiced concerns about yet another layer of regulation.

"The BIA continues to believe that it would be more efficient and effective to build upon and expand existing competencies within MHRA rather than create a new body to oversee the regulation and governance of health research, as recommended by the AMS report," says Alan Morrison, chairman of the BIA's Regulatory Affairs Advisory Committee.

Bea Perks