immunosuppression do remain. But, instead of considering why facial transplantation cannot be justified, we may find it hard to justify why it should not be done.

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Extra scrutiny for industry funded trials

JAMA's demand for an additional hurdle is unfair—and absurd

Suppose that a biomedical journal invoked a new policy requiring that all authors based in western Europe or North America would receive ordinary peer review, but authors from other countries would receive a peer review with additional hurdles. This policy may seem unfair, but suppose the journal claimed that research has shown that there is a greater prevalence of fraud, bias, and sloppy work among papers coming from these other countries.

If these events actually transpired, we hope that other biomedical journals would rapidly point out that adopting such a policy would be unfair to authors from non-western countries, even if the premises for it were valid. Indeed, we hope that other editors would decide that it would be unethical to create any hierarchical system for submissions of papers to a biomedical journal. Peer review ought to rest on the content of a submission rather than solely on the basis of presumptions inferred from group affiliation such as nationality.

We would hope so, but we are not sure. A logically similar situation has actually occurred, with a few small differences from the above scenario. The new instructions for authors at *JAMA* include the following[1 2]:

> For reports containing original data, at least 1 author (eg, the principal investigator) who is independent of any commercial funder should indicate that she or he 'had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.' For industry-sponsored studies, the data analysis should be conducted bystatisticians at an academic center, rather than only by statisticians employed by the company sponsoring the research.

The additional hurdle for research submissions with industry funding comes before peer review, and requires authors to hire an academic statistician before their submission will be considered by *JAMA*. Other submitters need not be concerned about this requirement.

This policy is manifestly unfair. It violates the proposition that each submission should be considered on its merits and it creates a hierarchy of purity among authors. We presume that the intent is well motivated, in the sense that the editors at *JAMA* have recognised the potential for a problem—perhaps bias, fraud, or shoddy work—in submissions funded by industry. *JAMA*'s draconian solution, however, punishes the innocent along with the guilty, and denigrates the reliability and professionalism of industry-employed statisticians, whose credentials *JAMA* apparently considers insufficient.

Following these new instructions raises many questions that require arbitrary distinctions. The instructions require an academic statistician either to conduct or to bless the analysis. But what is the mark of a qualified statistician? A degree? Certification by the Royal Statistical Society? And who is academic? A retired professor who becomes an industry consultant? A retired industry statistician who joins a university? Once paid by industry, would an academic statistician remain independent? Will mail order universities be acceptable, or must the universities meet specific accreditation requirements?

These questions are meant only to illuminate the absurdity introduced by these new instructions. We suspect that if the new rule were to spread to other journals there would soon be a thriving cottage industry among "academic statisticians" to vet analyses from the private sector, along the lines of professional expert witnesses in tort cases. Even if the rules could be clearly and cogently stated, they would be objectionable simply because it is unfair to judge work solely on the basis of affiliation of the authors.[3] We recognise that there is growing and legitimate concern about the methods used by commercial enterprises to influence publication and consequently the public perception of their products.[4] Even so, as Smith says, "The companies seem to get the results they want not by fiddling the results, which would be far too crude and possibly detectable by peer review, but rather by asking the 'right' questions—and there are many ways to do this."[4] The broader problem will need imaginative solutions, not an attempt to police the work of industry funded statisticians as *JAMA* has proposed. The decision to publish should be based on content, and the process

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should be the same for all submissions regardless of country of origin or type of institution.

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Sharing the benefits of genetic research

Will the World Trade Organization act to stop the exploitation of biodiversity?

Campaigners are calling on policy makers at next week's sixth World Trade Organization ministerial conference in Hong Kong to make trade fairer for and improve the lives and health of the world's poorest people. This broad and important aim may dominate the headlines, but ministers will also be discussing technical issues surrounding international patenting laws. One issue with implications for the development of medical products is the tension between international patenting laws and benefit sharing requirements, which may threaten agreements on protecting biodiversity. If the biodiversity door shuts because of protests in developing countries, pharmaceutical research will be seriously hampered.

In Hong Kong the World Trade Organization can stop the exploitation of non-human genetic material and traditional knowledge by aligning the trade related intellectual property rights (TRIPS) agreement with the Convention on Biological Diversity. Over the past decade benefit sharing has become a recurrent theme in international debates on human and non-human genetics. The term arose from the Convention on Biological Diversity adopted at the 1992 earth summit in Rio de Janeiro, Brazil.[1] The convention has three objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits from the use of genetic resources ("benefit sharing"). Although benefit sharing is compulsory when the biosciences industry or research centres use biodiversity and associated local or indigenous knowledge to develop new products and services, it is not covered by legally binding international trade agreements, such as TRIPS,[2] nor does it cover human genetic resources.

Benefit sharing is particularly important in three contexts in genetics: access to non-human genetic resources and associated traditional knowledge, human genetic banking, and research on rare genotypes.[3] The few benefit sharing agreements that have been signed to date have been widely criticised (see box on bmj.com).[4–7]

Concerns regarding benefit sharing for non-human genetic resources and traditional knowledge have included practical problems such as: how can prior informed consent be obtained from large communities without adequate means of representation; how can the socioeducational gap between negotiating partners be bridged; how can lack of trust between negotiating partners be overcome; and which benefits should be made available when and to whom? Principled objections have included concerns about incompatibility between the concept of communally owned traditional knowledge and the intellectual property rights system; views that sacred knowledge ought never be patented; and the fear that benefiting individual communities according to ethnic distinctions is divisive.

These concerns should not detract from the fact that 187 countries and the European Union have agreed in the Convention on Biological Diversity that benefit sharing for non-human genetic resources and traditional knowledge is legally binding.[1] It is in this context that an earlier ministerial conference of World Trade Organization members agreed the Doha Mandate in Qatar in November 2001.[8] This mandate identified the need for further negotiation on the clash between TRIPS and the Convention on Biological Diversity. This was reinforced by a series of submissions to the World Trade Organization from a group of Latin American and Asian countries which suggested how to bridge the gap between the two agreements.[9] These submissions urged that patent applicants should provide disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; evidence of prior informed consent through approval of authorities under the relevant national regime; and evidence of fair and equitable benefit sharing under the relevant national regime.

Without the proposed revision of TRIPS, the Convention on Biological Diversity is legally binding but lacks "teeth" because it does not include the strong mechanism for dispute settlement that is provided by World Trade Organization treaties. Ministers will consider the revision in Hong Kong and are in an excellent position to stop the exploitation of non-human genetic resources and traditional knowledge.

Aside from the discussions in Hong Kong, benefit sharing for human genetic resources is an even greater challenge, as none of the relevant international guidelines are legally binding (HUGO Ethics Committee statement on benefit sharing,[10] UNESCO International Declaration on Human Genetic Data[11]). It has therefore been suggested that the Convention on Biological Diversity should be extended to include human genetic

P+ *Box showing benefit sharing agreements is on bmj.com*

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