

Universities should foster neglected-disease work

Shifting the focus from patents and revenue to human welfare would speed progress.

Sir—Your Editorial “Wanted: social entrepreneurs” (*Nature* 434, 941; 2005) rightly points out the positive steps taken by not-for-profit pharmaceutical ventures to find cures for neglected diseases. But your gentle criticism of universities as impediments to these advances does not go far enough.

My experience is with a group known as Universities Allied for Essential Medicines (www.essentialmedicine.org), composed primarily of students seeking to hold universities to their avowed public mission in the arena of health-technology policy. We believe that universities’ reluctance to engage with non-traditional pharmaceutical partners stems in part from a myopic focus on taking out patents, executing licences and generating revenue. Success in technology transfer should be measured by its impact on human welfare, which requires an emphasis on innovation in neglected diseases and access to public-health goods.

The fact that neglected-disease drug ventures have to search and negotiate for molecules of interest reveals how upside-down the situation is. When patented

innovations have not yet been licensed to an external agency for further development, universities should allow other non-profit institutions to use them in research for neglected diseases, as a matter of policy. When innovations have been out-licensed, universities should include an exemption for research on neglected diseases in their licensing agreements. In either case, the university should forgo royalty payments on products sold in developing countries.

These exemptions can be constructed in such a way that they create a ‘dual-market opportunity’: any products developed could require cross-licensing (agreements between the beneficiary of the neglected-disease exemption and the original licensee) for sale in high-income countries, while being sold in poor countries without further licensing or payment of royalties.

Another point is that the criteria for academic promotion reinforce the difficulty of translating basic research into end-products. In addition to publications and grants, universities should consider a candidate’s work in finding treatments for

neglected diseases. They could reward participation in preclinical development projects, particularly open-source initiatives pooling research resources to speed commercialization, such as Tropical Disease Initiative (www.tropicaldisease.org) and Biological Innovation for Open Society (www.bios.net).

Of course, we are a long way from having neglected-disease research free of such hurdles. In the meantime, universities should look to their peers who are leading the charge in overturning the status quo. Yale University, the University of Washington, the University of California, Berkeley, the University of California, Santa Barbara and the University of Nebraska have all struck deals with non-traditional pharmaceutical ventures transferring intellectual-property rights to further neglected-disease research.

One hopes they are out in front of a much broader trend.

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Two-stage drug approval would reduce the risks

Sir—Your timely News Feature “The safety catch” (*Nature* 434, 554–556; 2005) points out the need for better post-marketing safety surveillance of new drugs by the US Food and Drug Administration. At present, after a drug is approved on the basis of trial results, its effects in widespread use are difficult to assess and authorities have little power to control its promotion. Let us consider the consequences of a two-stage approval process for new drugs.

During the period of a few years between initial and final approval, the drug would not be promoted to doctors or (as is legal in the United States) to patients; it would be used only by patients whose conditions had not responded to existing drugs. In return, the clock would be stopped on patent expiration, which would compensate the manufacturer for the delay in promoting the drug more widely.

The public would benefit from the gathering of necessary safety data; the risk would be taken by a limited number of patients, in return for the chance of a more helpful medicine. Both manufacturer and public would benefit from the saved cost of not promoting new drugs that fail the post-marketing safety surveillance.

Incidentally, a similar but more

prolonged postponing of patent expiration on new antibiotics would help to delay bacterial resistance to them, because they would not be used initially unless the previously available agents were ineffective. This would also make the economics of limited use of new antibiotics much more fair to the manufacturers.

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Seeing clearly is not necessarily believing

Sir—I was interested to see your News Feature “CSI: cell biology” (*Nature* 434, 952–953; 2005) on digital photography and image manipulation in cell biology. Photoshop-based enhancement of images raises questions of proper conduct, for which journal guidelines are necessary.

In my field, the problem (and it is here a problem, not an issue of misconduct) is much greater in electron than in light microscopy.

An example of good practice is the cover of the 2 December issue of *Nature*. This enhanced image is taken from an Article by A. Fotin and colleagues on clathrin lattices (*Nature* 432, 573–579; 2004). The authors are to be congratulated

for their unusually open disclosure of the difference between the original and the published image.

The Methods section of this Article makes a clear distinction between the data collected by the cryo-microscope and the pictures in the article. The authors list all the image-processing programs used in preparation of the illustrations: IMAGIC, CTFTILT, FREALIGN, O, EMAN, Chimera, MAVE, LSQ_EXPLICIT, MAMA and MODELLER. These are mostly ‘off the shelf’ programs that produce symmetry enhancements, density averaging and many of the same effects as Photoshop.

In my experience, unless the scientist/postdoc/technician knows a great deal more about the guts of these programs than most, they are performing ‘black-box’ image enhancements that they do not control to any significant degree.

The full disclosure by Fotin and colleagues is remarkable for being so rare. The scarcity of such imaging disclosures elsewhere in the published record shows us just how far we have come towards inverting the purpose of scientific images. Where we used to have “seeing is believing”, we now have the possibility of “believing is seeing”, courtesy of our image-processing and enhancement software.

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