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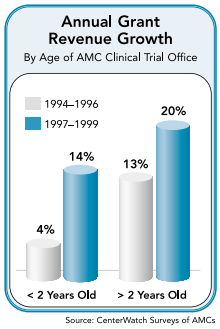
Industry support for medical centers grows

Driven by several factors, industry funding for clinical research at US academic medical centers has increased significantly over the past two years, according to a new survey. If the trend continues, it may eventually counter a nearly decade-long decline in industry revenues that has exacerbated financial difficulties at many academic centers.

According to Centerwatch, the Boston-based market research organization that carried out the survey, the growth of for-profit clinical research centers, called site management organizations, steadily siphoned industry-funded research away from costlier, less efficient academic medical centers through most of the 1990s.



"Typically the academic medical centers provided slower service as well as poorer quality [of research administration]. That's why the sponsors started going to the independent centers," says Annick DeBruin, a market analyst for Centerwatch.

However, the survey of 20 academic medical centers around the country shows that the return of industry funding is linked to the establishment of central clinical research coordination offices, which streamline the process of setting up trials and reduce bureaucratic red tape. Between 1997 and 1999, the proportion of academic centers with a centralized clinical trial office rose from 9% to 45%; at the same time, industry-sponsored clinical grant revenue grew by 17%, compared to a 15% increase in NIH-funded clinical research.

The expansion of pharmaceutical research pipelines has also driven many companies back to academic centers, and the majority of industry-sponsored research at these centers now consists of the larger phase II and phase III drug trials, rather than initial investigations, according to Centerwatch.

Edward McWilliams, a project manager at Merck, explains that pharmaceutical companies are increasingly targeting complex diseases in highly specific ways and that the patients who are appropriate for such trials are typically treated by a specialist, which usually means they are to be found within the setting of an academic medical center. McWilliams adds, "Placing studies with these centers gives us both faster recruitment rates and, in the long term, may help with the marketing of a drug."

Thus, companies do not seem to object to the comparatively high cost of doing clinical trials at the centers now that the bureaucratic problems are being solved, and they are willing to absorb the extra costs in exchange for access to top researchers and specific patient populations. The increase in revenue is timely for the centers, many of which have been hit hard by changes in federal funding rules and the high cost of overhauling their clinical research procedures in the wake of a crackdown by the Office of Protection from Research Risks (*Nature Med*., **6**, 611, 2000).

Alan Dove, Philadelphia

Folkman countersuit attacks "fraudulent" Abbott

In a vicious counter-attack, the Children's Hospital of Boston has countersued Abbott Laboratories for defamation and conspiracy, accusing the Illinois pharmaceutical giant of implementing a fraudulent scheme to obtain the patent rights to anti-angiogenic agents studied in the laboratory of Judah Folkman.

The 47-page legal document was filed with the District Court of Massachusetts in response to a lawsuit filed by Abbott last May, which claimed that Folkman, along with co-workers Yihai Cao and Michael O'Reilly, stole Abbott's discovery of the anti-angiogenic fragment of plasminogen known as Kringle 5 (*Nature Med* **6**, 723, 2000). Abbott's original lawsuit claimed that its own biochemist Donald Davidson was the first to observe that Kringle 5 blocked angiogenesis. Abbott requested that Cao, Folkman, and O'Reilly be removed as inventors on the patent, known as the '221 patent,' and replaced with Davidson.

According to the countersuit, Davidson and Abbott learned about the anti-angiogenic properties of plasminogen fragments from Cao and asked him to teach them the angiogenesis research techniques that subsequently allowed Abbott to begin its own research in this field. The countersuit states that Abbott began attempts to appropriate the discovery by convincing Children's Hospital to enter into contracts—Confidential Disclosure Agreements (CDAs)—that would give Abbott sweeping rights to Folkman's findings.

Abbott claims that Folkman signed a CDA in June of 1995, giving Abbott all rights to Kringle 5 and patent 221. However, the countersuit contests that a technology transfer officer at the hospital refused to authorise the CDA on the grounds that it was improper, and furthermore, that Abbott's lawsuit contains an 'improperly, deceptively and fraudulently edited' form of the CDA which omits the officer's comments. A second CDA giving Abbott sole ownership of all 'information and developments' based on any Kringle 5 fragment was also rejected by the office of technology transfer in 1996.

The countersuit states that Abbott tried to obtain its own patent by making material misrepresentations to the US patent and trademark office: in May of 1996, the suit alleges, Abbott secretly filed a patent application purporting to claim methods of treating angiogenic diseases with Kringle 5, listing Davidson as the sole inventor. This patent application was rejected in January 1999 as being anticipated by the Children's Hospital 221 patent.

To overcome the examiner's rejection, Davidson submitted a declaration claiming that he conceived the idea of using Kringle 5 as an angiogenesis inhibitor prior to the filing of Children's 221 patent, and never disclosed that he had derived his knowledge from Children's Hospital. The countersuit claims that Abbott received the patent, known as the 484, patent based on these false representations. However, Children's Hospital still has the dominant 221 patent, which forces Abbott to pay royalties from any therapeutic developments based on Kringle 5 to Children's Hospital.

According to Folkman, "Abbott laboratories, in a deliberate attempt to claim for itself a discovery that it neither made, nor owns, has seen fit to attack the integrity of the scientists at Children's Hospital and to publicize its false allegations world-wide". The countersuit requests that Abbott's original complaint be dismissed, and that the court award damages of an undisclosed amount to the hospital.

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