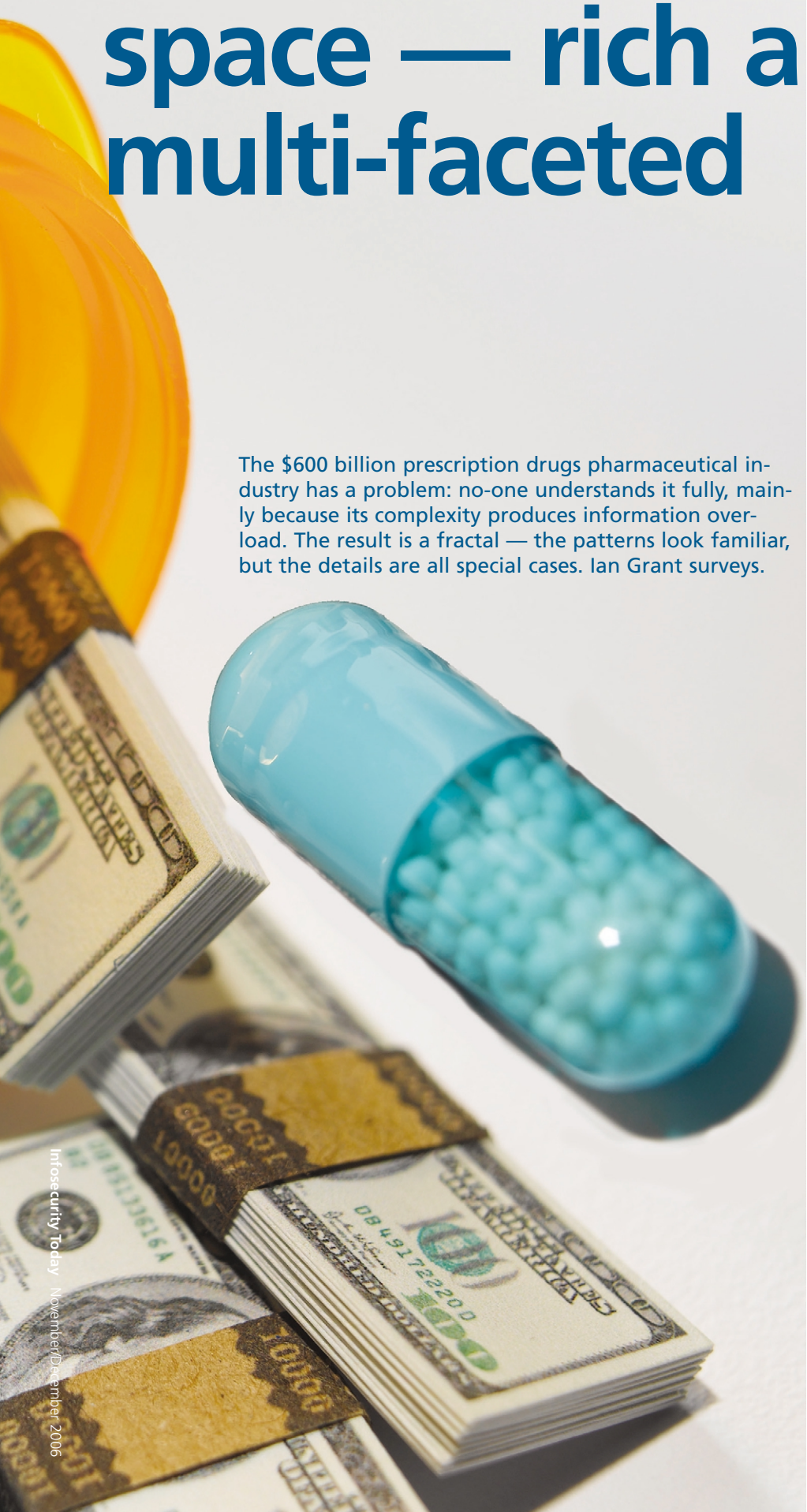
Pharma's information space — rich and multi-faceted



Ian Grant

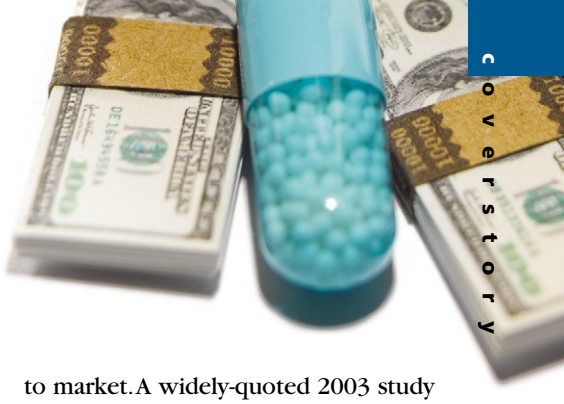
The $600 billion prescription drugs pharmaceutical industry has a problem: no-one understands it fully, mainly because its complexity produces information overload. The result is a fractal — the patterns look familiar, but the details are all special cases. Ian Grant surveys.

The information problem in the pharmaceutical industry falls, broadly speaking, into two parts: one is to find the molecular needle in the haystack that will become the next billion dollar bestseller; the other is to preserve the quality and integrity of materials in the supply chain from raw material to patient, and thus ensure patient safety and brand reputation.

Profits available from ethical drugs elicit envy from firms in other industries. According to a 1993 study by the US Office of Technology Assessment, "economic returns to the pharmaceutical industry as (a) whole exceeded returns to corporations in other industries by about two to three percentage points per year from 1976 to 1987, after adjusting for risk among industries."

The ability to track and trace ethical drugs through the supply chain is a vital issue for drug makers, healthcare regulators and workers, and consumers. The UK Department of Health is looking at possibly exploring the use of Radio Frequency Identity (RFID) technology. The US FDA has already said it wants an electronic 'e-pedigree', and hopes that RFID will enable it.

So far costs, technology and privacy issues have made drug firms pause for thought. To justify the cost they are looking for more than just guaranteed provenance. They also want the e-pedigree to contribute to better stock control, lower cost, more accurate forecasting, fewer product



recalls and returns, and better insight into their consumers.

This requires a much greater integration of the firm's manufacturing systems with their business systems, with those of suppliers and customers up and down the supply chain and with regulators, customs officials and other authorities. It also puts an absolute premium on the quality of information entering the system; garbage in, garbage out. It also places a premium on interoperable systems, and on a global scale.

An indication of how far this might go is that Britain's National Infrastructure Security Coordination Centre, together with the Association of British Pharmaceutical Industries, has set up an information exchange system for the pharmaceutical sector. The aim is to detect and prevent computer-based attacks on the sector and individual companies. The US Department of Homeland Security is equally concerned, making the national drug and vaccine supply a high priority item in its national critical infrastructure plans.

However, a new global study of infosecurity practices by management consultancy PricewaterhouseCoopers and CIO magazine, found most drug firms reacting to events, especially legal and regulatory changes, rather than developing an infosecurity strategy that integrates with the corporate business goals. See table: 'Infosecurity in the Pharmaceutical sector, 2006'.

The US, which represents about half the total market and also produces about half the new drugs, is key to the future development of infosecurity in the pharma sector. As the cost of bringing an effective new drug to market rises, the more governments will have to support their development. This means more fundamental information should come into the public domain. That should make patent protection less important and reduce the threshold requirement for returns on investment, thus making drugs cheaper. Cheaper drugs will reduce the sector's attractiveness to criminals, thus making trace and trace less important for brand protection and law enforcement reasons, though not for internal quality and stock control reasons. Given this, infosecurity in the pharma sector is likely to remain reactive rather than proactive.

Once out of patent

When branded drugs lose their patent protection, there are scores of firms and governments eager to make 'generics' that capitalize on their hard-won ideas. Moreover, massive potential profits from counterfeit and arbitrage trading have attracted opportunists and criminals into the ethical drugs business.

Last year the OECD countries spent $450 billion on healthcare, more and more of it on prescription drugs. This, plus the rising cost of health insurance, smuggling, safety and potential terrorism, has alarmed the authorities. Meanwhile, the man in the street sees a healthcare industry that is meeting expectations less and less in terms of costs and benefits, and for which he partly blames the pharmaceutical industry.

PR problems aside, it is becoming harder to find effective new drugs. Jürgen Drews of Swiss-based International Biomedicine Partners reckons there are between 5,000 and 10,000 potential drug targets; this is "at least 10 times as many molecular targets that can be exploited for future drug therapy than are being used today." Meanwhile, Harvard Medical School's Richard Frank reckons 78% of candidate molecules never get to market because of concerns over clinical safety, toxicology, and efficacy. However, at least a fifth was ditched because of 'portfolio concerns'.

Twelve years hard

It is common cause that tougher regulators are raising the bar for patient safety and clinical effectiveness. This has lengthened the period from discovery to market, raising costs. The OFTA study found that it took on average 12 years and an average cost of $194 million to bring a drug to market. A widely-quoted 2003 study by DeMasi *et al.* for the US-based Tufts Center for the Study of Drug Development put the average out-of-pocket cost at $403 million, but the economic (time value) cost at at $802m. Management consultancy Bain & Co reckons it comes to $1.7 billion if you include the first year's marketing costs. This is when firms spend up to 70% of the marketing budget in the hope of launching a 'blockbuster', a drug with sales of $1 billion/y.

The problem is, almost 80% of drugs launched are essentially line extensions that offer only marginal improvements in efficacy. In 2005, the US Food and Drug Administration (FDA) found that of 487 new products that received market authorisations in the US between 1998 and 2003, 78% were by and large similar to previously authorised medicines. Only 14% had a marked therapeutic improvement.

Patently protected

Drugs that reach launch are usually heavily protected by patent. In the US, patent protection lasts 20 years. For most industries this gives an effective 'patent life' of 18 years or more; the long lead time to market for new drugs can cut the effective patent life to five or six years. This makes massive profit margins essential if the firm is to recover its investment over the remaining protected period.

Dr Merrill Matthews, the Institute of Policy Ideas