Report predicts burgeoning vaccine markets

Although not one of the current billion-dollar, best-selling medicines is a vaccine, a prominent consulting firm is predicting that four major types of vaccines have the potential to become pharmaceutical profit leaders over the next decade: influenza, pneumococcus, HIV and hepatitis C.

In order to identify the most promising indications, analysts at Massachusetts-based Decision Resources quantified the unmet need for vaccines against specific diseases and the sizes of susceptible populations in the major pharmaceutical markets, which are Europe, Japan and the US. The list was narrowed by considering the scientific feasibility of developing vaccines for each disease within the next 10 years.

Although influenza vaccines are widely available, physicians and patients have complained that the need for a painful injection each year discourages some patients from getting vaccinated. In response, pharmaceutical companies have developed inhaled flu vaccines, including Aviron/American Home Products' FluMist and Berna's Nasalflu; the latter already is marketed in Europe. The initial response to these vaccines suggests that similar products now in development will enjoy considerable market success.

HIV vaccine research has also intensified in recent years, although Decision Resources analyst and report author, John Lebbos, cautions that predictions for this vaccine market hinge on basic research, as first-generation HIV vaccines might not have sufficient efficacy to be market successes. Currently, the lead HIV vaccine is VaxGen's Aidsvax, which is in Phase III clinical trials. The value of this market will also rest on the ability of the poorer countries that comprise the epicenter of the disease to buy vaccines through the newly proposed Global Purchase Fund (Nature Med. 7, 647; 2001).

For both HIV and hepatitis C virus, "what's going to be critical in the future is identifying the most effective conserved epitopes to induce a T-cell response, and doing that on a developmental platform that's efficient," says Lebbos. Chiron has entered Phase II clinical trials with a hepatitis C virus subunit vaccine, but new bioinformatics and high-throughput strategies may bring a new generation of rationally designed vaccines that could be therapeutic as well as prophylactic.

The appearance of antibiotic-resistant bacterial strains is the main factor driving pneumococcal meningitis vaccine development, with one vaccine already approved in the US (Wyeth-Lederle's Prevenar) and others in clinical trials. Sales of Prevenar hit $400 million in the first year—a long way from the $6 billion sales of the leading prescription drug omeprazole, but good revenue for a vaccine.

Alan Dove, Philadelphia

Trials suspended due to death at Hopkins

Johns Hopkins has become the latest in a line of American universities forced to suspend clinical trials because of its failure to comply with federal oversight rules. Last month it placed 22 trials on hold following the death of a healthy volunteer in a study that government inspectors say failed to follow proper patient protection measures.

In a trial designed to assess lung function in asthma, healthy volunteers were asked to inhale substances that irritate the airways. The participant who died had inhaled hexamethonium as part of the study one month previously. Hexamethonium is a ganglion-blocking drug that can temporarily paralyze some nerves in the airways. It was initially approved in the 1950s by the Food and Drug Administration (FDA) for its vasodilatory properties to treat hypertension and was therefore being used for a different indication—so-called 'off-label' use—in the Hopkins trial.

The case has alerted many researchers to the fact that they may need FDA approval for clinical trials that use a drug already approved for another indication. The FDA virtually ignores doctors when they engage in the common practice of prescribing drugs for conditions that are not officially sanctioned by the agency. But in this case, the FDA said that the researchers should have obtained investigational new drug (IND) approval before using a medicine for another purpose.

The National Heart, Lung and Blood Institute (NHLBI) was funding the trial, led by two prominent pulmonary researchers, Solbert Permutt and Alkis Togias, under a four-year, $400,000 grant. However, the NHLBI has now frozen the funding and has notified all of its lung researchers of the death and asked them to "reassess" and "consider suspending research with hexamethonium in light of this event until more information is available." No researchers have yet reported using the drug, according to an NHLBI spokesperson.

In a statement released by Johns Hopkins, school officials say that both the investigators and the school's institutional review board felt the IND was unnecessary for the use of hexamethonium because it was already approved by the FDA. However, the trials suspended by the school cover all studies that use FDA-approved agents that do not have an IND for that indication.

Tinker Ready, Boston

Businesswoman to lead Italian research ministry

AP Photo/Plinio Lepri

Silvio Berlusconi and Letizia Moratti

Newly elected Italian prime minister, Silvio Berlusconi, has merged the Ministry of University and Science and Technological Research and the Public Education Ministry and appointed a media businesswoman, Letizia Moratti, with no scientific experience to run the 'superministry'.

Moratti has announced that she aims to implement a culture of entrepreneurialism throughout Italian science. To this end, viceminister of research Guido Possa told *Nature Medicine* that the government has lifted a ban on publicly funded investigators holding financial interests in research work. "Scientists who were prohibited from holding shares can do so, and we hope this will cultivate a taste for [financial reward] and flexibility throughout the university system," he said. As part of the new approach, there will be a deliberate effort to award government funding to universities that demonstrate the ability to set up companies and patent discoveries—old news in the US and the UK, but a revolutionary effort for Italian science.

Martina Ballmaier, Milan