NEWS IN BRIEF

First priority review voucher wasted

Novartis redeemed its priority review voucher earlier this year to secure a speedy assessment of canakinumab in gouty arthritis, but the FDA nevertheless recently ruled against approval.

The lowdown: In 2007, the US government created priority review vouchers to encourage companies to work on drugs for neglected diseases. Through this programme, firms that successfully developed new therapeutics addressing these unmet medical needs would be rewarded with a single-use voucher guaranteeing a priority review for a subsequent drug submission of the sponsor's choice. David Ridley and his colleagues at Duke University, Durham, North Carolina, USA, who first proposed the scheme in 2006 (*Health Aff.* **25,** 313–324; 2006), estimated that the faster review time and potentially speedier move towards commercialization could be worth as much as US$320 million.

The first, and as yet only, voucher was granted to Novartis in 2009 when the US Food and Drug Administration (FDA) approved the artemether plus lumefantrine combination therapy for the treatment of malaria. Novartis used the voucher to secure a 6-month review for canakinumab in gouty arthritis, but the agency rejected the dossier in August and asked for more data to assess the antibody's profile in refractory patients. Although the decision highlights the uncertainty surrounding the valuation of the vouchers, Ridley argues that the experience demonstrates that the FDA will honour the coupon. He adds that it was a bit of a surprise that Novartis received the voucher in the first place because the firm's antimalarial had been in use since 2001 outside the United States. "In the future, we'd like to reward products that would not have otherwise been developed," says Ridley. Companies developing tuberculosis drugs that are currently in Phase II trials could be the next recipients of the voucher, he adds.

An effort is also underway to sweeten the terms of the voucher. If the US government approves the Creating Hope Act, vouchers would become easier to redeem and fully transferable (they can currently only be sold once).

Proposed PDUFA V deal unveiled

The recently unveiled proposed PDUFA V programme includes a longer review time, increased communication between regulators and drug developers, and a focus on advancing regulatory sciences.

The lowdown: Ahead of the expiration of the Prescription Drug User Fee Act (PDUFA) IV next year, the FDA and industry representatives have been working to hammer out the terms of PDUFA V, a 5-year agreement that outlines what the agency must provide in exchange for the user fees it collects for drug review. Foremost among the changes in the proposed scheme (http://go.nature.com/2KVR8b), a 60-day filing period will be added to the review of drugs and biologics, effectively extending the priority review period to 8 months and the regular review period to 1 year. There will also be more meetings between agency representatives and drug developers — such as pre-filing and mid-review meetings — in the hopes of improving the efficiency and effectiveness of the first-cycle review process. Some observers speculate that these changes could result in fewer advisory committee meetings during the drug review period.

PDUFA V outlines other measures that could improve communication between regulators and industry sponsors, and commits the agency to making specific efforts to meet the challenges of clinical trial end point assessment tools, biomarkers, pharmacogenomics, meta-analysis and the development of drugs for rare diseases. PDUFA V is currently expected to generate a 6% increase in user fee revenue.

The terms of the agreement will be subject to public debate later this month, before heading to the Senate for final approval. Once approved, they will run through to 2017.

Lasker rewards natural product drug discovery

Winners of the Lasker award this year included Tu Youyou, for the discovery of the antimalarial artemisinin. Franz-Ulrich Hartl and Arthur Horwich also shared an award for their role in elucidating the protein-folding process.

The lowdown: This year's Lasker–DeBakey Clinical Medical Research Award honoured Youyou, of the China Academy of Chinese Medical Sciences in Beijing, China, for the discovery of artemisinin, a current standard of care for the treatment of malaria. Youyou started working to discover an antimalarial in the 1960s, when she headed up a Chinese institute in which practitioners of traditional medicine worked alongside chemists, pharmacologists and other scientists. While participating in a military project to develop treatments for chloroquine-resistant malaria, Youyou scoured ancient texts and folk remedies for possible leads. After an extract from the *Artemisia annua* (qinghao) plant provided promising preliminary *in vivo* data, Youyou worked to isolate an active ingredient, with help from a 1,700-year-old text that described how to prepare the plant as a traditional medicine. By the time the first English-language paper on artemisinin was published, in 1979, the drug had already been administered to over 2,000 patients in China and Youyou had purified potent artemisinin derivatives, including dihydroartemisinin.

The Basic Medical Research Award, meanwhile, was shared by Hartl, of the Max Planck Institute of Biochemistry in Martinsried, Germany, and Horwich, of the Yale University School of Medicine, Connecticut, USA. Starting in the 1980s, while working to understand how proteins that are made in the cytoplasm enter into mitochondria, the pair discovered and unravelled functional properties of the proteins that facilitate and ensure proper protein folding. Companies like FoldRx, which was bought by Pfizer last year (*Nature Rev. Drug Discov.* **9,** 825–827; 2010), have since sprung up to focus exclusively on protein-misfolding diseases.