Box 1 Dendreon advocates lose transparency battle

In January, a US federal appeals court ruled against cancer advocacy group Care to Live over their demands to see internal correspondence relating to the cancer vaccine Provenge (sipuleucel-T). The advocacy group sued the FDA in 2007 for access to documents from the vaccine's manufacturer, the Seattle-based biotech Dendreon. The FDA approved the autologous cellular immunotherapy cancer treatment last May (*Nat. Biotechnol.* **28**, 531–532, 2010) after a three-year delay during which the agency cited a need for more clinical data, despite an FDA advisory panel voting overwhelmingly in favor of approval.

Soon after the FDA's decision to request more information in 2007, allegations emerged that experts on the FDA review committee had serious conflicts of interest and deliberately wanted to delay the drug's approval. Suspecting foul play, Care To Live filed a Freedom of Information Act request to see copies of letters circulated among FDA's medical experts regarding the drug. Dissatisfied with the FDA's slow and incomplete response to its request, the group sued the agency. After FDA released the requested documents, a district court ruled in FDA's favor, but Care To Live appealed, arguing that FDA did not hand over all the relevant documents.

The recent federal court decision affirmed the district court's ruling, stating: "The [Freedom of Information] Act does not require that agencies account for all of their documents, so long as they reasonably attempt to locate them. To defeat a motion for summary judgment the requestor must identify specific deficiencies in the agency's response, which Care To Live has failed to do…."

If FDA adopts current proposals as part of its ongoing transparency initiative, such lawsuits might be precluded in the future, says FDA spokesperson Crystal Rice. One draft proposal would require the agency to explain its rationale when it declines to approve medical products. *GS*

In 2005, IQWiG was commissioned to review the efficacy of Edronax, which has been sold in the EU since 1997. The average daily cost of Edronax was 3 times higher than for the most commonly prescribed antidepressants, selective serotonin reuptake inhibitors. Published literature suggested that drug was tested in at least 4,600 patients, says Wieseler. Data were published, however, on only 1,600 of these. When IQWiG requested the complete clinical data on Edronax, Pfizer initially balked, but then relented when the German agency first concluded that it could not prove the drug was effective because of a possible bias in the published data. After reviewing all the data (some of which were collected after the drug was approved in the EU), IQWiG concluded that Edronax was no more effective than placebo and potentially harmful (*Br. Med. J.* **341**, 473, 2010). As a result the German statutory healthcare system will no longer pay for the drug.

Such publication bias by the pharmaceutical industry is widespread, says Gøtzsche. "We know that companies frequently manipulate their data so that the results look more positive. All [these] data really should be shared. It would lead to a tremendous advance in healthcare."

In the US, the FDA Amendments Act of 2007 has put transparency measures in place (*Nat. Biotechnol.* **25**, 1189–1190, 2007), such as mandating that all clinical trials be registered and their results published, partly to reduce publication bias. Even so, the FDA's act does not cover trials completed before 2007, so published information on older drugs will remain potentially biased. Also, critics argue that unless clinical trial sponsors are required to register full study protocols and plans for statistical analysis, the problem of publication bias will remain. In the EU, the EudraPharm EU Clinical Trials Registry is being revamped to include more information. The new database, which is scheduled to go live later this year, will not only contain summary information on medicines, but also include information on clinical trial sponsors, protocols and more data. The registry is publicly accessible (https://eudract.ema.europa.eu/).

"EMA's transparency policy is a step in the right direction," Wieseler adds. Both industry and public health will benefit from the policy. "In principle, it's not in the interest of industry to hide clinical trial data. It disturbs the public trust [in medicine] and that can't be [in] the interest of industry."

Indeed, some in industry are cautiously welcoming the recent initiatives. "This really isn't anything new," says Thomas Reese Saylor, CEO of Cambridge, UK–based Arecor. "There will continue to be protection of commercially sensitive data."

Gunjan Sinha, ***Berlin***

IN brief

First public-private vaccine

The first new vaccine developed as a public-private partnership, and prequalified by the World Health Organization (WHO) of Geneva, made its debut in December. Twelve million children and young adults across Burkina Faso, Mali and Niger were inoculated with MenAfriVac a new conjugate vaccine against meningitis A (group A *Neisseria meningitides).* Group A epidemics occur every 7 to 14 years in sub-Saharan Africa and in 2001, the nonprofit PATH, of Seattle, and the WHO set up the Meningitis Vaccine Project (MVP) to introduce an affordable vaccine specific for Africa. With $70 million in seed funding from the Bill and Melinda Gates Foundation in Seattle, the partners developed a vaccine priced at $0.50 a dose. Development took less than a decade and cost less than one-tenth the $500 million usually required to bring a new vaccine to market. Success depended on forging key collaborations: Amsterdam-based Synco Bio Partners provided the polysaccharide ingredient, the Serum Institute of India in Pune contributed the tetanus toxoid and affordable manufacturing, and the US Food & Drug Administration laboratories in Bethesda, Maryland, licensed a technology for conjugating vaccine components. The WHO approved MenAfriVac in June 2010. Marc LaForce, MVP global program leader, is pleased with the "outstanding" 95% vaccination coverage. "It speaks to the high level of acceptance on the part of the population," he says. *Nidhi Subbaraman*

Mobile vaccine factories

GE Healthcare and G-Con Manufacturing of College Station, Texas, have signed a collaboration to produce a low-cost, flexible, good manufacturing practices (GMP) vaccine-manufacturing facility to meet the needs of developing countries and as a swift response to pandemic situations. The quick-to-build vaccine manufacturing station will combine Buckinghamshire, UK–based GE's single-use bioprocessing technologies with G-Con's modular, portable, clean-room technology. The facility is equipped to grow cell lines up to 1,000 liters and is easier to operate than existing technologies. Catarina Flyborg, general manager of bioprocess products at GE Healthcare's Life Sciences unit, explains that the stations will use GE's ReadyToProcess range of disposables, and G-Con's mix and match modules. Other companies offering single-use GMP bioreactors are Xcellerex of Marlborough, Massachusetts, and Pharmadule of Nacka, Sweden. Miriam Monge, vice president, global key accounts Biopharm Services in Buckinghamshire, UK, a specialist in the disposable technology arena, commented, "During the last flu pandemic many developing countries realized how ill-equipped to face the situation they were. The combination of portable facilities, disposable technologies that can be rapidly deployed and GE's global infrastructure appears an ideal solution for delivering rapid response manufacturing to these developing countries." *Susan Aldridge*