higher, and that may also be counterproductive."

Consumer advocates on the FDA panel agree, pointing out that U.S. users of such a vaccine will be reluctant to see components added if they offer little additional protection but perhaps more risk and certainly more cost. The question of escalating costs is even more troublesome when considering how to design combination vaccines for wide use in developing countries where budgets for public health programs to administer vaccines are extremely tight.

The World Health Organization (Geneva, Switzerland) sees the development and wide distribution of such vaccines "as a major priority," Klugman notes. Of even more immediate importance, the clinical testing of a multivalent conjugate vaccine containing nine distinct types of pneumococcal polysaccharides will soon begin in Soweto, South Africa, he says. "A major problem will be to get these vaccines to the third world, so it's quite exciting to begin these tests."

Provided that these and other clinical tests prove successful, making the conjugate vaccines available to countries in the third world is of global importance for another reason, points out Margaret Hostetter of the University of Minneapolis (Minneapolis, MN), who also spoke at ICAAC. It will help to address the problem of antibiotic resistance in these pathogens. To reduce or eliminate these pathogens, particularly the antibiotic-resistant strains that sometimes move rapidly about the globe, "we will want to do so everywhere," she says.

—Jeffrey L. Fox

Wyeth-Ayerst and Apollon sign vaccine deal

"It was very important for Apollon to have a partner that would contribute more than just money to the deal."

ALLENTOWN, PA—Vaccine development, so often in the shadow of its dashing therapeutic counterparts, is starting to shake off its tall-dark-dependable-but-unexciting image. If proof was needed that there is a lot of vaccine development to be done, the $100 million deal involving Wyeth-Ayerst Laboratories (Radnor, PA), a division of American Home Products (AHP, Philadelphia, PA) and Apollon (Malvern, PA) surely provides it. The deal concerns the development and commercialization of Apollon's facilitated DNA injection technology, Genevax, and specifically encompasses Genevax-HIV, an HIV vaccine currently in phase I/II clinical trials, and DNA-based vaccines that target herpes simplex virus (HSV) and human papilloma virus (HPV). In return for upfront and milestone payments, Apollon will manufacture the products and sell them to Wyeth-Ayerst for worldwide distribution.

"It was very important for Apollon to have a partner that would contribute more than just money to the deal," says Vincent Zurawski, Jr., president and CEO of Apollon. "We very much wanted to have a research collaboration, and someone interested in the development of this product in the long term."

Together with Merck (Rahway, NJ), SmithKline Beecham (London, U.K.), and Connaught Laboratories (Swiftwater, PA), American Home Products is a leader in the pediatric and adult vaccine market worldwide. In November 1994, Wyeth-Ayerst merged with Lederle-Praxis (Rochester, NY), a leader in pediatric vaccines, as part of AHP's acquisition of American Cyanamid.

Apollon's vaccine technology involves injecting the DNA for viral antigens, together with facilitating agents that enhance DNA uptake and gene expression. "In order to have a DNA-based vaccine for an infectious disease agent, it may require only local, transient, and low level expression of the DNA infected," says Allan Jarvis, vice president of business development and strategy for the Wyeth-Lederle Vaccines and Pediatrics division. He likens the transient antigen presence to subclinical infection with a natural pathogen: both result in a protective humoral and T-cell-mediated immune responses.

The Genevax-HIV product now in clinical trials in HIV-infected individuals contains genes for the gp160 viral envelope protein, other HIV accessory proteins, and the facilitating agent, bupivacaine. The company anticipates filing an IND for a prophylactic HIV vaccine construct by mid-1996. HSV may be a more straightforward target than HIV. Apollon expects that an effective prophylactic vaccine might target a single antigen, such as the gD2 envelope protein.

—Vicki Glaser

Vicki Glaser is a freelance science and medical writer in Allentown, PA.

European food rules creep forward

OXFORD, UK—After more than 12 months of wrangling, ministers from European Union (EU, Brussels, Belgium) member states have agreed to a form of wording for the European "novel foods" regulation that introduces a requirement to label some—but not all—genetically modified foods. Industry will accept the requirements, albeit reluctantly, on the basis that it can work with one somewhat unsatisfactory set of Europe-wide rules more easily than it can work with 15 sets of national rules. It would, undoubtedly, have preferred a less prescriptive approach.

Companies such as Zeneca (London, U.K.) and Unilever NV (London, U.K. and Rotterdam, the Netherlands) have long advocated that labeling should only be required if it is useful to the consumers. This view is shared by EU Industry Commissioner Martin Bangemann. Bangemann suggested that foods or ingredients that had not been substantially modified by genetic engineering or ingredients processed into another form (such as tomato juice from genetically engineered tomatoes) shouldn't be labeled. Labels like "substantially modified" or "sub-

stantial modification" in such cases would only confuse consumers, Bangemann felt. Andrew Dickson, of the Senior Advisory Group Biotechnology (Brussels, Belgium), welcomed the proposed rules, calling them "an elegant compromise."

Environmental groups and some parts of the European Parliament (EP, Strasbourg, France), however, are expected to continue to push for stricter controls. Friends of the Earth (Brussels, Belgium), for instance, announced that it would pressure the EP to tighten the legislation.

Food labeling has been a rallying cry for a "rainbow coalition" of political allegiances that includes Greens, liberals, and the religious right. The signs are that many of these groups are not happy with the council's proposed text. To those one could add a number of otherwise uncommitted members of the EP (MEPs) from the four nations—Austria, Denmark, Germany, and Sweden—which objected to the proposals in the Council.

There is also a long-standing division among the governments of EU member states as to the best way of coping with food labeling. Austria, Denmark, Germany and Sweden have pressed for strict labeling rules, believing consumers should always be informed that a foodstuff has been genetically modified. Other countries argue that it is unfair to stigmatize new foods through systematic labeling. The proposed rules are a compromise, requiring foods to carry labels saying they are genetically engineered only if they differ in a "significant" way from an existing food.

For example, specific labeling would be required for a tomato containing a strawberry gene/protein to alert consumers who are allergic to strawberries. Similarly, a yogurt containing a genetically modified organism (GMO) would also have to be labeled, because an ingredient was different. But sugar from beet that had been genetically modified to resist disease or tolerate herbicides would not have to be labeled, since the sugar would be no different from that produced by other beets. Thus, the new rules would apply to products that could realistically be identified as having been genetically engineered.

Strangely, it was the Council of Education Ministers at its meeting in October, rather than their colleagues from trade, industry, or agriculture, that closed the most recent chapter on the draft regulation on novel foods (COM(92) 295). This was because the council only had to "nod" assent to the measures, all the details of which had been beaten out at an earlier meeting of the Committee of Permanent Representatives (Brussels, Belgium), a forum for national "ambassadors" to the EU.

The council decision is, however, not the end of the story. The agreed text has next to go before the EP for a second reading. Since the legislation is being adopted under co-decision-making procedures, Members of the EP can veto the directive if a real majority—a majority of all members and not just of those attending a debate—opposes it.

Biotechnology was a victim of one of the most recent occasions on which that happened. The "biotechnology patents" directive failed in the EP in March 1995 largely because it was to be voted on a day when an unusually large number of members were in Strasbourg to vote on enlargement of the EU.

European parliamentarians seem particularly keen to introduce labeling requirements for recombinant products by any credible means. Recently, an old 1979 directive covering the labeling, presentation, and advertising of foodstuffs (79/112/EEC) was being amended to bring it into line with requirements of the Maastricht Treaty. During the second reading of the amendments (95/0380(COD), the EP's Committee on the Environment, Public Health, and Consumer Protection took the opportunity to reinstate a proposal from German conservative Horst Schnellhardt, from the European People's Party, for introducing special labeling for foodstuffs produced with gene technology. A virtually identical proposal had been put forward by the Parliament during the first reading, only to be removed by the European Council.

What industry objects to most, perhaps, in the European rule-making process is uncertainty. Morris Tabaksblat, chairman of Unilever, has called on the European Commission (Brussels) to adopt a secure regulatory framework for Europe's biotechnology users as soon as possible. He warns that delays, such as the extremely slow progress on the novel foods regulation, could affect the global competitiveness of European companies. Today, for instance, while the U.S. Food and Drug Administration (Rockville, MD) can approve genetically engineered herbicide-resistant soya beans for food uses, the same product would have to clear a variety of regulatory hurdles before it could be sold in the EU.

—Mike Ward

Mike Ward is a freelance writer based in Oxford, U.K. Stan Kulp, a freelance writer based in Hoboken, NJ., contributed additional reporting.

European parliamentarians seem keen to introduce labeling for recombinant products by any credible means.

COMMENTARY ON THE PRESS **Russ Hoyle**

Media mutates mouse with human ear

Several years ago, a mainstream U.S. environmental organization took a thrashing in this space for publishing egregious distortions about the uses of biotechnology. The Green critics had made much of dated transgenic animal experimentation, from arthritic pigs stuffed with human growth hormone to plants injected with antifreeze genes from arctic flounders. To capture the horror of it all, the writers rolled out the tired old "brave new world" canard and mischievously described the industry's agenda as a "sci-fi menu."

All of this came to mind recently when a bald, three-year-old mouse with a "human" ear on its back became an overnight sensation in the international media and on late-night U.S. talk shows like those of David Letterman and Jay Leno. And on trash radio's Howard Stern.

The first time around, a lesson emerged from the unwitting and willful misinformation about an admittedly complex and controversial in-