Getting Testy

February 1, 2000 By Denny Lee

Abbott Laboratories was under the microscope again in November when the Food and Drug Administration (FDA) levied a $100 million fine—the biggest ever of its kind for the behemoth pharmaceutical industry. The charge? The world's largest maker of HIV tests, despite six years of prodding by the government agency, still failed to meet quality-control standards.

Abbott is not the friendliest drug company, from a consumer's perspective. The company has faced criticism by HIV treatment activists since 1990, when it resisted efforts to get U.S. approval of clarithromycin (Biaxin), an antibiotic often used to treat MAC (Mycobacterium avium Complex). Biaxin was already on the market in Europe, and activists said Abbott was willing to sacrifice profits here to avoid community conflict. "They were the most arrogant and unpleasant company we had to deal with," said HIV treatment advocacy group Project Inform's Martin Delaney, though he acknowledged that their community relations have since improved. But alliances were tested again in 1998 when the company had to temporarily yank its protease inhibitor, ritonavir (Norvir), off the shelves because of as-yet-unexplained production problems.

Though the FDA stopped short of questioning the tests' safety or accuracy, a court-approved settlement requires Abbott to permanently halt production of 125 of its 300 medical kits (including the world's first HIV-antibody test, HIV1 EIA, and a viral load test, HIVAG p24 Antigen) used by doctors to test a range of diseases. The remaining 175 kits were deemed "medically necessary" by the FDA—mostly because few alternatives exist—and will continue to be sold to hospitals and laboratories as the company improves its manufacturing process. Of the HIV tests that will stay on the market, one is a diagnostic test and four are kits used to screen blood donors for HIV and hepatitis C. The FDA has not recalled any products and is not recommending that patients get retested, although "the firm's failure to follow good manufacturing requirements decreases the level of assurance," said Jane E. Henney, MD, the FDA's commissioner of food and drugs.

The fine capped a six-year effort by the feds that began when inspectors found manufacturing-process violations at two of the company's Illinois plants. Abbott spokesperson Joe Daab insisted that none of the kits were defective and that the company has "invested a lot of money to conform to those systems." But FDA officials said that numerous attempts to work with Abbott were met with broken promises, missed deadlines and Band-Aid fixes.

Whether the FDA's action will prompt Abbott to improve its production standards remains to be seen, said Stephen Northrup, executive director of the Medical Device Manufacturer's Association, a trade group. "It's a reminder to this industry that quality-control systems are an important part

of the manufacturing process," he said.
