

hibitively expensive for most people.)

Ultimately, the panel recommended that the agency license the drug only for advanced patients and urged the company to consider designing trials that would enable it to achieve accelerated approval for all other patients. Abbott officials told the panel they were eager to do this, and immediately after the meeting, they huddled with FDA officials to negotiate an agreement. Abbott officials promised the long-term confirmatory trials that would enable the drug to receive accelerated approval as well as full approval. The company also committed to designing and launching pediatric trials.

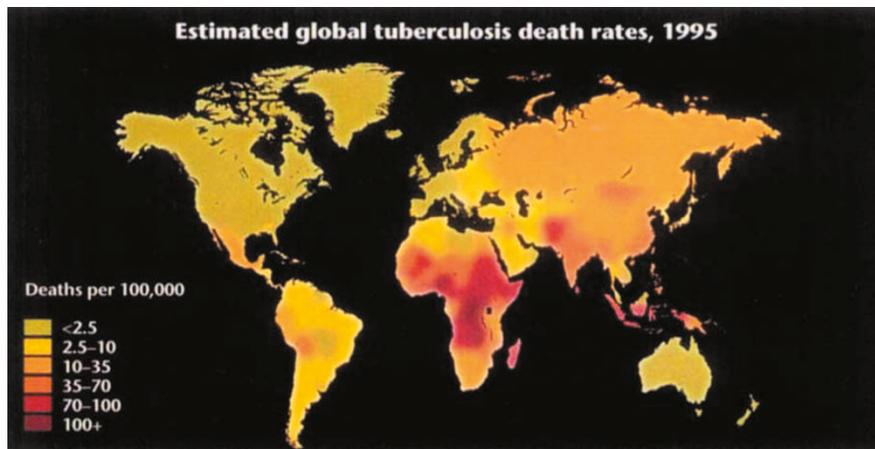
By morning, it was a done deal. And the FDA, later that day and with considerable fanfare, announced that the drug would soon be on the market for anyone who needed it, either for monotherapy or for use in combination with other antiviral drugs. "We have high-powered guns, and we want to make them available," Kessler said, in explaining his reasons for the rapid movement on the drug.

The quick action even evoked a statement of praise from President Clinton. On the same day, Clinton also asked Congress to appropriate an additional US\$52 million in funds under the Ryan White Act to assure financial assistance to AIDS patients who cannot afford these expensive drugs.

Almost lost in the commotion over the FDA's efforts to quickly approve ritonavir was the panel's decision to recommend accelerated approval for a third protease inhibitor, indinavir, developed by Merck & Co. Merck had sought accelerated approval based on surrogate marker research that has shown that the drug, when used in combination with nucleoside analogs, suppresses HIV to almost undetectable levels in the bloodstream.

Merck's New Drug Application (NDA) was submitted to the agency about six weeks after Abbott's, so the FDA was not as far along in its review of the Merck drug. But Kessler promised that the agency would act just as quickly, adding that the agency already had begun inspecting the company's plants to ensure the quality of the manufacturing process. "This is day 72 [since the NDA was submitted] on Abbott and it is day 29 on Merck," Kessler said. "We are committed to making a decision when Merck is ready to launch its drug. When that time comes, we will not hold the company up."

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WHO issues another gloomy tuberculosis report

More people died of tuberculosis (TB) in 1995 than any other year in history, according to the 1996 report of the World Health Organisation (WHO) on the TB epidemic, released on March 24. This is despite increased efforts to combat the disease, sparked by the WHO declaration of a global emergency three years ago. WHO's forecast that 30 million people will die from TB in the next ten years is unchanged. One-third of the world's population — nearly two billion people — is now infected, and an estimated five to ten percent of these will become sick.

TB infection appeared throughout 1995 in parts of the world normally considered "safe" from the disease. For example, one person in Minneapolis infected 41 people in a neighborhood bar. A health-care worker in western Canada gave TB to 100 people. According to the report, "in recent years outbreaks of TB in wealthy countries have been investigated in discotheques, churches, subways, schools, aeroplanes, courtrooms and even on a river boat casino."

Perhaps more frightening are the outbreaks of multidrug-resistant TB in New York City, London, Milan, India, Thailand, South Africa, Estonia and Pakistan. WHO blames this on careless treatment practices. The report estimates that 50 million people are now infected with drug-resistant strains of the TB pathogen.

The increase in number of HIV infections has helped quicken the pace at which TB spreads; WHO now estimates that in the next four years HIV will help cause more than 3 million new TB cases.

Patients infected with both TB and HIV are overwhelming health systems in sub-Saharan Africa. The dual epidemic is most serious in Asia, home to two-thirds of the world's active TB cases, and where HIV is spreading more rapidly than anywhere else in the world. The percentage of TB cases attributable to HIV is expected to rise from two percent in 1990 to 14 percent by the end of the decade.

The most frustrating aspect of the epidemic, according to WHO, is that TB is curable. According to the report, "the secret to curing TB is as simple as making certain that patients regularly swallow the right medicine." Supervision is the cornerstone of WHO's TB control strategy, known as "DOTS" (directly observed treatment, short course). Since 1993, the number of countries running DOTS programs has reached forty, compared with just eight before WHO put out the alarm. TB programs set up in the 1990s led to 80 percent of TB patients being cured by 1995 in Guinea, Peru and Bangladesh (areas where the DOTS regime is in use). The report says that if the DOTS strategy was used throughout a dozen countries that have the largest number of cases of TB (Bangladesh, Brazil, China, Ethiopia, India, Indonesia, Mexico, Nigeria, Pakistan, Russia, South Africa and Zaire), nearly 75 percent of TB cases in the world could be cured. As of 1995, only 5 of the 12 countries have committed themselves to a comprehensive TB control program based on DOTS.

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