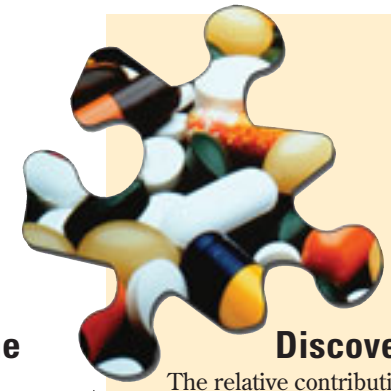

newsinbrief

TB costs: On the second line

The World Health Organization (WHO) estimates that tuberculosis (TB) infects 8 million people and kills 2 million people annually; infection rates are greatest in the poorest regions of the world.

The standard treatment for new cases of TB is a six-month regimen using a combination of antibiotics. Patients who do not respond to or fail to complete the treatment, or who suffer relapses, can develop multidrug-resistant (MDR) strains of TB. A cure is still possible for these people if they have access to treatment with second-line antibiotics. However, until recently, there were no data on the feasibility and cost-effectiveness of second-line treatments in low- or middle-income countries. Researchers from the Peruvian Ministry of Health's National Tuberculosis Control Programme and WHO conducted a study of 466 patients to provide the missing information (*Lancet* **2002,** *359,* 1980–1989). These patients were not cured by the standard first-line treatment, and 298 of them had MDR TB.

Patients receiving an 18-month second-line drug regimen were compared with patients treated with a single antibiotic (when second-line drugs were not available) and patients receiving individualized treatment tailored to their drug susceptibility patterns. After 18 months, 48% of the second-line patients were cured, compared with a 46–56% cure rate for patients who underwent a retreatment regimen using first-line drugs. The average total cost per second-line patient was U.S.$2381 (Peru's 1999 per capita gross national income was $2390), and the calculated mean cost per disability-adjusted life year (DALY) gained was $211 ($165 using drug prices projected for 2002). The cost-effectiveness threshold for individualized treatment was calculated at $1500–$6000 per patient.

The test program succeeded largely because Peru already had functioning first-line and MDR TB treatment programs. Peru, a middle-income country, has already achieved and sustained the WHO goals for TB control (70% case detection, 85% cure rate) using first-line treatments. Peru's National Tuberculosis Control Programme has adopted several policies based on the results of the study.

The researchers think that the study indicates second-line drug treatment for chronic TB can be feasible and cost-effective in other middle-income nations as well, provided a strong tuberculosis control program is in place.

—NANCY K. McGUIRE

Discovery puzzle

The relative contributions of the U.S. public and private sectors to the discovery and development of pharmaceuticals cannot be determined simply by counting publications, according to a May 2002 report, partially funded by the drug industry, from the Tufts Center for the Study of Drug Development (CSDD, Boston).

As part of the perennial controversy over drug pricing, interest has emerged in assessing the role that U.S. taxpayer money plays in developing high-impact, big-selling pharmaceuticals. The consumer watchdog group Public Citizen and the Joint Economic Committee (JEC) of the U.S. Congress have released reports that suggest that the role of industry in developing therapeutically important drugs does not merit the profits that are collected. The CSDD white paper questions the methodology of these studies.

Public Citizen focused on an NIH case study that attempted to quantify the respective roles of public and private research by tabulating authorship of publications related to the five top-selling drugs of 1995. The case study asserted that U.S. taxpayers or foreign academic institutions sponsored 85% of the total number of research projects for these drugs.

The CSDD, however, found several flaws in this result, most notably that the methodology was inherently biased because publicly funded scientists have a much greater incentive to publish than industry researchers. The white paper pointed to a more recent NIH report that indicated that the NIH possesses "use or ownership rights" to patented technologies used for the development of only 4 of the 47 drugs that have received NIH funding and have garnered more than $500 million in annual sales.

Public Citizen and JEC also cite several studies that examined 21 drugs deemed to have a high impact on therapeutic practice between 1965 and 1992. Both reports assert that approximately 75% of the key enabling discoveries for the drug had public-sector input; however, the CSDD counters that neither report mentions the fact that 14 of these 21 drugs were first synthesized by scientists from industry.

The Tufts group performed an independent analysis of the same 21 drugs by using an approach similar to the NIH case study. Their analysis showed that both the NIH and the private sector made substantial contributions, but this method was unreliable for quantifying them. The CSDD observed that it was impossible to ensure that all publications were found. Also, there was substantial non-U.S. involvement in various aspects of the development of these drugs, and the relevance of NIH-funded clinical trials to drug approval could not be determined.

How these conclusions should affect the arguments over drug pricing and taxpayer-funded research is not explicitly discussed.

—DAVID FILMORE

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