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Arthur D. Little Bio-Pharmaceutical Study Finds Significant Link Between Innovation and Market-Based Drug Pricing

May 9, 2002 (Cambridge, MA) – Bio-pharmaceutical innovation has thrived under a system of market-based pricing, according to a study by Arthur D. Little's Technology & Innovation division that becomes TIAX, an independent, privately held company, as of May 10, 2002.

"As the largest market in the world, and as the only nation with a market-based pharmaceutical sector, the United States occupies a unique position. Thanks to America's free market for prescription medicines, its citizens have access to more new treatments than do any other people in the world," said Phyllis Gardner, Associate Professor of Medicine at Stanford Medical School. "Almost every pharmaceutical and biotech company from around the world seeks to launch its products here first, making the country the epicenter of global innovation. The United States is likewise the world's meeting ground for pharmaceutical intellectual capital."

The Arthur D. Little study defines a range of bio-pharmaceutical innovation, from incremental changes to existing products, such as new drug-delivery systems, to groundbreaking treatments that cure the underlying causes of disease. According to the study's authors, innovation in biotechnology and pharmaceuticals is created and driven by a multitude of factors, such as: the existence of market-based pricing, the size of pharmaceutical companies' R&D budgets, the level of venture capital investment in pharmaceutical and biotech companies, and the level of government intervention in the market.

"This study raises the concern that price intervention would have a significant impact on the level of investment in pharmaceuticals and biotechnology, which would ultimately result in fewer options for patients," said Grace Marie-Turner, president and founder of the Galen Institute, a think-tank focusing on health policy. "Recent history has shown that even the threat of price controls drives investors out and dries up the resources that researchers must have to develop tomorrow's medical miracles."

The study was based on an analysis of existing data complemented by interviews with 58 individuals representing consumer groups, payers, legislators, economists, policy makers, venture capitalists, and pharmaceutical and biotech executives. It found that under the current market-based pricing system:

The bio-pharmaceutical sector maintains a level of profit that is appropriately aligned with the level of risk involved in bringing new drugs to market.

- The sector's risk-adjusted rate of return remained steady from 1981 to 2000. Its rate of return above the cost of capital is actually lower than that of some other R&D-intensive industries, such as computer network equipment and software services.
- Price intervention in the U.S. market would have a greater impact on U.S.-based firms than on their European counterparts. A 20 percent reduction in U.S. revenue would cause a 13 percent drop in total revenues for U.S. pharmaceutical companies versus an 8

percent drop for European companies. Furthermore, a 20 percent reduction in U.S. revenues would cause a 14 percent decline in total revenues for major U.S. biotech firms.

The bio-pharmaceutical sector experienced significant decreases in venture capital investment, particularly in the biotech sector, when price intervention was proposed. The response to President Bill Clinton's proposed government regulation in 1992-94 suggests that price intervention or regulation would negatively affect the level of investment. During the time of Clinton's proposal:

- The annual growth rate of R&D spending by the top seven U.S.-based pharmaceutical companies dropped to seven percent in 1993 and four percent in 1994. This compares to a 15 percent growth in 1992 and a 23 percent growth in 1995.
- The growth rate for venture capital investment in biotechnology contracted by six percent in 1994 and 16 percent in 1995, before expanding by 44 percent in 1996.

American patients are the beneficiaries of more new drug approvals than patients in any other country in the world. A country-by-country analysis of first launches of new chemical entities (NCEs) and first launches of FDA priority-review drugs showed that the U.S. market leads the world in pharmaceutical innovations.

- From 1963 to 1999, major U.S. pharmaceutical firms contributed 62 percent more NCEs to the U.S. market than did their European counterparts. The number of novel biotechnology product approvals in the U.S. nearly doubled from 1990 to 1999.
- The United States launched 259 drugs in the 1990s, compared to Japan's second-place showing of 151 launches. It also launched 78 FDA priority-review drugs, compared to 36 by the United Kingdom in second place.

The pharmaceutical sector contributes over \$200 billion to the U.S. economy in terms of:

- Direct, indirect and induced revenues, labor income, and employment. The pharmaceutical sector contributed \$101.5 billion in direct sales, \$57.8 billion in indirect sales, and \$69.9 billion in induced sales to the U.S. economy in 1999. It also employed a total of nearly 1.1 million people through direct, indirect, and induced means totalling over \$75 billion in labor income
- Deployment of venture capital funding. Of the \$36.5 billion in venture capital funding available in the United States in 2001, about \$3 billion—or 8.2 percent—went into biotech. In Europe, about half that amount, or 1.7 billion euros, went into similar research.

"By relying on market mechanisms, we have the best chance of most efficiently creating innovations that meet the needs of patients," said Roger Edwards, ScD, director of life sciences at Arthur D. Little and lead investigator for the study. "Establishing this explicit link between market-based bio-pharmaceutical pricing patterns and a high level of innovation is essential to the future development of new treatments."

The study was made possible by Aventis, Harvard University, JP Morgan, the New York State Office of Science, Technology & Academic Research (NYSTAR), Pfizer, Pharmacia, Stanford University and Wyeth.

About Arthur D. Little, Inc.

Arthur D. Little is recognized as the world's premier consulting firm working at the interface of business and the technologies that drive innovation and growth. The firm's Technology and Innovation business unit will become an independent, privately-held company operating as TIAX, LLC. TIAX scientists, engineers, and management experts work to advance science and technology, develop novel products, direct strategy and policy decisions backed by technical know-how, and leverage intellectual property for business gain. The company provides a broad range of business services to life science organizations including pharmaceuticals, biotechnology, and medical device industries. TIAX is ISO 9001 certified and has more than 70 research and development laboratories.

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