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### Patents Over Patients

By RALPH W. MOSS  
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WE could make faster progress against cancer by changing the way drugs are developed. In the current system, if a promising compound can't be patented, it is highly unlikely ever to make it to market — no matter how well it performs in the laboratory. The development of new cancer drugs is crippled as a result.

The reason for this problem is that bringing a new drug to market is extremely expensive. In 2001, the estimated cost was \$802 million; today it is approximately \$1 billion. To ensure a healthy return on such staggering investments, drug companies seek to formulate new drugs in a way that guarantees watertight patents. In the meantime, cancer patients miss out on treatments that may be highly effective and less expensive to boot.

In 2004, Johns Hopkins researchers discovered that an off-the-shelf compound called 3-bromopyruvate could arrest the growth of liver cancer in rats. The results were dramatic; moreover, the investigators estimated that the cost to treat patients would be around 70 cents per day. Yet, three years later, no major drug company has shown interest in developing this drug for human use.

Early this year, another readily available industrial chemical, dichloroacetate, was found by researchers at the University of Alberta to shrink tumors in laboratory animals by up to 75 percent. However, as a university news release explained, dichloroacetate is not patentable, and the lead researcher is concerned that it may be difficult to find funding from private investors to test the chemical. So the university is soliciting public donations to finance a clinical trial.

The hormone melatonin, sold as an inexpensive food supplement in the United States, has repeatedly been shown to slow the growth of various cancers when used in conjunction with conventional treatments. Paolo Lissoni, an Italian oncologist, helped write more than 100 articles about this hormone and conducted numerous clinical trials. But when I visited him at his hospital in Monza in 2003, he was in deep despair over the pharmaceutical industry's total lack of interest in his treatment approach. He has published nothing on the topic since then.

Potential anticancer drugs should be judged on their scientific merit, not on their patentability. One solution might be for the government to enlarge the Food and Drug Administration's "orphan drug" program, which subsidizes the development of drugs for rare diseases. The definition of orphan drug could be expanded to include unpatentable agents that are scorned as unprofitable by pharmaceutical companies.

We need to foster a research and development environment in which anticancer activity is the main criterion for new drug development.

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