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Statement

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The Clinton Administration's health care reform plan imposes a system of incipient price controls on pharmaceuticals. The most stringent of these controls are targeted toward new drugs, especially major therapeutic advances. Under the plan, an Advisory Council on Breakthrough Drugs would evaluate the reasonableness of prices for all significant new drug therapies. Furthermore, global budget constraints would be expected to impact disproportionately on new medical technologies, including innovative pharmaceuticals.

All Medicare drug reimbursements would be subject to rebates of at least 17 percent. However, the Secretary of HHS could "negotiate" an extra rebate for all new drugs marketed at a lower price in 21 reference countries and new drugs whose prices are determined to be "excessive." Where HHS and the manufacturer cannot agree on a negotiated rebate, a new drug can be excluded from Medicare coverage. Under the proposed legislation, a new drug is defined as any drug first marketed in the United States after June 30, 1993.

Referencing U.S. new drug prices to foreign ones in the Medicare Program will import the outcomes of foreign regulatory schemes with diverse objectives into this country. All twenty-one of the cited countries regulate drug prices in one way or another.

Most of these countries have significantly lower standards of living than the United States. Few have research intensive pharmaceutical and biotechnology industries of any consequence.

Utilization of a foreign reference pricing scheme will almost certainly lead to unintended and undesirable market responses. For example, U.S. and foreign multinational firms will have incentives to delay the introductions of products into markets with lower expected prices than the United States. The resulting distortions in the international diffusion of new pharmaceuticals will neither benefit U.S. or foreign patients. The end result will be reduced resources and incentives for new drug innovation.

The Secretary of HHS also can utilize a public utility-type cost analysis in determining whether new drug prices are excessive (either costs supplied by manufacturers or estimated by HHS). The Secretary can be expected to invoke this criteria for any new drug that significantly increases the Medicare drug budget, no matter how cost beneficial the drug is to patients (1). In effect, the most innovative and commercially important new drugs will be susceptible to public utility-type price controls. It should be kept in mind that Medicare will be a larger purchaser of drugs than almost all other countries with single payor systems. In addition, the Advisory Council on Breakthrough Drugs will be located within HHS and will be utilizing the same criteria to evaluate drug prices both within and outside the Medicare program.

The incentives for drug research would suffer enormously under this proposed regime of price controls. One cannot think of

another industry where there is more potential to do harm to innovation incentives. In this regard, my work on the pharmaceutical industry shows that the distribution of returns in pharmaceuticals is highly skewed (2) (3). A large percentage of new drugs tested in man never reach the marketplace. Only about a third of new drug introductions earn premium returns while the majority do not cover average R&D costs. If profits on these major commercial successes are held to costs plus a "fair" rate of return, expected aggregate returns will not be sufficient to bring forth the desirable level and type of R&D expenditures.

Put another way, how many firms will be inclined to pursue lengthy and risky R&D projects if the rewards for major successes are likely to be highly constrained by price controls? John Vernon and I have recently modeled the effects of subjecting the returns on the top decile of new drug products to a public utility type cost standard (4). We found a precipitous drop in overall expected returns from new drug introductions. Under these circumstances, the high rate of technological progress that has been characteristic of this industry would not be sustainable.

The introduction of price controls here will not only affect U.S. firms, but will also have adverse consequences for new drug innovation emanating from foreign firms. This is because the research-oriented pharmaceutical industry is a global industry, and the United States is the world's largest and most important market. The U.S. pharmaceutical industry, however, will be most adversely affected because it has been the principal source of major

therapeutic advances, and it also has the highest market shares in this country (5).

The proposed price controls on new pharmaceuticals are likely to have especially devastating effects on the dedicated biotechnology sector. Currently this group of firms is in the early stages of its evolution with R&D activities spread over hundreds of relatively small research-oriented firms. While the majority of these firms may be unsuccessful, the prospect of "winning the R&D lottery" has been a powerful economic force attracting venture capital and external investment funds. Currently all but the very largest biotech firms operate with "burn" rates of only a few years in terms of available cash for R&D. Few are likely to survive a system of controls targeted to breakthrough products.

Increasing insurance coverage for outpatient prescription drugs is a worthy objective. While prescription drugs provide the most cost-effective approach to treating many diseases, they are currently the least insured element of basic health care in the United States. However, universal insurance coverage for prescription drugs does not require price controls and global budget constraints. Evolving drug management plans and managed care systems offer a better way for containing pharmaceutical costs. While these organizations have become tough bargainers with pharmaceutical firms over drug prices and quality, they have not curtailed innovation incentives. A pluralistic market-oriented system will continue to reward innovative products that offer value

to medical patients. One cannot place the same trust in a government system of price controls and global budget constraints.

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