Chicago Tribune FINAL

ty & Suburbs: 75¢ Elsewhere THURSDAY, SEPTEMBER 2, 2004 CHICAGO

Putting drugs on a faster track

By Bartley J. Madden

Illustration by Dean Rohrer

Forever etched in golf fans' memories is not the remarkable 65 shot by Tom Watson in the first round of the 2003 U.S. Open, but rather the courage of his caddy, Bruce Edwards. Fans knew Edwards, Watson's caddie for 30 years, was afflicted with the always terminal ALS (Lou Gehrig's disease), and throughout the tournament the outpouring of affection was deeply touching.

Edwards died within a year. There is no Food and Drug Administration-approved drug that gives people suffering with ALS a reason to be hopeful. But what if there were, say, an experimental drug in early stage FDA clinical trials indicating breakthrough potential? Should not Edwards have been free to purchase it if all available risk-reward information were known to him and his doctors? Today's drug regulations deny citizens that personal freedom.

That freedom would be regained if Congress would pass and President Bush would sign legislation giving drug developers, after a new drug successfully completes Phase I safety evaluations, the option to sell the not yet FDA-approved drug.

This new approval track for especially innovative drugs would not replace the current conventional FDA clinical process. The proposal is for an optional second track, creating a "dual-track" process for drugs whose developers elect to utilize it.

The proposal is politically viable because it does not require changing the FDA bureaucracy. Although details would have to be worked out, the goal is plain and hardly controversial: remove prohibitions that now deny informed people the freedom to purchase early-stage medical treatments.

A dual-track environment would offer three important benefits. First, because developers would be required to provide public Internet access to all clinical trial data for dual-tracked drugs, doctors and their patients would have real-time access to the very latest information by which to assess the risk-reward tradeoffs.

Second, the experiences would provide, for the first time, consumer feedback relevant to the total costs (monetary and time) and benefits of risk reduction from the FDA's extended testing and analysis process. Third, the medical experiences of dual-track users, who could be large in number, would be available to the FDA to supplement evaluations under the standard process.

Because of their importance, reportable data and their presentation format under dual-track legislation would be specified by a government agency. Drug developers would be liable only if they failed to report as required or were dishonest in their reporting. They would be explicitly exempt from liability for adverse outcomes. Litigation risk, if not circumscribed, would kill developer participation in the program.

There are a number of economic incentives for developers with early-stage drugs that appear to have genuine potential to radically improve health care. They would get supplemental information on the drug's efficacy that could inform decisions to push ahead with the FDA process or abandon the drug. They would get some revenue from early sales, yet would be motivated to keep prices down in order to attract more customers to hopefully demonstrate the effectiveness of their products.

And demonstrated early success in improving disease treatments or achieving faster cures could result in enhancing the ability of firms to raise additional capital for the development of more new drugs.

Now is the time to put the dual-track drug option into the political mix. If made a 2004 campaign issue, the debate would highlight contrasting views of the role of government. Those in favor of the legislation would demonstrate support for the American tradition of respecting promises (legally binding contracts) and the personal responsibilities entailed. They would also recognize the necessity of reining in Trial Lawyers Inc. to enable dual track to function.

Opponents of the proposal would espouse the need for a regulated America with the FDA as gatekeeper. Although their intentions are for a better America, their one-size-fits-all regulatory approach prohibits those who disagree with the FDA's role from making their own medical decisions. But the real battle to be won is in passage of dual-track legislation that structurally breaks the FDA monopoly and restores freedom of choice to those directly affected by the medical treatment decisions made.

Bartley J. Madden is an independent researcher based in Naperville. This piece was adapted from "Breaking the FDA Monopoly," which appears in the summer issue of Cato Institute's Regulation magazine.