Economic Rewards of Dual Tracking

Which country will reap the rewards of providing patients and doctors with faster access to experimental life-saving drugs?

Author's note: The current U.S. political environment is unsuitable for implementing a system permitting patients to use late-stage experimental drugs if they choose. That environment would improve if another country did this first and gained significant health improvements not available in the United States.

If you know an influential government official or thought leader in a developed country who might find this challenge appealing, please email them and copy us at **bartmadden@yahoo.com**. We will follow up and keep you informed of any progress.

By Bartley J. Madden

Because developed countries regulate access to drugs by controlling their approval, patients and doctors are not free to choose experimental drugs that have passed safety trials. What would happen if a country did let them choose those drugs?

People wanting to assume responsibility for their own medical decisions could put themselves and their doctors in control of their medical treatment instead of the government. Those comfortable with using only government-approved drugs could ignore the expanded options.

The first country to do this would benefit in surprising ways. Let's review the current drug regulatory environment in the United States, then outline the economic advantages of this bold, new approach.

Long Delays

The U.S. Food and Drug Administration (FDA) has a history of relentless growth in regulatory power. Highly publicized safety issues typically lead to FDA requirements for more extensive clinical trial testing. Today it takes an average of eight years and more than $800 million for a drug company to complete FDA testing and gain approval to market a single drug.

FDA employees naturally worry about the consequences of mistakes. Allowing an unsafe drug to reach the market is the worst kind of mistake for a career-minded bureaucrat. They will avoid it even if it means delaying approval of effective drugs.

Also, governments don't know the optimum level of clinical trial testing, which relates directly to the fact that choice has been denied. Expensive, lengthy clinical trials leading to excessively high drug prices and patient frustration demonstrate the need for an alternative.

Dual Tracking

Envision a system where access to new drugs can be obtained by choosing one of two tracks. On one, patients and their doctors try to minimize risk by using only approved drugs. On the other, patients and doctors can choose not-yet-approved drugs by contracting directly with drug manufacturers.

With Dual Tracking, patients would be able to balance their own preferences for risk with new opportunities for health improvement.

FDA says such a plan could hurt clinical trial enrollment. If so—and experts don't all agree—it is hardly obvious that future patients' interests should trump those of current patients. Current patients are being forced to suffer longer—and some to die earlier—so others may (or may not) benefit later.

"Because developed countries regulate access to drugs by controlling their approval, patients and doctors are not free to choose experimental drugs that have passed safety trials. What would happen if a country did let them choose those drugs?"

To achieve the health benefits of Dual Tracking, legislation is needed to enable patients and their doctors, drug developers, and government regulators to continuously evaluate what best meets their needs and develop better ways of doing things. We suggest a three-part reform.

Tradeoff Evaluation Database

First, the current ban on the sale and use of experimental drugs must be amended to allow patients to use those that have successfully passed Phase I clinical safety trials.

Second, a government-operated Tradeoff Evaluation Database (TED) needs to be created to document all treatment outcomes and side effects from experimental drugs for both tracks of the new system. Patients and doctors could use TED's continuously updated information to decide whether to try approved or experimental drugs. Importantly, TED must operate independently of drug companies and FDA.

Third, legislation must clearly define the informed consent requirements so patients can properly waive their right to sue drug developers in exchange for early access to experimental drugs. Otherwise, drug developers who are willing to provide unapproved drugs would almost certainly decline to do so for fear of being sued.

Consequently, the legislation must explicitly lay out the minimum acceptable information about an experimental drug deemed adequate to inform patients about risks and potential benefits. Drug companies that meet this threshold would not be held liable for adverse side effects.

Health Benefits

Internet access to TED information would reveal how expanded choices affect patients, helping others and their doctors learn about the outcomes to make their own informed medical decisions. As a result, the total use of approved versus not-yet-approved drugs would be determined by individual patients' decisions about what is in their own best interest.

Moreover, competition from Dual Tracking could help the government develop innovative ways of analyzing a broad spectrum of medical information.

Dual Tracking would provide critical feedback on the conventional regulatory process's effectiveness. Although government drug regulators would likely oppose such a radical change, consumers always benefit when a monopoly is broken and choices expand.

Economic Rewards

Major economic benefits will flow to the first country to implement Dual Tracking. Companies based there would have a significant advantage over those elsewhere by being able to sell their Dual Tracking drugs up to six years earlier than competitors stuck with a conventional drug-approval track.

Because businesses benefit by being near the customers who use their products, pharmaceutical firms would be motivated to locate employees and facilities in the country where Dual Tracking is implemented. The first country to adopt Dual Tracking would be a magnet for venture capitalists funding drug discovery startup firms employing top scientific talent.

Other parts of the prescription drug industry would have an incentive to move or expand to countries with Dual Tracking—particularly those specializing in medical research, marketing, distribution, and wholesale and retail sales.

Increasing Wealth

Stock prices would appreciate for those firms (especially small startups) that demonstrate significant health improvements from expanded use of their experimental drugs. Quite possibly, companies in general would be accorded higher stock market valuations by participating in Dual Tracking.

Finally, countries that lead the world by implementing Dual Tracking could also lead in developing information technology to design and operate the Tradeoff Evaluation Database—benefiting their computer software industry.

Government officials have a unique opportunity to put Dual Tracking into action and greatly improve the health, and increase the wealth, of their people.

Bartley J. Madden (**bartmadden@yahoo.com**) *is an independent researcher in Naperville, Illinois.*