If you or a member of your family were facing a life-threatening illness, would you want the freedom to try an experimental drug?

What about a painful but non-life-threatening illness?

Under today's new drug approval processes, you are not free to choose unapproved drugs. Only drugs that pass through clinical trials and the Food and Drug Administration's (FDA) new drug application process are permitted to be sold, and it takes an average of 8.5 years for a new drug to be approved.

According to Bart Madden, "reforming" FDA is not the answer. In this short essay, he proposes a Dual Tracking System whereby patients and their doctors would be free to choose between FDA-approved drugs and experimental drugs, using a Tradeoff Evaluation Database (TED) to make fully informed decisions.

> Bart Madden brings to his task a thorough knowledge of the issues that must be confronted, and a deep concern for improving the rules that govern FDA processes. ... This is a document that can be studied fruitfully by all who have a concern for these problems. It is fundamentally bipartisan and should be read in that spirit.
>
> Vernon L. Smith
> Interdisciplinary Center for Economic Science
> George Mason University
> 2002 Nobel Laureate in Economics

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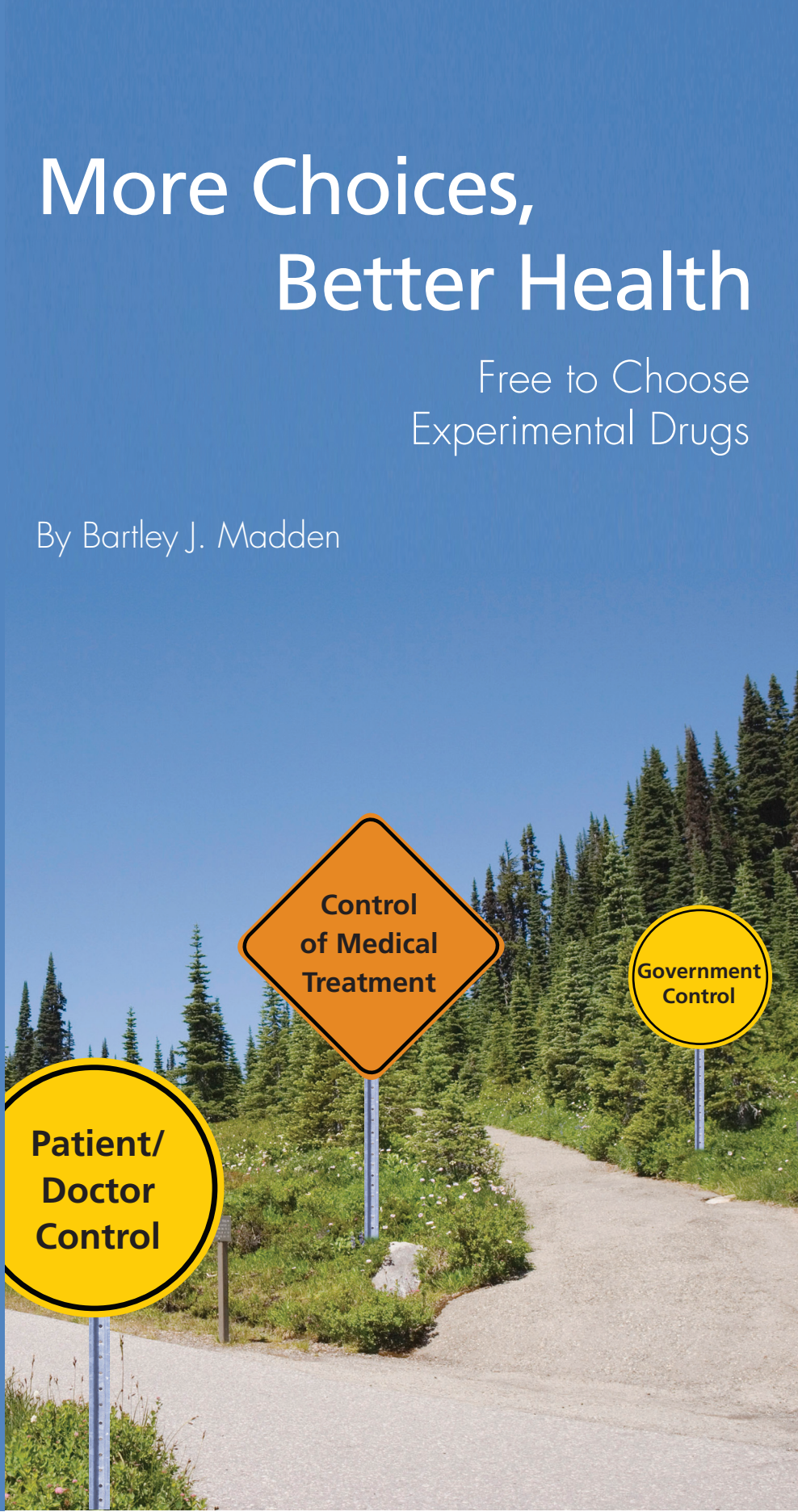
More Choices, Better Health

Free to Choose Experimental Drugs

By Bartley J. Madden



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Preface

It is my pleasure to endorse Bart Madden's thoughtful call for careful reevaluation of the Food and Drug Administration (FDA) process of drug approval.

The issue is not, nor should it be, that there is no role for standards of quality and testing, but that such processes must not interfere arbitrarily with what are properly and legitimately decisions between physicians and patients based on individual circumstances.

There are two kinds of error in considering the harm that any drug testing-approval process can cause. There is the error of approving a drug that may have safety and efficacy risks, and the error of failing to approve in a timely manner a drug that can prevent deaths *already occurring*. The balancing of these two errors is politically difficult for the FDA. Why? Because any drug that gets through the FDA screen and causes injury or death is likely to cause widespread negative publicity for the agency, calls for action, for tightening the FDA's already too-fine screen, placing the FDA under pressure to "do something" to prevent reoccurrence.

Alternatively, any drug that is delayed for a year or two or longer and would have been efficacious will fail to prevent injury or death for those who are not treated—silent private events that are not newsworthy, but in aggregate cause large amounts of unnecessary suffering and deaths. This tradeoff is inherent in the uncertainties of medical treatment and the advance of knowledge. It is not due to evil people. Everybody involved can be doing his or her job faithfully according to the rules, but those rules are failing to correct a growing imbalance between the damages caused by these two types of error.

Bart Madden carefully develops the fundamental reasons for breaking the FDA's monopoly on access to drugs. One stake in the ground is the common-sense principle that patients and their doctors should control medical treatment, including access to not-yet-FDA-approved drugs.

Using sound economic principles, he argues that the FDA's one-size-fits-all regulatory scheme is flawed. It does not allow individuals to express their preferences for risk versus potential health improvement. Moreover, there is no feedback mechanism to evaluate the benefits versus costs of the hugely expensive and lengthy FDA clinical trials. The negative consequences to society of failing to modify this regulatory process will worsen as the

pace of medical innovation accelerates. Hence, the importance of modernizing overdue reforms in FDA procedures.

Madden's market-based solution offered has two key design components. It appeals to economists like me who are keenly aware of the critical importance of institutional design for a system to promote decentralized responses close to the local knowledge that is available to physicians and their patients, but not to the FDA.

The first component of that design is a "dual tracking" arrangement. On one track, a new drug continues along the conventional FDA clinical-testing procedures. On a separate track, *independent* of the FDA, new drugs that have passed Phase I safety trials can be bought by *informed* consumers (patients with advice from their doctors) by legally contracting with drug developers. Patients and their doctors could choose either FDA-approved drugs or new drugs still in clinical trials.

The second component is a Tradeoff Evaluation Database (TED) that allows convenient access to the information patients and doctors need in order to be adequately informed about the risks of adverse side effects and potential health improvements. TED also incorporates the private sector in a way that promotes informed choice among alternatives throughout the system.

These design components for patient/doctor control of medical treatment are both innovative and soundly based. With Madden's conceptual blueprint, legislation could be crafted to promote both expanded consumer choice and the discipline of choice to the long-term benefit of society.

Bart Madden brings to his task a thorough knowledge of the issues that must be confronted, and a deep concern for improving the rules that govern FDA processes. It's about defining an FDA track that empowers the patients and physicians who have the relevant knowledge and need the freedom to choose to use that knowledge without harming others. This is a document that can be studied fruitfully by all who have a concern for these problems. It is fundamentally bipartisan and should be read in that spirit.

Vernon L. Smith
Interdisciplinary Center for Economic Science
George Mason University
2002 Nobel Laureate in Economics

More Choices, Better Health

Free to Choose Experimental Drugs

Bartley J. Madden*

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 the courage of his caddy, Bruce Edwards.

Edwards, who had been Watson's caddie for 30 years, had Lou Gehrig's disease, which is always terminal. The outpouring of fans' affection throughout the tournament was deeply touching. Edwards died the following year.

Even today, there is no Food and Drug Administration (FDA)-approved drug that gives people suffering with amyotrophic lateral sclerosis (ALS, commonly referred to as Lou Gehrig's disease) a reason to be hopeful. But what if there were an experimental ALS drug in the early stages of FDA clinical trials showing breakthrough potential? Should Edwards have been free to purchase it if all available risk-reward information were known to him and his doctors?

Approval Process

We have grown accustomed to the FDA's monopoly on market access to drugs. But prior to 1962, new drugs had to pass only safety trials to be legally marketed. Effectiveness was left to consumers and doctors to evaluate.

Today, for drugs to be marketed as FDA-approved, they must pass a Phase I (safety) trial, followed by Phase II safety as well as effectiveness testing in a small sample of patients, followed by a Phase III clinical trial with a much larger number of patients.

On average, the three clinical trials take seven years. Next comes a new drug application (NDA) containing relevant data to be examined by the FDA. On average, that review process takes an additional 1.5 years. Thus, those who might benefit from a promising new drug cannot get it for, on average, 8.5 years after it enters FDA clinical testing.

Not only do the clinical trials and NDA submission take time,

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they also take money. Drug developers experience a substantial outflow of hard cash, a long delay in possible revenues ... and no guarantees the drug will be approved at all. That combination boosts drug prices for consumers.

Tradeoffs

With its current clinical trial procedures, FDA must deal with a difficult tradeoff situation. Since no drug is completely safe, FDA can mistakenly approve a drug that subsequently produces harmful side effects that greatly outweigh therapeutic benefits. Alternatively, FDA can delay or deny approval for a drug that subsequently shows clear effectiveness and possibly life-saving ability.

When FDA errs on the side of overcaution, thousands of patients may die who could have been saved. But those deaths are rarely documented and never make the nightly news. Thus, it should not be surprising that in practice FDA is much more concerned with avoiding highly visible errors and clearly identified victims than with the hidden, rarely identified victims of denied access to drugs in the FDA approval pipeline.

For FDA officials, approving an unsafe drug brings public humiliation from the media, affected patients, and politicians. That far outweighs any benefit they might receive for more quickly approving an effective new drug.

What has been the overall effect of FDA's extreme focus on minimizing bad publicity? Daniel Klein and Alexander Tabarrok have assembled a large body of research on FDA at www.fdareview.org. Concerning FDA's effectiveness, they conclude:

> We argue that FDA control over drugs and devices has large and often overlooked costs that almost certainly exceed the benefits. We believe that FDA regulation of the medical industry has suppressed and delayed new drugs and devices, and has increased costs, with a net result of more morbidity and mortality. A large body of academic research has investigated the FDA and with unusual consensus has reached the same conclusion.[1]

Focusing the Debate

A serious debate about FDA's regulatory role should begin with a focus on the common-sense principle that the power to make medical decisions rightly belongs first and foremost with patients

and their doctors. The U.S. Court of Appeals of the D.C. Circuit recently gave support to this principle by affirming the right of dying patients to access not-yet-FDA-approved drugs.[2]

Because of FDA's lengthy drug approval process, a second focus should be on the harm done by the long delays before drug innovations reach the public. FDA's one-size-fits-all approval procedure is simply not attuned to the fast pace of twenty-first century medical innovations.

A third focus should be on solving an emerging dilemma facing pharmaceutical companies that are gaining insights into how diseases (often rare diseases) relate to patients' genetic profiles. The dilemma is that the greater the gain in personalizing medicine, the smaller the target population for such drugs, the smaller the prospective revenues, and the less likely there will be a worthwhile return on investment. This is due, for the most part, to the high cost of having to conduct the full set of FDA clinical trials.

Given these top priorities, what could be the structure and optimum level of FDA regulatory power? Neither Congress nor FDA knows because the optimum level depends on the tradeoff decisions (risk versus benefits) that only individuals and their doctors should make. The current FDA regulatory approach ignores or suppresses these decisions.

ACCESS Act

The Abigail Alliance for Better Access to Developmental Drugs has been instrumental in promoting Senate bill S.1956 (the ACCESS Act). It addresses the right of seriously ill patients to access promising drugs before completion of the full gamut of FDA clinical trials. ACCESS does not change fundamentally the FDA process because that is not its purpose. The goal of ACCESS is admirable, yet achieving that goal is partially dependent on FDA cooperation in formulating and administering implementation rules.

Avoiding the entanglements of FDA rules is not easy. As Henry Miller, a medical doctor and former FDA regulator, noted:

> What many fail to realize is that a regulatory statute, even if it is not amended, is not static. When the statute is first enacted, its implementation is generally narrow and limited to the specific requirements of the law, and its impact, therefore, is often modest. As time goes on, however, each successive generation of administers tends to redefine the scope of jurisdiction and add new requirements. Seldom does the scope

> narrow; almost never do requirements disappear. Regulation begins to take on a life of its own. And as regulators interpret statutes ever more broadly and comprehensively, they become, in effect, a special interest group with a vested interest in expanded responsibilities, budgets, and empires. In the absence of effective, conscientious congressional oversight, what develops is an increasingly burdensome and inefficient regulatory system. Nowhere can this be seen more clearly than in the evolution of premarket licensing mechanisms for drugs.
>
> The current system of oversight of pharmaceutical development includes no mechanism for public accountability … premarket approval severely limits individual freedom of choice. Personal autonomy is subjugated to government controls. Citizens are precluded from obtaining products they wish to purchase and have no recourse other than to await government approval.[3]

One might well be concerned about how FDA would formulate rules to implement legislation designed to reduce its regulatory power. Nevertheless, passage of the ACCESS Act would be a genuine step forward in helping some patients with life-threatening illnesses and chipping away at FDA's absolute control of access to unapproved drugs.

Individual Preferences

If you or a member of your family were facing a life-threatening illness, would you want the freedom to try an experimental drug? Would you be willing to take responsibility, including the risk of adverse side effects, for your decision to use not-yet-FDA-approved drugs? What would your answer be if the health problem were non-life-threatening—macular degeneration, severe arthritis, or another debilitating condition? Answers vary, depending on an individual's evaluation of the risk and scope of adverse effects versus potential health improvement.

The problem is that in today's regulatory environment, your tradeoff evaluation doesn't matter. FDA does not allow the use of not-yet-approved drugs, except in clinical trials and certain highly restricted circumstances.

To allow individuals to express preferences for risk would undermine FDA's monopoly on drug access. FDA contends it needs total control in order to benefit society, i.e., *future* patients, by applying rigorous statistical evaluations to its extensive clinical trials data. According to FDA, patient/doctor freedom to use not-yet-approved drugs would interfere with clinical trial

enrollment. Finally, there is an FDA assumption, unspoken, that patients and their doctors are incapable of making decisions about experimental drugs.

But there is more involved than merely segmenting consumers into risk-takers and risk-avoiders. The critical point was made by economist Friedrich Hayek and summarized by Vernon Smith as follows:

> No one understood that [market] exchange process better than Friedrich Hayek, when he said, ... "Nobody can communicate to another all that he knows because much of the information he can make use of, he himself will elicit only in the process of making plans for action. As he will not merely make use of given knowledge, he discovers what he needs to know in order to make appropriate actions." This is the reason why survey instruments of opinion can only give you a very limited indication of what constitutes people's "knowledge:" people don't know what it is they will do until they face particular circumstances and then they start to come up with solutions.[4]

Many of those who have not experienced the heavy personal cost associated with the current FDA process are unlikely to demand freedom of choice. Hearing media reports of approved-drug recalls (Vioxx), they are most likely to support additional FDA testing if their opinions were sought in a survey.

But put those individuals in a different context. If they, or a member of their family, became afflicted with ALS, as did Bruce Edwards, they would be faced with a deterioration of muscular function and death within three to five years. They and their family members would experience an order-of-magnitude shift in their attitudes and need to gain knowledge about ALS in general, and, in particular, about ongoing prospects for not-yet-FDA-approved drug treatments for ALS. Their responses to a survey about FDA's current practices and an expansion of its power almost surely would be different.

As for changing times, we can almost certainly expect accelerating medical innovations in the future.

Now consider an environment in which consumers have up-to-date and easily understood information via the Internet about the ongoing safety and effectiveness of experimental drugs. We would expect to observe more drugs in early-stage clinical trials with effectiveness that makes obsolete existing FDA-approved drugs.

Wouldn't this environment motivate more consumers to want

patient/doctor control of the decision to use experimental drugs, rather than FDA monopoly on market access to drugs?

Where is the present level of FDA regulation of new drugs compared to the optimum level? No one really knows. Let's think about how a system could work that is *designed* to reveal the optimum level.

Optimum Regulation

What deserves Congressional debate is the idea presented here that *existing* patients should be at the front of the line, not future patients. This idea is rooted in the principle that society benefits both immediately and in the long run from freedom of choice and competition. Breaking FDA's monopoly by legislating so competition can function would compel FDA to develop new ways of analyzing a broader spectrum of information.

For Congress to push forward on the core principle of patient/doctor control of medical decisions, it is helpful to understand how the current system could be improved to let the optimum level of regulation surface. When politicians act to reduce government regulations in order to gain market benefits, some market supporters may dismiss the need for careful planning in the belief that Adam Smith's invisible hand in the marketplace will automatically make any needed adjustments. Not so. Much care—a visible hand—needs to be given to institutional design to be sure it enables expanded choice and competition to operate. California's fatally flawed plan for deregulating electricity is a sobering demonstration of the crucial importance of institutional design when implementing deregulation.

The task, then, is to use competition to stimulate patients and their doctors, drug development firms, and FDA to continuously evaluate what best meets their needs and to develop better ways of doing things. As a practical matter, this requires two innovations.

First, the current one-track new-drug approval system, whereby all new drugs must be approved by FDA before they are available to the public, must be augmented by the creation of another track, creating a Dual Tracking system for experimental drugs.[5] Dual Tracking gives patients the freedom to choose FDA-approved drugs *or* experimental drugs. In exchange for the possibility of achieving health improvements by using drugs not otherwise available, consumers agree to take responsibility for the possible higher risks that attend the use of unapproved drugs.

Second, a new and robust information system is necessary to adequately inform patients and their doctors of the risk-reward tradeoffs of choosing experimental drugs. I call this system the Tradeoff Evaluation Database (TED), and will briefly describe how it could operate. Providing consumers and doctors with objective data about experimental drugs is the key to making a Dual Tracking system safe and workable, and also to promoting competition.

Dual Tracking

On one track, a new drug would continue along conventional FDA clinical testing procedures. On a new, separate track independent of FDA (but only after the successful completion of FDA Phase I, toxicity and safety evaluations), drug development firms would have the option to legally contract with consumers (individual patients advised by their doctors) to sell them a not-yet-FDA-approved drug.

To function successfully, Dual Tracking requires that consumers be fully informed of the possible risks of using pre-FDA-approved drugs. This is the function of a Tradeoff Evaluation Database (TED). TED would contain clinical trial results and non-clinical trial results (including side effects) of not-yet-FDA-approved drugs. TED's continuously updated, Internet-housed information could be accessed by patients and their doctors to decide whether to try an experimental drug that has passed FDA Phase I safety trials.

A TED Web site would receive details from doctors about patient treatments, and this information would then become available to drug developers and the public. In this way, a process would evolve for accelerating medical solutions in an ever more effective manner. Presumably, physicians would be enthusiastic about the TED opportunity to creatively utilize their unique knowledge built up over their medical careers. Communication of specific details of patients' conditions and treatment results would help drug developers as well as other doctors.

Implementation of Dual Tracking would reveal how well or poorly patients fare who choose immediate access to experimental drugs. Other patients would soon learn about the outcomes and make more-informed choices for either experimental drugs or approved drugs. As a result, the total use of approved versus not-yet-approved drugs would be the aggregate of individual decisions.

Unchanged, the traditional FDA clinical trial track enables

patients who prefer the least risk from unknown side effects of a developmental drug to await FDA drug approvals. Those who are on death's doorstep could access TED to determine the most promising experimental drug and most likely would choose to use it. Anyone in the grey area between these two poles could access TED to help make their tradeoff decision on risk versus potential health improvement.

To maintain its regulatory monopoly, FDA would probably oppose this opportunity for patient/doctor control, even though the results would be uniquely useful for improving its own testing and approval procedures.

A troublesome obstacle for drug developers who want to provide drugs not yet approved by the FDA is their fear of lawsuits from people who experience adverse side effects. If not addressed, the threat of litigation would undermine Dual Tracking. To prevent this problem, legislation needs to define the acceptable amount of information about experimental drugs deemed adequate so that patients and doctors can give informed consent, and then to grant immunity from tort liability to drug developers who follow this process.

To avoid lawsuits, drug developers would have to promptly and fully report all outcomes from not-yet-approved drug treatments, including all adverse side effects. Although the construction and operation of TED would likely be contracted out to a private-sector company, the government would have oversight to ensure adequate information is available publicly. Importantly, just as auditors are independent of the firms they audit, TED must operate *independent* of FDA.

Benefits of Dual Tracking

In the current FDA environment, information from highly specified and lengthy clinical trials is almost exclusively sought based on its relevance to FDA statistical milestones. This surely is not a broad, open feedback environment conducive to learning, evolving, and speedy allocation/reallocation of drug developers' resources.

By contrast, Dual Tracking would involve a diverse group of patients. In this environment, doctors are a knowledge resource, empowered to use their medical experience and problem-solving skills to focus exclusively on helping their patients, yet benefit other patients and society as well by sharing information.

Every American family would have Internet access to TED for real-time, continuous updates about the safety and efficacy of

all experimental drugs. In a Dual Tracking system, patients and their doctors could choose whether to use an experimental drug now, wait for more information, or rely on only FDA-approved treatments.

Dual Tracking offers unique opportunities to small drug development firms with enormous scientific skill, but lacking financial resources and/or skill in dealing with the FDA bureaucracy. Such entrepreneurial firms would be able to generate significant revenues and stock market gains if their new drugs are highly effective for early users. Although some people would object, drug developers should be free to set prices as they do for approved drugs. The benefits from obtaining a number of positive-outcome early users would likely be a major factor in initial pricing decisions, and this should encourage developers to hold prices down.

Further, scientific skill in discovering breakthrough medical treatments would become more valuable than skill in dealing with the FDA bureaucracy—a skill that large drug companies possess to a far greater extent than small companies.

Importantly, as for drug prices over the long term, if early drug access after Phase I safety trials is successful, that would set into motion a fundamental evaluation of the enormously costly and time-consuming requirements for Phase II and III clinical trials. Such an evaluation could well lead to streamlined clinical trials, large-scale cost reductions for drug developers, and a big reduction in drug prices for consumers.

To get to a world of patient/doctor control, legislation must be designed that will enable the flow of information to allow freedom of choice in medical treatments. It is important as well to facilitate learning and continuous improvement.

Learning Environment

An environment of learning and continuous improvement requires an information system that will:

(1) help patients and their doctors by providing up-to-date summaries of ongoing clinical trial results;

(2) orchestrate the processing of up-to-date results of experimental drug usage by patients (non-clinical trial data), including adverse side effects;

(3) document that patients, collaborating with their doctors, are

informed and capable of assuming responsibility for the use of drugs still in clinical trials so that good-faith drug developers are protected from lawsuits; and

(4) promote more choice and competition, not only for patients and their doctors, but also for drug developers and FDA.

Tradeoff Evaluation Database

The diagram on page 15 shows the functional components of TED and their interaction.[6]

Starting at the bottom of the diagram, all results of experimental drug usage would be input into TED. This includes "clinical trial results" from on-going trials along the FDA conventional track as well as for "non-clinical trial results" along the track for not-yet-FDA-approved drug usage.

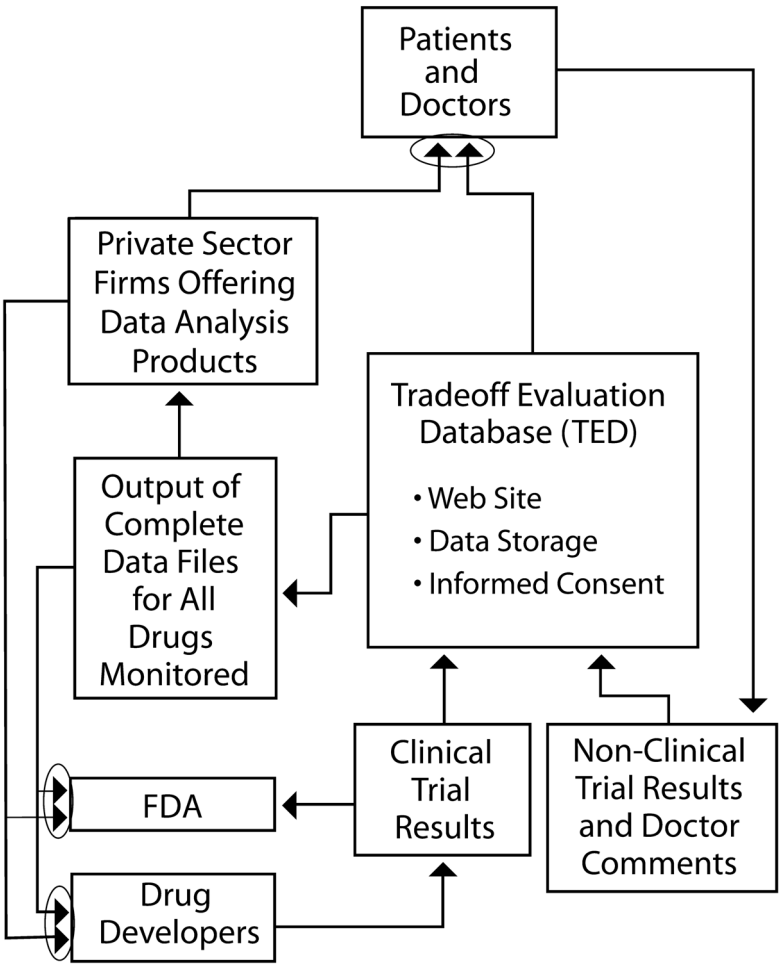
Moving upward on the diagram, there are two types of output from TED. One type provides patients and their doctors with up-to-date data on drug safety and effectiveness. This enables patients to give informed consent to use drugs that are not FDA-approved. TED needs to specify data requirements, organize appropriate data input procedures, and make standardized and relevant information available to the public. Companies' fear of litigation could be eliminated by federal and possibly state laws granting immunity from tort liability as long as companies fulfilled TED requirements.

The other type of output is complete information for all drugs monitored, and it is made available to drug developers, FDA, and private-sector firms offering data analysis products. This enables competition to operate at three points, identified by circles in the diagram.

The circle at the top of the diagram indicates that patients (consumers) would have competing information offerings to use in evaluating a drug. There would be the opportunity to purchase private-sector products offering a variety of analyses. As with markets for any product, consumers would benefit from expanded choice and competition.

The two circles at the bottom indicate the options of using in-house data analyses or the purchase of outside analyses. Observe that FDA's circle identifies raw data input as well as input by private sector firms. Top management at FDA, and those in Congress who oversee FDA's use of resources, would be able to compare FDA's efficiency in processing and analyzing clinical trial data versus private-sector alternatives.

Dual Tracking System



Information flows in the direction of the arrows.

The drug developers' circle shows that they, like FDA, would have a choice of either conducting in-house analyses of clinical and non-clinical trial data or purchasing outside analyses.

It is noteworthy that a treasure trove of continuously updated data would now be in the public domain. For example, insights as to why drugs work or do not work for specific patients is extraordinarily useful. Scientists would gain insights and increasingly be able to determine, at an early stage, whether a research approach is likely to be productive.[7] This speaks directly to the concern about the recent slowdown in drug approvals,

especially for drugs that are not "me too" drugs, but ones that offer a new standard of care.

This essay has described the Dual Tracking-Tradeoff Evaluation Database model in broad strokes. Certainly there are many issues concerning implementation that need to be addressed. For example, should the government construct TED from the ground up by using the private sector and the competitive bidding process? How might the existing infrastructure for tabulating and communicating the results of clinical trials and off-label drug usage fit into a Dual Tracking environment? Issues such as these can be debated after the critical design, shown in the diagram, is accepted.

Jump-Starting Personalized Medicine

Dual Tracking enables drug development firms to achieve an economically viable solution to the earlier-mentioned problem related to personalized medicine. The same characteristics of personalized medicine that offer the prospect of dramatic strides in health for individuals undermine FDA's insistence on large-population, lengthy clinical trials.

Society would benefit if pharmaceutical firms could implement a personalized medicine business model linking profits to successful innovation in four steps:

(1) develop a genetically targeted drug with exceptional effectiveness in early usage;

(2) after Phase I safety evaluations are successfully passed, achieve near-term revenues from sales to consumers who choose not to wait for final FDA approval;

(3) on one track, produce a documented record of outstanding drug performance from patients who meet the stringent genetic patient profile and make an informed decision to use the experimental drug; and

(4) on another track, meet a greatly reduced burden of FDA clinical testing for Phase II and III trials.

Dual Tracking would facilitate such a business model and accelerate the delivery of drug advances stemming from expanding genetic knowledge.

Conclusion

Should we not expect our elected representatives to seek a better world in which patients and doctors control medical treatments and priority is given to existing patients? A Dual Tracking system would achieve this end. Specifically, Dual Tracking would bring about:

- greater freedom of choice for medical patients;
- faster feedback on the safety and effectiveness of new drugs;
- a higher rate of new drugs made available to doctors and their patients;
- access to "unregulated" comments and ideas from doctors, which can lead to insights with immediate, practical benefit;
- a fundamental shift in the pharmaceutical industry wherein skill in developing drugs that deliver a new standard of care is valued to a far greater extent than skill in navigating the FDA bureaucracy; and
- the possibility of greatly streamlined FDA clinical trials, resulting in a huge decrease in costs to drug developers, dramatically lower drug prices for consumers, and ultimately healthier and longer lives.

The most powerful argument for Dual Tracking, one that has appeal across political affiliations and every other possible source of disagreement, is that individuals and families ought to be free to improve or save a life, even if doing so incurs some risk. The current regulatory regime is profoundly at odds with this simple and compelling idea, and it calls out for genuine reform.

Endnotes

1. Daniel Klein and Alexander Tabarrok, "Is the FDA Safe and Effective?" www.fdareview.org, accessed March 6, 2007.

2. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach,* 445 F.3d 470, 484-86. Washington DC Circuit Court, 2006.

3. Henry I. Miller, *To America's Health: A Proposal to Reform the Food and Drug Administration*, Stanford, CA: Hoover Institution Press, 2000, pp. 16-17.

4. Vernon L Smith, "Hayek and experimental economics," *Review of Austrian Economics,* 2005, 18(2), pp.139-140.

5. For an extensive analysis of the concept of Dual Tracking see Bartley J. Madden, "A Clinical Trial for the Food and Drug Administration's Clinical Trial Process," *Cancer Biotherapy & Radiopharmaceuticals*, 20, no. 6 (2005), pp. 569-578. This is available for download at the author's Web site, www.LearningWhatWorks.com.

6. Internet access to information on drugs and clinical trials includes the following sources: www.cancer.gov, www.centerwatch.com, www.clinicaltrials.gov, www.fda.gov/medwatch, www.ifpma.org/clinicaltrials, www.micromedex.com, and www.trialscentral.org.

7. Government Accountability Office (GAO), November 2006, Report GAO-07-49, "New Drug Development," p. 35, recommends a collaboration among government, industry, and academia that could:

   > Design a system to collect and analyze data on why drugs fail during clinical testing. For example, a team of FDA and pharmaceutical representatives could review FDA and company databases to obtain examples of drug failures and then perform a systematic analysis of the causes of these failures. This effort would need to ensure protection of each company's proprietary information on specific drugs. Such an effort may provide new information to prevent multiple companies from making the same or similar mistakes and may increase efficiency in clinical trials.

Additional Resources

1. **www.LearningWhatWorks.com**, the personal Web site of Bartley J. Madden. Madden originated the CFROI life-cycle valuation framework widely used by portfolio managers and is the author of *CFROI Valuation—A Total System Approach to Valuing the Firm*. More recently, he has focused on public policy issues that involve market systems.

2. "A Clinical Trial for the FDA's Clinical Trial Process," by Bartley J. Madden, *Cancer Biotherapy & Radiopharmaceuticals*, November 2005. It is available online at www.LearningWhatWorks.com and http://www.heartland.org/Article.cfm?artId=18838.

3. "Breaking the FDA Monopoly," by Bartley J. Madden, *Regulation*, Cato Institute, June 2004. It is available online at http://www.heartland.org/Article.cfm?artId=15758.

4. "Patients' Right to Choose," by Henry I. Miller, *Brief Analysis* published in October 2006 by the National Center Policy Analysis. It is available online at http://www.heartland.org/Article.cfm?artId=20105.

5. *PolicyBot*™, The Heartland Institute's free online clearinghouse for the work of other free-market think tanks, contains thousands of documents on health care policy reform. It is on Heartland's Web site at www.heartland.org.

6. *Health Care News*, a free monthly publication from The Heartland Institute. To subscribe, visit www.heartland.org or send name and address to The Heartland Institute, 19 South LaSalle Street #903, Chicago, IL 60603.

7. *Ten Principles of Health Care Policy*, The Heartland Institute (forthcoming 2007).

Directory

The following national organizations conduct research on health care policy reform. For a list of state organizations, go to www.heartland.org and click on "links."

American Legislative Exchange Council, www.alec.org

Association of American Physicians and Surgeons, www.aapsonline.org

Cato Institute, www.cato.org

Citizens' Council on Health Care, www.cchconline.org

Coalition for Affordable Health Coverage, www.cahc.net

Consumers for Health Care Choices, www.chcchoices.org

Council for Affordable Health Insurance, www.cahi.org

Galen Institute, www.galen.org

Heartland Institute, www.heartland.org

Heritage Foundation, www.heritage.org

Institute for Health Freedom, www.forhealthfreedom.org

Institute for Health Policy Solutions, www.ihps.org

Institute for Policy Innovation, www.ipi.org

National Center for Policy Analysis, www.ncpa.org

Pacific Research Institute for Public Policy, www.pacificresearch.org

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