With dual-tracking, patients can have early access to potential miracle drugs while the FDA maintains its testing regimen.

Breaking the FDA Monopoly

By Bartley J. Madden

Most Americans rarely encounter the Food and Drug Administration and consequently are not alarmed by its significant growth over the last few decades. Congress has facilitated FDA expansion by using well-publicized episodes of unsafe products to promote pro-expansion legislation and by allowing a silent but inexorable proliferation of FDA regulations.

On top of that, the news media feed Americans a steady diet of examples that purportedly cry out for increased government regulation of unsafe products and environmentally damaging behavior. What does not get reported is that every expanded piece of the FDA's bureaucratic machinery is matched by a loss of consumer choice.

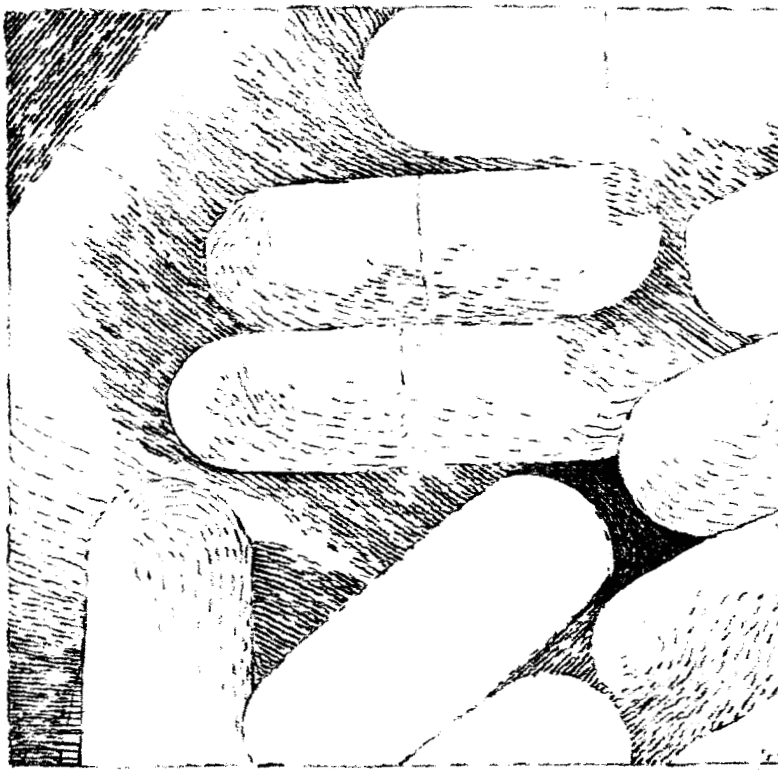
The nature of the FDA is to strive at any cost to prevent individuals from acquiring a drug that might cause serious harm or early death. Such occurrences generate widespread criticism and turn up the political heat on the FDA. The agency has been largely successful in that effort, but the significant costs of that prevention have received only limited attention. One such cost is the economic loss to society in the form of higher prices, in order to offset the hugely expensive clinical trials (on both failed drugs and approved ones) and for new drug applications. A second significant cost to society is from time delay before useful drugs become available to those who would benefit from them.

DUAL TRACKING

I propose to end the FDA monopoly on market access to drugs and medical devices. I believe a "second track" could be opened for consumers to access those products — a track that would allow informed consumers to purchase drugs that have undergone only the initial phase of the FDA drug-approval process. By opening this second track, patients would have access to potential miracle drugs after those drugs have passed their Phase I safety tests, while the FDA could continue the Phases II and III tests that examine the drug's efficacy.

Dual-tracking offers three compelling benefits:

- The Internet could be used to inform consumers about potentially useful drugs that have not undergone



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Phases II and III of the FDA testing. Consumers electing to obtain those drugs could be kept up-to-date on findings from the subsequent FDA clinical trials.

- The results experienced by "second-track" consumers would constitute a feedback mechanism, putting the spotlight on the FDA's costs from time delays for new drugs and the benefits from putting those drugs through the rigorous three-phase trials.

- New data obtained from consumers who use the second track and from their doctors could supplement the FDA's conventional analyses of clinical trials.

A prerequisite to a free-market economy is a set of rules that facilitate transactions in which both buyers and sellers mutually benefit. Such transactions generate information used for continually directing resources toward their most valued uses. In the dual-track drug-approval process, buyers and sellers must specify their joint responsibilities in legally binding contracts.

Let us assume a firm completes its Phase I clinical trial, satisfying the FDA's safety concerns. Let us further assume that clearly favorable results were subsequently documented for a small sample of patients in the early portion of the Phase II trial. At that point, the firm elects to use the dual-track option and posts data on the Internet covering Phase I and the ongoing Phase II trial.

Also assume that as part of the legislation authorizing dual-tracking, a government agency is assigned the task of specifying how the data should be recorded and presented. The data format should be configured to help consumers and their advisers evaluate the suitability of the drug and to serve as useful supplementary information for the FDA's approval process.

By having a government agency specify data requirements, trial lawyers would lose the opportunity to sue developers for negligence in the presentation of data, although firms would still remain liable for failures in reporting government-specified data. The agency's data demands should not be so complex that they deter drug firms from electing the dual-track process for the experimental drug.

Contracts between developers and consumers need to make clear that adverse consequences from using the experimental drug are risks assumed by the consumer. This agreement is straightforward and differs from the complexities associated with doctor-patient contracts.

Courts have disallowed doctor-patient contracts that specify responsibilities because the large information disparity between doctors and patients disadvantages the patients. Ideally, implementation of the dual-track proposal would include a specific legal authorization enabling developers and consumers to enter into legally binding contracts. In this context, an information disparity does not exist because developers and consumers would have access to the same Internet-posted database of all the drug's treatment outcomes. Moreover, the decision to use a dual-track drug would rest solely with consumers.

BACK TO THE FUTURE

Many readers might consider my proposal to be quite radical, but it simply returns us to the FDA's role prior to 1962: certifying that a drug is safe. In that era, the determination of how well the drug worked was left to patients and their doctors, i.e., to "the market." Thus, the key component of my proposal was accepted in the United States until 1962. And no evidence has ever been provided that post-1962 testing for

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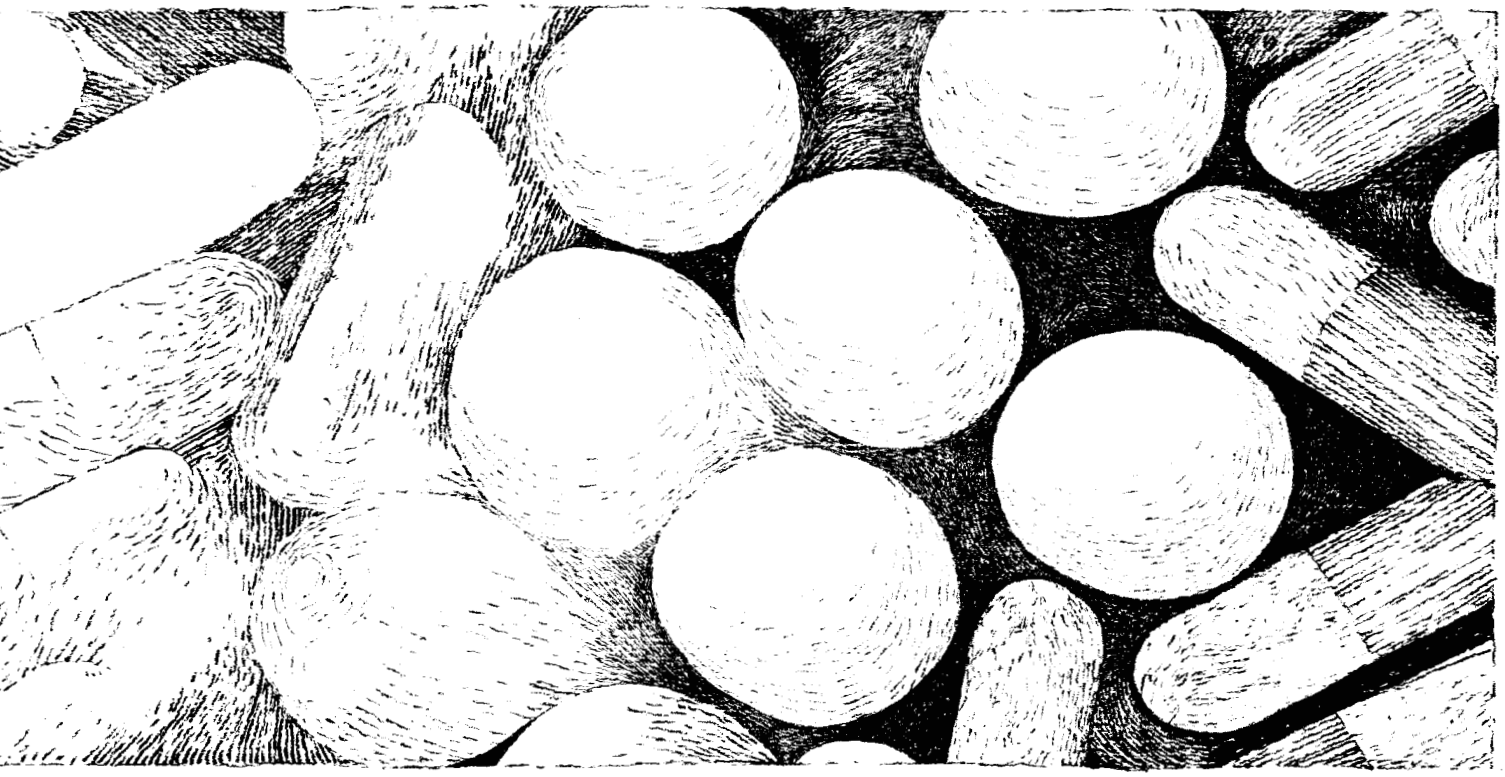

both safety and efficacy has produced aggregate benefits in excess of aggregate costs (inclusive of opportunity costs).

Dual-track drugs would generate needed feedback data for evaluating the overall benefits versus overall costs of the post-1962 efficacy requirements. Little doubt exists that under the status quo, society would continue to benefit from the ongoing approval of safe medicines that are incrementally more effective than existing treatments. Of great consequence is the currently unknowable cost to society from delays in making revolutionary medicines available and from abandoned innovations because of costs associated with the whole process. Dual-tracking not only holds the promise of providing faster access to paradigm-shifting, innovative drugs for improving health and saving lives, but it also would inform voters and politicians as to whether the FDA needs to be restructured for more effective twenty-first century medicine.

Higher-income, early users of dual-track drugs would not be buying government-guaranteed safe and effective drugs. They would be buying a reward/risk package having the potential for health improvement but also carrying a higher risk of worse outcomes than from FDA-approved and insurance-paid drugs. Those consumers' willingness to be informed risk takers with their own health and money is a prerequisite for faster health improvements and for reforming the FDA. Just as the general economy benefits from risk takers among us, general health care would be improved from having dual-track drug risk takers.

IMPLICATIONS FOR THE DRUG INDUSTRY

Firms are motivated by expectations of earning above-average returns on their investments. Successful innovators (many would-be innovations fail) earn returns above their cost of capital by efficiently providing value-added and cost-effective benefits to consumers. Competitors seek to siphon off some of the above-average profits for themselves by developing their own innovations, copying the originator's ideas when not patent-protected, and implementing more efficient manufacturing and distribution processes. Regardless of the products, the competitive process continually drives the allocation of resources to the firms more skilled at providing consumers with the best package of benefits and price as judged by individual buyers.

Along the way, some firms are successful in better serving customers and distinguishing themselves from competitors. Such competitive advantage gives investors reason to expect those firms to earn above-average returns on shareholders' capital in the future, and that warrants higher prices for their stocks today.

Which factors would be highly important, and which less important, should dual-tracking be successful? Firms with proven research capabilities for developing breakthrough medicines and new standards for disease treatment would stand to benefit the most. Their stock prices should increase when early dual-track usage clearly demonstrates the effectiveness of their new drugs, and additional revenues should flow to the firm for many years prior to any FDA approval.

In contrast, consider drug firms that have great skill in negotiating the FDA maze but below-average research skills. Many of their in-house drug candidates, having the potential to be only marginally more effective treatments, would be far less suited as dual-track candidates in comparison to early-stage drugs demonstrating truly exceptional improvements over existing therapies. What would happen to the ability of those firms to acquire rights to breakthrough drugs from small biotech firms? They would be in a weakened position because a record of success for a new dual-track drug would position small firms to negotiate more favorable terms with large firms seeking to partner with them.

With revenues from dual-track sales, small biotech companies not wishing to partner with large firms would be better able to expedite clinical testing, leading to faster decisions on applications for FDA approvals. Also, if small firms were to decide to raise capital for expediting clinical testing, they would be far better positioned with demonstrated dual-track favorable results.

What pricing for dual-track drugs might be expected? The proposed contract between developers and consumers would go a long way toward minimizing the myriad ways that trial lawyers can sue for large damages, which should allow for lower prices than otherwise. Moreover, firms would be motivated to keep prices down in order to attract more dual-track consumers. If a dual-track drug were destined to be unsuccessful, developers would benefit from an earlier decision to abandon it because resources could be shifted to more promising candidates. Conversely, if strikingly positive outcomes were to continue with accelerated use, developers would be motivated to allocate even more resources to expedite FDA approval. R

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