

# The Wrong Prescription

BY HENRY I. MILLER

*The Hoover Institution*

AND JEFF STIER

*American Council on Science and Health*

At a time when the American population is aging and more seniors are suffering from chronic diseases, the pharmaceutical pipeline is drying up. In spite of increasingly more powerful and precise technologies for drug discovery, purification, and production, development costs have skyrocketed over the past 20 years. Other trends are ominous as well: the length of clinical testing for the average drug is increasing, fewer drugs are being approved, and the number of applications to the Food and Drug Administration by industry for marketing approval has been decreasing for a decade. All of this bodes ill for patients.

Mismanagement and excessive risk-aversion at the FDA are largely responsible for these worrisome trends. Regulators keep raising the bar for approval, especially for innovative, high-tech products. The agency is requiring ever larger numbers of patients in clinical trials, its demands for post-marketing clinical trials have proliferated wildly, and “risk management” plans for newly approved drugs have been punitive and designed more to protect regulators than patients.

Historically, there have been various opinions about what kinds of problems with the regulation of drug development predominate. Thirty years ago, the concerns were primarily about “drug lag” — indolent reviews and approvals by the FDA that put Americans at a disadvantage to consumers in other countries. But in recent years there have been accusations about what might be called “drug leap” — too cozy a relationship between regulators and industry, and too little attention paid to drug safety, possibly as the result of regulators’ struggling to meet arbitrary deadlines.

**MISDIAGNOSIS** A September 2006 report from the quasi-gov-

**Henry I. Miller**, a physician, is a fellow at the Hoover Institution. He headed the FDA’s Office of Biotechnology from 1989 to 1993. Barron’s selected his book (co-authored with Gregory Conko), *The Frankenfood Myth*, one of the 25 Best Books of 2004.

**Jeff Stier**, an attorney, is an associate director of the American Council on Science and Health.



ernmental Institute of Medicine (IOM) reinforces the second view. But its recommendations will improve few of the FDA’s current shortcomings. In fact, many of the report’s proposals will make the agency even more risk-averse, further inflate the costs of drug development, reduce the number of drugs emerging from the pipeline, and have the net effect of compromising public health.

The report identifies within the agency a supposed “culture” of insufficient appreciation for drug safety, especially in the post-approval period. On the contrary, safety concerns are an integral part of the FDA’s involvement with every drug, from its first testing in humans through its lifetime on pharmacy shelves. If there is a culture — a tendency toward certain behaviors or beliefs — it is one of risk-aversion: conservative, defensive decision-making that takes a toll on the availability of new drugs. Not uncommonly, regulators use the rationale of “better safe than sorry” to require yet another primate study, another confirmatory clinical trial, or unnecessarily large numbers of patients in clinical studies to support approval.

Moreover, recently the agency has taken a number of actions to increase the surveillance and reporting on the safety of drugs. These include the creation of a Drug Safety Board, whose objectives are “to provide oversight and advice to . . . leadership on the management of important drug

safety issues and to manage the flow of emerging safety information to healthcare professionals and patients,” and a number of projects under the rubric of the Critical Path Initiative, such as much-needed improvements in the FDA’s Adverse Event Reporting System and research to ascertain the usefulness of cardiovascular biomarkers and on the genetic basis of adverse events.

**BAD MEDICINE** It is remarkable how many ill-advised, myopic organizational and procedural “solutions” to the FDA’s problems the supposedly expert IOM group was able to devise. For example:

- The IOM report recommends a six-year term for the FDA commissioner, with retention of confirmation — “advice and consent” — by the Senate. The panel ignores that this required confirmation, which has been in place for only the past decade and a half, has been fraught with problems. While mediocre and even awful appointees have slipped through, other mainstream appointments have been held up by capricious and abusive “holds” invoked by individual senators. (Largely as a result of the latter phenomenon, during the six years of the Bush administration, there has been a confirmed commissioner in place for less than 20 months.)

- The IOM panel recommends that a new drug’s labeling should include some sort of symbol as a warning for the first two years on the market, and that direct-to-consumer advertising be restricted. These are bad ideas.

Most side effects are identified in trials prior to a drug’s approval. These potential adverse reactions, whether common or rare, are then weighed in relation to the potential benefit of the drug. But it is impossible to identify every possible side effect, even in relatively large pre-approval trials. Only with careful post-marketing surveillance, in which data from a larger and more diverse group of patients is obtained, can the rarest reactions be detected. The IOM report observed correctly that the FDA “must strike a delicate balance in judging the drug’s risks and benefits, and whether the need for more study to increase certainty before approval warrants delaying the release of the drug into the marketplace and into the hands of health care providers and their patients.” This approach does not reduce the risk to zero — even wonder drugs, from aspirin and ibuprofen to flu vaccines, have side effects, sometimes lethal ones — but we do not live in a risk-free world.

Moreover, we must consider the risk of not making a drug available to sick patients. Consider the plight of patients newly diagnosed with pancreatic cancer, Lou Gehrig’s disease, or the hemolytic-uremic syndrome recently associated with E. coli-contaminated organic spinach. Federal regulators are seldom called to account for the unnecessary deaths of patients who do not get the new drugs they need in a timely way.

Should new drugs be stigmatized? In general, new drugs confer an advantage over older ones in reducing mortality. In a study of patients who took drugs during January to June 2000, those who took newer medications were less likely to die by the end of 2002. The estimated mortality rates were directly related to time that had elapsed since approval of the drugs: for pre-1970 drugs, the estimated mortality rate was 4.4 percent, while the mortality rates for drugs approved during the 1970s, 1980s, and 1990s were 3.6 percent, 3.0 percent, and 2.5 percent, respectively. Not surprisingly, drugs are getting better all the time.

As to restricting direct-to-consumer advertising of newly approved drugs, studies have shown that such advertising encourages patients to visit their doctors and to discuss their medical problems; in this way, they obtain diagnoses and treatment in a more timely way.

- The IOM panel recommends that FDA advisory committees be required to review all “new molecular entities . . . either prior to approval or soon after approval.” This one-size-fits-all prescription is unnecessary and unwise. Some new products are so similar to already approved drugs, or have such a well-understood mechanism of action — this year’s flu vaccines, for example — that expending time, money, and effort on holding advisory committee meetings is wasteful and dilatory. Arguably, the FDA already over-uses many of its advisory committees.

- Another ill-advised IOM recommendation — a call for at least 60 percent of medical experts who serve on FDA advisory panels to be free of “significant” financial involvement with pharmaceutical companies — would make it harder for the agency to obtain expert advice. The FDA needs more and better experts, not more restrictions on those most qualified to serve. Instead, all FDA panel members should possess genuine expertise in evaluating drug safety and efficacy, and should be required to reveal any possible conflicts of interest. Any actual evidence of bias — from financial or other causes — should be weeded out during committee review.

The exclusion from review panels of all scientists who have had relationships with industry would leave only a dubious pool of possible advisors — who have anti-industry or anti-drug views or who lack the expertise that would inspire companies to hire them as consultants — to opine on difficult scientific and medical questions.

- The IOM panel believes that the FDA’s “bully pulpit” to compel sponsor compliance” with various requirements, especially those that follow approval for marketing, is currently inadequate. Although too often in reality it has been a “bullying pulpit,” the IOM panel proposes that Congress grant the FDA

additional powers to punish companies by curtailing distribution if drug manufacturers fail to jump quickly or high enough when regulators snap their fingers. This will encourage regulators to make imperious, intransigent demands. The reality is that information flows in both directions during discussions between regulators and drug sponsors, and not infrequently the education of FDA officials results in significant modification of their original position. Moreover, the FDA already has the final say on labeling, including which patient populations should receive the drug, and on the content of the section that concerns warnings, contraindications, and reverse reactions. Federal law currently prohibits the sale of any drug that is misbranded (improperly labeled) or adulterated.

■ Finally, the report delivers a message on behalf of “the sponsor” of the study, the FDA itself: the supposed need for “substantially increased resources in both funds and personnel” for the agency. Nonsense. The FDA is fat, slow, and inefficient; instead of further fattening, it needs to be put on a diet. We would be pleased to provide the FDA with a list of programs and practices that could be trimmed or eliminated — and that would both lower agency expenditures and enhance public health. As economist and Nobel laureate Milton Friedman observed, only in government do we respond to a failed enterprise by making it bigger.

**THE FDA'S WAY** How could the IOM committee have gone so wrong? There are two reasons:

First, although the panel members observed correctly in the preface to their report that “the public are best served when safety and efficacy are considered together,” they then proceeded to focus exclusively on safety — apparently because the FDA, which commissioned the study, framed the IOM’s mandate in that way. Neglecting the overall benefit to patients from new drugs, however, is rather like performing a study on the environmental benefits of banning all combustion of oil, coal, and natural gas without considering the broader implications. It ensures unbalanced, specious conclusions.

Second, the panel had an inherent conflict of interest. The IOM and its sibling organizations at the National Academy of Sciences too often appear to perform commissioned regulatory studies according to the “Burger King Principle” — you pay your money, and you “have it your way.” They have produced egregiously flawed analyses of a number of critical subjects, including the federal regulation of gene-spliced plants and foods, and the supposed discrimination in academia against female scientists and engineers.

What the FDA needs is competent management, discipline in the ranks, more effective risk-benefit balancing, a commitment to permitting patients and physicians to assume more responsibility for the risk of medical interventions, and the banishment of politics from regulation. The IOM panel’s recommendations will not get us there. **R**

# Should Congress Mandate Audit Firm Rotation?

BY DENISE DICKINS

*East Carolina University*

Prior to the implementation of the Sarbanes-Oxley Act (SOX), it was commonly believed that it was more economical for firms to retain the same auditors year after year rather than periodically change auditors in order to get a different perspective on their books. Although successor auditors generally absorbed the start-up costs associated with their initial engagement and discounted their initial fees (i.e., practiced “low-balling”), the costs associated with switching auditors (e.g., filing requirements, “training” new auditors, any penalty the market might assess for changing auditors) were often believed to equal or exceed initial fee discounts.

The findings of prior research generally supported this belief. In the pre-SOX period, research confirmed the existence of auditor low-balling and negative abnormal returns were associated with certain auditor changes.

But SOX mandates have modified the relationship between external auditors, firms, and firm managers. For example, post-SOX, audit committee members are required to be independent and have responsibility for hiring the auditor. Section 404 of SOX requires that auditors evaluate and report on management’s assessment of the effectiveness of internal control over financial reporting. Audit engagement partners are now prohibited from remaining on a client engagement for more than five consecutive years. And auditors are now restricted from performing a variety of non-audit services.

**POST-SOX CHANGE** Auditors are willing to offer initial fee discounts in order to gain access to expected future audit fees, non-audit services, and acquired efficiencies that reduce the cost of performing future audits. The initial fee discount can be thought of as an investment that the auditor makes in anticipation of future fees. The SOX mandates have likely changed auditors’ estimation of future fees and, hence, they have likely changed auditors’ willingness to low-ball.

Switching costs include inefficiencies attributed to auditor changes and any market signal associated with changing auditors captured in changes in the company’s stock price on or around the date of the auditor change. Market signals can be negative or positive. For example, the market may perceive the dismissal of an auditor as signaling disagreement over an

**Denise Dickins** is an assistant professor in the Department of Accounting at East Carolina University’s College of Business. She may be contacted by e-mail at [dickinsd@ecu.edu](mailto:dickinsd@ecu.edu).



accounting issue — even if a disagreement is not disclosed in the company’s Form 8-K reporting the auditor change. Alternatively, the market may perceive an improvement in a company’s financial reporting quality, as when a company changes from a non-Big Four auditor to a Big Four auditor (“up-tier”). The SOX mandates have likely changed the market’s view of auditor changes and, hence, they have likely changed the amount of switching costs that a company may incur when an auditor change is announced.

I recently conducted an analysis, using 2003 data, to determine whether auditors are continuing to offer initial fee discounts in this post-SOX era. My findings suggest that they are. In addition — as identified by prior research — the audit fees of Big Four auditors continue to be significantly higher than those of non-Big Four auditors. However, unlike some pre-SOX studies, the results of my study suggest that the market’s reaction to switching auditors is insignificant *unless* the predecessor auditor resigns. Further, while pre-SOX Big Four-to-non-Big Four (“down-tier”) auditor changes were found to be associated with significant negative market reactions, my research finds that this may no longer be the case in the post-SOX period. In other words, it may be that the market no longer perceives a quality difference between the auditor tiers. The study’s results also suggest that successor auditor fees and switching costs are higher when the predecessor auditor resigns or when disagreements with the predecessor auditor are reported in the Form 8-K announcing the auditor change.

Collectively, these findings suggest that in the post-SOX

period, it may be more economical to change auditors periodically than to retain them. By not periodically changing auditors, the company potentially bears a cost equal to the forgone amount of the successor auditor’s low-ball (in the case of a “same-tier” or up-tier auditor change), or a cost equal to the forgone amount of future lower audit fees (in the case of a down-tier auditor change).

Regulators continue to consider the possibility of mandating audit firm rotations. If, as the results of my study suggest, SOX mandates make it more economical to change auditors than to retain them, routine audit firm rotations may be an unintended effect of SOX. Therefore, further regulation of audit firm rotations may be unnecessary. **R**

## The Forest Fight

BY JOSEPH A. ROTONDI

*Mercatus Center*

A recent California district court decision highlights the havoc that bedevils the U.S. national forest system. In President Bill Clinton’s final days in office, the U.S. Forest Service (USFS) promulgated a midnight regulation that permanently prohibited “road construction, reconstruction, and timber harvest in inventoried roadless areas,” which comprise approximately one third of the 192 million acre national forest system. When President Bush came into office, his administration immediately suspended implementation of this “roadless rule.” A firestorm of litigation followed.

In 2003, a Wyoming district court overturned the roadless rule. In 2005, the USFS promulgated a new rule that allowed state governors to petition the Forest Service for the power to control inventoried roadless areas within their jurisdictions. Then, this past September, the California decision struck down that rule and, pending appeal, reinstated the Clinton-era roadless rule. The forests are in flux.

**MULTIPLE USE** Since national forests were created in the 1890s, Congress has proclaimed multiple, often conflicting aims for forest management. Originally, it emphasized forest protection, watershed maintenance, and a continuous supply of timber. Later, it added “outdoor recreation, range, timber, watershed, and wildlife and fish purposes.” Because no priority was assigned to one use over another, a vague principle of “multiple-use management” was left to guide the USFS.

Yet from the 1950s through the 1980s, one particular use dominated: timber. Clear-cutting wiped out large tracts of forest land. Incensed conservationists responded by demand-

**Joseph A. Rotondi** is a legal fellow in the Regulatory Studies Program at the Mercatus Center. He may be contacted by e-mail at [jrotondi@gmu.edu](mailto:jrotondi@gmu.edu).



ing “protection” for this government-owned land. The USFS answered in the Clinton administration with the blanket national roadless rule.

**ROADS NEEDED?** A ban on roads is an understandable political response to concerns about clear-cutting and misuse. But the one-size-fits-all rule does not address the ecological or economic problems facing national forests.

From grasslands and cactus deserts to pine and rain forests, national forests from Alaska to Arizona exhibit tremendous variation. Diverse resources require diverse management strategies. In many cases, that requires roads, which need not be high-cost or ecologically damaging. Temporary unpaved roads, which are cheaper and less intrusive than traditional timber-harvest roads, can be restored to natural appearance or converted to hiking trails after use.

Roads may be needed to facilitate recreational forest uses like fishing, hunting, camping, and motor recreation. They also may be needed to restore damaged ecosystems and prevent abnormally vicious wildfires, both consequences of the USFS’s decades-long fire suppression policy. Fire suppression has led to an increased stock of trees and vegetation, creating competition for space that has weakened trees and made them prone to insect and disease problems. Moreover, the increased stocking has built up an enormous excess of flammable, fine materials that feed wildfires’ voracity. (See “The Forest Service’s Tinderbox,” Winter 2000.) Without roads, it is more difficult to use plantings to restore natural diversity and to use thinnings, prescribed burnings, and other ecosystem restoration tools to remove buildup.

**MARGINAL ANALYSIS** How many miles of road will best

achieve multiple-use objectives like recreation, restoration, timber, and conservation? It is hard to say. Markets, through the dynamic intersection of individual values, define prices of particular assets. Resources are valuable insofar as humans value them, and humans by nature have subjective tastes and needs. In this case, federal ownership means no ascertainable market price exists for national forests. Therefore, we do not have enough information to deduce individual taxpayer preferences and decipher the optimal mix of road-accessible and roadless areas.

If a more local form of government owned national forests, decisionmaking would at least be closer to the people whom decisions affect most. That proximity, in turn, could lead to improved government accountability to taxpayers. For example, the state of Montana owns and manages a vast expanse of forests. The roads built in those forests are considerably different from the paved highways built in adjacent federal forest lands. While Montana’s state- and federal-owned forest road systems both serve the needs of contract timber management, the state-owned forests better embrace the stated objective of multiple use.

**REVENUE INCENTIVES** Absent localized control, we must examine the incentives inherent in national forest law. In a private business (or household, for that matter), the owner keeps the profit he or she earns. In the federal government, the USFS must hand over to the U.S. Treasury all net revenue (i.e., “profit”) it receives from timber sale or other activities. In addition, congressional funding subsidizes most agency budget shortfall, so there is little incentive to cut costs. Thus, managers tend to treat “profits” as “losses” in the form of budget reductions, and “losses” as “profits” in the form of budget increases.

Historically, this system and other congressional appropriations have produced a host of perverse public choice incentives that ruined ecology and severely wasted taxpayer money. Here are a few:

- The 1930 Knutson-Vandenberg Act allowed the Forest Service to spend an unlimited share of gross timber receipts on reforestation and other post-sale timber activities. Any timber sale receipts that the agency did not spend were returned to the Treasury. Consequently, especially from the 1950s to the 1980s, the USFS increased its budget (and hence its power) by choosing the timber harvest method that imposed the highest reforestation cost: clear-cutting.
- To spend more money, the USFS paid timber companies to build ecologically damaging and expensive permanent roads that require high ongoing maintenance costs. When timber sales declined in the 1990s, this practice largely accounted for the agency's \$8.4 billion road reconstruction and maintenance backlog leading up to the roadless rule's enactment.
- As early as 1908, Congress created an emergency fire suppression fund that allowed the USFS to spend unlimited amounts of money to put out fires. As a result, the agency developed an "out by 10 o'clock" policy, meaning that all fires would be extinguished by 10 o'clock the morning after they were detected. Thus, fire suppression crews would parachute or hike into the wilderness, sparing no cost to put out fires even when putting them out was a poor use of resources or the fire would be helpful to the forest.

**PRESCRIPTION** The congressional appropriations process has provided unsatisfactory incentives. New incentives would find alternative funding sources and provide checks to ensure that local managers make decisions based on both current science and efficient problem-solving methods. Two possibilities follow:

First, Congress might permit forest managers to charge fair market value for a wider variety of renewable resources instead of just timber. With other viable sources of revenue, the agency could cut fewer trees and remain afloat.

Second, Congress could force the agency to use its own revenues to fund its spending and, as some states do, appropriate any "profits" for a specific cause. That way, USFS managers would have incentive to avoid wasteful spending. Montana, for example, earmarks state-managed forest "profits" to pay for public schools. As a result, interested school administrators, teachers' unions, school boards, and parent organizations check inefficient forest management. Similarly, Forest Service "profits" could go to a special fund to promote biological diversity, ecological restoration, and other green values. Such a funding mechanism would both check Forest Service waste and support a life-giving ecosystem that everyone can enjoy. **R**

# Why Illegal Drugs?

BY PAUL H. RUBIN

*Emory University*

**T**he world is not libertarian, and libertarians and economists with a libertarian bent disagree with average citizens on many issues.

One of the areas of strongest disagreement is the best policy for illegal drugs such as marijuana, heroin, and cocaine. Milton Friedman long advocated legalization of these drugs, and economists studying the issue such as Jeffrey Miron and Bruce Benson have pointed out the substantial costs of our current policies. Nonetheless, voters and politicians are almost unanimously opposed to liberalization and in favor of the current policy in spite of its substantial costs.

**YOUNG MALES** When there is a strong preference for policies that appear to be irrational or inefficient, it is worth asking if there is some evolved tendency that explains this preference.

Consider the role of young males in our evolved past. Societies have always depended on young males for military strength. For our ancestors, it was the strength and prowess of the young males of the group that determined if the group actually survived. Therefore, it was important for the group of young males to be strong and fit.

We can see this even today when we observe preferences for watching sports. In sports, the actions of the players are closely related to what would have been military actions in the evolutionary environment. Running, throwing projectiles (balls), kicking, hitting with clubs (bats, hockey sticks), and knocking down opponents — all of these actions are direct modifications of ancestral actions that would have been related to defense from others or offense against others.

We enjoy watching young males engage in such activities because, in the evolutionary environment, the lives of our ancestors often depended on the strength and prowess of their young males. So, we are selected to pay attention to the strength of our males and to obtain enjoyment from watching our young males prove more powerful than others. If the young males were more effective than those of competing tribes or clans, then the group survived and became our ancestors; if they were not, then we are not descended from those individuals.

Today, teams are, of course, not engaged in military activities, but the geographic identity of teams mimics the evolutionary past: a team is "our" team just as the youths of the tribe were "our" youths. Even the behavior of the fans — for example,

**Paul H. Rubin** is the Samuel Candler Dobbs Professor of Economics and Law at Emory University. He is the author of *Darwinian Politics: The Evolutionary Origin of Freedom* (Rutgers University Press, 2002).

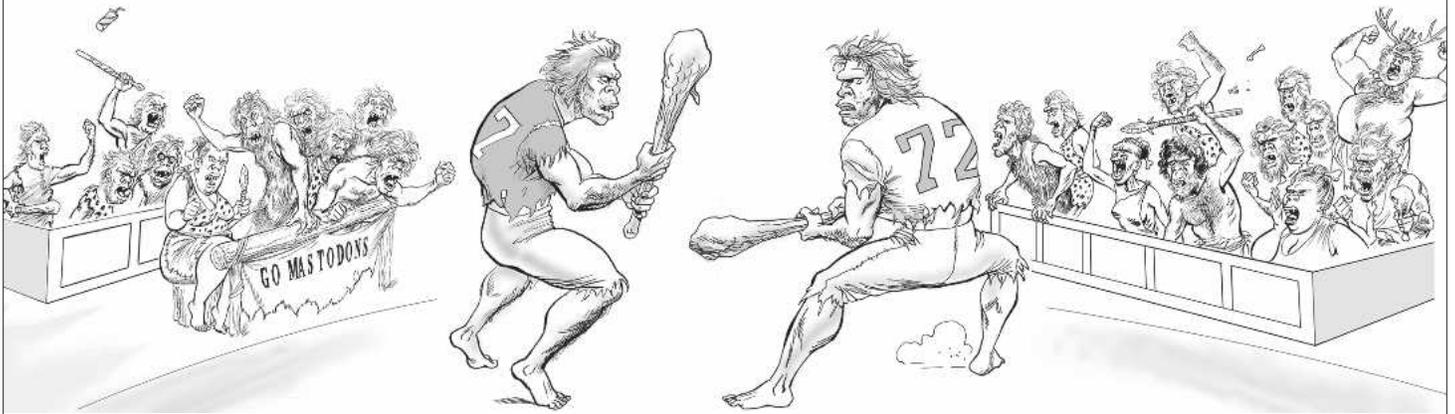
shouting instructions to the players — could be descended from evolutionarily useful behavior, as older, more experienced, but less-strong males would have been teachers of the young males.

Given this emphasis on the strength of young males, it is easy to see why there would be a preference against the use of drugs. Drugs would degrade performance in exactly the areas that would have been important for survival. Performance-enhancing drugs such as steroids improve performance in the short run, but often lead to long term harm to the body. A tribe with a group of drugged-out young males would have lost to a tribe with a group of alert males.

**HANDICAP COMPETITION** Why would young males use drugs if they have the effect of degrading performance? Here another

and military strength, it is no longer the entire set of such males that is relevant. We can hire some youths to be in the military and screen for harmful behaviors. There are still some costs from handicap competition, but there are also substantial costs of our current drug policy. This policy may even make us less, rather than more, safe as it entails foreign policy decisions (such as destroying poppy fields in Afghanistan) that may lead to an increased international threat. Intermediate positions, such as making drugs illegal (and hence more expensive) domestically but not allowing drug policy to interfere with our international relations, may be a useful compromise.

What does this mean? First, it means that libertarians may have difficulty convincing others to accept beliefs with



aspect of behavior is relevant. Within the set of young males, there is fierce competition for dominance. In the evolutionary environment, this would have been crucial because people would have lived their entire lives in the same community and the hierarchy established in adolescence would have lasted throughout one's life. This is less true today, as we are much more mobile than our ancestors, but the patterns of dominance-seeking among adolescents and young adults are hard wired.

Competition among young males may be socially beneficial if it is competition for achievement in academics, sports, business, or the arts. But there is a less benign form of competition. This is what biologists call "handicap competition." In handicap competition, the competitors deliberately handicap themselves; if one can successfully compete while handicapped, this shows that one is exceptionally strong.

Among young humans, use of drugs or other harmful substances is a particularly virulent form of handicap competition. The competition is in the form of showing that one is so strong that he can successfully compete even when handicapped by use of a harmful substance. For example, the ability to "hold your liquor" has long been viewed as a sign of maturity and strength. Handicap competition is only useful if the handicap is actually potentially harmful, so parental warnings and public service ads stressing the danger of smoking or drugs increase the usefulness of these substances for this form of competition.

**IMPLICATIONS** These evolved preferences may be less relevant today. While we still depend on young males for defense

respect to drug policy. Indeed, we must consider the biology of handicap competition in arguing for legalization of now-illegal substances. The cost of legalization of these substances might be higher than libertarians believe if this legalization would lead to increased use in an escalating arms race of handicap competition.

However, if we want to discourage the use of drugs (or of similar substances, such as tobacco) then the best policy may not be to advertise their harmful effects. If we continually stress the harmful effects, then the substances become even better as methods of handicap competition. We might do better with advertising and publicity campaigns stressing that only "losers" use these substances. We may also want to consider the tradeoffs between any benefits of a "war on drugs" and other costs of this policy, including effects on actual wars.

More generally, it is a puzzle to many libertarians as to why their ideas, which often seem self evident, are not accepted. The story of drug policy may have a sobering effect on libertarians. It may be that we humans have not evolved to be libertarians. In the evolutionary environment that shaped our preferences and many of our behaviors, paternalistic and similar interventions may have had survival value. In advocating libertarian policies, it may be useful to consider this evolutionary background to determine which policies are feasible for humans as they actually exist, and also which may be made politically acceptable. In performing cost-benefit analysis of such policies, it may be useful to turn to our evolutionary past to determine the nature of these costs and benefits. **R**