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Freeing the Biotech Revolution

by Henry I. Miller and Gregory Conko

This is the second of two excerpts from The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution, *by Henry I. Miller and Gregory Conko (Praeger 2004).*

Soon after the techniques of recombinant DNA modification were first demonstrated in 1973, the scientific community engaged in a long-term effort to gauge the relative safety and risk of this new biotechnology. Within a short period of time, a broad scientific consensus began to gel around the conclusion that the new molecular biotechnology—also known variously as gene splicing, genetic engineering, or genetic modification—is merely an extension, or refinement, of less-precise technologies that we have long used for similar purposes.

Except for wild berries and wild mushrooms, all grains, fruits, and vegetables grown in North America, Europe, and elsewhere come from plants that have been genetically improved by one technique or another. We discussed some of these techniques in the last issue of *Monthly Planet*.

Scientific discoveries and increasingly sophisticated laboratory techniques have brought us a long way from basic hybridization. Conventional plant breeding has long been far more sophisticated than the basic selection and hybridization of plants of a single species. Early in the 20th century, for example, plant breeders discovered how to breach the so-called "species barrier," much revered by biotechnology's opponents, to produce entirely new plant species that never existed before and that could not occur in nature. Compared with these more crude forms of genetic modification, the new biotechnology is far more precise and predictable, and poses neither new nor unique risks.

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Nevertheless, despite the recommendations of countless scientific organizations that recombinant DNA-engineered varieties be evaluated in the same way as the products of conventional plant breeding, regulators in the United States and many other countries, over the past two decades, have created a series of rules that treat biotechnology as though it were inherently risky and in need of intensive oversight and control.

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In This Issue

From the Vice President for Policy

Cybersecurity
Markets or Mandates?

by Clyde Wayne Crews, Jr.

One of the Internet's greatest strengths—the ability for anybody to contact anybody else in the world—is also one of its biggest weaknesses, opening the door to virus writers, spammers, and "phishers."

Phishing ruses are those whereby online miscreants trick you into entering personal information—particularly passwords—into a phony website, allowing them to go on a spending spree with your money.

As it happens, just recently, I received an email that appeared to be from Paypal, saying that I needed to click on a link and verify my account. I had, coincidentally, been setting up a Paypal account for CEI and for a moment, wavered. This kind of "double-checking" is what we want from online vendors—yet we have problems when the fakers are faking the verification. The problem is real.

Costly computer virus attacks like MyDoom and SoBig caused tens of billions of dollars in damage. Homeland security and cyber-czars Amit Yoran and Richard Clarke have expressed frustration over the lack of attention to cybersecurity. And the tech industry group Cyber Security Industry Alliance recently released a report calling for President Bush to grant cybersecurity more attention in his second term.

Yet it's not clear how much government can do. Politicians, when they do weigh in on the matter, will seek millions to establish numerous research grants for cybersecurity initiatives; set up cybersecurity agencies, programs, and subsidies; and steer students toward cybersecurity research.

Government regulation to address cybersecurity would be premature. Proposals include mandates for firewalls and virus protection, disclosure and reporting mandates, and more liability for software makers. But legislation—like the anti-spam law—would be ineffective, since the bad guys don't obey the law anyway.

Washington has a proper role, but it entails protecting government's own networks and setting internal security standards, not regulating markets. It involves arresting computer criminals, and avoiding threats to individual privacy in the form of proposed national ID cards and proposals to re-regulate encryption.

Private sector experimentation in cybersecurity is messy but necessary. The marketplace is increasingly forced to address cybersecurity, and those decentralized market approaches will outperform centralized government ones. Companies like Microsoft are automating security; biometric technologies are restricting access to critical facilities. Moreover, the lessons learned from coping with spam, privacy, and digital piracy will carry over to cybersecurity.

When the market makes mistakes—like overly aggressive spam filters—those mistakes are easier to correct than bad legislation. Regulation can quickly become so entrenched that genuine deregulation, however warranted as conditions change, simply cannot occur.

Government should facilitate market institutions, not try to imitate or replace them. One of the more non-controversial cybersecurity tasks often ascribed to government is coordinating information sharing. But sometimes there are legal impediments to voluntary information sharing—antitrust laws may inhibit needed coordination among firms, as may overly aggressive interpretations of the Freedom of Information Act. Government should rethink both.

Indeed, improving private incentives for information sharing is at least as important a pursuit as more government coordination to ensure security and critical infrastructure protection. That job will entail deregulating critical infrastructure assets—like telecommunications and electricity networks—and relaxing antitrust constraints so firms can enhance reliability and security not just by sharing information but though "partial mergers" of the kind that are anathema to today's antitrust enforcers.

Private cybersecurity initiatives will gradually move us toward thriving liability and insurance markets. Heavy-handed cyber-czar gestures and legislation cannot address the inability to exclude bad apples that is at the root of today's cybersecurity problems. Nonetheless, it's not surprising that officials such as Yoran and Clarke were frustrated. The problem is, even if they had gotten their way, it's not clear what government could really fix. But it could break a lot.

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Freeing the Biotech Revolution

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Regulations specific to gene splicing have hugely inflated the costs of research and development and made it difficult to apply the technology to many classes of agricultural products—especially ones with low profit potential such as non-commodity crops and varieties grown by subsistence farmers. This is unfortunate, because the introduced traits—including the ability to grow with lower amounts of water and agricultural chemicals—often increase productivity and are beneficial to the environment. The world would have been far better off if, instead of implementing regulation specific to the new biotechnology, governments had approached the products of gene splicing in the same way they regulate similar products—pharmaceuticals, pesticides, new plant varieties, and so on—made with older, less precise and predictable techniques.

But regulators, always eager to expand their power and budgets, have responded to calls by activist groups whose members fear technological progress and are suspicious of for-profit agricultural companies. The activists understand that overregulation advances their agenda by inflating R&D costs and discouraging innovation. And, sadly, instead of demanding scientifically sound, risk-based regulation, some biotechnology firms have lobbied for this same kind of discriminatory, excessive government regulation in order to gain short-term advantages.

Biotechnology's early promise of more nutritious and better tasting foods has not come to full fruition because it is simply too expensive to obtain regulatory approval for gene-spliced varieties of any but the most profitable crops.

These firms hope that superfluous regulation will act as a type of government stamp of approval for their products. The time and expense engendered by overregulation also act as market entry barriers to start-up competitors. Tragically, those companies seem not to understand the ripple effect from overly restrictive regulations based on the false premise that there is something uniquely worrisome and risky about the use of gene-splicing techniques.

Biotechnology's early promise of more nutritious and better tasting foods has not come to full fruition because it is simply too expensive to obtain regulatory approval for gene-spliced varieties of any but the most profitable crops. Regulatory requirements alone can add over $1 million in costs for developers of biotech varieties in the United States alone—and several million more to secure regulatory approval in major export markets.

New varieties of the big commodity crops—such as corn, cotton, soybeans, and wheat—are often worth tens of millions of dollars in seed sales annually for several years. But seed sales of a new fruit or vegetable variety can be as low as a few hundred thousand dollars during their entire marketable lives. Naturally, adding a million dollars in regulatory costs to these "small market" crops can make them commercially non-viable.

Academic research labs and the many small start-up firms created during the 1980s have developed scores of biotech crop varieties, but, as a result of costly overregulation, precious few of them have ever been brought to market. More and more small-scale researchers, who once saw gene splicing as the future of food, are leaving biotechnology behind.

According to the director of Harvest Plus, an alliance of charitable organizations devoted to producing and disseminating staple crops rich in micronutrients such as iron, zinc, and vitamin A, the group has decided that, although it will "investigate...the potential for biotechnology to raise the level of nutrients in target crops above what can be accomplished with conventional breeding...there is no plan for Harvest Plus to disseminate [gene-spliced] crops, because of the high and difficult-to-predict costs of meeting regulatory requirements in countries where laws are already in place, and because many countries as yet do not have regulatory structures."

To remove the unnecessarily stringent controls on the new biotechnology will require reform both within the United States and abroad. Some of the remedies needed here are also applicable to other areas of research: Regulatory policy must, like doctors, first do no harm. Sound science and common sense should be the basis for decisions. Both the degree and the cost of oversight must be commensurate with the potential risk. And policy makers should design regulations to work with market forces, which will come into play in any case.

Federal agencies also need to reform the way they approach the new biotechnology specifically, by replacing scientifically unjustified process-oriented regulatory triggers with risk-based paradigms. Just because an activity involves the process of gene splicing does not mean that it should be subjected to case-by-case review. Of course, forces outside government must push in a more constructive direction before we can expect government to change the public policy that is hamstringing the new biotechnology.

First, individual scientists should participate more in the public dialogue on policy issues. Scientists are especially well qualified to expose unscientific arguments and should do so in every possible way, including writing scientific and popular articles, agreeing to be interviewed by journalists, and serving on advisory panels at government agencies. Scientists with mainstream views have a particular obligation to debunk the claims of their rogue colleagues, whose declarations that the sky is falling receive far too much attention.

Perhaps surprisingly, most scientists have not demanded that science policy be rational. Instead, they have insisted

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Unbundling the Confusion over Declining Marginal Cost Pricing

by Braden Cox

A controversy is brewing, pitting business realists against legal idealists—directly affecting consumer welfare. The debate centers around what economists call "declining cost industries." Burdened with such economic concepts as "marginal costs" and "price discrimination" and generally played out in arcane antitrust enforcement actions, a sexy policy debate this is not. Yet comprehending the pricing methodologies of declining cost industries is a must if policy makers are to properly understand 21st century business.

A declining cost industry is one characterized by the selling of a good or service whose average production costs decrease with each new unit produced. Let's say that I create a product that required lots of up front investment with high research and development costs. Despite all the initial costs, once I have perfected the product, the cost of reproducing another product—my "marginal cost"—is miniscule. So what is the best way to price my product?

It's easy, right? Just factor into the price the cost of development along with production costs. Wrong. Determining how much to charge over marginal cost is extremely difficult in practice, which makes charging a flat price impractical. Instead, businesses have found that they can best recoup their massive up front costs by charging a price based on what various buyers are willing and able to pay.

A pricing practice that differentiates based on the characteristics of the buyer may seem fishy to some. After all, this is discrimination! But what is good for sellers isn't necessarily bad for buyers, as both parties benefit from voluntary transactions. Indeed, price diversity in declining cost industries is socially efficient precisely because it extracts more value from those who are willing to pay more.

Fighting for Survival – Declining Cost Industries

Declining average costs are not a new phenomenon. Yet they remain a widely misunderstood but pervasive economic reality.

Many economists incorrectly equate a firm's ability to price discriminate with its having monopoly or undue market power. Most economists argue that a perfectly competitive market pushes price toward marginal cost—and it is only an occasional aberration where some allowance is required for up front capital costs. Too often this mantra finds its way into regulatory policy—especially antitrust law. Antitrust regulators view with suspicion what they consider undue deviations from marginal cost pricing.

The risk is that government regulators or the public at large will misconstrue the cost recovery strategies employed by declining cost industries as harmful to consumers.

Yet many important industries operate within a market characterized by declining average costs—including airlines, entertainment, pharmaceuticals, software, and telecommunications. In all of these industries, the challenge is similar: The amount one must charge to pay for overhead is small compared to the amount one must charge to remain viable.

The risk is that government regulators or the public at large will misconstrue the cost recovery strategies employed by declining cost industries as harmful to consumers. Pursuing regulation or litigation would drive prices below those needed to ensure dynamic, creative change. As a result, we would benefit from one generation of "cheap" goods or services but nothing thereafter.

An Unheralded Economic Freedom – The Freedom to Price

If declining costs are the problem, then diversity in pricing is the answer. Derided by economists and antitrust lawyers as "price discrimination" or "price differentiation," this simply entails a firm charging different customers diverse prices for an identical product or service. The practice is actually quite common. Bulk discounts—such as for large quantities of copy paper or for "family size" restaurant meals—are one common form of price diversity.

As Economics Nobel Laureate Ronald Coase of the University of Chicago long ago noted, in his 1946 article, "The Marginal Cost Controversy," a declining cost industry must find some way to finance itself. He explained that there are two main ways to achieve the necessary level of revenue—via creative multipart pricing or through some form of government subsidy. The government subsidy approach inevitably entails government regulatory and/or price controls, as there are no "free" subsidies. So how can we let the market work?

A market solution requires for the seller to be able to distinguish between those buyers who are willing to pay a high price from those who are not. A seller must also be able to keep low-price buyers from reselling to those willing to buy at a higher price. This necessarily involves price diversification and contractual terms or technological barriers.

Thus, allowing the market to work means that laws under the rubric of

"privacy" should not prevent consumers from voluntarily sharing personal information with sellers, or prevent sellers from collecting consumer data. In addition, the legal system should enforce contractual obligations governing subsequent resale.

Price Diversity is Consumer Friendly

It is easy to find examples of how price diversity helps consumers and maximizes resources that benefit all of society. Movie theaters have lower prices for matinees and restaurants have child menus to attract families who are, on average, more sensitive to prices than patrons without children. People who clip coupons are rewarded at grocery stores with a lower price. Senior citizens' strong price sensitivity provides the rationale for discounts at museums, drugstores, and even Broadway plays.

Bundling different goods together is another form of price diversity. For example, package deals from travel agents and online travel sites often provide consumers great savings. Hotel rooms and airline seats adhere to declining cost economics—the fixed cost of the building and airplane are large, but the cost of cleaning one extra room or flying one extra passenger is negligible. Product bundling allows hotels and airlines to fill excess inventory at a price that won't compete with its regular fares but will still allow it to make a profit.

There are those in government—particularly state tax regulators—who argue that consumers must be able to see the price of each component of their purchased item. But this is one instance where business "transparency" would hurt consumers because business would stop offering lower prices if it would undercut sales at its regular prices.

Declining cost businesses must have ways to engage in price diversity experimentation. Unfortunately, too many view any difference in price as anti-consumer or even unlawful. The reality is that "price discrimination" is a market solution that even the most ardent consumer advocate should embrace.

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Meet CEI's Experts
Ben Lieberman

Ben Lieberman is Director of Air Quality Policy and Associate Counsel at CEI. His most recent work on energy prices has appeared in publications including the New York Post, Chicago Sun Times, Weekly Standard*, and others. He received his J.D. from the George Washington University. He recently told* Monthly Planet *about himself.*

You've written extensively on the Clean Air Act. How did you become interested in this issue?

My father was an engineer with a strong science background, and I remember how he complained that federal environmental policy lacked a reliable scientific foundation. In law school, I took courses in environmental law, and realized how right he was. This sparked my interest in environmental policy, and it led me to CEI.

When I first came to CEI, I worked on the issue of stratospheric ozone depletion, but then branched into other issues covered by the Clean Air Act, and into the subject of air quality. I've since come to believe that the only good part of the Clean Air Act is its title—who can be against clean air?—but the statute itself is fraught with poorly designed and outdated provisions.

What are the most common misperceptions you encounter held by people regarding public policy?

When I started work at CEI, I assumed that policy analysts conducted research and wrote long policy papers. I quickly learned that research and writing are only part of the overall strategy for advancing policy. I have written not only monographs, but also op eds and magazine articles to influence public opinion. And my giving print, radio, and television interviews has also proven important in advancing our message. Another thing I did not expect was having to file comments and participate in agency-level meetings in the hopes of convincing regulators to see things from our perspective.

Could you comment on the *Granholm v. Heald* Supreme Court case dealing with interstate wine sales?

Granholm v. Heald, heard by the Supreme Court on December 7, involves challenges to two state laws that restrict direct-to-consumer wine sales from out-of-state wineries. This, of course, effectively bans a form of internet commerce that offers wine lovers more product choice and lower prices. But the alcoholic beverage wholesalers and distributors, who enjoy very high markups, do not want consumers to be able to bypass them, so they prevailed upon states to create these protectionist laws. But since these laws exempt in-state wines, they discriminate against out-of-state commerce and run afoul of the Constitution's commerce clause. This case is the first challenge to e-commerce to reach the Supreme Court, so the decision could set a precedent for other products sold online.

Q & A with Jarol Manheim:

An Expert on Communications and Media talks about his Groundbreaking Work on the Success of the Left's Communications Strategies

CEI's Monthly Planet *recently interviewed Jarol Manheim, Professor of Media and Public Affairs and of Political Science at the George Washington University's Elliott School of Media and Public Affairs, and author of* The Death of a Thousand Cuts: Corporate Campaigns and the Attack on the Corporation *(2000) and* Biz-War and the Out-of-Power Elite: The Progressive-Left Attack on the Corporation (2004). *In these two ground-breaking books, Professor Manheim analyzes the phenomoenon of corporate campaigns—multi-faceted coordinated attacks upon companies by labor unions and advocacy groups seeking to advance an agenda. His books are available from Lawrence Erlbaum Associates—www.erlbaum.com—Amazon.com, and barnesandnoble.com. A longer version of this interview is available online at www.cei.org.*

CEI: To give readers a better understanding of your area of research, please provide nutshell definitions of your two books' central theme. What constitute an anti-corporate attack campaign's basic elements?

Jarol Manheim: My books look at the history, components, strategy, and evolution over the past 30 years or so of the increasingly sophisticated ways in which labor unions, environmentalists, and other activists bring pressure on companies to yield to their various demands. I generally distinguish between two kinds of campaigns—corporate campaigns and anti-corporate campaigns—which differ less in their components than in their objectives.

A corporate campaign is generally one undertaken by organized labor to obtain some economic objective—usually union recognition, but sometimes a more advantageous contract with a unionized employer. An anti-corporate campaign is one undertaken by some other type of antagonist for a policy or ideological objective. The union campaigns

are usually better funded and more elaborate, but also more constrained because ultimately the union hopes to come to terms with the company as an employer and source of members. Other advocates, however, generally have no particular interest in sustaining the viability of the target company.

These attack campaigns include various combinations of psychological, economic, regulatory, legal, and political warfare against the company—essentially leveraging its reputation against it—all carefully planned and deployed. The diversity and integration of these attacks, and the manner in which they are often channeled through a series of alliances and surrogate groups, make them different in both degree and character from the demonstrations, boycotts, and the like of an earlier era. But the thing that really sets them apart is their grounding in what the anti-corporate activists term "power structure analysis."

Power structure analysis is a process in which an antagonist identifies all of the key stakeholder relationships upon which a given company depends for its daily well-being, then researches each relationship with an eye toward identifying potential vulnerabilities. Examples of such stakeholders would be the company's customers, suppliers, bankers and insurers, investors, principal regulators, the media, and the general public. The idea is to figure out ways of getting one or more of these stakeholders to act in his own self interest, and yet in ways that advance the interests of the antagonist and become points of pressure against the company.

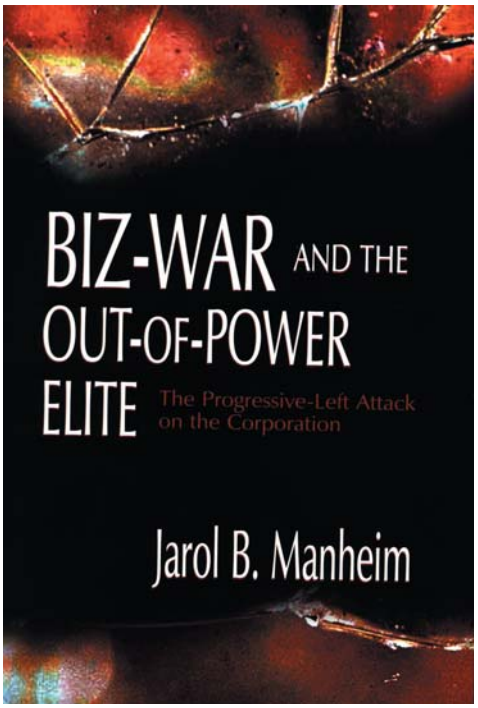
CEI: How did you first become interested in studying strategic attacks as a conscious activist strategy?

Manheim: About 15 years ago, I was nearing the conclusion of a long-running study of the ways foreign governments tried to manage their news images in the U.S. in order to gain trade or foreign policy concessions. One of my students at the time was intrigued by some new communication techniques then being employed by the United Mine Workers. That was the first I had heard of these campaigns. Not too long afterward, I began to hear about them from others as well.

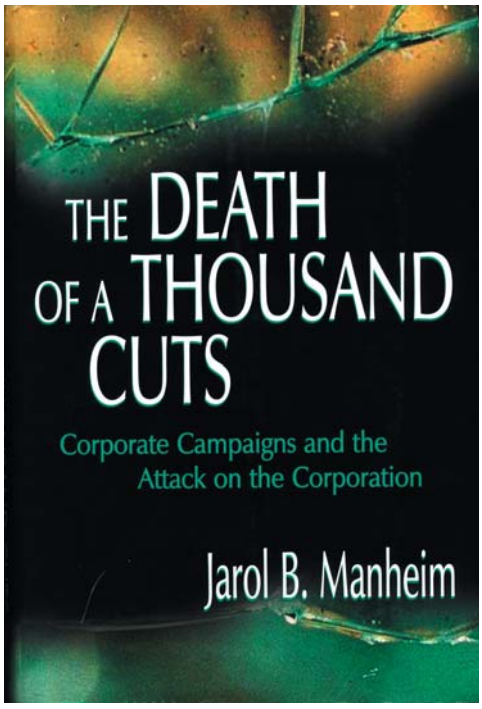
The thing that *keeps* me interested is the utter sophistication of corporate campaigns. Because they are carefully planned, long-running, often well-funded, multi-faceted efforts at persuasion and pressure employing many different kinds of organizations and institutions, these campaigns are very nearly a perfect laboratory for the study of image management in politics.

CEI: Could you comment on the importance of Saul Alinsky's 1971 volume *Rules for Radicals* for the post-Cold War Left? Does it include lessons for other movements?

Manheim: *Rules for Radicals* was Alinsky's last book, written shortly before his death, and was, in many ways, a last will and testament in which he left the benefit of his experience to



later generations of activists. He actually wrote the book because he thought that the "New Left" activists of the 1960s were losing their way, and in the process, putting at risk the opportunities their activism had created. Anecdotally, it seems that Alinsky's book is required reading for every would-be activist. Empirically, the best evidence of its influence may be the fact that it is still in print, nearly 35 years after its publication and the death of its author, and still selling well.



CEI: In *The Death of a Thousand Cuts*, you mention sociologist C. Wright Mills as a guiding light of the New Left, which laid the foundations for the corporate campaigns that organized labor would later adopt as a favorite tactic. In addition to Mills and Alinsky, what other writers have influenced the rise of coordinated reputational attacks as a tactic for pushing an agenda?

Manheim: There are several ways to answer that question. As a general influence, many of the more sophisticated campaigners have probably studied Sun Tzu's *The Art of War*. More specifically, David Vogel's *Lobbying the Corporation* (1978) provided a solid basis for understanding the nature of the pressures advocates could generate, not only on companies, but through them, on public policy.

Sociologist G. William Domhoff, in a series of books but most notably in *Who Rules America?*, picked up where Mills left off, and is both active and widely read within what is now known as the "Progressive Left." Then there are many how-to manuals, either general guides to activism like Randy Shaw's *The Activist Handbook*, or more specific guides to research and activism like the World Resources Institute's book, *Leveraging the Environment*, which lays out a differentiated strategy for attacking the various parts of the financial services industry.

CEI: What lessons could people in the corporate world learn from your research findings? What do you think of the argument that John Micklethwait and Adrian Woolridge of *The Economist* put forth in their book, *A Future Perfect: The Challenge and Promise of Globalization*, that corporate managers today are too technocratic to be able to confront attacks, that they are more likely to take the easy way out by trying to appease anti-corporate activists than try to defend their enterprise?

Manheim: A corporate campaign is often designed to come at a company indirectly, carried forward by a large number of the company's own stakeholders who may not even realize they are being "played." In such a circumstance, it is essential to understand the breadth and nature of the attack, and, especially, to recognize the real antagonist, whose identity may be masked through a variety of allies, surrogates, and intermediaries. That can help in designing defenses, or perhaps on occasion even in turning the tables on the antagonist.

We need to realize that companies are generally organized for the purpose of doing business, presumably with some efficiency. But companies are not organized to wage war. They are not generally prepared to confront an antagonist whose true objective may be to drive them out of business. Corporate campaigns are wars. So it is not, in my view, that technocracy drives complaisance or appeasement, but rather that corporate cultures were simply never intended or designed for hand-to-hand combat. Corporate campaigners count on that for their edge.

Companies are generally organized for the purpose of doing business, presumably with some efficiency. But companies are not organized to wage war. Corporate campaigns are wars.

Medicine Could Reach For Stars, FDA Willing

by Ed Hudgins and Sam Kazman

When Bill Gates and Paul Allen founded Microsoft in 1975, they shot for the stars and succeeded.

More recently, Allen shot for the stars again. The two successful launches of his SpaceShipOne won the $10 million Ansari X competition for private manned space flights. This feat may ultimately do for private space ventures what Charles Lindbergh's crossing the Atlantic did for commercial aviation.

The success of these enterprises obviously depended on such factors as genius, guts, and foresight. It also depended on the less obvious absence of something—government regulation.

Yet this is something that both Gates and Allen may be forgetting in another field that they are entering—medicine.

Microsoft created new, innovative software that let us use computers for everything from word processing to e-mailing to superhero gaming. Its products created an explosive demand for personal computers, which in turn led to the ubiquitous Internet.

But little of this would have happened, let alone so quickly, if computers and software had been heavily regulated.

Regulatory advocates in that period routinely claimed government wasn't moving fast enough to "keep pace" with technology. A good thing, too—they intended this as a complaint, but, for consumers, government inaction was, and remains, a blessing.

On the other hand, until very recently this was not true of private space launches. In fact, if Allen had begun his space project at the same time he began Microsoft, it would have run into a lethal regulatory labyrinth.

Hurdles Lowered

Luckily, that did not happen. Telecom deregulation gradually opened the door to private space satellites. By 1998, with the enactment of the Commercial Space Act, many of the regulatory obstacles facing private space launches had been liberalized.

This brings us to medicine, a field in which both Gates and Allen have become major philanthropists. Gates has contributed billions to global health issues, including in July a $50 million international grant to fight AIDS and malaria.

Last year Allen gave $100 million to establish the Allen Institute for Brain Science. Its mission is to produce a comprehensive cellular map of the brain—the neurological equivalent of the human genome project.

The involvement of such figures as Gates and Allen in medicine should be an exciting prospect. Medicine, like computers and space flight, is a field rich in technological promise. Any day, it seems, a new scientific breakthrough could open the door to a world of new treatments for previously incurable conditions. If Gates and Allen manage to duplicate in medicine a mere fraction of their computer achievements, the health payoffs could be astounding.

FDA's veto power over new therapies has a gruesome side effect: Every approval of a new life-saving drug or device means that people died waiting for that approval to be issued.

But this image may also be a false one. Medicine is pervasively regulated. Because of the Food and Drug Administration (FDA), with its inclination toward deadly overcaution, it can require 10 to 15 years and nearly $1 billion to create, test, and bring to market a new drug. In the wake of the Vioxx recall, that situation will get only worse.

New Thinking Needed

And that is only for the one in 5,000 drugs that succeed. How many "medical Microsoft" startups could survive such hurdles?

Men such as Gates and Allen may enter medicine, but whether they'll be able to revolutionize it is another matter. Consider how the heavily regulated field of biotechnology has produced hardly any billionaires.

P.R. Newswire Photo Service

Jim Benson, CEO of Poway, California-based SpaceDev, signs one of the company's three hybrid rocket motors that would blast SpaceShipOne to win the $10 million Ansari X Prize.

What is to be done? The conventional wisdom is that massive government oversight is essential to assuring the safety and effectiveness of medical therapies. But Gates and Allen did not get to where they are by accepting conventional wisdom, and for that reason they should rethink just where to put their money and effort.

Devoting just a fraction of those resources to researching medical regulation, rather than medical science, could be incredibly fruitful. Advances in medicine may require difficult scientific breakthroughs. Advances in medical regulatory policy might only require the reframing of basic questions, such as the role of FDA.

FDA's veto power over new therapies has a gruesome side effect: Every approval of a new life-saving drug or device means that people died waiting for that approval to be issued.

Is FDA really the only institution capable of evaluating new therapies? Are doctors and patients truly incapable of deciding whether to use experimental therapies?

Rethinking these issues, especially in the context of the very information technologies that Gates and Allen helped create, might well change the world.

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Freeing the Biotech Revolution

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only on transparency, or predictability—even if it only delivers the predictability of research delays and unnecessary expense. Others have bought into the myth that a little excess regulation will assuage public anxiety and neutralize activists' alarmist messages. Defenders of excessive regulation have made those claims for decades, but the public and activists remain unappeased, and technology continues to be shackled.

The second strategy involves groups of scientists: professional associations, faculties, academies, and journal editorial boards. These organizations should do much more to point out the flaws in current and proposed policies. For example, scientific societies could include symposia on public policy in their conferences and offer to serve as advisors to government bodies and the news media.

Third, reporters and their editors can do a great deal to explain science-related policy issues. But in the interest of "balance," the news media often give equal weight to all the views on an issue, even if some of them have been discredited. All viewpoints are not created equal, however. Journalists need to distinguish between honest disagreement among experts, on the one hand, and unsubstantiated extremism or propaganda, on the other.

Fourth, biotechnology companies should eschew seeking short-term advantage and actively oppose unscientific, discriminatory regulations that set dangerous precedents. Companies that passively accept government oversight triggered simply by the use of gene splicing techniques, regardless of the risk of the product, ultimately will find themselves the victims of the law of unintended consequences as excessive regulation stifles them.

Fifth, venture capitalists, consumer groups, patient groups, philanthropists, and others who help bring scientific discoveries to the marketplace, or who benefit from them, need to increase their informational activities and advocacy of reform. Their actions could include educational campaigns and support of organizations that advocate rational, science-based public policy.

Finally, the government should no longer assume sole responsibility for regulation. Nongovernmental agencies already accredit hospitals, allocate organs for transplantation, and certify the quality of consumer products ranging from seeds to medical devices. Moreover, in order to avoid civil legal liability for damages real or alleged, it is in the best interests of the practitioners of agricultural biotechnology to adhere to sound practices.

Flawed, overly risk-averse federal regulation of the new biotechnology has slowed the rate of innovation in that crucial area of research. We need to find other, more scientific and efficient ways, to guarantee the public's safety while encouraging new discoveries.

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The Good, the Bad, and the Ugly

The Good: FCC Preeempts State VoIP Regulations

On November 9, the Federal Communications Commission (FCC) unanimously ruled that Voice over Internet Protocol (VoIP) services are a form of interstate commerce and therefore not subject to certain state rules and rate regulations. The decision marks a victory for consumers, as it prevents state utility regulators from imposing myriad restrictions that could have stifled this nascent technology.

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In 2003, the Minnesota Public Utilities Commission (PUC) informed Edison, New Jersey-based Vonage Holdings, a VoIP provider, that the company needed to register as a Minnesota telecommunications provider, subjecting it to certain taxes and regulations. This would have opened the door for states to impose countless disparate regulations on VoIP providers. However, the FCC ruled against the PUC, determining that VoIP was an interstate service, and therefore under federal jurisdiction.

The FCC did not rule on whether Vonage is an information service or telecom company, which would have exempted VoIP providers from even more taxes and regulations, but the decision is a step in the right direction. As CEI Technology Counsel Braden Cox remarks: "A patchwork quilt of VoIP regulations would have burdened companies and stifled the deployment of this new and exciting technology. The FCC ruling respects federalism principles and bodes well for the future of telecommunications to the benefit of consumers."

The Bad: States, Provinces Carry on Anti-CO_2 Crusade

Recently, several states and Canada have banded together in an effort to have carbon dioxide (CO2) labeled a pollutant. Sixteen states and cities—California, Connecticut, Illinois, Maine, Massachusetts, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, American Samoa, the District of Columbia, Baltimore, and New York City—have joined leading environmental groups in filing lawsuits against the Environmental Protection Agency to force the agency to regulate greenhouse gas emissions from motor vehicles. In addition, nine Northeastern states have announced the introduction of a regional-level cap and trade greenhouse gas initiative (RGGI), with Maryland, Pennsylvania, and Washington, D.C. agreeing to act as observers in the process. Meanwhile, the Canadian government has called for a 25 percent reduction in greenhouse gas emissions from all cars by the end of the decade, and some of Canada's eastern provinces plan to act as observers in the RGGI.

Such efforts will do little to help the environment—but will do much to damage the North American economy. For example, regarding the Canadian efforts, Canadian Vehicle Manufactures Association President Mark Nantais warns, "It means that roughly 95 percent of the passenger cars in Canada won't make the cut."As CEI senior fellow Marlo Lewis writes, "there is no device...that can scrub CO2 out of the exhaust system." Thus, to impose mandatory caps "is to use less of the affordable, plentiful, increasingly safe and clean hydrocarbon fuels that power the U.S. economy and contribute mightily to America's competitive edge in global trade."

The Ugly: NAFTA Panel Takes up NGOs' Anti-GM Jihad

On November 8, an international scientific panel convened under the North American Free Trade Agreement (NAFTA) issued a report that claimed that the unintentional spread of American genetically modified (GM) corn to Mexico poses a potential threat to native Mexican corn varietes. American and Canadian officials have denounced the report as "unscientific."

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The report, "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico," a response to a 2001 petition by Mexican farmers and non-governmental organizations, advises the Mexican government to label imported U.S. corn as potentially containing GM products and to continue its ban on planting GM corn. The United States and Canada, Mexico's NAFTA partners, have both condemned the recommendations, with the Canadian government bluntly stating, "some recommendations are not supported by—and do not appear to be based on—the evidence presented in the key findings."

If Mexico were to adopt the recommendations proposed by the NAFTA report, the effect on trade would be devastating. Mexico imports about 5.6 million tons of American corn annually, 50 percent of which is genetically modified. Both EPA and U.S. Trade Representative Robert Zoellick have said that implementing the recommendations—especially the call for labeling—would hurt U.S. farmers, confirming what CEI Director of Food Safety Policy Gregory Conko has asserted about mandatory labeling: "It is more likely that mandatory labeling will merely raise the cost of GM products, and add to many consumers' groundless fears about GM foods."

Media Mentions

Senior Fellow Iain Murray finds an answer to Amtrak's woes:

Amtrak's infrastructure is crumbling. As the inspector general, Kenneth Mead, says, there are "interlockings, bridges, and tunnels that are well beyond their economic life." Amtrak has been deferring capital expenditure on these assets for years. Mead goes on, "Continued deferral brings Amtrak closer to a major point of failure on the system, but no one knows where or when such a failure will occur."

This state of affairs is familiar to me, as I was part of the team that privatized the British rail infrastructure body, then called Railtrack, in 1996. We were aware that there had been a huge backlog in capital expenditure on the railway throughout the 40-plus years of public ownership of the British railroad system. That, indeed, was one of the reasons Railtrack had to be privatized, in order to bring in new flows of investment capital that would not be dependent on the political vagaries of the British appropriations process, where rail was pitted against schools and hospitals in the battle for taxpayers' money.

- *National Review Online*, December 8

Director of Air Quality Policy Ben Lieberman analyzes the waning influence of old-style environmental activism:

The big green groups, most of whom maintain only a pretense of nonpartisanship, began their attacks as soon as Bush took office and never let up during the ensuing four years. When the President wasn't poisoning the children with arsenic in drinking water or mercury in fish, he was handing over national forests to loggers or walking away from the international consensus to fight global warming. The elite media gave these and other factually questionable allegations ample publicity and minimal scrutiny.

The League of Conservation Voters handed Bush a grade of F on the environment, and at a press conference expressed regret that there was no lower grade to give. Natural Resources Defense Council activist Robert F. Kennedy, Jr. called Bush "America's worst environmental president," and was far from alone in doing so. The *New York Times*, *Washington Post*, *Los Angeles Times*, CBS, NBC, and ABC gleefully ran with nearly every hit piece the green groups fed them. And Democratic politicians tried to make the most of these attacks.

But on Election Day, "America's worst environmental president" lost very few votes because of the environment. The eco-vilification could not have been any more intense, yet politically it amounted to nothing.

- *Human Events*, December 8

Adjunct Fellow Henry I. Miller details the increasing problems at the FDA:

The FDA is the nation's most ubiquitous regulatory agency. It oversees products that account for 25 cents of every consumer dollar, with a value of over a trillion dollars annually—and it's in turmoil.

First the agency was blindsided by Chiron Corporation's inability to provide flu vaccine this season due to contamination at its manufacturing facility, depriving Americans of half the usual supply. Then came Merck's withdrawal from the market of its blockbuster anti-inflammatory drug, Vioxx, because of cardiovascular and cerebrovascular side effects. This led one of FDA's medical officers, in congressional testimony last week, to accuse his own colleagues of discounting recommendations from the agency's safety researchers, and of consistently being in denial when data indicates safety problems from an approved drug.

The FDA is a favorite target of critics, who variously accuse regulators of excessive risk-aversion and delay of approvals, or of too cozy a relationship with the drug industry. Former FDA Commissioner Frank E. Young once characterized his agency as "a slow-moving target that bleeds profusely when hit."

- *The Wall Street Journal*, November 26

Warren Brookes Fellow John Berlau finds yet another U.S. government policy allegedly alienating our allies around the world:

The issue is stock options, and an effort by an unelected group of accountants to change the law by fiat and force U.S. companies to take a hit in reported earnings.

In March, the Financial Accounting Standards Board (FASB), a private group selected by accountants and financial executives, ruled that by next year, U.S. companies must expense an estimate of the future value of stock options against current earnings. Since the Securities and Exchange Commission (SEC) adopts FASB's accounting pronouncements, this standard will have the force of law. Some companies that offer broad-based stock options as incentives for their employees say this could reduce their reported earnings by 40 percent.

Due to public outcry, FASB recently delayed the rule until June but otherwise refused to budge. Invoking Enron and other companies caught cooking the books, FASB and its supporters argue its standards will make balance sheets more transparent for investors. But a close reading of FASB's statements points to another agenda for this radical step: to have "harmonization" and "convergence" with the pronouncements of European accounting bureaucrats. The Europe-based International Accounting Standards Board has announced that, pending final approval by the European Union, all companies must expense stock options to list on EU stock exchanges by 2005, or 2007 if they also list on U.S. exchanges.

- *The Washington Times*, November 7

Somalia's Telecom Revolution

An active testimony to the dynamism of the market is happening now in Somalia. The country has had its share of problems—including war—due to the breakdown of government authority during the 1990s. But its telecommunications industry is growing rapidly—free from state intervention—according to a recent BBC report. Three phone companies compete for both mobile and landline customers. Internet cafés are opening across the country. It takes only three days to have a landline installed, compared to a waiting list of several years in neighboring Kenya. And local calls are unlimited for a monthly $10 fee. Security is still a problem, but telecom entrepreneurs have been resourceful. Fighting by militias ravaged the main airport, but businessmen have had access to supplies through privately built airstrips. And despite the absence of courts, contracts are enforced through Somalia's traditional clan system.

...END NOTES

Coming Soon: Air Taxis?

A group of entrepreneurs—including former American Airlines CEO Robert Crandall—backed by the likes of Bill Gates and Goldman Sachs Group are planning to launch a new line of low-cost tiny jets—called very light jets, or VLJs—for wealthy travelers and corporate executives, reports *The Washington Post*. While the initial projected market for the new planes will be upscale, their development will help lower the cost of air travel, with the potential to eventually make custom air travel affordable to the wider public.

Yet Another PETA Update

Yes, People for the Ethical Treatment of Animals (PETA) is at it again. On November 29, PETA filed a complaint with the U.S. Department of Agriculture over alleged improper slaughtering practices—at a kosher slaughterhouse. Also in November, PETA launched its "Fish Empathy Project," a campaign to promote the idea that fish are intelligent animals on par with domestic dogs and cats. "Fish are so misunderstood because they're so far removed from our daily lives," said Empathy Project manager Karin Robertson, daughter of an Indiana fisheries biologist. "They're such interesting fascinating individuals, yet they're so incredibly abused." But, says University of Wyoming neuroscientist James Rose, "Fish are very complex organisms...But to suggest they know what's happening to them and worry about it, that's just not the case." And on November 10, PETA activists dressed as tampons to protest the use of rhesus monkeys for menstrual cycle research at a Columbia University lab.

A Winning Anti-Obesity Strategy

The federal government is considering warning labels for carbonated soft drinks. Lest anyone confuse sodas with health food, a draft of federal dietary guidelines currently under review and expected in final form by February state that there is a "positive association between the consumption of sugar-sweetened beverages and weight gain."

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