

SPECIAL REPORT

National Legal and Policy Center

The Interfaith Center on Corporate Responsibility: The Religious Left vs. Health Care Markets

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Reducing the Cost of Drugs: A Case of Friendly Persuasion

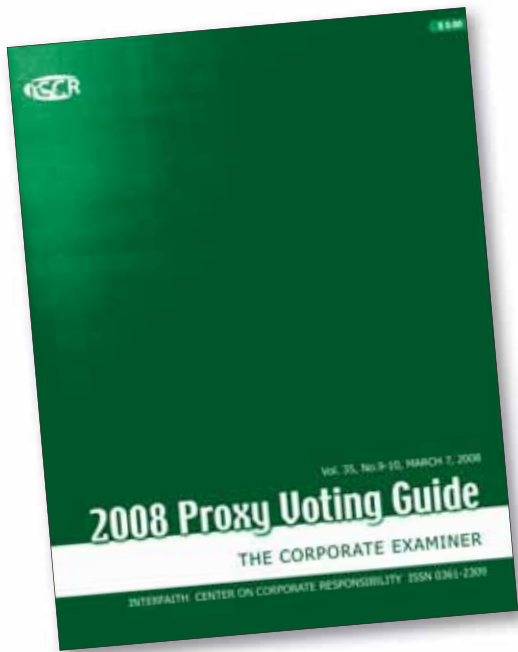
It takes a certain amount of spine to corral top executives of Pfizer, Merck and Bristol-Myers Squibb into a private meeting to play hardball. These companies, after all, are pharmaceutical industry giants, each generating billions of dollars in annual sales. Yet a large network of investors, often religiously-motivated, is doing just that with these and other companies. They are the vanguard of a growing movement known as Socially Responsible Investing, or SRI. A recent example should suffice in conveying how effective they can be in winning concessions on behalf of an ostensibly greater good.

In October 2005, a trio of SRI activists—Sister Judy Byron, a Dominican Sister representing the Northwest Coalition for Responsible



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Investment, Sister Susan Vickers, a Sister of Mercy representing Catholic Healthcare West, and Daniel Rosan, director of public health programs for a New York-based investor umbrella group, the Interfaith Center on Corporate Responsibility (ICCR)—met for two hours with top officials of a San Francisco biotechnology firm, Gilead Sciences, at company headquarters.¹ The activists were on a mission: to persuade the company to allow the sale in African nations of generic (i.e., non-branded) versions of two patented

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anti-HIV/AIDS drugs, “tenofovir” and “emtricitabine.” This was more than a matter of profit, the activists argued. This was a matter of moral duty, to the world as well as to company shareholders. Nearly a third of the attendees at the company’s previous annual meeting had supported an ICCR-supported proxy resolution to that effect.

Months later, the activists received a response, though not the kind for which they had been hoping. Gilead announced plans to make tenofovir available in India, but in commercial form, thus precluding all generic sales. SRI investors and AIDS activists, angered that the drug would be unaffordable to the poor, swung into action. The company knew it was being watched carefully because the ICCR already had published the results of a survey that graded Gilead Sciences and over a dozen other pharmaceutical companies on what they had done to combat the disease.² Gilead shareholders in May 2006 presented the ICCR resolution for a second time, again winning nearly a third of the vote. And SRI investors kept up the heat. Their efforts paid off. Company management announced a series of “voluntary” licenses for tenofovir, paired with technology transfer. By the fall of 2006, nearly a dozen generic drug makers had accepted assistance from Gilead to produce the drug.

Such a campaign amounted to a crushing defeat for patent law. But the Interfaith Center and its allies viewed it another way: a triumph for people in need. “The increased competition should lower prices and ensure continuity of supply, although not every generic firm has launched commercial products,” ICCR’s Rosan wrote hopefully.³ The agreement, the author emphasized, was mandatory:⁴

In the Gilead controversy, the presence of institutional investors changed the nature of the debate. As shareholders, Sister Byron’s constituency requires solid financial performance from the company. Every policy Sister Byron recommended to Gilead had to conform to this standard. The result was a better understanding by Gilead management of how it could respond without sacrificing public health or losing valuable brand equity.

There is a coda to this story. On January 23, 2008, the U.S. Patent & Trademark Office revoked four key tenofovir-related patents held by the company. A Left-leaning nonprofit group, the Public Patent Foundation, had challenged their validity, claiming that the drug’s chemical properties already had been known at the time of Gilead’s application for the patents.⁵

This case illustrates a long-term trend in shareholder governance. Sectarian and lay organizations of the Religious Left, increasingly sophisticated in the world of investment, are pressuring corporations into “a better understanding” of the need to change ways of doing business. They are effective as well as relentless, having learned negotiating as well as investing skills.⁶ The resulting “partnerships” are products of coercion, subtle or otherwise.

The financial engine of this “Socially Responsible Investing” movement is the above-mentioned Interfaith Center on Corporate Responsibility. To understand how progressive shareholders are transforming the nature of doing business in America and throughout the world, it is essential to understand the ICCR and the elaborate investor network it has worked to cultivate.

The Interfaith Center on Corporate Responsibility: Financial Engine of the Religious Left

The Interfaith Center on Corporate Responsibility (www.iccr.org) is a non-

profit coalition with an avowed membership of about 275 institutional investors, most of them of a religious nature, with a combined stock portfolio of more than \$110 billion.⁷ The group operates on the belief that the best way to revolutionize a publicly-traded company is to become part of it. By buying enough stock to qualify for voting membership, in other words, an investor affiliate can introduce proxy resolutions at shareholder meetings, and even better, win private meetings with the CEO and other top brass. Sell-offs and boycotts, while intermittently effective, only can go so far in reshaping corporate governance. And the ICCR by now has planted its flag at hundreds of companies.⁸

Founded in 1971 as a project of the National Council of Churches, the Interfaith Center occupies the same West Side Manhattan street address as the NCC: 475 Riverside Drive. The center's affiliate organizations include pension funds, mutual funds, foundations and churches. Each operates out of a desire to use assets as leverage to redirect corporate practices toward activities that presumably benefit all of society. They argue that corporations must operate under a new paradigm, one that puts human needs first and profits second. In its own words, ICCR "seeks to build a more just and sustainable society by integrating social values into corporate and investor decisions."

On the surface, the Interfaith Center on Corporate Responsibility would seem an unlikely source of influence. For the year ending December 31, 2006, total ICCR expenditures were only \$1.4 million, a figure comparable to previous years of this decade. Yet on this modest budget, the center coordinates activities among a wide range of shareholder activists and



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operates an effective clearinghouse to disseminate research. The center, guided by a 15-member governing board, coordinates efforts with investor affiliates to target industries and companies for pressure. Like Jesse Jackson's Rainbow/PUSH Coalition, the Association of Community Organizations for Reform Now (ACORN), and other radical nonprofit activist networks, ICCR investors aren't afraid to identify and negotiate with companies whose practices they deem morally irresponsible. Interfaith Center activists devote much energy to setting up meetings with corporate officials and engaging them in "dialogues." In practice, these negotiations amount to an ultimatum: Repent or prepare for some bad publicity and potential stock price declines. And this is a means toward a larger goal of *systemic* change. Through discussions with target corporations, ICCR-affiliated investor groups believe they can produce commitments not only from them, but from the entire corporate world. It's a domino theory of conflict resolution.

Led by current Executive Director Laura Berry, the ICCR covers a wide range of policy issues. Working group areas include: Access to Health Care,

Contract Supplier System, Corporate Governance, Enabling Access to Capital, Environmental Justice, Global Warming, Promoting Human Rights, Violence & Militarization of Society, and Water & Food. The Access to Health Care working group is the main focus of this report, but it can't be separated from the other groups. ICCR sees each social problem as connected to others under a reigning capitalist ethical paradigm that encourages greed, negligence and recklessness. Moreover, exacting concessions to advance the objectives of one study area helps advance the objectives of other study areas. By demanding, for example, that pharmaceutical companies lower the price of drugs in the Third World, the Interfaith Center believes it is addressing human rights, corporate governance and contract supplier issues as well.

Interfaith Center pressure has two mutually reinforcing ends: 1) divestment from socially irresponsible activity; and 2) investment in socially responsible activity. Objectionable activity may include destruction of wildlife habitats, trade with countries with documented human-rights violations, and tolerance of inter-

nal corruption. Desired alternative activity may include reduction of underwriting standards for loan eligibility among low-income borrowers, investment in water-purification plants, and support for community-education and adult-literacy programs. The organization's early years were concentrated in the first area, as the ICCR spearheaded highly-publicized campaigns to oppose nuclear power, block Nestle's marketing of allegedly tainted infant bottle formula in developing countries, and urge corporate divestment from (apartheid-era) South Africa. The focus since has shifted toward promoting desirable activity. But whether the focus is on cursing the darkness or lighting a candle, the goal remains the same: a transfer of key decision-making from company officials to insurgent Left-leaning shareholders. Shares of stock are the bargaining chips.

Major corporations usually offer stock for sale. As publicly-traded entities, they are susceptible to outside pressure. Fully aware of this, ICCR affiliate investors have devised various techniques to apply pressure. They include dialogues, letter-writing campaigns, public-relations campaigns, boycotts and shareholder resolutions. The latter play an especially prominent role. In 2006, center affiliates sponsored a combined 258 proxy resolutions at 163 companies on issues ranging from environmental practices to executive compensation to employee ethnic diversity. The ICCR also has been at the forefront of many "corporate campaigns," which are highly coordinated multidirectional attacks upon a particular company to protest supposedly offensive practices. Working with labor, civil-rights, public-health, religious and environmental organizations, the Interfaith Center

tries to pressure companies, in potentially visible and embarrassing ways, to discontinue certain practices and/or adopt new ones.⁹ Whatever the tactics, the goal is a permanent shift in the structure of corporate governance.

Shareholders as Stakeholders: A Theology of Corporate Governance

The Interfaith Center on Corporate Responsibility from the start has been a hybrid of religious and economic doctrine. Founded by a coalition of Christian clergy and laymen,¹⁰ the ICCR sees corporations, left to their own devices, as rogue entities. Corporate success is attributable to base instincts wholly at odds with great religious teachings, most of all those of Christ. As such, argue shareholder activists, people of religious conscience have an obligation to realign corporate priorities and practices. While the idea of morally sound investing has roots among colonial-era Methodists and Quakers, in modern form it emerged in the early 1970s with the founding of the ICCR. The Interfaith Center made an impact. By 1980, *Fortune* magazine would cite ICCR as a "confluence of radical Christian and Marxist thinking."¹¹ The center today likely would eschew the word "Marxist" in favor of "progressive," but its grievances against capitalism remain real and far-reaching.

The ICCR views business and the general public as part of the same economic "church." As business must exhibit a conscience in its dealings, the center believes, the public has an obligation to invest only in businesses that display a conscience. In this way, they can encourage other, less enlightened businesses to turn away from moral squalor. More so than laws, which are perennially subject to co-optation or

evasion, shareholder insurgency is the best antidote to corporate irresponsibility. In its absence, a corporation will ravage the environment, exploit workers, cheat consumers, threaten public health, and even wage covert war against indigenous peoples.¹²

Clergy and laymen of the Religious Left provide *theological* ammunition. PBS commentator Bill Moyers, an ordained Baptist minister who four decades ago served as President Lyndon B. Johnson's press secretary, is a prime example. In a June 2007 speech before the United Church of Christ General Synod at the Hartford Civic Center, he likened contemporary America to corporate-occupied territory:¹³

You have raised a prophetic voice against the militarism, materialism, and racism that chokes America's arteries. It's a mystery to me. Jesus said, 'Let the little children come to me'...You have to wonder how this so-called Christian nation leaves so many children to suffer...For 30 years, we have witnessed a class war fought from the top down against the idea and ideal of equality. It has been a drive by a radical elite to gain ascendancy over politics and to dismantle the political institutions, the legal and statutory canons, and the intellectual and cultural frameworks that checked the excesses of private power.

This private power, Moyers emphasized, came about as the result of "corporate activism," "intellectual propaganda," "the rise of a political religion of fundamentalism" and "a series of political decisions favoring the interests of wealthy elites."

Other Religious Left commentators endorse this view, with an eye toward a morally sound asset portfolio. The Unitarian Universalist Association, an ICCR affiliate, made this appeal to members early in the decade:¹⁴

Before socially responsible investing, we would pray for peace on Sunday, and invest in war on Monday through Saturday. There were painful contradictions around espoused values and then what really happened to investment of dollars. In your congregation, ask whether

the leaders of the congregation feel that moral imperative to do that kind of examination. Then take steps to make an approach that is sensible and can work. Create a working group that is broadly constituted—people from social responsibility, from finance committee, and with investment experience.

In the same spirit, Ted Ketcham, editor of the Santa Fe, N.M.-based *Green Money Journal*, argues that coaxing greedy, irresponsible corporations into changing their ways affirms the Scriptures. Citing the Apostle Paul's admonition against "sordid gain,"¹⁵ Ketcham notes that the phrase, originally intended to serve as a guide to choosing leaders of Christian communities, also could serve as a guide to investing with a conscience.

Now corporations always have had outside critics. The public inevitably will have concerns over how companies do business. Indeed, a company needs critics, whether they are consumers, employees, shareholders or community leaders. Accepting criticism may lead to decisions that improve profitability. The location of a new manufacturing plant or the introduction of a new life-saving drug may have harmful impacts that a company's officials should know about in advance. Entry into a previously untapped market might boost company growth. Highly successful CEOs in recent years such as Jack Welch (General Electric) and Lou Gerstner (IBM) have touted the importance of soliciting constructive criticism. They know that today's complaints may form the basis for tomorrow's innovations—or at least the avoidance of tomorrow's headaches.

Socially Responsible Investing operates from a different frame of reference. In the view of its advocates, corporations have to go beyond simply taking advice; they must cede decision-making authority to SRI activists,

presumably better attuned to frustrations and aspirations of the larger world. Corporations effectively must *give up the idea that they have a right to maximize profits or even necessarily keep them*. The ICCR and its affiliates aren't just critics of free enterprise, they are decidedly unfriendly ones.

The business world is by nature competitive. To win requires an economic calculation that appears to SRI activists as morally rudderless. To them, business habitually takes moral shortcuts in the search for profit, inflicting serious damage upon the world in the process. Even honest businessmen, left to pursue their own interests, will look the other way. Ethical persons and communities the world over, most of all here in the U.S., therefore must persuade companies that their continued profit depends on shifting toward responsible priorities.¹⁶ And the ICCR and other Religious Left organizations are determined to redefine "responsible."

Such activists claim they don't oppose profits per se, merely the rogue manner in which they normally are made. Yet the distinction is less than clear. For in accusing business leaders of failing to adopt basic humanitarian, civil rights, health care, environmental and other standards, they are calling into question their right to run their own companies. Steven Schueth, a former chairman and president of an SRI group, Social Investment Forum, defines responsible investing this way: "Generally, social investors seek to own profitable companies which make positive contributions to society."¹⁷ Such a definition merely raises questions: Why should a company already have to be profitable in order to be a legitimate investment opportunity? And what is a "positive" (as opposed to a "negative") contribution to soci-

ety? Such activists are saying rather palpably that a firm's obligations to the public take precedence over its obligations to shareholders.

In opposition to shareholder primacy, the activists have devised their own term to describe the larger social sphere that ought to rule: **stakeholders**. "A stakeholder," wrote environmental activist Harry Van Buren in a recent Interfaith Center report, "can be defined as any group or individual who can affect or who is affected by a firm's activities. There are lots of stakeholders to consider, including employees, communities, stockholders, suppliers, governments, and activist groups."¹⁸ That would seem to cover a lot of ground. Common sense dictates that it is self-anointed *spokesmen* for affected individuals and communities who make demands on behalf of stakeholders. ICCR-affiliated shareholders fit the bill here. They can rattle corporate cages from the inside in ways that as mere outside "protestors" they cannot. They especially can speak for persons whom Van Buren calls "dependent stakeholders," those with legitimate and urgent claims, but who lack recourse to satisfy them.

But Socially Responsible Investing has a far-reaching set of goals separate from those sought by conventional shareholders. After all, if all those other stockholders haven't been able to steer companies toward a straight and narrow moral path, then someone else has to do the job. "Stakeholder... is leftspeak for representatives of employees, consumers and environmentalists," recently wrote social critic Keith Windschuttle. "In other words, instead of corporate boards being elected by and accountable to the majority of their shareholders, the Left wants them to be dominated by

trade unionists, consumer advocates and Greens.”¹⁹ Call it a Trojan Horse strategy, but SRI investors, armed with intense moral conviction, are entering the gates of corporate America with the intent of conquering it—one resolution and dialogue at a time. As SRI investor capital reached \$2.3 trillion in 2005, roughly 9 percent of all professionally managed assets that year, they are a force to be reckoned with.²⁰

The Interfaith Center on Corporate Responsibility sees morally-grounded business decisions as requiring extensive input from stakeholders. Dialogues and shareholder resolutions are crucial to altering corporate behavior, whether (to use two recent examples) to persuade Bed Bath & Beyond to hire more minorities and women for managerial positions or to coax Bristol-Myers Squibb, Pfizer and other pharmaceutical companies into adopting “voluntary” restraints on raising prescription drug prices. Companies must feel the heat whenever possible, even if that means delaying or canceling certain decisions. Should a corporation yield, its concession(s) must be understood only as a good first step. Oddly enough, companies are learning to acquiesce.

Ford Motor Company offers a recent case in corporate fecklessness. Sister Patricia Daly, executive director of the Tri-State Coalition for Responsible Investment, a Montclair, N.J.-based alliance of Catholic institutional investors that works closely with ICCR, filed a proxy shareholder resolution calling for the automaker to address how its product fleet may be creating greenhouse-gas emissions and to develop fuel-efficient alternatives. Ford agreed to meet the demand, whereupon shareholders withdrew the resolution. Yet the company, shaken by the possibility of further proposals, went the extra mile, publishing the proposal

and its response. Daly was filled with praise for her newfound partner. “We congratulate Ford for leading the U.S. auto industry in responding to shareholder concerns by addressing a variety of climate change-related policy and business scenarios,” she said.²¹

This case amply summarizes the modus operandi of the shareholder Left—targeting, dialogue, victory, flattery, partnership. Desiring to eliminate moral corruption, activists want to transform the corporation into a vehicle for radical social change. For them, a corporate decision is a social decision, and as such, a CEO and other company officials should consult the larger society before making it.

Health Care Price Controls: Who Pays The Bills?

ICCR Campaigns for Drug Price Containment

The Interfaith Center on Corporate Responsibility has poured much of its energy over the last decade into its Access to Health Care Working Group. In 2006, 32 of the 258 proxy resolutions filed by its affiliates pertained to health care. The center has placed much of its focus on making available drugs to combat Acquired Immune Deficiency Syndrome (AIDS) in developing countries. At the XVI International AIDS Conference that year in Toronto, ICCR released a monograph, *Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets*.²² This report rated the world’s top drug companies on their provision of “access” to medicines.

The center followed up this effort with a series of initiatives. ICCR members worked with Bristol-Myers Squibb, Gilead Sciences, Boehringer-Ingelheim and other major drug

companies to create new technology-transfer and voluntary-licensing agreements to speed generic production of life-saving medicines. The center also worked with nonprofit activist groups such as Oxfam America and the Ethical Globalization Initiative. The ICCR and Boston Common Asset Management released a report titled, *How & Why: Corporations Responding to AIDS*, a compilation of best practices among oil & gas, beverage, technology and consumer products companies. The study provided, in the words of ICCR, “a clear roadmap for engaging companies operating in India, China, Southeast Asia, and sub-Saharan Africa who are facing substantial AIDS and other public health risks.”²³ Daniel Rosan, until recently the ICCR program director for public health, explained his organization’s position following a month-long fact-finding tour of Botswana, Kenya and South Africa:²⁴

Corporate reactions tend to be late, relatively small, and driven by a small number of dedicated people who may or may not be creating sustainable programs. There is a clear benefit for corporate programs begun by employees acting in response to the AIDS crisis in their communities.

But eventually, corporate Boards and headquarters need to step in and provide strategic direction for their companies. Otherwise companies will not create long-term programs, and will spend decades playing catch-up to the AIDS pandemic, instead of being part of the global effort to end it.

The endgame of SRI activists is to create in developing nations an ongoing de facto price control program for prescription drugs. They argue, from conviction if not from sound economics, that millions of adults and children in African and other Third World countries will die needlessly from AIDS and other illnesses because the price of drugs is set out of reach. It is nothing short of immoral, the ICCR and its allies argue, that major

pharmaceutical companies rake in large profits while allowing the most vulnerable to suffer and die. Shareholders in pharmaceutical companies involved in AIDS research and development have a fiduciary duty to alter company practices.²⁵

ICCR shareholders are calling upon pharmaceutical corporations to produce and make publicly available studies on the economic impact of HIV/AIDS and their own institutional steps to lessen the incidence and impact of the disease. Their appeals have not fallen on deaf ears. If anything, corporate leaders have been accommodating. On December 6, 2004, for example, Mary Ann Gaido, a spokesperson for St. Joseph Health System, a Catholic health care ministry of the Sisters of St. Joseph of Orange, California, read a shareholder resolution that St. Joseph and ICCR (on whose governing board she serves) had filed with the Ford Motor Company. The result was a decision by Ford management to prepare a report on what it plans to do about HIV/AIDS.²⁶

It is not just about doing the right thing for people who are living with HIV and AIDS. Frankly, it is about doing the right thing for us—for shareholders. HIV and AIDS is an emerging market risk. And denial is not a risk management strategy.

That is why St. Joseph Health System and ICCR took action. That is why St. Joseph Health System and ICCR took action. As a shareholder, we filed a shareholder resolution with Ford Motor Company asking for a report on the economic impact of the HIV/AIDS Pandemic, and a report on what Ford is doing about it.

Essentially, we asked for the report—the report that Ford is releasing this morning. And we asked them to do better, and to raise the bar for corporate America.

Rosan followed with these flattering words:²⁷

So I have a great deal of confidence when I say that Ford Motor Company's commitments today make it a leader in the fight against

HIV and AIDS. Not an industry leader. Not a regional leader.

Today, Ford becomes a truly global leader in the fight against HIV and AIDS.

Over the next months and years, ICCR will work with Ford to ensure that Ford's HIV and AIDS programs are world-class, and stay world-class, for as long as HIV continues to threaten Ford's workforce, its markets and shareholders....Now ICCR will be asking of other companies, "Are you doing your part?"

A couple years later, ICCR extracted a commitment from Wal-Mart to promote another initiative near and dear to the center. On February 7, 2007, the Interfaith Center lauded the world's largest retailer as a team player in its "Better Health Care Together" shareholder resolution campaign. This campaign is designed to achieve universal health coverage in this country by 2012. ICCR affiliates, owners of more than two million shares of company stock, believed that they could push Wal-Mart into a declaration of support for expanded government funding for health care. True to form, current ICCR Board Chairman Margaret Weber, director of the Michigan-based Adrian Dominican Sisters, used flattery. "Wal-Mart did not challenge this proposal at the Security (sic) & Exchange Commission, but rather has constructively engaged with unions, businesses, shareholders, and others to develop a set of Common Sense Principles for reforming the US health system," she said. "These principles serve as a basis for fundamental, systemic change and closely mirror principles articulated by ICCR's Access to Health Care working group."²⁸ She ruefully added that the other six companies with whom it had filed similar shareholder proposals—Ford Motor Co., Kohl's Department Stores, General Motors, Macy's (formerly Federated) Department Stores, Target, and 3M Corp.—each decided to challenge the resolution. The SEC later ruled

that five of the companies could omit the resolution. As an act of poetic justice, only Ford, the very company ICCR's Rosan had praised in 2004 as a "global leader" in the fight against AIDS, was denied permission.²⁹

The ICCR has made clear its intention to extract commitments from pharmaceutical companies to sell AIDS drugs at prices far below market levels, effectively creating a large subsidy from the U.S. to developing nations. For them, a "responsible" company is one that recognizes that saving lives takes precedence over maximizing revenues. The ICCR and affiliate investors cannot accept the possibility that the logic of the market is what enables companies to develop and sell life-saving drugs in the first place. Moreover, they are issuing a veiled threat. The ICCR believes that if the pharmaceutical industry will not voluntarily lower prices to desired levels, then government ought to step in and do the job, either through establishing price ceilings, replacing private-sector price negotiators, or canceling existing patents. They especially are supportive of legislation that would authorize our federal government to serve as a purchasing agent, directly negotiating with Health Maintenance Organizations (HMOs) and pharmaceutical companies to lower the price of drugs. At present, the Medicare program does not operate in this manner, though Department of Veterans Affairs (VA) health plans do.

The Interfaith Center and its affiliates are possessed of an unwavering conviction that adequate health care by U.S. standards, whatever the cost, is a universal right. Every corporation, including those outside the health care sector, must do its part. Offering health benefits to all full-and part-

time employees is merely a start. More importantly, a company ought to support legislative and other measures that drive down the price of medicine for those who cannot afford it. The issue of who pays, and how much, is of secondary importance. To the ICCR, economics is more about moral absolutism than costs and benefits.

Drug Price Controls: The Consequences of Good Intentions

It has become a growing article of policy wisdom that U.S. drug companies charge far too much for patented drugs, and in the process, cause untold hardship for people here and abroad. Americans alone spent \$274 billion on prescription drugs in 2006, an increase of 82 percent since 2000.³⁰ The antidote to this untrammled greed and profit are price controls of one kind or another. In the October 17, 2000 presidential debate in St. Louis, Al Gore stated: “I have never been afraid to take on the big drug companies... They’re trying to artificially extend the monopoly so they can keep charging high prices. I want to streamline the approval of generic drugs so that we bring the price down.”³¹ Health and science journalist Merrill Goozner calls for aggressive enforcement of “reasonable pricing” applying to any National Institutes of Health (NIH)-funded research that leads to patents and commercial distribution, arguing, “We need legislation to ensure that publicly funded innovations are broadly available at moderate prices.”³² And the *New England Journal of Medicine*, a flagship periodical of the American medical profession, expressed this position in an editorial:³³

The pharmaceutical industry is extraordinarily privileged. It benefits enormously from publicly funded research, government-granted patents,

and large tax breaks, and it reaps lavish profits. For these reasons, and because it makes products of vital importance to the public health, it should be accountable not only to its shareholders, but also to society at large.

Not only do health care firms charge too much, critics charge, but they have bought Congress to make sure things stay that way. Companies and trade associations now spend more than \$100 million a year on lobbying and campaign contributions to keep industry profits remain high by any means necessary.³⁴

It’s odd that the drug industry continues to be subject to charges of making “obscene profits,” given its recent hard times.³⁵ During the period 2002–06, the industry brought to market 43 percent fewer new chemical-based drugs than during the second half of the Nineties, despite a more than doubling of R&D spending. In December 2007, Bristol-Myers Squibb announced plans to cut 10 percent of its work force and close or sell about half of its 27 manufacturing plants by 2010. In October 2007, Moody’s Investors Service, which rates about \$90 billion worth of pharmaceutical-firm debt, lowered its outlook for the U.S. drug industry from “stable” to “negative.” And during 2011–12, projects the research and consulting firm Datamonitor, industry revenue will decline, the first such decline in at least four decades.

The Interfaith Center on Corporate Responsibility and its affiliates aren’t deterred by such indicators. In 2000, an ICCR-sponsored coalition of shareholders in 10 pharmaceutical companies weighed in with resolutions calling for restraining prices for retail customers. “Concern about the high price of prescriptions for those who are un-insured or under-insured inspired these resolutions,” said Regina Murphy, then-director of the

ICCR’s international health program. “As it is, people are having to choose between food or other necessities and needed drugs.”³⁶ Several years later, the ICCR-affiliated Evangelical Lutheran Church in America, issued a policy paper, “Domestic Access to Health Care,” establishing 10 resolution guidelines for investors. Guideline Two reads: “We support a report on the company’s initiatives to create, expand, and implement policies and programs to extend pharmaceutical accessibility, taking into account the costs and benefits.” Guideline Three reads: “We support reports disclosing the extent and types of payments, incentives, or rebates that are made to doctors, pharmacy benefit managers, and other pharmaceutical purchasers in order to influence the selection of a particular drug.”³⁷

From the ICCR’s perspective, the concerns of stakeholders take precedence. And stakeholders want price controls—or so it would seem. A recent Kaiser Family Foundation poll indicated that 65 percent of respondents favored legal limits on drug prices, with 46 percent of those in favor saying they would prefer controls even at the expense of research and development.³⁸ But popularity and soundness are two different matters. Even assuming that the critics of drug pricing are possessed of selfless intentions, it is unlikely their campaign, once put into place, would benefit those on whose behalf they speak.

The market for prescription drugs, like the market for air travel, phone service or housing, is a testament to the millions of daily interactions between buyers and sellers seeking to maximize competitive advantage. Consumers pay an advertised price for medicine because they believe

they are better off after the purchase, even if they would have preferred to pay a lower price. Likewise, producers charge a price less than what they would like to, but high enough to be profitable. If government intervenes on behalf of consumers to drive down prices, it is presuming knowledge about an “appropriate” price. To render a firm less able to recoup the costs of production through the price mechanism diminishes the willingness of the firm to continue production at present levels, if at all.

Prescription drugs are not exempt from this market logic. If pharmaceutical companies are forced, directly or indirectly, to charge less than what they consider revenue-maximizing prices for certain drugs, they will respond by developing or selling other, possibly less effective drugs. The up-front investment to develop, test and bring a new brand-name drug to market is enormous, even when it does not directly involve Food and Drug Administration (FDA) regulations. Advocates of Socially Responsible Investing, unfortunately, see this as a secondary consideration. What matters most is *price minimization*, a strategy that enables the poorest consumers to afford items for sale. The result supposedly would be a healthier society, and without selfish profiteering by drug companies and distribution networks. The evidence, however, strongly suggests that pharmaceutical price controls, here and outside the U.S., have produced serious negative consequences.³⁹

One argument made by advocates of price controls is that they would allow consumers to spend less money on drugs, and thus would have more money left over for other necessities of life. Such a view, however, overlooks the possibility that drugs have a

long-range preventive effect. In other words, by paying more today for “overpriced” drugs, health-care consumers may be avoiding greater physician and hospital expenses, including surgery, later on.

Empirical evidence supports this view. A paper by Columbia University’s Frank Lichtenberg for the National Bureau of Economic Research concluded that each \$1 increase in spending on drugs was associated with a \$3.65 reduction in hospital-care expenditures.⁴⁰ A 1999 report by the Boston Consulting Group noted that in 1977, when the brand-name acid-blocking drugs Tagamet and Zantac were introduced, surgeons in this country performed about 97,000 operations for peptic ulcers. Yet by 1987, the figure had fallen to less than 19,000. By 1990, the annual cost of a patient’s ongoing drug therapy was a mere \$900, compared to \$28,000 for each surgical intervention.⁴¹ And American Enterprise Institute resident scholar John Calfee in his book, *Prices, Markets and the Pharmaceutical Revolution*, noted that anti-schizophrenia drugs costing \$4,500 per year actually reduce annual institutional treatment costs by more than \$70,000. Additionally, he pointed out, drugs designed to break apart blood clots cut hospital and rehabilitation costs for stroke victims by about four times the cost of the drug.⁴²

Perhaps even more importantly, long-term savings also can be measured in life extension. In a study of 1,100 patients, Humana Hospitals discovered that drugs designed to combat congestive heart failure, aside from cutting hospital costs by 78 percent, reduced the death rate from 25 percent to 10 percent.⁴³ The Boston Consulting Group reported the following declines in diseases treated with pharmaceuticals over the period 1965–96:

rheumatic fever/rheumatic heart disease (83 percent); atherosclerosis (74 percent); stomach ulcers (72 percent); ischemic heart disease (62 percent); emphysema (57 percent); and hypertension (21 percent).⁴⁴ Columbia University’s Lichtenberg, analyzing data for the period 1991–2004, concluded that the strongest factor associated with improved life expectancy was the availability of newer drugs. He found that longevity increased most of all in states where access to newer drugs—measured by “vintage” (i.e., year of FDA approval)—was highest. Lichtenberg calculated that a one-year advance in overall drug vintage was associated with a two-month gain in life expectancy. In other words, if a Medicare patient with a particular condition had bought a drug approved in 2002 rather than in 1998, he or she would have lived on average an extra eight months.⁴⁵

Life extension, even more than cost-savings, can be seen as the end of improved drug treatment, a point that AEI’s Calfee makes. “The ability of pharmaceuticals to reduce the total expenditures for health care, as well as business costs, is important but secondary,” he wrote. The primary benefit is that “patients and consumers...are gaining...better health, longer life, reduced pain and discomfort, and other blessings.”⁴⁶

Forcing down prices would have an even more baneful consequence: *Drug manufacturers would have less incentive to develop new drugs.* The European experience, far more a product of price controls than our own, is instructive. In a study published in the early Nineties, the U.K. National Heart and Lung Institute concluded that roughly 90 percent of Europeans who had experienced heart failure and were candidates for receiving ACE-

inhibitors in fact had not received them, despite the demonstrated ability of these drugs to prevent second heart attacks and left-ventricle dysfunction. In France, where the figure also was around 90 percent, the estimated toll of shortages over four years was 16,000 lives and \$528 million.⁴⁷

Other international studies also suggest that price controls have adverse effects. In 2004, the U.S. Department of Commerce conducted a study of 11 member countries of the Organization for Economic Cooperation and Development (OECD) that rely heavily on government fiat to set prices. The report found that price controls in these nations (there are 30 OECD countries in all) caused a \$5 billion-to-\$8 billion reduction in funding for drug research and development. Restoration of such funding “could lead to three or four molecular entities annually.”⁴⁸ That’s no small reason, for example, why 57 percent of British men and nearly half of French and German men who get prostate cancer will die from it. In the U.S., by contrast, the figure is only 20 percent.⁴⁹ In April 2006, the American Enterprise Institute’s John Calfee, Mario Villarreal and Elizabeth DuPre reported that prescription prices of 43 drugs were substantially lower in Australia, Canada, France, Germany and Great Britain than in the U.S., but that this finding only applied to less-unique drugs; i.e., those readily available over the counter and subject to strong competition.⁵⁰ With highly unique drugs, by contrast, relative prices were proportional to per-capita GDP, if not higher. “Our results,” the researchers stated, “suggest that price controls operate to blunt these incentives for follow-on drug research, leaving most of the burden to U.S. purchasers. Because these follow-on R&D results are often extremely

valuable, the implications merit substantial concern.”

Studies examining the impact of price controls solely within America have yielded similar conclusions. A few years ago the Manhattan Institute’s Center for Medical Progress estimated the effect of price controls on pharmaceutical industry investment in research and development. Using various benchmarks for controls, such as those practiced by Europe countries and by our own Department of Veterans Affairs, the authors estimated that R&D spending would drop by almost \$300 billion, or nearly 40 percent, over the following two decades. This, the researchers estimated, translates into a loss of 277 million life-years.⁵¹ That is the chief reason, noted the center’s then-director, Robert Goldberg, why U.S. biotechnology and pharmaceutical firms during the course of 2003 *increased* R&D investment by 16 percent, whereas their European counterparts *decreased* investment by 2 percent. That is also why Europe has more biotech firms than us, yet we account for 75 percent of worldwide biotechnology revenues, 75 of R&D expenditures, and 80 percent of key patents.⁵²

John Vernon, professor of finance at the University of Connecticut, has been especially prominent in debunking the case for price controls. He and colleague Joseph Golec in 2006 published a paper concluding that R&D spending among European Union drug companies grew at a real annual compounded rate of 5.4 percent during 1986–2004, well below the 8.8 percent rate among U.S. companies. The authors argued that while EU price controls did reduce inflation, they also led to 46 fewer medicines and 1,680 fewer research jobs.⁵³ In a separate study, Vernon and Thomson-

Medstat-USA’s Thomas Abbott concluded that if prices were fixed at 40 to 45 percent below market levels, the number of compounds moving from laboratory to human trial would decrease by 50 to 60 percent. “Because of the uncertainties involved,” observed the authors, “fewer compounds moving into clinical trials directly translate into fewer new products—the effects of which wouldn’t be fully felt for several decades because of the long development cycle. Moreover, because of the spillover effects of R&D, less activity today reduces the possibilities for new opportunities in the future.”⁵⁴

In yet another study, Professor Vernon used nationwide data from 1960 to 2000 to simulate consumer outcomes under an assumption of a hypothetical drug price control policy that limited price increases to the rate of inflation during 1981–2000. He found that consumers would have had an extra \$472 billion on hand by the end of 2000. That looks impressive on the surface. But such a policy, the author cautioned, would have led to 198 fewer drugs brought to market in the U.S., an average opportunity cost of \$2.4 billion per drug.⁵⁵

Where price controls don’t prevent the launch of new drugs, they are likely at least to delay it. A multinational study released in 1999 by the Boston Consulting Group concluded that government interference resulted in delays in approved drugs reaching the marketplace. The authors observed: “Greece, Belgium, and France, countries with considerable market intervention, have the longest delays between product approval and marketing, whereas Germany, Norway, the U.S. and the U.K., countries with relatively less intervention, have the fewest delays.”⁵⁶

Here is a good way to summarize all these findings. Price controls make today's life-saving medicine more affordable. But they do so by discouraging the development of *tomorrow's* medicine. The politically attractive short-term benefits are visible; the long-run costs are a good deal less so. But unintended consequences seem to be of little interest to the ICCR and its affiliates.

Government Price Negotiation as Price Control

Price-control advocates in this country may favor formal ceilings, but as a bow to political reality, they have focused most of their efforts on authorizing, and better still, mandating direct government negotiation. More than anything else, they want the U.S. Department of Health and Human Services (HHS) to replace private entities as the negotiating agent for achieving price discounts from drug companies. To understand why this course of action would be poorly advised, it's necessary to understand the rudiments of negotiation generally.

The drug industry is highly circumscribed by price negotiation, a process which though informal, follows a recognizable protocol. Each party establishes a limit—known as the “walk-away” price—that defines the bounds of acceptability. For the seller, this price is expressed as a minimum; for the buyer, it is expressed as a maximum. Negotiation is about feeling out extremes and then getting to a mutually acceptable point. If a producer, for example, says flatly he will not sell his product below \$100 per unit, while the buyer is adamant about not paying a penny more than \$60 per unit, all subsequent negotiation represents an attempt to arrive at an agreement within the \$60–\$100



Source: bigstockphoto

range. Each side has an interest in yielding ground, though not *too* quickly, to reach a compromise.

All negotiated decision-making follows this logic. Anyone familiar with how labor-management talks operate, for example, knows that a union and an employer begin with widely divergent demands, but gradually yield ground, fearing a possible strike or lockout. The world of prescription drugs is no exception. Moreover, its main focus is on the demand side. “(P)atient reactions,” observes The Heritage Foundation’s Edmund Haislmaier, “inevitably shape and limit the negotiating freedom of those who

negotiate on their behalf. This means that the ‘buy side’ negotiators must always be mindful of how patients will react to their decisions, lest their actions produce a consumer response that undermines their negotiating strategy. Indeed, they must also be sensitive to the possibility that the ‘sell side’ negotiators could spark or encourage such a consumer reaction as a way of altering the negotiation parameters in the sellers’ favor.”⁵⁷

Because the pressure that government faces is more political than economic, its incentive is not to maximize profits, but to please constituencies. Hence, government negotiators have

every reason to prolong the process, *even when it is clear that the delay may be preventing the marketing and sale of life-saving drugs.* The Boston Group concluded as much:⁵⁸

One of the causes of such delays can be negotiation over price. Interviews with industry leaders confirmed that the time it takes to negotiate pricing was increasingly the bottleneck in launching new medicines. While governments try to achieve the lowest possible price, and companies hold out for a price they will accept, large segments of the population that may benefit substantially from the new treatments are left waiting. The problem is particularly acute in Europe, where parallel trade and cross-country reference pricing can cause uneconomically low prices to spread between countries.

Supplanting the private sector in the process could result in less research and development of life-saving drugs, especially for the most vulnerable populations.

The Interfaith Center and its network of shareholders take a much different view. What they want at minimum is legislation that would authorize, and better yet, mandate the Department of Health and Human Services to negotiate drug prices under Medicare Part D; i.e., to require what the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173) explicitly bans.⁵⁹ Private-sector negotiators, also known as Pharmacy Benefit Managers (PBMs), the ICCR argues, operate as avaricious middlemen, taking hefty cuts for themselves, leaving the elderly and disabled at the mercy of the marketplace. With an estimated 43.7 million people now enrolled in Medicare, argue progressive investors, the time is now for legislation to give HHS the authority to take private greed out of negotiation.⁶⁰

These activists lately are relying heavily on a study sponsored by Families USA.⁶¹ The Washington, D.C.-

based nonprofit health-care research group sought to evaluate the imposition of the act's "non-interference" clause after one year. Families USA analyzed prices for the 20 drugs most frequently prescribed to seniors among the five largest Part D insurance plans—United Healthcare, Humana, WellPoint Unicare, Member Health and WellCare. These plans accounted for more than 9 million enrollees. The study found that for each of the top 20 drugs prescribed, the lowest price charged by any of the five insurers was still higher than the lowest price secured by the Department of Veterans Affairs, which does allow for direct federal negotiation. Moreover, as a median, the lowest Part D plan price was 58 percent higher than the lowest VA price, with differences in some cases being far more dramatic. For the lipid-reduction agent, Zocor (20 mg), the lowest VA price for a year's treatment was \$127.44, while the lowest Medicare Part D price was \$1,485.96, or 1,066 percent higher. And for protonix (40 mg), a generic gastrointestinal agent, the lowest VA and Medicare prices, respectively, were \$214.52 and \$933.88. These are whopping differences, large enough for the ICCR and its allies to cast the pharmaceutical industry as a rogue entity at odds with the public interest. Government, say critics, has a responsibility to disrupt the pursuit of excess profit on behalf of people in need.

This is an emotionally satisfying understanding of reality, one pitting the forces of virtue, "the people," against opportunistic middlemen raking in unconscionable fees and passing the cost along to the manufacturer and ultimately the consumer. But Pharmacy Benefit Managers, who represent more than 3,000 private-sector national, regional and

local health plans, should be seen in a different light. Like stock brokers, real estate brokers and sports agents, these middlemen are in the business of increasing the range of information to buyers and sellers. In the pharmaceutical industry, knowledge is power—a power that works on behalf of consumers.

It isn't simply industry forces who question the wisdom of requiring HHS to negotiate for prescription drug purchases in the Medicare program, which amount to about 60 percent of all U.S. purchases.⁶² A few years ago, the Congressional Budget Office (CBO) issued a statement in response to an inquiry by Sen. Bill Frist, R-Tenn., himself a trained physician, indicating that striking the non-interference clause would have "a negligible effect on federal spending."⁶³ CBO Director Douglas Holtz-Eakin went even further in January 2004 Senate testimony:⁶⁴

If you put in a provision and language into a bill as passed which said the (Health and Human Services) Secretary 'should' or 'must' negotiate, we think there is the potential for savings in some drugs, presumably the non-preferred drugs...But given bottom lines, to the extent that you move down the prices on one drug, you probably move up the prices on the preferred drugs, and on balance, you could raise costs.

Holtz-Eakin's message was clear: Government-negotiated pricing not only would not lower prices, *but in all likelihood might raise them.* A little over a month later, he reiterated this point in a letter to Sen. Ron Wyden, D-Ore., indicating that there would be "little, if any, potential savings."⁶⁵

The Congressional Budget Office isn't the only source of skepticism over the wisdom of supplanting private with government negotiation. In late 2006, the Health and Human Services Department's Centers for

Medicare & Medicaid Services estimated that average premiums for the basic Medicare Part D benefit had fallen to an average of \$22 a month for seniors, well under the \$37 monthly figure that it earlier had projected the coverage to cost. The cost-savings, noted the researchers, was mainly due to strong competition and beneficiary choices. Moreover, beneficiaries were saving nearly \$1,200 annually on their drug costs.⁶⁶

So how is it that Pharmacy Benefit Managers manage to *lower* prices?⁶⁷ They do so in several ways.

First, managers take advantage of economies of scale. They have created large-volume mail order pharmacies to handle refills for long-term maintenance and drug therapies. What's more, they have developed retail networks through which enrollees can enter a service agreement. Under this kind of arrangement, a PBM steers patients to a particular pharmacy; in turn, the pharmacy reduces its per-prescription dispensing fee.

Second, benefit managers, with prior patient or doctor approval, can produce savings by substituting less-expensive for more-expensive drugs. This includes prescriptions for generic rather than branded drugs. Because patient or doctor approval is required, PBMs can devise "formularies" by which they can weigh costs and benefits. A formulary is a list of drugs within a therapeutic class, with each class ranked by preference. Effectiveness, side effects and cost all determine a drug's inclusion on a given list. And rendering judgment here requires expertise. To create and update its drug formulary, the PBM assembles a Pharmacy & Therapeutics Committee of physicians, pharmacists and other persons with clinical knowledge. The PBM then creates formulary-

preference incentives for doctors and patients, such as lowering patient co-payments for generic drugs and persuading pharmacists to call doctors for approval to make drug substitutions.

Third, by virtue of getting drugs included on a given formulary, Pharmacy Benefits Managers are more likely to obtain other price-reducing incentives. That is, if the PBM has a large market share, its programs to encourage drug substitution can be used as leverage to persuade drug manufacturers to offer further discounts or rebates. Even though drugs are not perfect substitutes for one another, armed with accurate information, doctors and patients can decide the extent to which their decisions are driven by cost considerations.

Fourth and finally, pharmacy benefit managers can reduce health care costs by instituting improvements in prescription and dispensing practices. Volume counts here as well as price. If a particular drug is more expensive but also more effective, its ultimate long-run cost may be lower than cheaper, but less effective alternatives. PBMs can derive reasonably accurate information through a process called "drug utilization review." Doctors and pharmacists may have accurate knowledge, but all too often it is a *partial* picture. Managers are in a position to see the picture whole, using information to improve the quality of care while reducing costs within the context of a comprehensive health insurance plan.

Unfortunately, the ICCR and other critics of close working relationships between pharmacy benefit managers, doctors and health-plan providers see inefficiency and possibly corruption in all this. In their haste to condemn the apparently incestuous networks that profit from patients, they overlook the inescapable reality that markets

require information to strike a balance between quality and cost. *And it is PBMs who are best positioned to gather and disseminate such information.*

Undaunted, Congress continues to push for direct federal negotiation. Led by House Speaker Nancy Pelosi and Rep. Henry Waxman, both California Democrats, the U.S. House of Representatives in January 2007 passed by a 255-170 margin the Medicare Fair Prescription Drug Price Act of 2007 (H.R. 4), requiring the HHS secretary to negotiate prices. But the Senate in April could muster only a 55-42 majority to invoke cloture (i.e., prevent a filibuster) in its bill (S. 3), well short of the 60 votes needed to bring a vote on its milder bill (which allowed rather than required federal negotiation) to the floor. "It's beyond me why the Senate would not choose to stand up for seniors," Senate Finance Committee Chairman Max Baucus, D-Mont., a bill co-sponsor, said afterward. Such a statement misstates the issue. Everyone, regardless of age, wants to stand up for seniors. The problem with Senator Baucus and legislators like him is that they deeply mistrust the capacity of markets to produce a beneficial set of results.

Federal Employees: Prime Beneficiaries of Private Negotiation

The irony of the opposition to private negotiation is that the federal work force long has enjoyed a system of privately-negotiated drug prices: the Federal Employees Health Benefits Program (FEHBP). This program provides health insurance through various networks for more than 8 million government employees, retirees and family members.

The evidence appears to weigh in favor of private negotiation. In 2002,

the General Accounting Office (now known as the Government Accountability Office) obtained prices for 18 drugs in selected states that three FEHBP plans paid to their Pharmacy Benefits Managers for retail and mail-order prescriptions, and then compared them to (non-PBM) prices paid at retail pharmacies.⁶⁸ The GAO found that average prices for 14 brand-name drugs negotiated through retail and mail order prices were, respectively, \$72.85 and \$64.44. By contrast, the average price for the same drugs without third-party coverage at three dozen selected pharmacies was \$88.59. In other words, private negotiation *reduced* prices by 18 and 27 percent. For four generic drugs, the cost-savings were even more dramatic. Average negotiated retail and mail-order prices were a respective \$7.86 and \$7.08, well below the pharmacy non-covered price of \$14.90.⁶⁹

Families USA and other supporters of government price negotiations for Medicare prescription drug contracts note that the Department of Veterans Affairs (VA) already uses federal negotiation on behalf of its 5 million beneficiaries. They point to the program's ability to generate low prices. A 2005 study by the Congressional Budget Office found, among other things, that the VA paid only 42 percent of the Average Wholesale Price—that is, the suggested list price—for single-source brand-name drugs.⁷⁰ On the surface, such a result would make a strong case for at least allowing government negotiation under Medicare. But on closer inspection, the program is based on a model that doesn't translate well either to Medicare or private practice, something the CBO itself admits.⁷¹

Briefly, the Veterans Affairs pharmacy benefit adheres to federal procurement rules. Manufacturers who

sell brand-name drugs listed on the Federal Supply Schedule (FSS) must offer the VA a price that is at least 24 percent lower than the non-federal average manufacturer price. Moreover, the VA is authorized to enter into multi-year contracts for other drugs, lowering the price to levels even below the discounted FSS rate.

The arrangement has at least three cost-cutting features that enable drug companies to pass their savings to customers. First, participating firms can more than offset the potential loss of revenues by picking up volume from non-participating competitors that produce substitute drugs. Second, because more than 75,000 doctors, residents, fellows and students each year receive some or all of their medical training at VA hospitals, drug manufacturers have a ready-made revenue base at those facilities. Indeed, this advantage is even more pronounced over the long term because medical students, once engaged in post-training practice, tend to prescribe according to patterns they picked up during their stay at a VA hospital. Third and finally, the VA receives a discount from its prime vendor of roughly 3 percent, or about 1.4 percent of the average wholesale price, for prompt payment.

So if this program structure is so sensible, why doesn't Medicare emulate it? The reason is that the VA program is set up to be wholly unique.⁷² First, the Department of Veterans Affairs uses a *closed* network of doctors, hospitals, and pharmacies working off a highly restricted formulary. And this formulary is available, for the most part, only through drug prescriptions from participating VA doctors and pharmacies. That is why less than a third of the drugs available to Medicare patients are available to

VA patients.⁷³ Second, only about 4 percent of prescriptions filled by the VA are off-formulary. Third, VA drug prices do not include administrative or service costs, which are covered separately in the VA budget. Finally, the VA keeps prices low by restricting drug choices and by filling 75 percent of its prescriptions through its own mail order system rather than through local pharmacies.

Transforming Medicare Part D into a VA-like program on the surface seems like a sound idea. But in practice it would necessitate creating restrictions on access to drugs, a strategy to which seniors repeatedly have expressed opposition.⁷⁴ And those restrictions in the end likely would not even lower operating costs.

The Guiding Reality: Economies of Scale

The pharmaceutical industry is marked by wide competition and high entry costs. Developing and bringing to the market even one life-saving drug requires an enormous up-front investment, both in time and money, to produce any returns. To impose controls on the price of the eventual product is tantamount to diminishing the incentive by the firm to develop and launch the drug. In 2006, America's drug and biotechnology firms spent \$55.2 billion on pharmaceutical development.⁷⁵ That kind of investment has paid off, at least relative to the rest of the world. In recent years, the U.S., where prices are comparatively uncontrolled, was responsible for more than 80 percent of the top 15 drugs in the world, and nearly 70 percent of all new drug sales.⁷⁶

The effort to bring these drugs, especially "miracle" drugs, to the marketplace involves a good deal of trial and error. That is why the final product

costs so much. An appropriate analogy would be oil or gas exploration, whose test drills inevitably yield far more “dry holes” than successes. Likewise, prices of the relatively few medicines that yield successful results represent the absorption of losses incurred during the entire exploration process. “As with public utility natural monopolies,” writes the University of Chicago’s Richard Epstein, “pharmaceutical products are characterized by an extremely high fixed cost to get a given product to market, coupled with a relatively low marginal cost for the production of additional units of the product.”⁷⁷ Alison Keith, a former science and policy director at Pfizer, put it similarly: “A pill is very small, so people have the intuition that it shouldn’t have a high price. But a better way to think about our medications is that they are small tablets wrapped around in huge envelopes of information.”⁷⁸

Even with government-supported research from the National Institutes of Health (which generally are not central to medical breakthroughs),⁷⁹ it’s a costly process from inspiration to assembly line. Tufts University’s Center for the Study of Drug Development in 2001 estimated that each new drug in this country takes roughly a dozen years to reach the market at a cost of \$802 million per drug.⁸⁰ This figure was up from \$54 billion in 1979 and \$231 million in 1991. In 2003, using a different methodology than the Tufts researchers, the Boston consulting firm Bain & Co. estimated the sum at \$1.7 billion.⁸¹ The Tufts study has been the target of criticism, most significantly by journalist Merrill Goozner, who alluded to the center’s 2001 report in his book, *The \$800 Million Pill*.⁸² He and other critics, including the Ralph Nader-founded advocacy group Public Citizen,⁸³ argue that a drug’s true

R&D outlay lies somewhere in the \$100 million-to-\$250 million range. But this criticism is itself questionable, for it examines the cost of developing that particular drug *by excluding all “dry holes” preceding it*. The Tufts researchers noted, in fact, that out of every 5,000 medicines undergoing initial tests, only five make it to clinical trial testing. And of those five, only one eventually receives FDA approval for patient use.

Critics of the drug companies counter that government subsidizes much of the research allegedly paid out of the drug companies’ pockets. The American people pay twice, first as taxpayers and then as consumers, generating outlandish profits for these firms. What’s more, the critics say, government researchers outperform their private-sector counterparts in terms of generating key discoveries. Too often, drug companies put their resources into semi-copycat, “me-too” drugs, especially when the patents for innovative drugs expire. The proliferation of close substitutes serves to inflate drug prices. Goozner has been particularly prominent in making this charge. From an analysis of FDA data and an interview with Tufts’ DiMasi, he concluded that roughly 40 percent to 50 percent of all private industry research is aimed at developing me-too drugs.⁸⁴ He concludes:⁸⁵

Research driven by scientific inquiry and public health goals, namely work funded by public agencies, is likely to produce a better use of scarce dollars than research driven by the entrepreneurial desire for market share. Drug companies have a legitimate role in bringing new medicines to market, but it would be better public policy to lower drug prices, even at the cost of deterring some private investment, and to rely more heavily on publicly funded research.

This statement misconstrues the process of innovation. For one thing, “me-too” drugs may be similar, but

that doesn’t mean they are identical. Tagamet and Zantac, for example, each treat acid-reflex stomach, but have different active ingredients. Second, companies aren’t so much copying as *competing with each other*; each firm wants to be the first to develop breakthrough medicine for a given illness or disease. The “winner” in this race is the firm that brings the drug to market. Third, copycat drugs, rather than inflating prices, lower them, providing differentiation of therapeutic substitutes. This is especially true as the time elapse between the appearance of a drug and its cheaper substitutes has become shorter. The new anti-depressant medicines that hit the shelves in the mid Nineties, Bailey notes, cost only 53 percent as much as Prozac did when introduced back in 1988.⁸⁶

Successful pre-clinical in vitro or animal experiments represent merely the beginning of the process of bringing a drug to market. The real challenge comes with human testing, which typically consists of three phases.⁸⁷ **Phase I** studies involve a few dozen healthy volunteer subjects. The purpose here is to determine how a drug is absorbed, distributed, metabolized and excreted by the body, and to identify any side effects, especially those associated with increased dosages. **Phase II** studies, assuming the previous phase has generated promising results, determine the scientific validity of the drug. They generate data on the effectiveness of the drug for patients with particular conditions, and help identify common short-term side effects. Closely monitored, these studies involve relatively small patient samples. If the company decides further research is desirable, it goes on to **Phase III**, which are expanded controlled and uncontrolled trials. This phase seeks to gain additional



data about the drug's effectiveness and safety, so as to serve as a basis for physician labeling. Whereas 20 to 300 persons take part in a Phase II trial, around 300 to 3,000 participate in Phase III.

The Food and Drug Administration supervises the whole process. Since landmark 1962 legislation, the FDA has had broad authority to review safety, efficiency, quality, and promotion of new drugs. All R&D must be in accordance with standards set forth by the FDA's Center for Drug Evaluation and Research. The center has the authority to halt any study it deems unsafe or unable to meet stated objectives, and it often hires outside advisors to conduct evaluations. It's a slow process, though the agency may expedite it for drugs with unusual promise or for diseases with no adequate cures at present. FDA is a complex bureaucracy,

subject to influence from political and peer-review forces and a temptation to arbitrarily exercise of authority.⁸⁸

The drug industry's alleged runaway profits should be seen as mainly the result of a high front-end investment. Subsidized or not, its R&D component is substantially higher than for industry as a whole. The University of Pennsylvania's Patricia Danzon estimates that while R&D costs at U.S. drug companies account for about 13 percent to 20 percent of sales, for all U.S. industry the figure is only 4 percent.⁸⁹ Adding to this dilemma is that the drug industry's marginal costs—the cost of producing each additional unit for sale—are low. A firm has to be confident that it can charge a price for a given drug that exceeds the marginal cost. *Otherwise, it will not make the drug.* The Interfaith Center on Corporate Responsibility and its

affiliates appear misguided in their attempts to exact commitments from drug companies to allow lower-priced generic drugs to be available parallel to on-patent versions.

Yet that is not the whole story. For the ICCR has concentrated its campaign to lower drug prices on a worldwide basis, concentrating on Third World nations faced with an epidemic of AIDS. A marginal-pricing strategy here in the U.S. would be difficult enough to generate any return. But in developing nations, with far lower household incomes and assets, it would be impossible in lieu of a huge subsidy.

Let us elaborate. R&D, by its nature, is a "joint" fixed cost. That is, its benefits cannot be limited to specific countries. A new wonder drug that benefits patients in America inevitably confers similar benefits on patients

in France, Japan, Nigeria and India. All nations, rich or poor, in economic terms, are “free riders” in realizing the benefits of discovery. It follows that if American firms are to sell brand-name drugs in developing countries—the ones most devastated by AIDS—they must be confident that revenues from those drugs in the U.S. and other high-income countries will remain unaffected. In absence of country-by-country price differentiation, argues Danzon, manufacturer revenues will drop, possibly to the point where the company will cease production. If that happens, *all patients throughout the world are worse off*.

Fortunately, there is a mechanism that allows our drug manufacturers to engage in differential pricing. It is called the patent. Ironically, ICCR and allied activists are doing what they can to undermine its legitimacy.

Foreign Circumvention of U.S. Patent Laws: Price Controls by Any Other Name

Patent laws protect the right of an inventor to enjoy revenues from the sale of his invention. They are a necessary element in preventing theft. Without such protection, an inventor would be far less likely to spend the time and cost necessary to create an economically viable product. But patents are a two-edged sword. By definition, the power to grant a patent is also the power to deny, revoke or undermine it. And through that kind of control, national governments, here and elsewhere, have at their disposal the ultimate veto over a producer's ability to set prices.

A patent, like a copyright, is a government grant of monopoly. It provides the holder of a discovery—in this case, a prescription drug—an exclusive and enforceable right to

sell the product under a brand name for a specified period of time. Once a drug's patent expires, anyone can copy and sell it, provided they can convince authorities that the product is identical to the original and safe for use. The introduction of the drug under a generic name prior to the expiration of the patent period has the potential to drastically reduce manufacturer revenues. After Merck's cholesterol-lowering drug, Zocor, lost its patent protection in mid 2006, for example, sales plummeted. Major pharmaceutical companies, here and abroad, are establishing generic subsidiaries, such as Greenstone (Pfizer) and Sandoz (Novartis), precisely for the purpose of recapturing lost post-expiration revenues.⁹⁰ Even with a patent, a drug company is not assured of profitability. The international standard for a patent (subject to waivers) is 20 years, a period that starts on the date of filing rather than commercial availability. And between now and 2012 any number of best-selling drugs will lose their patent protection. Prominent among them are Fosamax (Merck), Prevacid (Abbott/Takeda), Lipitor (Pfizer), and Plavix (Bristol-Myers Squibb).⁹¹

The ICCR's price-reduction campaign is focused on the Third World, especially those nations ravaged by HIV/AIDS. Affiliated investors, working with foreign governments, are coaxing companies to allow cheaper, generic versions of on-patent drugs to be sold in their respective countries. Now even in developed nations, drug prices are lower than in the U.S. Our own International Trade Administration (part of the U.S. Department of Commerce), analyzed data from nine OECD countries, and discovered drug prices in seven of those nations ranged from 35 to 48 percent lower than prices here,

due in large measure to government controls.⁹² But in developing countries, most people cannot afford drugs even at these levels. As a result, governments of AIDS-ravaged nations have begun to respond by issuing parallel licenses to undermine patent protection in lieu of manufacturer price cuts. This opens the flood gates for generic copies of questionable value.

In July 2005, for example, Brazil's Ministry of Health announced a six-year “agreement” with Abbott Laboratories, in which the manufacturer would lower the price of its HIV/AIDS drug Kaletra.⁹³ The pact also included a technology transfer procedure to enable the government-run Farmanguinhos Laboratories to begin producing Kaletra in 2009 and a provision to provide Brazilian patients greater access to Meltrex, a heat-stable version of Kaletra. Abbott wasn't in a position to argue. The Brazilian government had declared Kaletra a drug “of national interest,” and gave Abbott a 10-day ultimatum to either agree to lower its price or face the loss of its patent protection. Initially, Abbott had denounced the ultimatum as illegal—which it certainly was under U.S. law—and warned that developing unproven, alternative HIV medication posed “significant consequences for patients.” Yet soon after, the company announced it would be open to an “agreeable solution.”

Brazil at least is consistent in its contempt for rule of law. In May 2006, it announced an “agreement” with Gilead Sciences to reduce the price of the HIV retroviral drug Viread by about 50 percent; the alternative was the government issuing a compulsory license, undermining the patent's effectiveness. A year later, it issued a compulsory license to produce a low-cost generic version of Merck's Efa-

virenz, after giving the firm a week to “negotiate” a lower price.

The South African government is of like mind. In 1997, it passed a law granting its health ministry the power to override existing patents, with or without the patent holder’s consent, to “determine that the rights with regard to any medicine under a patent granted in this Republic shall not extend to acts in respect of such medicine.” The new law also opened the door to compulsory licensing, which allows the government to license domestic companies to produce generic drugs at far lower prices, following payment of a licensing fee to the affected companies. Several dozen pharmaceutical firms doing business in that country went to court to challenge the law, but wound up sustaining so much public-relations damage that they dropped the suit unconditionally.

Meanwhile, the Thai government issued compulsory licenses that allowed cheap generic versions of Kaletra while its patent was still in effect, something that won praise from the ICCR in a November 2006 update of its *Benchmarking AIDS* report. The decision would have consequences. In early 2007, Abbott Laboratories pulled Kaletra and six other drugs from that country.

Combating these “agreements” is easier said than done. Legalized patent infringement is ingrained in the World Trade Organization-administered Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994⁹⁴ and the more strongly-worded Doha Agreement of 2001, each of which authorizes Third World governments, under cover of meeting a national emergency, to issue compulsory licenses without securing the permission of patent holders, so as to promote “access” to medicines.

Doha waived the “local requirement” provisions in TRIPS, paving the way for the European Union and Canada several years later to formally allow compulsory licensing for the manufacture of patented drugs exported to developing nations.

Not surprisingly, the United Nations, a virtual mouthpiece for the Third World, also has pulled this stunt. In the spring of 2000, several companies, following weeks of discussions with U.N. officials, pledged to sell to their anti-AIDS drugs in Africa for as little as pennies above operating costs. Under the agreement, Bristol-Myers Squibb, Merck, Roche, GlaxoWellcome (now GlaxoSmithKline) and Boehringer-Ingelheim would sell their products at prices well below even discounted levels. “It’s the first time the companies are collectively willing to discuss a truly significant decline in prices,” said Peter Piot, director of the United Nations AIDS program. “It is something many of us have long hoped for.”⁹⁵

Such practices, though dressed up as adherence to high moral principle, amount to legalized extortion. Governments of high-poverty nations effectively are telling U.S. drug manufacturers: “Pay now or pay a lot more later on.” Their officials are forcing U.S. pharmaceutical companies into a choice of either lowering drug prices or watching their patent protection become next to meaningless. Such a policy inadvertently raises prices for customers in other countries. Ironically, individuals in those high-poverty countries suffer the most. The University of Chicago’s Richard Epstein explains:⁹⁶

Decisions like those in Brazil and Thailand cripple incentives to invest in new drugs, particularly for AIDS, for which sick people worldwide will pay the price tomorrow. What drug company will invest in new and useful products when the ensuing harsh policy will

damage its global brand? Better to stand aside and let someone else take the heat. But who will step forward?

The ICCR and its affiliates do not object to such strong-arm tactics. Indeed, they encourage them as part of a long-range cost-cutting strategy. And they make threats in the process. When the center released its update of *Benchmarking AIDS*, its health care project director Daniel Rosan justified the Thai government’s issuance of compulsory licenses for Kaletra with a less than subtle warning: “Single-source drug suppliers in developing countries create public health risks—shortages, stock-outs, and so on. Generic competition is the only proven way to lower drug prices and Abbott would be better served to allow such competition and reap the licensing fees than court the kind of negative attention shareholders have seen recently.”⁹⁷

Foreign re-importation, the buying by foreign sources of American-patented drugs and the reselling of these drugs to this country, is a growing and insidious form of patent infringement. It also happens to be illegal. While people are free to travel to a foreign country to buy U.S.-patented pharmaceuticals, they cannot order these drugs through a foreign pharmacy, whether through the Internet or regular mail, from an American location. Under current U.S. law, re-importation is allowed only if the Secretary of Health and Human Services determines that such action would not result in health risks and would lead to a significant drop in drug costs. Despite intense political pressure, the Bush administration has been no more willing to exercise this option than was the Clinton administration.

In an American context, the prime re-importer is Canada. Aside from

location, there is another advantage: Prescription drugs in Canada on average sell for about 40 percent less than here.⁹⁸ Much ink has been spilled on the alleged superiority of the Canadian system relative to ours, on how Canada provides the same high level of service and products at far more reasonable prices, thanks to that country's single-payer (i.e., government-run) health insurance.⁹⁹ What such a claim overlooks is that legalizing re-importation of U.S. drugs from Canada would represent a de facto system of Canadian price controls on America, to the benefit of our neighbors to the north. Even Canada's then-Minister of Health, Ujjal Dosanjh, admitted a few years ago that his country's drug industry "is based on a false economy and on a price differential that was created for the benefit of Canadians and not for the consumption of Americans."¹⁰⁰ Interestingly, R&D spending in Canada sharply increased after the late 80s, when the Canadian government curtailed and eventually eliminated compulsory licensing for drug innovations, effectively restoring patent protection.¹⁰¹ If the Canadian health care system works, it's because it fitfully resembles our own.

The case for re-importation looks impeccable on the surface. American consumers who order products from Canadian locations get the best of both worlds: high quality and low prices. But this "ideal" arrangement falls apart when confronted by the dynamics of producer behavior. Common sense dictates that if a pharmaceutical company can't recoup the cost of developing a particular drug or group of drugs, it eventually will cut back on research and development. *Allowing re-imported drugs to be sold here produces the same effect as price controls.* The University

of Connecticut's John Vernon stated as much in recent Senate testimony. "Using established economic models and statistical techniques," he noted, "we estimated that a new policy that reduces pharmaceutical profit margins in the U.S. to non-U.S. levels will cause firm R&D spending to decline by between 25 and 35 percent, all things considered. An importation policy that imports regulated prices from foreign markets will theoretically have this effect on U.S. profit margins."¹⁰²

A potentially greater source of patient avoidance is the black market, much of which is transacted over the Internet. Such pharmacies are open to all buyers, without prescription. Unfortunately, they also are open to counterfeit artists masquerading as legitimate businessmen peddling medicine that is useless, and on due occasion, dangerous. Very often, drugs are mislabeled; dosages are misstated; expiration dates don't match the medication; and labels are in the wrong language or outdated. The Center for Medicine in the Public Interest (CMPI), a New York-based research group, estimates that counterfeit-drug commerce worldwide will grow at an annual rate of 13 percent through 2010, by such time fake drugs will generate some \$75 billion in revenues, up by 92 percent from 2005. The World Health Organization estimates that counterfeit drugs as a share of the total market commonly ranges anywhere from 10 to 40 percent of a nation's total market.¹⁰³

The Interfaith Center on Corporate Responsibility and its affiliates would counter this trend by calling for safeguards to protect the unsuspecting poor against fraud. But that is far easier said than done. As CMPI co-founder Peter Pitts explains:¹⁰⁴

The issue is global. National borders mean nothing to these criminals. Pharmaceuticals are easily smuggled because medical supplies are a humanitarian need. Law authorities are frequently stymied. Our FDA must work with the World Health Organization, Interpol and other international public health and law enforcement organizations. Jurisdictions overlap. Fake drugs, substituted for the real thing, move under the cover of aid efforts. And then both can be sold to double profits.

Now it is true that a certain amount of drug fraud will occur even under a system of strong patent protection. But the circumvention is made easier when official means of discovery are weak. Counterfeiting, by its nature, is about evading normal channels.¹⁰⁵

Unfortunately, Congress is yielding to arguments of activists seeking to weaken patent protection under the guise of reforming it. The basic law governing drug patent protection is the Drug Price Competition and Patent Term Restoration Act of 1984. The legislation, led by the still-active Sen. Orrin Hatch, R-Utah, and Rep. Henry Waxman, D-Calif., tried to strike a balance between providing financial incentives to create generic drugs and promoting pharmaceutical company research and development. On one hand, the Hatch-Waxman law created a revolution by expanding the availability of generic drugs, allowing them quick FDA marketing approval through submission of "bioequivalence" studies, as opposed to the far more costly clinical studies. On the other hand, it granted pharmaceutical firms an extra five years on top of the existing 20 years for marketing exclusivity, so as to make up for the time a patented pipeline drug remains in development. Moreover, the law granted a 30-month stay to drug companies that file suit against generic drug makers that challenge their patents.

Critics over the years have denounced the law's "loopholes" as



Rep. Lamar Smith (R-TX)

being unable to prevent major drug manufacturers from keeping generic equivalents off the market. Both major presidential candidates in 2008, Sen. Barack Obama, D-Ill., and Sen. John McCain, R-Ariz., have indicated they seek to eliminate these loopholes. Indeed, McCain, along with Sen. Charles Schumer, D-N.Y., in 2001 sponsored legislation (which passed in July 2002) designed to do just that.¹⁰⁶ In the current 110th Congress, Reps. Howard Berman, D-Calif., and Lamar Smith, R-Tex., have co-sponsored the Patent Reform Act (H.R. 1908), passed by the full House in September 2007 by a 225–175 margin.¹⁰⁷ The product of numerous hearings and working groups, the measure would expand opportunities for patent infringement—and without recourse by the patent-holder to sue for compensation. One of the bill's key provisions would require every patent application to be published on the Internet within 18 months of filing.¹⁰⁸ This overlooks reality, particularly in the pharmaceutical industry. The time elapse between the filing of a patent application and its approval is typically longer, often twice as long as in industry generally. Even with-

out waiting for FDA approval, most patents reflect extensive testing by outside sources. Without strong protection, many drug companies might well relocate elsewhere or simply withdraw support from complex areas of research for which there is little short-term payoff.¹⁰⁹

Another proposal in Congress effectively would legalize the black market by awarding prizes to drug companies with innovative ideas who allow their work to become part of the public domain. The key person behind this legislation is Jamie Love, head of a Washington, D.C. think tank, Knowledge Ecology International (KEI), which lobbies Congress on technology, intellectual property and health issues. KEI was the driving force behind a bill introduced by Sen. Bernie Sanders, I-Vt., the Medical Innovation Prize Act of 2007. The measure would authorize the disbursement of federal cash awards to companies developing medicines for use in the Third World that otherwise might be viewed as unprofitable.

Love insists his proposal is soundly rooted in the interests of private enterprise.¹¹⁰ “We’re saying we want to give \$80 billion a year to biotech, Big Pharma,” he states. “Is that really anti-business? To me, it’s a market-oriented alternative to an unproductive, ethically-challenged system. Patients prefer a free market, but they don’t like monopolies where you pay \$100,000 a year for cancer medicines.” Love summarizes his proposal this way: “It’s either going to be price controls or prizes.”

The reality is that the two alternatives amount to the same thing. Most of the \$80 billion in prize money, Love admits, would come out of the presumed savings from having the

federal government negotiate drug prices under Medicare. What’s more, the capacity for favoritism of certain classes of drugs over others would be substantial, given that a 13-member board, nine of them presidential appointees, would decide what innovations to award and in what amounts. To top things off, federal regulators would have the authority to put a new drug’s formula in the public domain, ready for duplication and sale by all other drug makers. The plan thus not only would lend new meaning to the term “picking winners and losers,” it would render our patent system almost meaningless.

Broadening the basis for patent infringement, like other forms of price controls, is a counterproductive way to provide medicine to persons most in need. That it contributes heavily to an international black market of fraudulent drugs sold over the Internet and other media merely adds insult to injury. The poorest of the poor do not benefit under such a situation. As an indirect form of price control, the end result of patent avoidance will be to reduce the incentive of pharmaceutical manufacturers to develop and market beneficial therapeutic drugs. By demanding the sale of generic drugs through parallel agreements, the ICCR and its affiliates believe they are fulfilling higher moral laws. In the process, they are revealing their inattentiveness to the laws of supply and demand.

Sunny Rhetoric and Shady Practices: The Strange Case of Catholic Healthcare West

The investor and health care organizations that comprise the Religious Left are possessed of misguided economics. Yet less obviously, at least

one major affiliate has appeared to engage in dishonest business practices, most of all at the expense of low-income patients on whose behalf they speak. The organization is Catholic Healthcare West (CHW). Founded in the mid Eighties, the San Francisco-based nonprofit health care network represents about 40 hospitals and clinics in California, Arizona and Nevada, making it one of the nation's leading regional health care providers. Catholic Healthcare West is a member organization of the Interfaith Center on Corporate Responsibility, thus formally committing itself to the highest fiduciary standards. Significantly, its vice president of community health, Sister Susan Vickers, is one of the three activists cited at the beginning of this report and also a member of the 15-person ICCR board.

The hospital network makes explicit on its website (www.chwhealth.org) its Christian humanitarian mission:

Catholic Healthcare West and our Sponsoring Congregations are committed to furthering the healing ministry of Jesus. We dedicate our resources to: delivering compassionate, high-quality, affordable health services; serving and advocating for our sisters and brothers who are poor and disenfranchised; and partnering with others in the community to improve the quality of life.

These are noble-sounding words. And the nonprofit consortium on occasion has lent credibility to them, providing roughly \$500 million annually in free health care to the poor.¹¹¹ But there is a darker side to this charitable impulse. More than once, Catholic Healthcare West has been the target of a whistle-blower lawsuit seeking compensation for abusive business practices, especially toward individuals and families lacking health insurance. These suits have tended to result in costly out-of-court settlements.

A decade ago, responding to a whistle-blower's complaint, the U.S. government and the State of California sued Catholic Healthcare West and one of its subsidiaries, Mercy Healthcare Sacramento. George Baca, formerly CHW's executive director of patient services, in 1998 had filed a *qui tam* lawsuit¹¹² under the False Claims Act alleging his ex-employer knowingly had defrauded Medicare and other federal health insurance programs. Mercy Healthcare, the suit charged, systematically had inflated reimbursement claims at two of its clinics, Woodland Clinic Medical Group and MedClinic of Sacramento. The defendants, without admitting wrongdoing, settled with the government in May 2001, agreeing to pay \$10.25 million in damages.¹¹³

Just three months later, in August 2001, Catholic Healthcare West agreed to a \$10.7 million settlement in a separate *qui tam* case. The U.S. Department of Justice claimed that four of its hospitals during the period 1987–94 illegally charged the government for surgeries conducted with experimental equipment. Prosecutors alleged that the surgeries were not covered under Medicare and that the health care provider was aware of this when it filed for reimbursement. The CHW-affiliated hospitals named in the suit were Mercy General Hospital (Sacramento), Sequoia Hospital (Redwood City, Calif.), Seton Medical Center (Daly City, Calif.), and St. Joseph's Hospital and Medical Center (Phoenix). A complaint filed by Kevin Cosens, a former medical device salesman, had triggered the case.¹¹⁴

By no means was this the last such case. In 2002, CHW agreed to pay more than \$9 million to settle a suit filed on behalf of former Mercy Healthcare Sacramento reimbursement analyst

Joseph A. Kimball. Kimball alleged that during the period 1990–99, CHW and 13 of its hospitals knowingly had submitted false reimbursement reports under Medicare and other federal health programs. The government accused CHW of maintaining two sets of books, one it showed to auditors and the other it kept hidden indicating the false claims. Elements in the latter document included refinanced hospital bonds, a hospital purchase, treatment of indigent patients, and cost allocation among affiliates. Under the settlement, Catholic Healthcare West agreed to pay the U.S. government \$8.5 million, plus plaintiff's attorney's fees.¹¹⁵

The biggest actions were yet to come. In 2004, attorneys for Lief Cabraser Heimann & Bernstein of San Francisco and the Scruggs Law Firm of Oxford, Miss. sued CHW, alleging that the nonprofit chain had charged uninsured patients excessive and unfair prices. After extensive negotiations, the nonprofit hospital network succumbed. The agreement, finalized in San Francisco Superior Court in January 2007, entitles roughly 780,000 class plaintiffs with household incomes of \$250,000 or less to file claims for refunds or bill reductions of 35 percent based on visits occurring during July 1, 2001–September 25, 2006. The estimated value of these adjustments is \$423 million. The settlement also commits CHW to offering discount prices to uninsured patients for at least four years and to adopting more "compassionate" overdue bill collection practices than the rogue methods employed by third-party collectors.¹¹⁶

Meanwhile, in October 2005, a Los Angeles-based Hispanic advocacy group, Consejo de Latinos Unidos (Council of United Latinos), filed a class-action suit against CHW for

price-gouging. The organization's founder and executive director, K.B. Forbes, had made news two years earlier by coaxing a settlement out of Tenet Healthcare Corporation, the nation's second-largest hospital chain, for alleged Medicare fraud and illegal kickbacks to doctors.¹¹⁷ His suit against Catholic Healthcare West likewise was ambitious. Forbes accused the nonprofit group of overcharging uninsured CHW patients up to five times what it charged private insurers and government agencies for the same services. The suit also alleged the hospital chain had engaged in abusive third-party collection practices.

Now Consejo de Latinos Unidos is an egregious booster of mass immigration, including the illegal kind.¹¹⁸ And Forbes, despite his Anglo-Scots last name, is a radical Hispanic ethnic politician, rarely ceasing to note that many Hispanics lack health insurance.¹¹⁹ Still, the lawsuit has some real basis. Data from the State of California's Office of Statewide Health Planning and Development indicate that the uninsured accounted for a tiny fraction of all patients at Catholic Healthcare West's California hospitals, yet more than three-fourths of its profits.¹²⁰ The suit has yet to be resolved.¹²¹

These suits, it is worth noting, were instrumental in bringing about what amount to government price controls in California. In October 2006, California GOP Governor Arnold Schwarzenegger signed a bill making the state the second in the nation (after New York) to protect uninsured and low-income patients from abusive hospital billing and collection practices. On the surface, that looks commendable—who could be against abusive practices of

any kind? But the new law, which took effect on January 1, 2007, may serve to put the state's hospitals at greater risk of fiscal insolvency. It bars hospitals from charging self-paying patients who earn up to 350 percent of the federal poverty line any more than levels charged by Medicare and other government programs. It's an old cliché, but often true: The cure may be worse than the disease.

If Catholic Healthcare West advocates for the poor and the disenfranchised, it doesn't scrimp on compensation for its top people, least of all CEO Lloyd H. Dean. Dean received a reported \$5.8 million in the year ending June 30, 2005, up from around \$4 million the previous year.¹²² That sum didn't include a \$2 million interest-free loan, due in five years, enabling him to buy a \$1.2 million penthouse condominium overlooking San Francisco Bay. The best part of the deal was that all but \$250,000 of the debt would be forgiven if he stayed on the job for at least five years.¹²³

Such generosity, however, doesn't necessarily extend to lower-ranking employees. In July 2007, two nurses in Arizona brought forth a class-action suit in U.S. District Court against the Arizona Hospital and Healthcare Association and a dozen other hospital corporations, among them Catholic Healthcare West, charging that since 1997 the defendants had engaged in a cartel to suppress the wages of temporary and traveling nurses. Two months earlier the U.S. Department of Justice and the State of Arizona sued the association. The action shortly thereafter coaxed an agreement from the association to abandon anti-competitive practices, but without providing compensation to the nurses. The more recent suit seeks to do the latter.¹²⁴

It is true that the plaintiffs in these cases may have their own self-interested motives. As is often the case, when a target with deep pockets gives in, the outcome sets the stage for future suits. It is telling that the Scruggs firm that helped arrange the January 2007 settlement (led by the irrepressible Dickie Scruggs, who in March 2008 pleaded guilty in federal court to attempting to bribe a state judge in a case relating to Hurricane Katrina litigation fees) was a key figure in the state attorneys generals' \$246 billion shakedown of tobacco companies back in the Nineties. His firm, as of the summer of 2006, was involved in 40 similar health care cases nationwide in "various stages of litigation."¹²⁵

That said, Catholic Healthcare West has much to answer for. Its officials, like those of other ICCR-affiliated groups, speak with passion and eloquence about helping the least financially able. Yet principles and reality haven't necessarily squared away with each other. The hospital chain is finding out the hard way that running an enterprise is a lot harder than lecturing those who do.

Conclusion: In Defense of the Self-Governing Corporation

The Interfaith Center on Corporate Responsibility has a radical vision: the transformation of the corporation, especially in America, into a vehicle for a power transfer. And their master strategy is to become shareholders, thus positioning themselves to advance the grievances of voiceless stakeholders.

In a real sense, the Left activists have won. Corporate officials prefer to endorse their rhetoric rather than challenge it. Writing a few years

ago in *The Economist*, Clive Crook observed:¹²⁶

Today corporate social responsibility, if it is nothing else, is the tribute that capitalism everywhere pays to virtue. It would be a challenge to find a recent annual report of any big international company that justifies the firm's existence in terms of profit, rather than service to the community...In public-relations terms, their [advocates of corporate social responsibility] victory is total. In fact, their opponents never turned up. Unopposed, the CSR movement has distilled a widespread suspicion of capitalism into a set of demands for action. As its champions would say, they have held companies to account, by embarrassing the ones that especially offend against the principles of CSR, and by mobilising public sentiment and an almost universally sympathetic press against them. Intellectually, at least, the corporate world has surrendered and gone over to the other side.

It is hard to imagine any CEO of today this side of Cypress Semiconductor's T.J. Rodgers and a few others favorably quoting the late Milton Friedman's famous words in 1970 that "there is one and only one social responsibility of business—to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud."¹²⁷ Indeed, in some image-conscious companies, uttering such words could be cause for termination.

Groups such as the Interfaith Center on Corporate Responsibility *appear* to be capitalists. After all, they hold shares in publicly-traded corporations. Yet that in itself doesn't translate into support for company self-determination. Indeed, the ICCR and its affiliated organizations are not so much capitalists as what economist David Henderson calls "global salvationists."¹²⁸ That is, these people see the corporation as a tool for affecting a broad soci-



Source: bigstockphoto

etal transformation. In their minds, business must assume the role of philanthropy. Salvationists are gaining in influence, especially through non-governmental organizations (NGOs), the more moderate of which corporate officials now often consult prior to making major decisions.¹²⁹

Most of these organizations are not extralegal provocateurs of the sort who rioted in the streets of Seattle in late 1999. But though tactics dif-

fer, the goals of violent and peaceful salvationists are remarkably similar. Each faction frames its arguments in highly emotional language designed to articulate shareholder grievances rather than boost firm productivity. And their claims and operating styles, in their minds, should have far less scrutiny than the companies they target. "(T)he fact that today's social pressures on businesses to take the path of CSR (Corporate Social Responsibility)

come from many sources, and are generally within the law,” writes Henderson, “does not mean that they are well-founded.”¹³⁰ In the minds of such activists, purity of motive counts more than verifiability of results.

These tireless warriors for equality and sustainability are making certain that the youngest generation is getting the message. In December 2004, for example, a group of well-trained (by the Rainforest Action Network) Connecticut second-graders converged upon the Manhattan headquarters of J.P. Morgan Chase & Co. to protest company policies that allegedly had been contributing toward rainforest destruction and global warming. Company officials responded in a way that must have pleased the kids’ handlers to no end. Rather than explain that its foreign investment might lead simultaneously to a cleaner environment and higher living standards, J.P. Morgan drew up and adopted a ten-page environmental policy requiring borrowers to report carbon-dioxide emissions and promising not to hurt “indigenous peoples.”¹³¹

Such pressure may not be necessary elsewhere in the world, especially Europe, where foreign governments and international legislative bodies have been loading requirements onto corporations.¹³² The European Commission, the executive branch of the European Union (EU), has endorsed the idea of “global social governance” with the strong support of the EU Council of Ministers. The Organization for Economic Cooperation and Development presented its revised Guidelines for Multinational Enterprises, as “a tool for promoting corporate social responsibility.” In 2004 the British government announced that companies operating in their country would be required to issue an annual “corporate social responsibility statement.” The United Nations,

in the agreed-upon “outcome document” of its 2002 Monterrey (Mexico) conference on development financing, stated: “We urge businesses to take into account not only the economic and financial but also the developmental, social, gender and environmental implications of their undertaking.”

All of this, laments Czech President Vaclav Klaus, is part of a broad tendency toward “denationalization of nation-states” and “supranationalism and global governance.”¹³³ As the idea of global corporate governance increasingly becomes accepted wisdom, American companies will be increasingly in a position where they either must play by the new rules or be locked out of doing business in foreign markets, and ultimately in their own country. And that is what Religious Left investors seek—a world in which “irresponsible” companies have no place to hide. Their campaign taps into deep wellsprings of populist resentment toward corporations.

Leftist activists are driven by moral and religious obligation. They may be savvy investors, but what motivates them is less the acquisition of wealth than the remaking of the corporation into a socially-conscious progressive institution, prodded by governments and NGOs. The reward here is mainly psychological: the satisfaction of helping to create a world in which stakeholders decide how to invest corporate resources. Call this 21st-century socialism with a human face, but ICCR shareholders have every intention of pressing companies around the world, one at a time, into service. If successful, they would permanently revolutionize the nature of doing business. ■

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NOTES

¹ A full account of this particular campaign can be found in Daniel Rosan, “Due Diligence: Access to Medicines as Fiduciary Duty,” New York: Interfaith Center on Corporate Responsibility, *The Corporate Examiner*, Vol. 35, No. 8, October 14, 2007, pp. 1, 17–18.

² Kieran Hartsough, Daniel E. Rosan and Lisa Sachs, “Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets,” New York: Interfaith Center on Corporate Responsibility, *The Corporate Examiner*, Vol. 34, No. 6 & 7, August 1, 2006.

³ Rosan, “Due Diligence,” p. 18.

⁴ *Ibid.*

⁵ “Patent Revoked on Tenofovir,” Medecins Sans Frontieres/Doctors without Borders, Press Release, January 29, 2008. The full name of the drug is tenofovir disoproxil fumarate (TDF).

⁶ See Stephen Davis, Jon Lukomnik and David Pitt-Watson, *The New Capitalists: How Citizen Investors Are Reshaping the Corporate Agenda*, Cambridge, Mass.: Harvard Business School Press, 2006.

⁷ The ICCR repeatedly has claimed to have 275 affiliated organizations. Yet a recent NLPC count, taken from the group’s own website, indicates less 180.

⁸ By the spring of 2006, ICCR members were engaged in more than 280 ongoing dialogues. See “Corporate Responsibility Challenges 2006,” New York: Interfaith Center on Corporate Responsibility, *The Corporate Examiner*, Vol. 34, No. 3 & 4, March 31, 2006, p. 1. This figure includes those cases in which a resolution was withdrawn prior to the shareholders’ meeting. However, such cases signify victory. Typically, ICCR shareholders withdraw a resolution after the target firm agrees to adopt or amend a practice.

⁹ Jarol B. Manheim, *Biz-War and the Out-of-Power Elite: The Progressive-Left Attack on*

the Corporation, Mahwah, N.J.: Lawrence Erlbaum Associates, 2004, p. 99.

¹⁰ The ICCR does have a small Jewish presence. A current board member is Rabbi Mordechai Liebling.

¹¹ Herman Nickel, "The Corporation Haters," *Fortune*, June 16, 1980, p. 126.

¹² Recent books that view the corporation as a pathological rogue entity in need of taming include Joel Bakan, *The Corporation: The Pathological Pursuit of Profit and Power*, New York: Free Press, 2004; Thom Hartmann, *Unequal Protection: The Rise of Corporate Dominance and the Theft of Human Rights*, Emmaus, Pa.: Rodale Books, 2002; Marjorie Kelly, *The Divine Right of Capital: Dethroning the Corporate Aristocracy*, San Francisco: Barrett-Koehler, 2003; Ted Nace, *Gangs of America: The Rise of Corporate Power and the Disabling of Democracy*, San Francisco: Barrett-Koehler, 2005.

¹³ Quoted in Mark D. Tooley, "Barack Denounces America for Jesus," *FrontPageMagazine.com*, June 27, 2007. Senator Barack Obama, D-Ill., the presumptive Democratic presidential nominee, spoke at the same conference to enthusiastic applause. At one point, he denounced religious conservatives who had "determined that [their] number one priority was tax cuts for the rich."

¹⁴ Presentation by Lawrence Ladd and William J. Gardiner, "Socially Responsible Investing," 2000 UUA General Assembly, Board of Trustees, UUA Workshop, Boston: Unitarian Universalist Association, <http://archive.uua.org/ga/ga00/317.html>. Ladd and Gardiner at the time of their presentation were, respectively, the association's financial advisor and director of anti-racism training.

¹⁵ Ted Ketcham, "Virtue, Vice, and the Gnashing of Teeth—A Survey of Faith-Based Investing," *Green Money Journal*, Summer 2007, <http://www.greenmoneyjournal.com>. In the New

Testament, Paul writes, "For the overseer must be above reproach as God's steward, not self-willed, not quick-tempered, not addicted to wine, not pugnacious, not fond of sordid gain" (Titus 1:7). Similarly, in Timothy 3:8, he admonishes, "Deacons likewise must be men of dignity, not double-tongued, or addicted to much wine or fond of sordid gain."

¹⁶ See Tibor R. Machan, "Business Ethics—True and False," paper presented to the Austrian Scholars Conference 7: *Proceedings*, Auburn, Ala.: Ludwig von Mises Institute, March 30–31, 2001.

¹⁷ Quoted in Henry Blodget, "The Conscientious Investor," *The Atlantic*, October 2007, p. 80.

¹⁸ Harry Van Buren, "Environmental Justice and the Need for Real Community Consultation," *The Corporate Examiner*, Vol. 33, No. 1, January 31, 2005, p. 7. For a critical discussion of the stakeholder idea, see Paul Driessen, *Eco-Imperialism: Green Power, Black Death*, Bellevue, Wash.: Free Enterprise Press, 2003, pp. 6–15.

¹⁹ Keith Windschuttle, "The Nation & the Intellectual Left," *The New Criterion*, Vol. 25, No. 5, January 2007, p. 16.

²⁰ Blodget, "The Conscientious Investor," p. 79.

²¹ "Investors Win Agreement from Ford Motor Co. to Prepare Climate Risk Report," Press Release, March 31, 2005, http://www.ceres.org/news/news_item.php?nid=93. See also Conrad MacKerron, "Shareholder Advocacy 2003: A Great Leap Forward," *Green Money Journal*, Summer 2007.

²² Hartsough, Rosan and Sachs, "Benchmarking AIDS."

²³ Interfaith Center on Corporate Responsibility, *Annual Report 2006–2007*, p. 2.

²⁴ Daniel E. Rosan, "HIV/AIDS in the Workplace," *The Corporate Examiner*, Vol. 32, No. 8, October 18, 2004, p. 7. Rosan left his position as Director

of Public Health and Access to Capital Programs to complete his MBA at Harvard. He remains, however, a consultant to the center.

²⁵ Rosan, *Due Diligence*, especially pp. 3–4.

²⁶ Remarks by Mary Ann Gaido, Interfaith Center on Corporate Responsibility, December 6, 2004, http://media.ford.com/print_doc.cfm?article_id=19744. Sister Gaido provided no hard evidence on how the disease affects the company, here or abroad. By her logic, the profitability of every corporation in America is threatened by AIDS, even if no employee can be verified as having the disease or the HIV virus.

²⁷ Remarks by Daniel E. Rosan, *ibid.*

²⁸ Quoted in "Faith-Based Investors Respond to 'Better Health Care Together' Announcement by Unions, Wal-Mart, Today," Press Release, Interfaith Center on Corporate Responsibility, February 7, 2007. Cathy Rowan, co-chair of ICCR's Access to Health Care Working Group, likewise commented, "As people of faith and investors in Wal-Mart, members of the Interfaith Center on Corporate Responsibility commend Wal-Mart, SEIU (Service Employees International Union) and their coalition partners for their call for systemic, fundamental change to America's health care system."

²⁹ "Shareholder Campaign for National Health Care Reform Faces Next Test at Wal-Mart," ICCR Press Release, May 31, 2007.

³⁰ John Simons, "A Radical Plan to Lower Drug Costs," *CNNMoney.com*, November 30, 2007.

³¹ Quoted in http://www.ontheissues.org/Al_Gore_Health_Care.htm. Throughout the campaign, Gore was not one to mince words on the subject. In his nomination acceptance speech, he mentioned "big drug companies" along with "big oil, big tobacco, and big polluters."

- ³² Merrill Goozner, "The Price Isn't Right," *The American Prospect*, September 11, 2000, p. 29. This article served as the basis for Goozner's book, *The \$800 Million Pill: The Truth Behind the Cost of New Drugs*, Berkeley, Calif.: University of California Press, 2005.
- ³³ "The Pharmaceutical Industry—To Whom Is It Accountable?," *New England Journal of Medicine*, Editorial, Vol. 342, June 22, 2000, pp. 1902–04.
- ³⁴ This estimate comes from a pair of recent reports issued by the Washington-based nonprofit journalism foundation, the Center for Public Integrity. A 2005 report indicated that the pharmaceutical and health care products industries spent more than \$800 million on lobbying and campaign donations at the federal and state levels during the previous seven years. Another report, published in 2007, concluded that health care firms and trade associations spent a combined roughly \$182 million on federal lobbying during January 2005–June 2006. See M. Asif Ismail, *Drug Lobby Second to None: How the Pharmaceutical Industry Gets its Way in Washington*, Washington, D.C.: Center for Public Integrity, July 7, 2005; M. Asif Ismail, *Spending on Lobbying Thrives: Drug and Health Products Industries Invest \$182 Million to Influence Legislation*, Washington, D.C.: Center for Public Integrity, April 1, 2007.
- ³⁵ The figures here are cited in Barbara Martinez and Jacob Goldstein, "Big Pharma Faces Grim Prognosis," *Wall Street Journal*, December 6, 2007.
- ³⁶ SRI World Group, Inc., "Shareholders Are Sick of Rising Pharmaceutical Prices," March 16, 2000, <http://www.socialfunds.com/news/print.cgi?sfArticleId=190>.
- ³⁷ "Domestic Access to Health Care," Issue Paper, Chicago: Evangelical Lutheran Church in America, approved by Church Council, November 11, 2004.
- ³⁸ Kaiser Family Foundation, "Views on Prescription Drugs and the Pharmaceutical Industry," *Kaiser Health Poll Report*, January/February 2005. See www.kff.org/healthpollreport.
- ³⁹ See Derek Hunter, "Guaranteed Future Pain and Suffering: The Recent Research on Drug Price Controls," Washington, D.C.: The Heritage Foundation, *WebMemo* #908, November 3, 2005.
- ⁴⁰ Frank R. Lichtenberg, "The Effect of Pharmaceutical Utilization on Innovation on Hospitalization and Mortality," Cambridge, Mass.: National Bureau of Economic Research, Working Paper No. 5418, January 1996.
- ⁴¹ *Ensuring Cost-Effective Access to Innovative Pharmaceuticals: Do Market Interventions Work?* Boston: The Boston Consulting Group, April 1999, p. 4.
- ⁴² John E. Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, Washington, D.C.: AEI Press, 2000.
- ⁴³ *Ensuring Cost-Effective Access to Innovative Pharmaceuticals*, p. 4.
- ⁴⁴ *Ibid.*, p. 2.
- ⁴⁵ Frank R. Lichtenberg, "Why Has Longevity Increased More in Some States than in Others? The Role of Medical Innovation and Other Factors," *Medical Progress Report* No. 4, New York: Manhattan Institute, July 2007.
- ⁴⁶ Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, quoted in Ronald Bailey, "Goddamn the Pusher Man," *Reason*, April 2001, p. 47.
- ⁴⁷ "ACE-Inhibitors Cost-Effective in CHF," *Scrip*, No. 284, 1993, p. 60. See also Robert Goldberg, "Ten Myths about the Market for Prescription Drugs," Dallas: National Center for Policy Analysis, NCPA Policy Report No. 230, October 1999, p. 10.
- ⁴⁸ *Pharmaceutical Price Controls in OECD Countries: Implications for the U.S. Consumers, Pricing, Research and Development, and Innovation*, Washington, D.C.: U.S. Department of Commerce, International Trade Administration, 2004. Though the Paris-based OECD is usually thought of as a European organization, the United States is a longtime member. Each member professes "a commitment to democratic government and the market economy." One hopes that the results of the study inspire member nations to increase their focus on the latter.
- ⁴⁹ "Cancer Prognosis," Editorial, *Wall Street Journal*, February 23, 2006.
- ⁵⁰ John E. Calfee, Mario Villarreal and Elizabeth DuPre, *An Exploratory Analysis of Pharmaceutical Price Disparities and Their Implications Among Six Developed Nations*, Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, Working Paper 06–07, April 2006.
- ⁵¹ John A. Vernon, Rexford E. Santerre and Carmelo Giacotto, "Are Drug Price Controls Good for Your Health?" Manhattan Institute, Center for Medical Progress, December 2004. See also Giacotto, Santerre and Vernon, "Drug Prices and R&D Investment Behavior in the Pharmaceutical Industry," *Journal of Law and Economics*, Vol. 48, Issue 1, 2005, pp. 195–214.
- ⁵² Robert Goldberg, "Drug Importation: Would the Price Be Right?" Testimony before the U.S. Senate, Committee on Health, Education, Labor and Pensions, February 17, 2005. See also Elizabeth Whelan, "Drug Importation Threatens Pharmaceutical Innovation," *Health Care News*, August 2005, www.heartland.org.
- ⁵³ Joseph Golec and John A. Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending," Cambridge, Mass.: National Bureau of Economic Research, Working Paper No. 12676, November 2006.
- ⁵⁴ Thomas A. Abbott and John A. Vernon, *The Cost of Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions*, Cambridge, Mass.: National Bureau of Economic Research, NBER Working Paper No. 11114, February 2005. See also Abbott and Vernon, "The Cost of Pharmaceutical Price Regulation:

A Financial Simulation Model of R&D Decisions,” *Health Economics*, Vol. 28, Issue 4–5, pp. 293–306.

⁵⁵ John A. Vernon, “Assessing Consumer Gains from a Drug Price Control Policy in the United States,” *Southern Economic Journal*, July 1, 2006.

⁵⁶ *Ensuring Cost-Effective Access to Innovative Pharmaceuticals: Do Market Interventions Work?* Boston: The Boston Consulting Group, April 1999.

⁵⁷ Statement of Edmund F. Haislmaier, Research Fellow, Domestic Policy Studies, The Heritage Foundation, before the U.S. Senate, Committee on Finance, “Hearing on Prescription Drug Pricing and Negotiation for the Medicare Prescription Drug Benefit,” January 11, 2007.

⁵⁸ Boston Consulting Group, *Ensuring Cost-Effective Access to Innovative Pharmaceuticals*, p. 25.

⁵⁹ The Medicare Modernization Act of 2003 states in part: “The Secretary of Health and Human Services (HHS) may not interfere with the price negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. In addition, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.” (Sec. 1860D-11). Despite the fact that the overall legislation is expensive, raising Medicare costs by a projected \$534 billion over the first 10 years (up from the Congressional Budget Office’s initial estimate of \$400 billion), Sen. Ted Kennedy and other left-leaning legislators bitterly opposed the measure because of this clause. Within only a few months, Senate Democrats introduced three separate bills to repeal it, each unsuccessful.

⁶⁰ PBMs manage prescription drug benefits for roughly 200 million Americans. See U.S. General Accounting Office (later the U.S. Government Accountability Office), *Federal Employees’ Health Benefits: Effects of Using Pharmacy Benefit Managers on*

Health Plans, Enrollees, and Pharmacies, GAO-03-196, January 2003. In another study a few years later, the GAO found that the FEHBP’s new high-deductible consumer-directed health plans (CDHPs) typically had lower premiums than did traditional PPO plans with similar benefits. CDHP enrollees, the study found, bore a larger share of the initial costs. U.S. Government Accountability Office, *Federal Employees’ Health Benefits Program: Early Experience with a Consumer-Directed Health Plan*, GAO-06-143, November 2005.

⁶¹ Marc Steinberg and Kim Bailey, *No Bargain: Medicare Drug Plans Deliver High Prices*, Washington, D.C.: Families USA, January 2007.

⁶² For how the 60 percent estimate came to be, see Rexford E. Santerre, John A. Vernon and Carmelo Giacotto, “The Impact of Indirect Government Controls on U.S. Drug Prices and R&D,” *Cato Journal*, Vol. 26, 2006, pp. 143–58.

⁶³ Letter to Senate Majority Leader Bill Frist from the Congressional Budget Office, January 23, 2004.

⁶⁴ Testimony of Douglas Holtz-Eakin, CBO Director, U.S. Senate, Committee on the Budget, Hearing, “The Budget and Economic Outlook: Fiscal Years 2005 to 2014,” January 27, 2004.

⁶⁵ Letter from Douglas Holtz-Eakin to Senator Ron Wyden, D-Ore., from the Congressional Budget Office, March 3, 2004.

⁶⁶ “Projected Net Medicare Drug Costs Drop by Another 10 Percent,” *Medicare Fact Sheet*, Washington, D.C.: U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, January 8, 2007; “Medicare Prescription Drug Benefit Cost Almost \$13B Less in 2006 than Expected, According to CMS,” *Medical News Today*, December 1, 2006. See also “Medicare Part D Spending Projections Down Again,” Office of the Actuary,

Department of Health and Human Services, July 11, 2006.

⁶⁷ Edmund Haislmaier, “Hearing on Prescription Drug Pricing.”

⁶⁸ U.S. General Accounting Office, *Federal Employees’ Health Benefits Program*.

⁶⁹ ICCR shareholder activists attach a certain sinister significance to the fact that brand-name drugs cost far more than their generic counterparts. But as this paper explains, the disparities are not the result of corporate price-rigging, but of the enormous front-end costs of developing a drug, winning FDA approval, and bringing it to market. A jar of pills may be cheap, but it does not reflect the years of effort that made its existence possible. Without the protection offered by a patent, drug companies would have little or no incentive to develop “miracle” drugs in the first place. See Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation*, New Haven: Yale University Press, 2006. Marketing, in particular, seems costly, but in fact can knock down average costs on a per-unit basis (Epstein, pp. 143-64). Moreover, federal patents typically bar the sale of generic drugs during the period in which the patent is in force. The availability of low-cost generic drugs thus can be seen as a welcome by-product of a patent system that delineates property rights rather than an alternative to it.

⁷⁰ *Prices for Brand-Name Drugs under Selected Federal Programs*, Washington, D.C.: Congressional Budget Office, June 2005, p. 9.

⁷¹ U.S. Senate, Republican Policy Committee, “Competition vs. Price Controls: The Road to Lower Prescription Drug Prices,” March 9, 2004.

⁷² The arguments in this paragraph summarize “Medicare Part D and Prescription Drug Prices,” *Policy Fact Sheet*, Washington, D.C.: American Enterprise Institute, January 5, 2007.

⁷³ See David Blumenthal and Roger Herdman, eds., *Description and Analysis of the VA National Formulary*, Washington, D.C.: National Academy Press, 2000; “Observers Predict Shake Up in PDP Market in 2007,” FDC Reports, *Medicare Drug Reimbursement Guide*, Vol. 2, No. 5, November 2006.

⁷⁴ The Kaiser Family Foundation recently released a survey showing 85 percent of Americans support direct government negotiation of Medicare prescription drug prices. But support dropped to a mere 30 percent in another survey when respondents learned this would result in a restricted list of approved drugs. See Dutko Research, December 6, 2006, conclusions summarized in www.prnewswire.com, December 21, 2006. Another study by The Tarrance Group indicated only 28 percent of seniors believed that government would do a better job of setting drug prices than the market. See The Tarrance Group, “A Survey of Voter Attitudes in the United States,” November 8–9 and 12, 2006, <http://www.tarrance.com/who/index.html>.

⁷⁵ Doug Bandow, “Stealing Drugs, Hurting the Poor,” *The American Spectator Online*, August 16, 2007, www.spectator.org/util/print.asp?art_id=11881.

⁷⁶ Cited in *Securing the Benefits of Medical Innovation for America’s Seniors: The Role of Prescription Drugs and Drug Coverage*, Washington, D.C.: U.S. Department of Health and Human Services, July 2002.

⁷⁷ Epstein, *Overdose*, p. 68.

⁷⁸ Quoted, in Bailey, “Goddamn the Pusher Man,” p. 48.

⁷⁹ A systematic study conducted by the National Institutes of Health on the impact of its own research indicates a modest role. NIH, it is true, funds much basic research, but the private sector does the heavy lifting beyond that point. The study, among other things, examined pharmaceutical firms having at least \$500 million in U.S. sales. Of the

47 drugs meeting that standard, NIH determined that it had an involvement in only four of them. See U.S. Department of Health and Human Services, National Institutes of Health, “NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests Are Protected,” July 2001, available at <http://www.nih.gov/news/070101wyden.htm>.

⁸⁰ “How Drugs Move through the Development and Approval Process,” Boston: Tufts University, Center for the Study of Drug Development, Backgrounder, November 1, 2001. For a full-length treatment, see Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics*, Vol. 22, 2003, pp. 151–85. DiMasi is director of economic analysis for the Tufts center; Hansen and Grabowski, respectively, hold faculty positions at the University of Rochester and Duke University.

⁸¹ See Peter Landers, “Cost of Developing a New Drug Increases to Almost \$1.7 Billion,” *Wall Street Journal*, December 8, 2003. A principal investigator of the Bain study, Preston Henske, emphasized that his and the Tufts studies were not comparable. Among other things, the report included commercialization costs, such as preparation of marketing materials. Still, taken together, the reports make for a compelling case that research and development costs for a groundbreaking drug are high, even if the government covers some of those costs.

⁸² Goozner, “The Price Is Wrong.”

⁸³ Public Citizen, “America’s Other Drug Problem: A Briefing Book on the Rx Drug Debate,” *Congress Watch*, No. 47, at www.citizen.org/rxfacts, 2002. This estimate, like that by Goozner, did not focus on the fact that much investment never goes beyond initial testing. See Epstein, *Overdose*, p. 69.

⁸⁴ Goozner, p. 28.

⁸⁵ *Ibid.*, p. 29.

⁸⁶ Bailey, “Goddamn the Pusher Man,” p. 50. For more evidence, see Sam Peltzman, “An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments,” *Journal of Political Economy*, Vol. 8, 1973, pp. 1049–91; W. Duncan Reekie, “Price and Quality Competition in the United States Drug Industry,” *Journal of Industrial Economics*, Vol. 26, 1978, pp. 223–37; Z. John Lu and William S. Comanor, “Strategic Pricing of New Pharmaceuticals,” *Review of Economics and Statistics*, Vol. 80, No. 1, February 1998, pp. 108–18.

⁸⁷ For a discussion of this process, see the 2001 Tufts University study. It should be noted that human testing on occasion involves two extra steps: Phase 0 and Phase IV. Phase 0, a recent designation, is typically employed for promising drugs for high-priority illnesses. Sample sizes are small (about 10 to 15 subjects), and as such, they do not provide a basis for conclusions about safety or efficacy. Phase IV, also known as a Post-Marketing Surveillance Trial, is designed to identify rare or long-term adverse effects among a much larger patient population and over a long time period. The Food and Drug Administration may require this phase under certain circumstances. Sometimes the sponsoring pharmaceutical company conducts the research.

⁸⁸ See Robert Higgs, ed., *Hazardous to Our Health? FDA Regulation of Health Care Products*, Oakland, Calif.: Independent Institute, 1995.

⁸⁹ Patricia Danzon, “Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents,” Philadelphia: University of Pennsylvania, The Wharton School, December 2001, p. 5. If anything, the author argues, the 13 to 20 percent range for the pharmaceutical sector *understates* the true figure because it omits “opportunity” cost (i.e., the cost of foregone revenues from alternative investments with cheaper start-up costs). Discounting for present value would yield a figure of about 30 percent.

⁹⁰ See Martinez and Goldstein, “Big Pharma Faces Grim Prognosis.” Seven of the top 10 drug launches in 2006 were generics. In the first nine months of 2007, Novartis’s generic-drug unit, Sandoz, grew roughly three times as fast as its on-patent drug unit, and accounted for nearly 20 percent of Novartis’ overall revenue.

⁹¹ *Ibid.*

⁹² U.S. Department of Commerce, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation.*

⁹³ “Brazil and Abbott Laboratories Agree on Lower Price for AIDS Drug,” *Agence France-Presse*, July 8, 2005.

⁹⁴ Kevin E. Noonan, “The Law of Unintended Consequences Arises in Applying TRIPS to Patented Drug Protection in Developing Countries,” Patent Docs, May 1, 2007. http://patentdocs.typepad.com/patent_docs/2007/05/the_law_of_unin.html.

⁹⁵ Michael Waldholz, “Makers of AIDS Drugs Agree to Slash Prices in Third World,” *Wall Street Journal*, May 11, 2000.

⁹⁶ Richard Epstein, “AIDS Drugs: Are Property Rights and Human Rights in Conflict?” Comment and Analysis, *FT.com (Financial Times)*, May 7, 2007.

⁹⁷ Quoted in Anne Moore Odell, “Shareholders Work to Make AIDS Drugs Available Worldwide,” April 26, 2007. <http://www.socialfunds.com/newsprint.cgi?sfArticleId=2279>.

⁹⁸ See F.A.I.R. Medicare, “Importation of Prescription Drugs from Canada,” October 10, 2003, http://www.medicarerights.org/fairmedicare_reimportation.html.

⁹⁹ For an excellent layman’s overview of why Canada’s health care system isn’t a model for us, see Sally C. Pipes, *Miracle Cure: How to Solve America’s Health-Care Crisis and Why Canada Isn’t the Answer*, San Francisco: Pacific Research Institute, 2004.

¹⁰⁰ Quoted in “Internet Pharmacies Forced to Open Shop Overseas: Concerned About Ottawa Crackdown,” *The Globe and Mail* (Toronto), February 7, 2005.

¹⁰¹ Boston Consulting Group, *Ensuring Cost-Effective Access to Innovative Pharmaceuticals*, pp. 39–40.

¹⁰² Testimony of John A. Vernon before the U.S. Senate Committee on Commerce, Science, and Transportation, “Hearing on the Policy Implications of Pharmaceutical Importation for U.S. Consumers,” March 7, 2007. The study is by Vernon, “Examining the Link between Price Regulation and Pharmaceutical R&D Investment,” *Health Economics*, Vol. 14, No. 1, 2005, pp. 1–17.

¹⁰³ Michele Forzley, JD, MPH, “Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation,” revised by World Health Organization, Health Technology and Pharmaceuticals, paper presented to international conference, “Combating Counterfeit Drugs: Building Effective International Collaboration,” Rome, Italy, February 16–18, 2006.

¹⁰⁴ Peter Pitts, “Pharmaceutical Fakery is Health Care Terrorism,” *Baltimore Sun*, August 15, 2006. The article also noted that the Food and Drug Administration has complained that counterfeiters likely are using their profits to finance global terrorism.

¹⁰⁵ See remarks by Scott Gottlieb, MD, Deputy Commissioner for Medical and Scientific Affairs, speech before the Parenteral Drug Association’s Pharmaceutical Counterfeiting Conference, March 3, 2006, www.fda.gov/oc/speeches/2006/pda0303.html.

¹⁰⁶ The bill did not become law because the House companion measure, introduced by Reps. Sherrod Brown, D-Ohio (now a Senator), and Jo Ann Emerson, R-Mo., stalled. As for Senator Obama, first elected in 2004, his position fully coincides with that of the ICCR. His official campaign website

has this to say: “Our seniors pay the highest prices in the world for brand-name drugs. To lower drug costs, Obama will allow the federal government to negotiate for lower drug prices for the Medicare program, just as it does to lower prices for our veterans. He also supports allowing seniors to import safe prescription drugs from overseas, and will prevent pharmaceutical companies from blocking cheap and safe generic drugs from the market.”

¹⁰⁷ As of this writing (June 2008), the Senate has yet to take action on its own version, S. 1145.

¹⁰⁸ Peter Pitts, “Killing Healthy Patents,” *The American Spectator Online*, November 26, 2007. www.spectator.org/util/print.asp?art_id=12332.

¹⁰⁹ The Coalition for 21st Century Patent Reform (www.patentmatter.com) provides a sensible critique of the legislation, much of it based on an extensive study sponsored by the National Research Council. See Stephen A. Merrill, Richard C. Levin and Mark B. Myers, eds., *A Patent System for the 21st Century*, Washington, D.C.: National Academies Press, 2004.

¹¹⁰ See Simons, “A Radical Plan to Lower Drug Costs.”

¹¹¹ Sister Susan Vickers, “Statement for the Annual Meeting of Abbott Laboratories,” April 22, 2005.”

¹¹² Qui tam is a provision of the U.S. False Claims Act (31 U.S.C. Sec. 3729) that allows for a private individual, especially a whistle-blower with knowledge of past or present fraud, to bring forth a suit on the government’s behalf. With roots in 13th-century England, the term is derived from the Latin phrase, “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*” (“He who sues for the king as well as for himself.”). The individual, also known as the “relator,” need not have been personally harmed by the defendant’s conduct. The False Claims Act provides

an incentive to relators by granting them between 15 percent and 30 percent of the government's recovery, plus attorneys' fees and costs.

¹¹³ *U.S. ex rel. Baca v. Catholic Healthcare West*, No. CIV-S-98-0569DFL (E.D. Cal.).

¹¹⁴ "Catholic Healthcare West Settles Federal Lawsuit for \$10.7 Million," Associated Press, August 9, 2001; David R. Baker, "Catholic Healthcare Settles Medicare Suit," *San Francisco Chronicle*, August 10, 2001. Cosens would receive \$2.15 million.

¹¹⁵ Denny Walsh, "Mercy Owner Settles Fraud Claim: A Whistle-Blower Gets Part of the \$9 Million Deal by Hospital Giant CHW," *Sacramento Bee*, June 8, 2002; "Hospital Chain to Pay \$8.5 Million Settlement," staff report, *San Francisco Chronicle*, June 7, 2002. Under the settlement, Kimball would receive \$1.9 million out of the sum payable to the United States.

¹¹⁶ "Court Grants Final Approval to \$423 Million Class Action Settlement in Uninsured Pricing Lawsuit Against Catholic Healthcare West," *Business Wire*, January 11, 2007; Reed Fujii, "CHW Settlement Gets Final OK: Hospital Chain to Pay \$423M in Suit Over Alleged Overcharges," *The Record* (Stockton, California), January 12, 2007. Catholic Healthcare West downplayed the importance of the settlement. In a prepared statement, the hospital chain remarked: "The settlement amount is a hypothetical figure, which assumes that 100 percent of uninsured patients paid their bills in full and all of them file a claim in this matter. In fact, CHW has not and has never expected to collect most of these charges; consequently, we are confident that the actual cost of the settlement to CHW will be much lower." See Fujii, "CHW Settlement Gets Final OK."

¹¹⁷ K.B. Forbes during the Nineties had been chief spokesman for successive presidential campaigns

of Pat Buchanan and Steve Forbes (no relation). His suit against Tenet benefited from timing as well as evidence. In 2002, he put together 10 lawsuits filed by uninsured Latinos against Tenet hospitals in Southern California. Two months later, federal officials began an investigation of the hospital chain for Medicare fraud and illegal kickbacks to doctors. Bad publicity helped short-circuit Tenet's bid to acquire facilities worth \$1.6 billion. In January 2003, the company decided to settle, agreeing to implement discounts for the uninsured and stop aggressive bill collection practices such as putting liens on patients' homes and filing suits against the unemployed. Forbes later admitted: "They (Tenet) were seized upon with situations in the stock market and the feds. Who pushed us to a deal? It was the federal government of the United States that raided them." See Tamar Lando, "Pocket Protector," *Mother Jones*, May/June 2005.

¹¹⁸ Forbes has denounced Catholic Healthcare West for "discriminating" against people who cross borders. In a remarkably candid statement, Forbes, a practicing Catholic, stated: "The Catholic Church has always stood for the human rights of immigrants who cross the border into the United States. In essence, the Church believes that immigration is, as one writer put it, 'a sacrament of unity,' a process through which the Holy Spirit moves the world toward greater brotherhood." See "Consejo: Catholic Healthcare West's Amended Settlement 'Goes Against Catholic Policies'; Hospital Giant Establishes Pseudo Borders to Price Gouge," *PR Newswire US*, July 18, 2006. One would think that if Consejo Latinos Unidos were fully committed to human rights, it would focus more on reforming Mexico, by far the largest sending nation for illegal aliens here. Even more importantly, the group's bizarre notion that there

is a "human right" to trespass upon another nation's territory contradicts not only the essence of sovereignty, but also Catholic teachings. See J. P. Zmirak, "The Brogue Wears Off: Why the Catholic Church Is Addicted to Immigration," *vdare.com*, May 22, 2003. Catholic Healthcare West is no slouch in promoting mass immigration either. Back in 2001, CHW and the Service Employees International Union jointly commissioned a highly manipulative "push poll" ostensibly revealing high popular support for amnesty for illegal immigrants already here—without, of course, using the word "amnesty." See "Push Poll Purports to Show Support for Illegal Alien Amnesty, Says FAIR," *U.S. Newswire*, August 21, 2001.

¹¹⁹ In 2005, 32.7 percent of all Hispanics in America lacked health insurance. For non-Hispanic whites, the figure was only 11.3 percent. See U.S. Census Bureau, "Income, Poverty, and Health Insurance Coverage in the United States: 2005," *Current Population Reports*, Consumer Income, P60-231, Washington, D.C.: U.S. Government Printing Office, 2006, Table C-1, Health Insurance Coverage by Race and Hispanic Origin: 1987 to 2005, pp. 60–67.

¹²⁰ Merrill Matthews and Randy Suttles, "Hospitals Find Profit in Treating Patients Who Are Uninsured," *Investor's Business Daily*, February 5, 2004.

¹²¹ Forbes may have had a hand in the January 2007 settlement against Catholic Healthcare West. When the plaintiffs and the hospital chain reached a tentative settlement in June 2006, he quickly denounced it as a sham because it preserved hospital price-gouging, adding "We will fight until the deal collapses." See "CHW Settles Lawsuit over Charges Made to Uninsured Patients," *Modesto Bee*, June 16, 2006. The deal did collapse the following month in San Francisco Superior Court.

¹²² “Not-for-Profit Catholic Healthcare West Gives CEO an Extra \$1.8 Million in One Year,” *PR Newswire US*, September 14, 2006.

¹²³ Harvy Lipman and Grant Williams, “Assets on Loan,” *Chronicle of Philanthropy*, February 5, 2004.

The article was an expose of the not uncommon practice by charitable organizations of making loans to their respective officers and directors. The *Chronicle* reviewed data on 10,700 IRS Form 990 tax returns filed by groups with annual revenues of at least \$25,000 and with some outstanding debt from such loans. Slightly over 1,000 charities clearly acknowledged debts during 1998–2001, and their cumulative figure was \$142 million. While the authors emphasized that the number of organizations acknowledging making loans was a small portion of the 264,000 charitable groups in the U.S. required to file a Form 990, they noted that two sources—the nonprofit monitoring organization Independent Sector and the U.S. Senate Finance Committee—had taken notice. Sen. Charles Grassley, R-Iowa, then-committee chairman, made reference to Lloyd Dean’s real estate package, stating: “Families giving to charities want to support good work, not penthouse

apartments for executives.” CHW spokesman Mark Klein defended the loan, saying it “enabled Mr. Dean to purchase a house in the San Francisco Bay area roughly equivalent to the home he had in Illinois,” where he previously had worked.

¹²⁴ The plaintiffs’ lawyers are prominent Washington, D.C. litigator David Balto and the Philadelphia firm of Berger & Montague, the latter of whom in 2006 had won a \$554 million jury award on behalf of landowners whose property was contaminated with plutonium released from the Rocky Flats nuclear weapons plant near Denver.

¹²⁵ This was according to Sidney Backstrom, partner with the firm, who pleaded guilty in the same case that brought down Scruggs. He added, tellingly, “Obviously, we would like everyone to do the right thing and settle like these four cases have. More than likely, the longer we go, the more aggressive we’ll be with the type of settlement we are looking for.” Cinda Becker, “Charitable Obligations,” *Modern Healthcare*, August 14, 2006.

¹²⁶ Clive Crook, “The Good Company, A Survey of Corporate Social Responsibility,” *The Economist*, January 22, 2005, p. 3.

¹²⁷ Milton Friedman, “The Social Responsibility of Business Is to Increase

its Profits,” *New York Times Magazine*, September 13, 1970. See also Friedman’s comments in a symposium, “Rethinking the Social Responsibility of Business,” *Reason*, October 2005, pp. 28–37, especially pp. 32–33.

¹²⁸ David Henderson, *The Role of Business in the Modern World: Progress, Pressures and Prospects for the Market Economy*, Washington, D.C.: Competitive Enterprise Institute, 2004, pp. 90–113.

¹²⁹ See Manheim, *Biz-War and the Out-of-Power Elite*, pp. 164–65. NGO networks, the author argues, have grown powerful not simply by sharing information, but, more importantly, “by their collective image, resource, programmatic, and ideological elements—into a new collective force.”

¹³⁰ Henderson, *The Role of Business in the Modern World*, p. 112.

¹³¹ See John J. Miller, “Birkenstocks and Stocks,” *National Review*, July 4, 2005, pp. 25–27.

¹³² For details here, see Henderson, pp. 86–88, 108–09.

¹³³ Vaclav Klaus, “Three Key Challenges to Freedom,” *Cato’s Letter*, Washington, D.C.: Cato Institute, Summer 2007, Vol. 5, No. 3, p. 3.

