

Access Versus Excess: Value-Based Cost Sharing For Prescription Drugs

Rationing based on value, not price, offers one way to ease the tension between medical research and medical excess.

by **J.D. Kleinke**

ABSTRACT: The preponderance of published medical literature and clinical guidelines compels the expansion of pharmaceutical use among Americans, at the same time that private and public health plans seek to restrict such use. The emerging collision course between the march of medical science and the countermarch of medical policy arises from diverging views about the optimal use of drugs and growing philosophical conflict over the abundance and inequities that characterize the U.S. health care system. The consequent turmoil in the market's approach to managing drug benefits can be remedied through adoption of a value-based (rather than price-based) approach to pharmaceutical spending.

THE TITLE OF A RECENT ARTICLE, "Successful Cardiac Transplantation in an HIV-1-Infected Patient with Advanced Disease," jumps off the prosaic cover of the *New England Journal of Medicine*.¹ It announces how far we have come since the sudden appearance two decades ago of "gay men's cancer."² In 1983 HIV infection constituted a death sentence; today it is a chronic disease, manageable with \$12,656–\$22,022 worth of drugs per patient per year.³ Our rapid success with HIV is the result of intense patient and survivor activism, combined with billions of dollars of public and commercial research spending. For all this money and effort, we now have the ability to keep an HIV patient alive even when his heart fails, at a cost of an additional \$177,743.⁴ As Americans working in a sprawling health care system, we react to this astounding medical news with a strange mixture of pride and shame. That we have developed the medical might to transplant organs into HIV-infected patients is health care's equivalent of the moon landing. But the implications of this medical achievement also raise an obvious and awful question: For what it costs to transplant new organs into every well-insured patient with advanced HIV disease, how many rural medical clinics could we staff?

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How many prenatal visits could we provide to uninsured women? How many early cancers could we catch among the working poor?

This conflict is what drives the bitter debate over the role and value of the pharmaceutical industry, which now dominates the U.S. health care landscape. In 1995 drug spending constituted 7 percent of all U.S. health care spending; by 2001 that number had grown to 10 percent.⁵ This growth hardly accounts for the bulk of the 15–20 percent annual increases in health insurance premiums during 2000–2003, as the health insurance industry attempted to argue while raising its prices and restoring its profitability.⁶ But three percentage points of a \$1.5 trillion industry constitutes the transfer of a sizable piece of a growing pie from other segments of health care. When this much share changes hands—and when it coincides with the emergence of \$2.5 billion in annual prescription drug advertising—several responses inevitably follow: private resentment, public demagoguery, and attempts at retrenchment through state and federal legislation.⁷

The dynamics of America's love/hate relationship with an increasingly visible pharmaceutical industry now dominate public and private debates over drug pricing, insurance regulation, and the future of Medicare and Medicaid. These debates will not go away until we address the fundamental inequities of the U.S. health care system. This is the other drug war. The progress of medical research runs headlong into a countermarch of private and public payers determined to contain medical excess. The truth about which drugs have value, and at what cost to society, seems difficult to discern. Do we have too many drugs? Do we overuse or underuse them? Do they cost too much, or are they a bargain? Like most things in health care, the answers exist in a gray area between two extreme positions. The questions I address in this paper underscore how the struggle over the expanding role of pharmaceuticals is really a struggle for the soul of health care in America.

The Pharmaceutical Revolution

The flow of most medical research moves us in one direction: More medicine is better. This is distinct from more diagnostic tests and more surgeries, many of which do not survive retrospective analysis. When we discover that more medicine is not better for patients (for example, recent findings against high-dose chemotherapy with bone marrow transplant for breast cancer or hormone replacement therapy), the news makes headlines.⁸ Why? Because such findings are the exceptions to the rule.

It should be obvious to anyone who has read a medical journal that the bulk of published and publicized medical research compels the expansion of pharmaceutical use among Americans. This warrants some investigation, though, if only to appreciate the magnitude. A quantitative analysis of original research articles published in the *New England Journal of Medicine* between July 2002 and June 2003 shows how strongly at least one voice in the medical literature argues for expanded use of drugs. Every week the journal publishes three or four “Original Ar-

ticles.” Roughly half describe breakthroughs in basic or applied medical research; the other half report on the clinical testing of new surgical techniques, drug therapies, or vaccines. During the study period the journal published fifty-seven such drug and vaccine articles. Researchers found superior clinical results associated with a new or newer drug, a higher dose, addition of a second drug, or use of a vaccine, in forty-eight of these studies (84.2 percent, $p < .01$). In six (10.5 percent) of the studies, the results were mixed. In three studies (5.3 percent), placebo or existing therapy was superior. The conclusion is obvious, unequivocal, and illuminating: If physicians adjusted their practice patterns in accordance with evidence published in the *New England Journal of Medicine*, in more than eight cases out of ten they would order more aggressive—and surely more expensive—drug therapies.

This analysis does not argue or even suggest that 84.2 percent of all applied clinical research conducted by potential contributors to the *New England Journal of Medicine* supports more aggressive drug therapy. The percentage could very well be the exact inverse. Numerous analyses of publication bias in medical journals have found that any study supporting a medical or surgical intervention is more likely to find its way into print than a study repudiating it.⁹ Many have suggested that this bias is attributable to the commercial sponsorship of most applied clinical studies.¹⁰ Although this could be true, there is probably a coincident and more subtle driver: scarcity. There is an enormous premium on publication space in our leading medical journals and on our overburdened attention spans. Given medical publishers’ responsibility to advance public health by publicizing proven breakthroughs in clinical research, few medical journal editors—and even fewer reporters who translate medical news for the general public—are likely to find the headline “Placebo Just as Good” as socially important or compelling as “Important New Cancer Treatment.” Also, since no drug company owns the patent on the placebo, there is even less commercial pressure for such headlines.

Regardless of the source of this bias, the impression left on the mind of the practicing physician and worried patient is the same. Every time one reads the *New England Journal of Medicine*—or the general media’s growing coverage of its latest finding—there is a mantra-like echoing of a core American cultural belief: More medicine is better.

Unintended Consequences Of Evidence-Based Medicine

If the *New England Journal of Medicine* represents the front lines in the war against disease, are clinical findings proliferated in the rear guard of daily medical practice any different? What is the aggregate impact of evidence-based medicine (EBM), as embodied in clinical guidelines published by legitimate public and private sources? A cursory review of these guidelines mirrors the clinical and cultural impact of what we find in the journal’s pages. Despite rampant and often angry skepticism about the appropriateness of growing pharmaceutical use, legitimate clinical guidelines usually support an expansion rather than contraction of such use

among Americans—with a few notable exceptions such as antibiotics and Ritalin—for nearly all major diseases.

■ **NIH guidelines.** The NIH is among the more visible and credible clearing-houses of such guidelines. Unlike commercial vendors of such guidelines—some of which are fronts for health plans, others for drug companies—the NIH is considered relatively free of biases either against or in favor of industry. Below is an overview of clinical guidelines that the National Heart, Lung, and Blood Institute (NHLBI) has published for U.S. doctors to use in their daily practice.

Hypertension. In 2003 the NHLBI reviewed all major clinical studies of hypertension, a disorder that often leads to stroke and cardiovascular disease.¹¹ It concluded that patients with a systolic reading (the first of the two numbers in blood pressure measures) as low as 120 should now be considered “pre-hypertensive.” It also lowered the systolic threshold for initiation of drug treatment to 140, much lower than what most physicians have been taught. The report confirmed what many doctors already do: use lower-cost thiazides as the first line of treatment for hypertension, then add angiotensin-converting enzyme (ACE) inhibitors (such as Zestril) and other more costly drugs for increasingly severe hypertension. If these guidelines were followed, the number of Americans on these drugs would rise from twenty million to forty-three million.¹²

Asthma. In 1997 and 2002 the NHLBI reviewed clinical studies of asthma, which affects a growing number of children.¹³ For those with moderate or severe symptoms, the institute recommends aggressive treatment with inhaled corticosteroids (Azmacort), plus a beta-2 agonist (generic albuterol) or theophylline (generic), or a leukotriene receptor antagonist (Singulair). One study found that only 10.7–45.5 percent of eligible patients receive treatment in accordance with the least costly of these guidelines.¹⁴ If these results were projected nationally and the guidelines followed, the use of asthma medications would increase two- to tenfold.

Obesity. In 2000 the NHLBI reviewed clinical studies of obesity, a broad-ranging condition associated with cancer, diabetes, heart disease, depression, and stroke.¹⁵ The institute provides good recommendations regarding the obvious—lifestyle changes—but also recommends drug treatment for all patients with a body mass index (BMI) of 30 and for patients with a BMI of 27 or higher who have progressed to a related medical condition. If the first of these two guidelines were followed, roughly 56.7 million Americans would be treated with drugs for obesity—more than twelve times the current number.¹⁶

High cholesterol. After analyzing all major clinical studies about the relationship between blood cholesterol levels and heart disease in 2002, the NHLBI lowered thresholds on those levels for when treatment with drugs called statins (such as Lipitor) should begin.¹⁷ If followed, these guidelines would increase the number of Americans on one of the five statin drugs by ten to fifteen times, depending on which estimate of the underlying epidemiology one believes.

■ **NCQA guidelines.** Clinical guidelines that would, if followed, expand the use

of pharmaceuticals pervade the National Committee for Quality Assurance's (NCQA's) quality measurement tool, the Health Plan Employer Data and Information Set (HEDIS).¹⁸ Specific types of drugs supported by HEDIS measures include beta blockers, cholesterol-lowering medications, vaccines, antihypertensives, antidepressants, and asthma medications.

■ **RAND guidelines analysis.** In 2003 RAND conducted a comprehensive study of adherence to clinical guidelines. Researchers analyzed the medical care received by 13,275 adults randomly selected from twelve U.S. metropolitan areas, using a combination of telephone interviews and medical chart reviews.¹⁹ Of the thirty-six "selected indicators" published, eleven involved the use of medications. Researchers found that participants were compliant with medication guidelines in only 68.6 percent of eligible cases.²⁰

■ **Disease Management 2.0.** One of the real-world incarnations of EBM is disease management, a high-minded business strategy that is back in fashion among health plans. In the mid-1990s, when the plans were flush with cash from managed care's rapid market gains and peppered with business ideas from a newly funded generation of information technology (IT) vendors, the concept of disease management made its commercial debut. In essence, it involves using clinically intelligent software, claims databases, and communication tools to identify and contact health plan members who are (1) assumed from their claims history to be suffering from an undiagnosed condition; (2) likely to benefit from changes in lifestyle; (3) non-compliant with their physicians' prescriptions and other orders for diagnosed conditions; and (4) at risk for serious progression of those conditions.

Disease management translates into two certainties: more new prescriptions and more refills. This explains why much of Disease Management 1.0 was funded by drug companies in partnership with the plans; that any health plan would allow such a commercial Trojan horse into its camp underscores the happier state of affairs between the industries before the managed care revolution was eclipsed by the pharmaceutical revolution.

In the late 1990s health plans' fortunes turned. A health maintenance organization (HMO) pricing war began; Medicare beneficiaries stampeded out of the private health plans as quickly as they had stampeded in; health plan profits disappeared; and with those profits went their investments in Disease Management 1.0. Health plans are again flush with cash and peppered with ideas from the survivors among the IT vendors, and disease management is back. The past few years have seen the emergence of a disease management trade association; the NCQA's mission has grown to include the belated accreditation of disease management companies; several of those companies have grown large enough to go public; and the largest, American Healthways, topped *Fortune* magazine's list of fastest-growing U.S. companies in 2003.²¹

Disease management as theorized by today's health plans represents something of a paradox. The surest way to manage disease more aggressively is with more and

better medicines. It is difficult to reconcile this strategy with plans' concurrent strategy of erecting more and bigger barriers to all medicines through the introduction of tiered copayments for drugs.

The Pharmaceutical Counterrevolution

Why are today's health plans simultaneously promoting and impeding the use of pharmaceuticals? Why do they embrace the tools of EBM, strive to improve their HEDIS scores, and launch disease management programs, while erecting barriers—this time economic rather than administrative ones—to more aggressive drug care? Ideally, health plans would promote drugs with the greatest clinical or economic value and block access to those with the least. However, tiered copayments do just the opposite. Such benefit designs signify health plans' mistrust of a pharmaceutical industry hell-bent on promoting its wares to consumers and their belief that overuse of drugs is a fact of fee-for-service medicine.

Where are the data to support this belief? A search of MEDLINE (an online database of medical journal articles) for “overuse+drugs” and “appropriateness+drugs” reveals some surprising and not-so-surprising results. Several dozen studies have found that antibiotics are overused. Because drug companies market antibiotics to no consumers and only a few physicians, this overuse is probably attributable to irrational patient demands and irresponsible physician prescribing habits. Several other studies have explored but never conclusively found that Ritalin is overused, while one actually found that it is underused.²² Beyond antibiotics and Ritalin, a MEDLINE search on the hypothesis of inappropriate drug use finds that the drugs studied either were not overused or, to the surprise of researchers, were actually underused.

Notwithstanding these search results and this paper's findings, it is widely believed that drugs are overused in American society. The simplest explanation for this could be economic: Drugs are expensive, we are using more of them than ever, and such a rate of growth cannot possibly be optimal, if only because nothing in our health care system that generates so much new spending so quickly can be trusted. This would be the simplest explanation for historical knee-jerk reactions to other expensive phenomena: the advent of Medicare, the introduction of new surgical technologies, or the rise of commercial managed care. Regardless, this unproven hypothesis has become folklore among health care payers, purchasers, and other third parties forced to pay for all our new drugs.²³ It conspires with other countervailing forces within U.S. culture, most notably a stoicism and self-reliance that coexist uneasily with our appetite for anything science can produce to help us. And it finds its voice in a steady stream of popular books, from *Prozac Nation* to *Better than Well: American Medicine Meets the American Dream*.²⁴

So what is the truth? Are we overusing or underusing drugs? In a third-party payment system characterized by market distortions, it is probable that overuse and underuse coexist throughout our system. Although testing this hypothesis is

beyond the scope of this paper, it is important to understand why the presumption of drug overuse has indeed become folklore, especially as the debate over Americans' access to drugs becomes increasingly polarized, and especially in lieu of the evidence of significant underuse presented in this paper.

There are seven potential explanations, all interrelated and all but one coincident with the past decade's rapid growth in pharmaceutical use. (1) Direct-to-consumer (DTC) drug advertising has allowed drug companies to circumvent health plans' gatekeeping and expand demand for products that those plans are forced to purchase, a strategy also used by providers to neutralize third-party payers during the rise of commercial managed care.²⁵ Many believe that DTC advertising induces unnecessary demand, aggravating what is already a systemic misallocation of health care resources.²⁶

(2) DTC drug advertising and expanded physician marketing have worked, as evidenced by the fact that pharmacy costs have grown more from increasing use than from rising prices.²⁷ This growth is an explicit business goal of the drug industry, and it parallels the findings of this paper.

(3) Rapid growth in pharmacy costs created what appeared to be a financial crisis for health plans, which they publicized—and subsequently retracted—as their profitability was restored in the 2001–2003 period.²⁸

(4) New drugs are expensive to develop and market initially, but many become immensely profitable once established, for a host of microeconomic reasons. To many, the price of a given drug appears excessive and excessively arbitrary, especially across national borders, thanks to extremely high fixed costs, relatively low marginal costs, and the enormous cost of capital for one of our economy's most risk-intensive enterprises.

(5) For three widely prescribed drug franchises (Nexium, Clarinex, and Glucophage), drug companies have successfully extended highly profitable franchises with patent extensions, repackaging, and profuse DTC advertising. While these drugs account for less than 3 percent of all U.S. drug spending, their broad visibility has opened up the entire industry to accusations of exploiting a dysfunctional marketplace and promoting unnecessary spending.²⁹

(6) At the other end of the spectrum, the industry has introduced a small number of supremely important breakthrough drugs, after years of costly failures, which are just as supremely expensive. Chemically complex new drugs now available to prolong the lives of patients with leukemia (Gleevec), severe sepsis (Xigris), and advanced HIV (Fuseon) represent significant new cost pressures on the system. As we spend this money to save people who, prior to the drugs' introduction, simply died, we are all, in effect, economic victims of our own scientific successes.

(7) Many new drugs driving up health plans' pharmacy costs do not save or even prolong life. Unlike the medications involved in the guidelines discussed earlier, a large number of new drugs “merely” enhance life. They might have legiti-

mate clinical purposes, but from the perspective of many payers and purchasers they have no legitimate place in the health insurance system. The resulting stand-off between pharmaceutical companies and health plans—and a rationale for the new wave of pharmacy benefit designs seeking to restrict access to prescriptions that those plans spent ten years liberalizing—is less about the amount of money spent on new medicines and more about what those medicines treat.

Deconstructing the first five explanations in the hunt for potential policy-based remedies is beyond the scope of this paper. The sixth and seventh, however, are at the heart of the conflict and thus are central to discourse over how the health care policy community and marketplace can cope with its own good bad luck.

A Rationing Policy By Any Other Name

Who decides how we ration our medical successes and excesses? With regard to expensive, truly breakthrough drugs, we decide by not deciding. A compelling series of articles in the *Wall Street Journal* in mid-2003 confirmed what David Mechanic first described in *Health Affairs* back in 1997: In the United States we do not explicitly ration our medical progress; we implicitly ration it, in a haphazard way, one sick patient and one medical claim at a time.³⁰ In a health care system characterized by economic conflict and philosophical ambivalence, we delegate rationing decisions to thousands of doctors, nurses, hospital managers, utilization reviewers, claims processors, and lawyers. This absence of explicit criteria might explain, more than anything else, the broad and perplexing degree of care variations that pervade our health care system. This is not rational or fair policy; it is the de facto collective abdication of policy.

The dense fog surrounding a system of implicit rationing is thickened by drugs' rapidly expanding importance. The health care enterprise has grown to encompass dimensions of human experience that medicine never before had to address and health insurance never before had to underwrite. We now have drugs proven, to varying degrees of efficacy, to treat baldness, shyness, childhood hyperactivity, adolescent adjustment problems, lackluster sex, premenstrual moodiness, incontinence, and ugly toenails. All of these conditions, once the normal burdens of living inside an aging or imperfect human body, have been transformed into pathologies, because they can now be treated with medications. The drug companies did not create these clinical realities; they uncovered them in their desperate search for the next drug they could make, test, and sell. In the process, they have done a brilliant job of medicalizing human unhappiness. An insured American suffering from one of these problems is grateful to have a medical remedy—purchased with the tax-advantaged status of a health care transaction—that did not exist ten years ago.

While life-enhancing medications represent a small part of total drug spending, they are disproportionately represented among DTC drug advertising. This

makes sense: They are essentially consumer products, routed through the health care system to ensure the safety of physician-gated use and to exploit the economic dysfunctions of third-party payment. But the growing promotion and use of these drugs, at a time when overall drug spending is increasing, chafes against the skepticism, embattled idealism, and deepening indignation over medical misallocation that defines the culture of today's health plan. The debate over "lifestyle" medications might be taking place at the other end of the medical spectrum from the transplanting of a heart into an HIV-infected patient, but it involves exactly the same question: What have we wrought with all our medicines and money?

While forty-three million Americans go without health insurance, at least as many are swallowing pills for smaller waistlines, quieter children, better erections, and stronger presentation skills. In each case, medical necessity is a question of severity—as perceived by ourselves and, as important, by outsiders. Too often what are derided as "lifestyle" disorders exist on a near-perfect continuum with serious medical pathology. Depression is the most obvious and problematic example: One of the more popular antidepressants, paroxetine (Paxil), is commonly used to treat major clinical depression, postpartum depression, and social phobia.³¹ The same medication ridiculed for ads that promote its ability to make someone a better salesman is also used to prevent a new mother from abusing her infant or a young adult from killing himself.

Making Value Judgments

The clinical complexities associated with a drug like paroxetine, as they play out in our system of implicit rationing, have eluded most pharmacy benefit management (PBM) systems. Notwithstanding clinical guidelines, HEDIS measures, or their own disease management pronouncements, the goal of today's health plans—and their outsourced PBM contractors—is to focus not on the clinical appropriateness of when a drug like paroxetine is used, but on its price for all patients, regardless of clinical severity. How cheaply can we get paroxetine? Can we get something in the same class that works for most patients, if not for each individual one, for a lower price? Can we switch the patient to something in an entirely different class that might or might not work, but for far less money, in which time her depression may go away on its own?

For several years health plans and PBMs pursued these "drug switches" through administrative means, a command-and-control approach mostly abandoned along with other first-generation managed care strategies. This approach has been supplanted by two new economic barriers: (1) across-the-board increases in patients' drug copayments for the first time since the liberalization of the drug benefit a decade ago; and (2) highly differentiated copayments for drugs that might or might not be clinically interchangeable, a subtle but clear continuation of the second-guessing of physicians' prescriptions.³² Both techniques represent implicit ration-

ing and, consistent with the practice in general, are enshrouded in coverage rules that vary by health plan and PBM. Such coverage rules are, by their purportedly “proprietary” nature, so obscure that consumer groups and labor unions have had to resort to lawsuits to unearth them.³³

The creation of economic barriers to drugs of a physician’s or patient’s first choice are part of the larger health care trend du jour known as “consumer-driven health care”—consultant-speak for “consumers pay more for health care.” The pharmaceutical version is the tiered pharmacy benefit, whereby a patient confronts up to four different copayments for different medication choices within the same or similar drug classes. The goal of such coverage is to bring consumer pricing discipline to the purchase of medicines and thus reduce excessive spending. Ideally, tiering would mitigate some of the misallocations that characterize U.S. medical consumption and would look something like this: (1) no copayment for a life-saving drug; (2) a low copayment for a productivity-enhancing drug; (3) a moderate copayment for a life-prolonging drug; and (4) a high copayment for a life-enhancing drug.

Unfortunately, pharmacy benefit plans are not structured along this axis of overall value; they are structured along the axis of price. A smaller copayment for a “preferred” drug has nothing to do with its clinical superiority or overall cost-effectiveness. Even more egregiously, it is alleged in lawsuits against the PBMs that a “preferred” drug does not even guarantee, as the PBMs have been claiming, the lowest price for the health plan. Rather, a smaller copayment reflects a bigger financial rebate to the PBM, which reflects a deeper discount negotiated with the drug’s manufacturer.³⁴ After the money has moved around in a circle and enough intermediaries have extracted their piece, new equilibrium prices are established, doctors and pharmacists have more paperwork to do, and nothing has changed. Drugs with low copayments started out with relatively low prices; drugs with high copayments started out with relatively high prices. As a result, the overriding effect of today’s tiered pharmacy benefit is either to move patients toward cheaper, less useful drugs or to make them pay the difference. The economics of this phenomenon have been shown, repeatedly in these pages and elsewhere, to be highly counterproductive and self-defeating: Cheaper drugs are not cheaper in terms of aggregate costs.³⁵ As the published flow of medical science and proliferation of clinical guidelines compel more people to consume more drugs, the negative effects of this implicit rationing surely will multiply.

This is indeed an inefficient, wasteful, and silly system, but it is the one we have in the private sector—hence the headlong rush to replicate it within Medicaid programs and the proposed Medicare drug benefit. If, as a society, we are compelled to ration the rising tide of pharmaceutical use, then we should do so in a rational, transparent, and fair way. An obvious approach would be to structure and manage a drug benefit—for both commercial and public health insurance programs—around value rather than price. To this end, drug coverage tiers created by

health plans and PBMs provide an excellent overall architecture, albeit one that went awry thanks to health care's propensity to reward perverse economic behavior. We could get back on track by simply adopting the simple value-based tiering system suggested above. Central to attaining this—that is, to basing drug coverage on overall value rather than incremental price—is transparency: of data, analytic methods, conclusions, and resulting coverage rules.

This idea dovetails perfectly with numerous proposals designed to promote collective, open, independent analysis of the value of individual drugs and classes of drugs. Uwe Reinhardt first proposed the creation of an independent “pharmacoeconomic research institute” in *Health Affairs* in 2001.³⁶ Such an institute should be funded by the federal government, not by the drug industry (which would make its findings suspect by health plans) or the health insurance industry (which would make its findings suspect to the patient advocacy community). Federal funding would make particular sense, given Medicaid programs' struggle to cope with increasing drug costs and given the enormous decisions that will come to bear on the proposed Medicare drug benefit. Such an institute would already have a good head start on its work: The health services research community has created a wealth of metrics (for example, quality-adjusted life years [QALYs], cost-utility measures, and Episode Treatment Group-based cost analysis). In fact, a detailed blueprint for using value rather than price was published in 2001 by Mark Fendrick and colleagues, but it has been largely ignored.³⁷

A value-based system would result in some startling reappraisals. Based on the fatality of HIV infection two decades ago, the \$22,000 we spend for a year's worth of HIV drugs for one patient would be considered a bargain. By contrast, based on the slow progression of disease and low mortality associated with mild obesity, the much smaller amounts we spend on drugs to “cure” this disease would probably be considered a waste. And what about the heart transplant for that HIV-infected patient? If the transplant cost the system the national average of \$178,000 and the patient lives twenty more years at 60 percent capacity, what at first glance seems like a colossal expenditure—“priced” now at \$14,833 per QALY—suddenly makes some sense. This is indeed a good outcome, as we will no doubt provide that transplant anyway, simply because we can.

Bitter Pills

That heart transplant was one among several gee-whiz stories making the rounds at the 2003 edition of an annual conference on HIV medicine.³⁸ At the conference a parade of researchers presented the latest clinical findings on new HIV drugs, new combinations of older drugs, and the addition of other drugs to existing regimens to improve the quality of life for HIV patients. Of the fourteen presentations at the conference, seven focused almost exclusively on the use of products manufactured by drug companies, which is not unusual. What is unusual was a statement made during the conference's opening remarks: The moderator

said, with a defiant pride, that the conference was not funded in any way by the pharmaceutical industry. The several hundred physicians, nurses, and social workers in the audience burst into raucous applause that lasted several minutes.

Why does a repudiation of drug industry support elicit applause from caregivers who depend on that industry for its tools? Is it for the same reason the *New England Journal of Medicine* frequently runs editorials that are critical of the drug industry, in pages that follow clinical research that overwhelmingly supports the industry's products—pages that are often difficult to find among the journal's drug ads? The bitter applause at the HIV conference and the journal's editorial coldness toward an industry that its own content overwhelmingly endorses would seem especially paradoxical, were this combination of economic dependence, clinical affirmation, and intellectual disdain not common throughout the rest of the U.S. health care community.

Nothing breeds contempt like success, especially in a nation so deeply conflicted between materialist ambition and populist sentiment, and especially in a system teeming with inefficiency, inequity, and human suffering. Like all large organizations in health care, drug companies seek to thrive in a vast, complicated, deeply flawed system not of their own making. The very nature of the drug business—making highly leveragable medical products rather than delivering non-leveragable medical services—is probably the biggest reason the drug companies have been the most financially successful health sector over time. Despite what many argue about the drug industry's reliance on government-funded research, the industry spends the equivalent of a small nation's gross domestic product (GDP) on research and development (R&D): \$32 billion in 2002, compared with the NIH's \$24 billion budget in the same year.³⁹ The industry depends on the NIH and its grantees to find 5,000 drug leads. All of us then depend on the industry to find the one viable drug that those 5,000 drug leads will, on average, produce.⁴⁰ Most of today's medical progress flows from this symbiosis, from the collaborative efforts of thousands of people within the NIH, grantee institutions, the U.S. Food and Drug Administration (FDA), and the drug industry.

Drug companies strive to meet our medical needs not because they act like the social service agencies some wish they were, but because there are vast amounts of cash to be made turning needles in the haystack of government-funded research into pills that rid our bodies of disease and our minds of demons. Their work has made it possible to transplant a heart into an HIV-infected patient. It might not be best use of our resources, but it is how society chooses to use them. The seeming misshapeness of these choices is one more outgrowth of capitalism, which most of us have accepted as the least worst way to organize our economic lives.

This could be the real source of the folklore, of the backlash against the rapidly expanding use, cost, and health system share of drugs. The pharmaceutical industry is a supreme example of the effectiveness of well-financed and highly regulated capitalism, warts and all. Most Americans still have access, 365 days a year, to the

astounding miracles that the industry has helped produce. Forty-three million uninsured fellow Americans might seem like a small price to pay for the privilege.

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NOTES

1. L. Calabrese et al., "Successful Cardiac Transplantation in an HIV-1-Infected Patient with Advanced Disease," *New England Journal of Medicine* (5 June 2003): 2323–2328.
2. AIDS was initially characterized as "gay men's cancer" in the medical literature and popular media in the early 1980s. See K. Roiphe, *Last Night in Paradise* (New York: Little Brown and Company, 1996).
3. Derived from data in K. Freedberg, "The Cost-Effectiveness of Combination Antiretroviral Therapy for HIV Disease," *New England Journal of Medicine* (15 March 2001): 824.
4. Average cost of heart transplantation (mean charge times Medicare cost/charge ratio) for all U.S. patients, 2001–2002, based on data from Solucient, Baltimore, Maryland. Does not include surgical or other physician fees or postdischarge care.
5. According to data from the Centers for Medicare and Medicaid Services, 1995 and 2001.
6. According to a press release by the National Institute for Health Care Management, September 2000; reiterated by hundreds of press reports regarding health plans' premium increases, medical costs, and profits; repudiated by Uwe Reinhardt's "Perspectives on the Pharmaceutical Industry" and J.D. Kleinke's "The Price of Progress," *Health Affairs* (Sep/Oct 2001): 136–149 and 43–60; repudiation confirmed in dozens of press reports in 2002–2003 regarding the restoration of health plan profits. See, for example, S. Wolfe, "Direct-to-Consumer Advertising—Education or Emotion Promotion?" *New England Journal of Medicine* (14 February 2002): 524–526.
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