Letters

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Better Medical-Injury Systems

Savvy pols protect pet programs from accountability by putting them off budget. Current U.S. “systems” for medical injury are far off budget: No one openly monitors legal systems’ costs or performance. Just identifying a few dozen cases a year in one state is a major effort (David Studdert, Y. Tony Yang, and Michelle Mello, July/Aug 04). The same holds for our manifold medical liability insurance mechanisms—hence the nonquantitative nature of William Sage’s (July/Aug 04) history. If tort-lawsuits-plus-liability-coverage were on budget, would informed buyers and taxpayers want these systems to regulate medical injury and pay restitution? Liability coverages cost only about $25 billion in 2002.1 Indirect costs are likely higher, as medical practitioners defensively order extra procedures; withdraw from certain locations, services, and patients; and to some extent hide their mistakes. Such pittances in a $1.5 trillion medical economy would be a bargain if they actually bought the compensation, injury deterrence, and justice that advocates claim. But they don’t.

Nonliability coverages like health insurance provide almost all compensation, as few patients sue and fewer collect—and only very slowly and with very high overhead. High rates of preventable error and injury persist, despite generations of ever more intrusive legalism. And justice is ill served by omitting most injuries, resolving them slowly, and paying out hugely variable amounts in similar cases. Better systems would make practitioners willing to disclose problems, mediate where possible (as suggested by Carol Liebman and Chris Hyman, July/Aug 04), feed back improvements in real time, and compensate consistently. Hospitals, large physician groups, and other medical institutions are the best actors on which to focus responsibility—not just because their deep pockets spread risk, as Sage argued, but also because they control the clinical and administrative systems that can better protect patients. Moving to better systems calls for experimenting with non-courtroom-based injury resolution by medical institutions, health plans (private as well as public), or states.

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NOTE

Trust And Verify

Should health plans try to measure patients’ trust in their physicians? It’s past time. The rise of managed care in the 1980s and 1990s coincided with a decline in patients’ trust. Few researchers paid attention to trust at the time, but by the late 1990s health plan executives were heeding the message. Driven by consumer demand, plans moved away from rewards to doctors for withholding care and from other incentives that pitted physicians’ interests against those of their patients. That Mark Hall has been legal academe’s most vigorous advocate of such incentives gives his paper (with David Thom and Gregory Pawlson, July/Aug 04) an ironic twist. They argue that plans—and those who evaluate them—should measure trust, and I agree. This seems like a no-brainer, but, as they note, health services
researchers have been slow to distinguish patient trust from patient satisfaction.

Can trust be meaningfully assessed by adding one or a few questions to health plans’ patient surveys, as the authors suggest? Here, I’m more skeptical. Such a snapshot is better than nothing, but it tells us little about the underlying psychological structures of faith and credibility—about whether trust is deeply imbedded in people’s understandings or whether circumstances have brought people close to a tipping point. I’m also skeptical about the authors’ claim that strengthening trust can save money. Greater treatment compliance and continuity of care have the potential to reduce costs, but improved trust is equally likely to encourage more people to see doctors and to seek out expensive tests and treatments.

Finally, the authors say that we must measure trust to know if patient protection legislation is “necessary…or counterproductive.” To be sure, market forces have helped to maintain trust by selecting for trustworthiness, but congressional action to make health plans accountable and to contain their excesses shouldn’t await proof that patients have already lost faith in their physicians.1

M. Gregg Bloche
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Trust And Verify: The Authors Respond

We appreciate Gregg Bloche’s letter regarding our paper and his statement that it is past time for health plans to begin measuring patient trust. Our intent was to examine the case for measuring trust based on the results of research in this area, recognizing that many people remain skeptical that measuring trust is helpful or even feasible. We disagree, however, with his focus on managed care by health plans as the predominant source of diminished trust. Other factors may affect trust negatively, which is why patient trust should be a core measure in all health care delivery.

Bloche is skeptical of two claims in our paper: the utility of assessing trust with a few questions on patient surveys, and the argument that strengthening trust can save money. Regarding the former, we advanced several arguments that assessing trust via patient surveys is feasible and likely to provide valuable information. Obtaining even more information on the “underlying psychological structures” and robustness or fragility of trust, as Bloche suggests, would also be valuable as a research endeavor but is probably not feasible as a large-scale, systemwide performance measure.

Regarding the effects of patient trust on costs of care, several decades of research on the role of interpersonal trust in business and social organizations has provided substantial evidence of the general economic efficiency of trust.1 It seems to us that similar savings could accrue in the medical setting via less patient pressure for referrals or additional tests. Also, strengthening trust may encourage people to establish care with a primary care physician, potentially leading to cost savings from fewer emergency department visits.2 Ultimately, however, the question of trust’s effect on medical care costs should be addressed empirically through additional research.

David Thom for the authors
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**Drug Patents In Poor Countries**

Amir Attaran (May/June 04) asserts that patents are not an important barrier to health in poor countries. He begins with the uncontroversial and often-reported fact that most products on the World Health Organization’s (WHO’s) essential medicines list (EML) are off-patent and that for a variety of economic and historical reasons, patent owners often did not file patents in poor countries, even when they could have. He notes the importance of poverty, a lack of donor funding, and poor medical infrastructure as key barriers to health. We agree with much of his factual analysis and some of his normative analysis, but his paper does not provide an accurate picture of concerns over the emerging global systems to project intellectual property (IP).

At the core of the global IP system is the relatively new requirement that World Trade Organization (WTO) members grant and enforce twenty-year patents on medicines. Important generic producers such as India will now have to grant patents on medicines. Firms will also have fewer places to sell generic products—every market of any economic significance will have patents in place. The cumulative effects of these and other measures are to increase innovators’ monopoly power and to delay the introduction of cheap generic copies of new medicines. It is absurd to argue, as Attaran does, that only nineteen patented medicines are important. Whatever the official criteria, as a practical matter, the EML is limited to products that are the most cost-effective to use. We need a new trade policy that recognizes the need to distribute new drugs at marginal cost and uses various mechanisms to share the burden of paying for research and development.

**Patent Status Matters**

Attaran argues that because few drugs on the EML are patented, patent status has no impact on access to medicines in poor countries. This contention is flawed in many respects. First, all countries are not equal. Drug companies tend not to patent in countries that lack market potential or manufacturing capacity. Not surprisingly, in South Africa, which has manufacturing potential for domestic use and regional export, more than 95 percent of antiretrovirals (ARVs) are patented. It only takes patents in a few key markets for patents to be a problem everywhere. Second, all medicines are not equal. Just a few expensive patented medicines can skew entire treatment budgets. Of the fourteen ARV drugs in the Brazilian National AIDS Program, three new single-source products accounted for 63 percent of total program costs in 2003.

Third, patented drugs have been excluded from the EML because of cost. While Attaran argues that cost is not an EML exclusion criterion, his own bibliography indicates that rules were only changed in 2001: For 95 percent of the EML’s life, cost was a concern. As such, the proportion of patented drugs on the EML can be expected to increase in the future.

Fourth, patent coverage will increase generally. Under WTO rules, developing countries must have patent systems in place by 1 January 2005, while least-developed countries have until 2016. It is not surprising that essential drugs are not patented in many developing countries, because for most of the past twenty years there was no requirement to do so.

In our experience providing medical aid in more than eighty countries, patents and other exclusive rights remain a major factor in increasing drug prices or in blocking availability altogether. In China, for example, GlaxoSmithKline’s patent on the ARV drug 3TC blocks the availability of the simplest and most affordable AIDS treatment available worldwide—the WHO-recommended fixed-dose combination of d4T/3TC/NVP. Doctors are forced to use brand-name medicines that are five times more expensive and prescribe individual drugs rather than the combined pill; this complicates...
the treatment regimen. Had there been no patent barrier, Chinese producers would have been able to manufacture and export generic versions of the recommended fixed-dose combination. Governments must ensure that drug prices are affordable to their populations by freely making use of their WTO rights to issue compulsory licenses to overcome patents whenever needed. These rights are openly being undermined through U.S. pressure to limit the use of compulsory licensing in regional and bilateral trade agreements in the developing world.4

We must do all that we can to alleviate poverty, but this is not the only answer to the immediate health crisis. Getting one billion people out of abject poverty is not going to happen overnight; doctors need to save lives now. Unless the exclusive power of patent holders to set prices is restrained, access to essential medicines will become an increasing concern for the world’s most vulnerable patients.

Eric Goemaere (South Africa), Michel Lotrofska (Brazil), Yves Marchandy (China), and Ellen ’t Hoen (Paris)

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Objective Patent Study

It is welcome to find an objective and rigorous study of the issues surrounding patents and health care access. Attaran’s research and analysis bring important data into the complex and often emotional debate regarding intellectual property rights and public health. By showing that the actual patenting of essential medicines in low- to middle-income developing countries is quite rare, he gives policymakers interested in improving public health the opportunity to move away from a debate overly focused on intellectual property rights.

Nonetheless, we take issue with the assumption underlying Attaran’s paper that if patents existed on essential drugs, access to these medicines would be restricted. In reality, patented essential drugs are being offered at cost, below cost, or even for free by the patent holders. For example, a recent study by the Hudson Institute using data collected by Médecins sans Frontières shows that the patent holders often provide ARVs at prices lower than those of generics manufacturers.1 Given this proven ability of patent holders to supply markets at dramatically reduced prices, it is not necessary for these companies to institute a general policy of voluntarily “out-licensing” their patented drugs on the EML, as Attaran suggests. Although some companies have chosen this route for specific products, it is unlikely that such a policy is necessary to improve access to medicines meeting the highest international quality standards, which patent holders are best placed to quickly supply.

Uganda’s President Yoweri Museveni stated the issue well when he noted that giving priority to medicine patents in trade negotiations has been a “red herring.”2 Our industry is committed to working together with national governments, the United Nations, and responsible civil-society organizations to help overcome the real barriers to access to medicines for developing countries.

Eric Noehrenberg
International Federation of Pharmaceutical Manufacturers Associations (Geneva)
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Drug Patents Abroad: The Author Responds

My paper was written for a simple purpose: to demonstrate empirically and accurately how essential medicines are or are not patented in developing countries. To that end, I collected and published about 20,000 data points, not one of which is now said to be wrong. I also wrote that “the value of these data,” properly viewed, was “to improve access to medicines for the world’s poorest people and not to polarize a debate among policy elites.” So why are three advocacy organizations having a polarized debate about my paper? The debate about patents and access to medicines is less built on data than on exaggeration and histrionics. Publishing accurate empirical data in a peer-reviewed journal undoes the exaggerations—and helps to calm the debate. That greatly threatens the professional advocates whose job security requires a fierce and ongoing debate. Space is lacking to list all the histrionics; a few will suffice.

Médecins sans Frontières (MSF) faults my paper for concluding that “because few drugs...are patented, patent status has no impact on access to medicines.” What I actually wrote is that “an absence of patents and barriers to treatment is the norm” but that “certain excursions from [the norm] can be highly significant for public health.” MSF and the Consumer Project on Technology (CPT) also make a normative distinction, unencumbered by evidence, between patented brand-name medicines (bad) and unpatented generic medicines (good). Both vituperate against brand-name companies’ patents, which prevent access to a generic, fixed-dose combination of AIDS medicine made in India (the d4T/3TC/NVP combination). So it is mysterious that MSF and CPT have never criticized the eighteen African patents that an Indian generic company (Cipla) holds on just that combination. They have known about it for years. Perhaps the concerned opposition to patents is really a knee-jerk opposition to multinationals?

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) also gets it wrong. With only 1.4 percent of essential medicines patented in developing countries, all pharmaceutical companies should be flexible and out-license those to aid health or the technology base. Some of the industry’s leading companies have done this and felt no apparent pain. For IFPMA to oppose this flexibility as “not necessary” because companies already provide medicines at “reduced prices” displays stunning incognizance that price reductions have barely improved the industry’s battered public reputation. Intransigence is not the way for the drug industry to win friends.

People who live on a dollar a day do not care about policy debates; they just want solutions that give them medicines and health. How unfortunate that hired advocates, on both sides, perpetuate a debate that could be solved in better faith.

Amir Attaran
Royal Institute of International Affairs (London)

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Quality Of Care In Five Countries

The paper by Peter Hussey and colleagues (May/June 04) is flawed by a false assumption, a serious omission, and the appearance of a politically motivated author. The authors claim that the United States ranks lowest in survival rates for kidney and liver transplants. Lower survival indicates lower-quality care, the authors glibly argue, “assuming that transplant recipients in the five countries are similar.”
That assumption is wrong. Transplant recipients are not similar. The United States alone routinely offers transplants to patients over age sixty-five and retransplants to patients whose first transplant has failed. Astoundingly, the authors fail to examine heart disease in the United States, a serious omission because it is the nation’s most costly health problem. How can the authors claim to prove that higher health care spending does not produce better results, if their study doesn’t examine the single largest use of the money?

The paper finds generally comparable quality in cancer care. One exception is breast cancer. In New Zealand, waits of twelve weeks or longer for radiation are outraging patients. Some of that outrage has been aimed at Colin Feek, a high-level administrator in the New Zealand Ministry of Health. Feek is also one of the authors of the “Five Countries” paper, but his situation makes him an apologist, not a credible, objective author. No wonder he is eager to prove that health care is just as good in New Zealand as in the United States. He is being pummeled in the press. The danger is that this flawed study will continue to be cited uncritically by advocates of government-run, single-payer health care systems. The national debate over health care is so polarized that many people don’t seem to care about the facts any more. That’s unfortunate.

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Statistical Issues And Quality Indicators

Hussey and colleagues provide important public health information for policymakers. However, we would like to point out two statistical issues that are not adequately addressed. First, the standardized quality indicators provided in the paper must be treated with caution because they are affected by a statistical problem common among ratio statistics: The figures will change dramatically depending on whether the ratio statistic centers on the event or the nonevent. Had the authors used acute myocardial infarction (AMI) thirty-day survival rates (like most of the other indicators in the same “survival rates” group) instead of AMI thirty-day case-fatality rates, the standardized quality indicators would have become 104 (Australia), 100 (Canada), and 103 (New Zealand), instead of 134 (Australia), 100 (Canada), and 121 (New Zealand). In other words, using case-fatality rates instead of survival rates artificially inflated the ratio statistics. Second, the authors report no statistical test of significance. Without this information, it is difficult to determine whether or not the ranking of a certain indicator by country makes sense.

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Care In Five Countries: The Authors Respond

We agree with Elizabeth McCaughey about the importance of facts in health systems comparisons. A desire for more useful information, not political considerations, motivated our study. She is correct that patient characteristics may be behind some of the differences in the indicators we collected, including transplant rates. It was beyond our scope and expertise to fully investigate the causes of all of the differences we reported, but we hope that our study will motivate others to do so. Our paper enables researchers in each of the five countries to identify areas deserving further study. We would welcome any data on the characteristics of transplant patients that McCaughey could share.

We also agree that many important areas of
care were omitted from our study. We wrote, “The limitations of this indicator list preclude the definite conclusions that any country has the best quality of care...More work is clearly needed to expand the scope and depth.” Measurement capabilities in the five countries could be improved drastically.

The facts that are currently available fail to show that any country has the best quality of medical care. Our study was an international collaboration between researchers and government officials who have access to national statistics. McCaughey's implied suggestion that we collect and compare mostly unpublished national statistics without the involvement of government officials is infeasible.

As for Bernard Choi, we agree completely with his first point. Unfortunately, any standardization of results leads to some distortion of the perceived real differences between countries. We elected to present standardized results rather than actual results so that countries could be compared easily. We used case-fatality rates for AMI and survival rates after cancer diagnosis in order to follow previous convention. All of our indicators were based on existing indicators in use in the five countries. We also agree that tests of statistical significance are important. However, given the number of indicators and the number of pairwise comparisons to be made, we elected to leave the results of the tests out of our paper.

For the indicator that Choi is interested in—case-fatality rates after AMI—each country's result is significantly different from each other's and from the pooled rate using t-tests of differences in sample proportions. We would be happy to supply our data for those interested in more details (send e-mail to phussey@jhsph.edu).

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Patient Harm
Kieran Walsh and Stephen Shortell (May/June 04) have made an important contribution to the growing literature on clinical errors and adverse events in health care organizations. They accurately identify the sizable obstacles that impede more rapid progress in changing ineffective organizational systems and selfish cultures that allow preventable harm to patients. Not surprisingly, these barriers also permit and produce administrative failures in the same organizations. Unless institutions demonstrate that such failures, whether clinical or management, are morally unacceptable, both patients and staff will continue to be compromised.

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NOTE

Erratum
Michael Schoenbaum was inadvertently excluded from the list of members of the Child Health Business Case Working Group in the acknowledgments to a paper written by that group (“Exploring the Business Case for Improving the Quality of Health Care for Children”) and published in our July/August 2004 issue.