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Ethics And Futility
We appreciate the thoughtful comments of Lindsay Hampson, Ezekiel Emanuel, and Robert Veatch that accompanied our paper on the costs of nonbeneficial treatment in the intensive care setting (July/Aug 05). We respond here to a few of Veatch's points.

Veatch seems to object that we located seven major hospitals where hospital personnel recognized the potential for an ethics consultation yet claimed that not recommending one was "usual care." We should not need to point out how often "usual care" treatments are found to be useless, or even harmful, when subjected to a randomized controlled trial.

Veatch called the study controversial because "it is hard to imagine how the patients in this study could have given informed consent to take part." Indeed, most of the time, as in any clinical trial involving seriously ill, incapacitated patients, informed consent was obtained from surrogates.

Veatch also objects to "evaluating ethics consultation by...whether it saves hospitals money." Our original, broader study, published in 2003, reported that ethics consultations reduced what we regarded to be nonbeneficial treatments—namely, treatments that failed to enable the patient to survive outside the acute hospital setting (the outcome measure of every published study of cardiopulmonary resuscitation, for example).1 There was widespread agreement among all parties—patients, surrogates, physicians, and nurses—that ethics consultations had a beneficial effect on patient care. We then analyzed the possible cost savings. Not to have done so, in our view, would have neglected one of the most important areas of health policy today.

Finally, Veatch contrasts "physiological" futility (treatment that cannot produce the outcome the patient is seeking) with "normative" futility (treatment that is likely to achieve the patient's goal although the clinician considers the goal valueless) as though only the latter is a "value judgment." We submit that limiting the definition of medical futility to physiological rather than patient-centered outcomes is a value choice, not a value-free action. We agree that although many hospitals are adopting futility policies that oppose continuing life support on permanently unconscious patients such as Terri Schiavo, some hospitals might advocate maintaining life support for such patients. In our pluralistic society, which accepts that certain hospitals will not perform abortions, this would constitute a "respectable minority" standard of care.2 If these latter hospitals would be willing to accept the transfer of permanently unconscious patients on life support, disputes over end-of-life treatments could be resolved without court intervention. So it is puzzling that Veatch considers "dangerous" the Texas law that carefully outlines steps to take in disputes over medical futility—including transferring patients—and then says that such decisions are "the moral responsibility of society or its agents administering health programs." The law was put in place after due deliberation by the Texas legislature. Is this not what Veatch means?

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NOTES
1. L.J. Schneiderman et al., “Effect of Ethics Consultations on Nonbeneficial Life-Sustaining Treatments in the Intensive Care Setting: A Random


**The FDA And The Safety Of Medical Products**

David Malenka and colleagues in one paper and Scott Gottlieb in another (July/Aug 05) propose that increased use of information and claims data from electronic health records (EHRs) could improve the ability to detect problems with medical devices and drugs. As more electronic data become available, they do, indeed, offer great promise to assess safety questions. The U.S. Food and Drug Administration (FDA) already has extensive experience in using these types of data sources to investigate safety issues. Our experience, however, coincides with that of Malenka and colleagues: Current data and analysis are limited by problems with accuracy, timeliness, completeness, electronic capture of crucial data elements, and data standardization, as well as the expense of analysis. There also are scientific challenges in dealing with the ever-present problems of potential bias and confounding of results.

The FDA is working closely with the Centers for Medicare and Medicaid Services (CMS), Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), and U.S. Department of Health and Human Services (HHS) to develop overall standards and procedures to help make regular use of health care data in assessing medical product performance a reality. A robust detection system is needed because previously undetected problems will always crop up after medical products are on the market. We at the FDA believe that better premarket evaluation during the development process also offers an important opportunity to prevent or detect many problems.

The medical products industry has capitalized on major advances in the biomedical sciences to discover and design many innovative products. Applying the new sciences to strengthen the premarket evaluation system could undoubtedly yield major advances in product safety. For example, developing and applying safety biomarkers using genomic, proteomic, or imaging technologies will provide early signals of various organ system toxicities and could be used to monitor patients during treatment. Similarly, markers that identify how patients will respond can screen out people with a low probability of benefit and thus minimize their exposure to potential side effects. In some cases, pharmacogenomic analyses might explain why these people respond differently and might offer the possibility of preventing adverse effects through prescreening.

The FDA’s Critical Path Initiative, www.fda.gov/oc/initiatives/criticalpath, is intended to stimulate scientific modernizing of the premarket evaluation system for medical devices and drugs. Scientific improvements and product assessment—combined with robust health care–based surveillance systems—could greatly increase the overall safety of using medical products.

**End-Of-Life Options**

Everyone dreads becoming the narrator of Jerald Winakur’s Narrative Matters essay about his father’s gradual decline into dementia and frailty (July/Aug 05). As he and other experienced clinicians know, “care” often makes things worse. Many also have thought about cutting life short, as Winakur did; but loyalty, awe, confusion, commitment, morality, and love ordinarily carry the day.

Why does Winakur find only two options—morphine overdose or calling 911—when his father endures another calamity? Our charitable and creative society could do better. Rather than only easy access to emergency services and hospitalization, the father and the
family should be able to count on (1) supports for family caregivers; (2) plans for expectable urgent situations; (3) round-the-clock coverage by competent clinicians who can arrive at the home quickly; (4) symptom treatment (including regional anesthesia for a fractured hip); (5) reliable institutional care; and (6) a societal attitude that the patient's life and the family's caregiving have meaning and honor.

At the end of life, most face frailty and dementia, with slowly ebbing capabilities. This is a small price for long life, but dying is becoming a small stumble off the long, medically supported high-wire act. Yet health care does not anticipate this or support patients and families when someone is “sick enough to die.” Financing reforms could encourage comprehensive care and allow families to plan for personal and financial burdens; research and innovation could ensure patient comfort and caregiver support.

Winakur’s evocative and clear narrative helps shape our maturing sense of appropriate behavior and policy. On television, in newspapers, and around the watercooler, society is learning to make progressive disability a part of life. In addition to grim, well-told stories by knowledgeable sons frustrated by dysfunctional care systems, we need to reshape services to match the priorities and possibilities for all of our parents. Then everyone could be grateful for a care system that we can count on when we need care most.

Joanne Lynn
RAND
Arlington, Virginia

End-Of-Life Options: Author’s Reply

I appreciate Joanne Lynn’s response to my essay. As a geriatrician, when confronted with an older patient whose inevitable decline I can predict, I ask myself: Is it time for assisted living? Maybe a nursing home? Do I suggest taking away the car? Do I call the children? And these are the easy, nonurgent questions. If we’re lucky, there is time to allow patients and families to consider the various options. Yet even then there is often much resistance, denial, and baggage between adult children and their aging parents.

Now make this an urgent situation. Dad is on the floor writhing in pain with a fractured hip. If the options have not been laid out in great detail in advance with his wife and children present (rare today due to geography, time constraints, managed care, a procedure-based reimbursement system, and so forth), I can say with virtual certainty that 911 will be called and the emergency medical service (EMS) will take him to an emergency room (ER).

Given the impediments to rational, best-choice decision making, someone still must do something to get Dad off the floor and mollify his pain. Mom cannot do the heavy lifting here.

In thirty years of practice, I have had just one patient in this situation opt for hospice care over acute hospital care and surgery. I knew him and his family for decades, much had been discussed beforehand, the patient was chronically ill but mentally intact, and it was his choice. And still this decision was made in the ER after EMS brought him from home. He died comfortably, yes, but it took several weeks.

“Society [might be] learning to make progressive disability a part of life,” as Lynn says. I know she would agree that society has a very long way to go in dealing with end-of-life issues as they affect our aging parents.

Jerald Winakur
Comfort, Texas

Vaccine Policy Challenges

Although vaccines were one of the most successful public health accomplishments in the past century, for decades now the United States has neglected problems in the vaccine market, and these problems could spark a multitude of preventable infectious disease and
public health crises. With the special issue on vaccines (May/June 05), Health Affairs is again at the forefront of furthering important conversations about a crucial public health matter.

By bringing together top thought leaders, the vaccines issue gave the public health community and policymakers serious food for thought on how to solve these problems. The paper on negotiating the vaccine infrastructure by Walter Orenstein and colleagues provided great context for understanding the complex issues that have ramifications for the health of our country and the world. Paul Offit's paper on why pharmaceutical companies are gradually abandoning vaccines had important insights into the factors that have made the vaccine marketplace unattractive to industry; additionally, if Congress were to effectively address issues such as liability and accounting requirements, Offit gave ways to encourage drug companies to reenter the market.

I hope that this issue of Health Affairs will help tackle ongoing vaccine policy problems. Among these are (1) getting the government to budget the relatively small additional amount that could help close the chronic gap of 20 percent of U.S. preschoolers not receiving routine vaccinations, and (2) investing in modernizing vaccine production so that we finally can move from developing egg-based vaccinations for seasonal and possible pandemic flu to ones that are technology-based.

I congratulate your journal and the authors for a clear and thought-provoking approach to vaccines. Thank you for taking a comprehensive look at the range of challenges facing the vaccine marketplace and how this relates to society as a whole.

Laura M. Segal
Trust for America’s Health
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Vaccine Risk And Benefit In The Developing World

In their paper about developing vaccines for disease-endemic countries (May/June 05), Julie Milstien and colleagues remind us that millions of lives in the developing world depend on decisions made by individuals and institutions in the industrialized world; furthermore, these decisions are made on the basis of industrialized-world considerations about the safety, effectiveness, and usefulness of vaccines. Yet when it comes to safety, the public health reality for industrialized countries often differs greatly from that in developing countries.

The major thrust of the authors’ suggestions on how to address risk-benefit analysis for the developing world is an action plan that consists of information exchange, process improvement, and infrastructure strengthening. These are excellent suggestions. The danger remains, however, that a different safety standard for the same vaccine for healthy subjects in different parts of the world, regardless of the benefits, still might not be acceptable.

A parallel approach could be to establish the safety of each vaccine only on the basis of scientific concerns about serious adverse events and in comparison to the safety of already accepted vaccines. For example, the authors discuss thimerosal-containing vaccines (which include mercury) and rotavirus vaccines (which create an increased risk in infants for intussusception, a potentially fatal bowel obstruction) as examples where industrialized-world analysis of the risk-benefit ratio has not been appropriate for the developing world. Scientific evidence does not support excessive risk of serious adverse events in the use of thimerosal-containing vaccines in spite of theoretical possibilities. Careful inspection of U.S. Centers for Disease Control and Prevention (CDC) data about the association of intussusception with the Wyeth rotavirus vaccine suggests no increased risk if the first
vaccine in the series is given when an infant is two months old. In helping design the Merck rotavirus vaccine safety trial, I found this observation to be an important consideration. In both of these cases, the proven safety risk is comparable to widely used vaccines, and no adjustment in risk-benefit calculation for using them in the developing world should be required.

Regardless of the specific approach, as the authors make clear, serious parallel efforts to solve this problem need to be taken—or millions of children will suffer.

Jerald C. Sadoff
Aeras Global TB Vaccine Foundation
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**Vaccines And The Next Pandemic**

I would like to amplify—from a state perspective—an aspect of Paul Offit’s paper (May/June 05) on vaccine manufacturing. On October 27, 2001, when I was Virginia's secretary of health and human services, headlines such as “Virginia Opens Treatment Centers” appeared across the state. It was the day we announced that within a seventy-two-hour period, Virginia and other localities in the Washington, D.C., area were going to test and treat as many as 26,000 people for anthrax exposure. We used doses available to us though the CDC’s U.S. Strategic National Stockpile; today Virginia remains among the few states with any real experience in large-scale access to this national stockpile. From my experience in the wake of September 11, stockpiling is a second-best solution.

Anthrax isn’t influenza, of course, but the issues of rapid access, distribution, and rationing are very much the same. Public or private stockpiling of antiviral drugs perhaps comes out of frustration about the current state of the U.S. supply of vaccine. We adopt antiviral stockpiling because there are so few vaccine manufacturers producing vaccine; if the risk and return on capital were reasonable, many more manufacturers would enter the market.

The best method for reducing infections and complications from influenza is immuno-

**Erratum**

The paper by Bruce Stuart and colleagues, “Riding the Rollercoaster: The Ups and Downs in Out-of-Pocket Spending under the Standard Medicare Drug Benefit,” *Health Affairs* 24, no. 4 (2005): 1022–1031, erroneously cited a report to the Centers for Medicare and Medicaid Services (CMS) by Docksum and Hassol (Note 21). The citation is incorrect and should not have been listed as a reference. The authors regret the error and any inconvenience that it might have caused.