

Medical Research in the 21st Century

To the Editor: The spectacular revelations of the human genome project promise precise “magic bullets” to cure a range of human diseases. Many of these opportunities are described in the these issue of *JAMA* devoted to opportunities for medical research in the 21st century (February 7, 2001). The brilliance of the prospects, however, may eclipse many more pragmatic but nonetheless important considerations.

For instance, in their article on burden of disease, Dr Michaud and colleagues¹ list automobile crashes as the ninth leading cause of disability-adjusted life years (DALYs) in 1990 and project that this will be the third leading cause by the year 2020. The projections may underestimate the relative importance of trauma as a cause of DALYs if some of the sophisticated research pays off with real cures for heart disease, cerebrovascular accidents, and cancer.

The possibilities of genomic research may distract attention from the importance of trauma as a cause of death and disability and lead to inappropriate research priorities. Michaud et al report that, during the time that automobile crashes will move from ninth to third as a cause of DALYs, funding for research into the causes, prevention, and management of injuries will fall from sixth to ninth in the list of priorities. By 2020, 65 times as much money will be spent on human immunodeficiency virus and acquired immunodeficiency syndrome as trauma, even though AIDS will be ranked 10th as a cause of DALYs. Research funding should reflect actual causes of death and disability in our society.

The possibilities for research into prevention and management of injuries deserved at least 1 article in an otherwise excellent issue of *JAMA*, and in the future, deserve more research funding in recognition of the importance of trauma as a cause of death and disability.

Adolph H. Giesecke, MD
Anesthesiology and Pain Management
University of Texas Southwestern Medical Center
Dallas

1. Michaud CM, Murray CJ, Bloom BR. Burden of disease: implications for future research. *JAMA*. 2001;285:535-539.

To the Editor: Dr Nathan and colleagues¹ set a generally exuberant tone for the *JAMA* issue devoted to opportunities for medical research in the 21st century. They noted that “biomedical science . . . promises almost unlimited opportunity for the betterment of mankind.” Most of the issue continues in this vein, with optimism for the development of ever more powerful medical science, well into the 21st century. Some counterpoint to this generally ebullient tone is provided in the global and public health perspectives of Dr Michaud and colleagues² and Drs Goldenberg and Jobe³ in the same issue, but a further cautionary note may be warranted.

We must question in what direction “progress” lies. In the century ahead, threats to human well-being are more likely to come from social instability and environmental degradation than from disease or premature mortality. The “compression of morbidity” envisioned by Fries⁴ has come to pass in large part, with average longevity in the industrialized West approaching the theoretical limits imposed by the human genome. Many of the biomedical breakthroughs described in this issue of *THE JOURNAL* will have little effect on longevity, because the primary beneficiaries will be those who are already in their 70s, 80s, and 90s. Moreover, much of the new technology will be expensive and therefore accessible to relatively few, contributing, in effect, to inequalities in health mediated by socioeconomic factors. The “haves” will not only have better lives than the “have-nots,” they will quite literally have more life.

In the introduction to his essays on research and neonatology, William A. Silverman observed that “It is a mistake to suppose that any technical innovation has one, and only one, effect.”⁵ The fact is that scientists do not have a good record of anticipating and averting the adverse effects of technology. The world population burden³ that underlies so many of the public health issues raised by Michaud et al was an “adverse effect” made possible and virtually inevitable by the public health miracles of a hundred years ago, coupled with the post-World War II “green revolution” mediated by fertilizers, herbicides, pesticides, and the advent of chemically controlled agriculture. Even the prosaic internal combustion engine may be seen as too complex and multifaceted for our social institutions, when one considers the unintended consequences that our mobility has had on families, communities and the environment. There are neonatal intensive care units and nursing homes filled with citizens “made possible” by medical advances. We hardly need to wait for the human genome project or cloning to discover that we do not have all of the social or moral equipment needed to manage our successes.

Of course, those who are struggling with the complex challenges of biomedical science may argue that social and moral questions lie beyond the scope of the research endeavor itself.

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Letters Section Editors: Stephen J. Lurie, MD, PhD, Senior Editor; Jody W. Zylke, MD, Contributing Editor.

However, this separation of what is done in research from why it is done has led to the current stockpile of expensive medical weaponry, and to Callahan's observation that "medicine has entered a new stage of its history: one where the successes, and not the failures, are the main source of our problems."⁶

Charles Gessert, MD, MPH
Division of Education and Research
St Mary's/Duluth Clinic Health System
Duluth, Minn

1. Nathan DG, Fontanarosa PB, Wilson JD. Opportunities for medical research in the 21st century [theme issue]. *JAMA*. 2001;285:533-534.
2. Michaud CM, Murray CJL, Bloom BR. Burden of disease: implications for future research. *JAMA*. 2001;285:535-539.
3. Goldenberg RL, Jobe AH. Prospects for research in reproductive health and birth outcomes. *JAMA*. 2001;285:633-639.
4. Fries JF. Aging, natural death and the compression of morbidity. *N Engl J Med*. 1980;303:130-135.
5. Silverman WA. *Where's the Evidence? Debates in Modern Medicine*. Oxford, England: Oxford University Press; 1998:259.
6. Callahan D. *What Kind of Life: The Limits of Medical Progress*. New York, NY: Simon & Schuster; 1990:318.

To the Editor: I was disappointed that the *JAMA* theme issue on opportunities for medical research gave no attention to the need to develop research in primary care. Rather, the issue centered almost entirely on biomedical research. While such endeavors are very worthwhile, research that will help improve the processes of care is equally important.

For instance, Dr Michaud and colleagues¹ described the DALYs in the United States in 1996. I note that the detection and management of most of these diseases (which often coexist) are within the realm of community primary care. Even "congenital abnormalities" are responsive, to some extent, to pre-pregnancy and prenatal interventions in the primary care setting. Another example is ischemic heart disease; it is clear that much remains to be done to identify patients at risk at a time when primary prevention is effective. It is similarly important to develop efficient ways to identify such patients that can be incorporated into day-to-day practice and that are acceptable to patients—who often may have multiple other medical problems. Another example is alcoholism. There needs to be as much emphasis on early detection and intervention² as on advances in transplantation technology.

Dr Nathan and colleagues state, "There seems to be widespread belief that miraculous cures can be effected by relatively simple means."³ While technological interventions have been and will continue to be enormously helpful, the fact will remain that the provision of care to people at risk for or experiencing these conditions remains poorly understood. Primary care is complex and badly in need of a major investment in good research

John W. Beasley, MD
Department of Family Medicine
University of Wisconsin at Madison Medical School

1. Michaud CM, Murray CJL, Bloom BR. Burden of disease: implications for future research. *JAMA*. 2001;285:535-539.
2. Fleming MF, Barry KL, Manwell LB, et al. Brief physician advice for problem alcohol drinkers. *JAMA*. 1997;277:1039-1045.
3. Nathan DG, Fontanarosa PB, Wilson JD. Opportunities for medical research in the 21st century [theme issue]. *JAMA*. 2001;285:533-534.

To the Editor: The current and potential advances in biomedical science outlined in the February 7, 2001, issue of *JAMA* make practicing medicine today even more exciting than when I entered medical school 40 years ago.

However, there is a missing ingredient that limits what these innovations could achieve. Absent from the discussion is recognition of the performance gap that exists between new knowledge and its application in everyday medicine.

Many studies have demonstrated this gap. For example, only 46% of Medicare beneficiaries in 1 study were given pneumococcal vaccine at least once and in some states the rate was as low as 32%.¹ Aspirin is recommended for all adult patients with diabetes but is given to only 20%,² and screening for diabetic nephropathy varied from 19% in a private health plan³ to 57% in a Medicaid population.⁴ A study of counseling of adolescents about diet, exercise, injury prevention, tobacco use, and HIV transmission during physician office visits found that less than 22% were given any counseling. Diet counseling was the most frequent intervention at 15%, tobacco use was 7.6%, and HIV transmission, 2.9%.⁵

Performance gap research is complex and should include these questions: (1) What are the variables that influence primary care's known positive influence⁶ on health indicators? (2) What motivates physicians to perform? (3) What system or practice management issues enhance performance? (4) What educational strategies⁷ can change physician behavior and improve health care outcomes?

We need more and better performance gap research. Without it, the dreams so well articulated by the authors in *THE JOURNAL* will never be realized.

Edward Shahady, MD
Department of Family Medicine and Community Health
University of Miami
Miami, Fla

1. Jencks SF, Cserdon T, Burwen DR, et al. Quality of medical care delivered to Medicare beneficiaries: a profile at state and national levels. *JAMA*. 2000;284:1670-1676.
2. Rolka DB, Fagot-Campagna A, Narayan KM. Aspirin use among adults with diabetes: estimates from the third national health and nutrition examination survey. *Diabetes Care*. 2001;24:197-201.
3. Mainous AG, Gill JM. Lack of screening for diabetic nephropathy: evidence from a privately insured population. *Fam Med*. 2001;33:115-119.
4. Srinivasan M, Przybelski M, Swigonski N. The Oregon health plan: predictors of office based diabetic quality of care. *Diabetes Care*. 2001;24:262-267.
5. Merenstein D, Green L, Fryer GE, Dovey S. Shortchanging adolescents: room for improvement in preventive care by physicians. *Fam Med*. 2001;33:120-123.
6. Shi L, Starfield B, Kennedy B, Kawachi I. Income inequality, primary care, and health indicators. *J Fam Pract*. 1999;48:275-284.
7. Davis D, Thompson O'Brien MA, et al. Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA*. 1999;282:867-874.

In Reply: Dr Giesecke makes a strong case for the need to increase investments in research into the prevention and management of injuries. It is important to note that estimates of expenditures per DALY for selected health-related research topics in 2020 assumed no increase in funding for research between 1990 and 2020. Changes in expenditures per DALY em-

phasize projected changes in the magnitude of burden for the different conditions.

Catherine Michaud, MD, PhD
Department of Population and International Health
Harvard School of Public Health
Boston, Mass

In Reply: The articles in the theme issue on opportunities for medical research serve to highlight important discoveries in biomedical science and forecast major advances likely to occur during the early 21st century.¹ However, the issue was not intended to include all research areas or address every aspect related to the application of future research discoveries, such as some of those noted by the authors of these letters.

Dr Giesecke emphasizes the need for additional research in trauma, especially that resulting from motor vehicle crashes. Multidisciplinary research efforts, including basic science investigations into the mechanisms of cellular injury and recovery following trauma, innovative studies on injury prevention, rigorous assessment of trauma resuscitation techniques, and evaluation of novel approaches for rehabilitation, are needed to reduce morbidity and mortality, and to improve quality of life and functional outcomes following trauma.

Dr Gessert suggests that the social, ecological, and moral consequences of research discoveries require careful consideration. We had noted these important issues in our Editorial,² and indicated that “formidable obstacles, some scientific and others psychological, environmental, or societal, must be overcome before these various advances can be applied to the human condition” and that “as long as health care delivery is inequitably distributed, the impact of new advances in understanding and preventing disease will be blunted, and overall improvement in health will not be optimal.”

Dr Beasley calls for additional research in primary care to improve the processes of care and to ensure appropriate delivery of care across a broad spectrum of disorders. Results of such investigations most likely would help narrow the “performance gap” that Dr Shahady suggests deserves further study. Moreover, with forthcoming advances in medical science, such as the virtually inevitable use of molecular techniques in routine clinical practice, additional studies will need to determine the optimal role of primary care physicians, specialists, and subspecialists in ensuring appropriate, timely, and cost-effective application of these and other promising discoveries for improving patient care.

David G. Nathan, MD
Dana Farber Cancer Institute
Boston, Mass

Phil B. Fontanarosa, MD
JAMA
Chicago, Ill

Jean D. Wilson, MD
University of Texas Southwestern Medical Center
Dallas

1. Nathan DG, Fontanarosa PB, Wilson JD. Opportunities for medical research in the 21st century [Theme issue]. *JAMA*. 2001;285:491-686.

2. Nathan DG, Fontanarosa PB, Wilson JD. Opportunities for medical research in the 21st century. *JAMA*. 2001;285:533-534.

Early Childhood Educational Intervention and Long-term Developmental Outcomes

To the Editor: Dr Reynolds and colleagues¹ concluded that an early intervention program in Chicago produced a long-term decrease in the rates of juvenile arrest and high school dropout. However, as noted by the authors, the study did not randomly assign children to the intervention or control groups. I agree that random assignment in this situation would have been unethical, but given this design, the study cannot lead to strong causal inferences. For instance, the intervention group included only children whose caretakers were able or willing to enroll their children in the program and provide for sustained involvement in the program. The control group included children who did not participate in the preschool program because they did not live in an area that offered it. The control group thus includes both children who could have completed the program as well as children who would not have completed the program due to lack of parental involvement, transportation problems, medical problems, or other variables. The intervention group, by definition, included only children who were able to complete the program.

I suspect that parental involvement, transportation, and other variables strongly contribute to a child's capacity to complete the program. It is possible that parental involvement explains more of the variance in outcome among inner-city children than do structured programs. In fact, Miedel and Reynolds found a relationship between parental involvement and academic achievement.² If policy makers mistakenly accept the conclusion that preschool intervention results in less criminal activity later, they may mistakenly invest in these programs when the money might be better invested in parenting-skill programs and other interventions to increase parental involvement.

Matthew D. Thompson, PsyD
Department of Psychology
Children's Hospital
New Orleans, La

1. Reynolds AJ, Temple JA, Robertson DL, Mann EA. Long-term effects of an early childhood intervention on educational achievement and juvenile arrest. *JAMA*. 2001;285:2339-2346.

2. Miedel WT, Reynolds AJ. Parent involvement in early intervention for disadvantaged children: does it matter? *J Sch Psychol*. 1999;37:379-402.

In Reply: We agree with Dr Thompson that one should be cautious in drawing causal inferences about the effects of early childhood program participation in our study. As we noted, biases due to nonrandom program assignment are a threat to the validity of the estimated effects. However, based on the matched-group alternative-intervention design, the pattern of findings, and the many statistical analyses we performed to address alternative explanations, we are confident that participation in the Child-Parent Center (CPC) Program from ages 3 to 9 years was the source of the group differences at age 20 years. Preschool participation demonstrated the greatest impact. Relative to the comparison group, it was associated with a 29% higher rate of high school completion, a 33% lower rate of juvenile delinquency, and a 41% lower rate of special education placement.

Thompson suggests that group differences in educational attainment and juvenile arrest were due to preexisting differences in parental involvement rather than participation in the CPC program. Two types of biases are possible. First, to the extent that program personnel purposely seek out and enroll children at risk of school failure due in part to lack of parental interest in school, estimates of program impact might be underestimated. Alternatively, as Thompson suggests, our results may overestimate the effect of the intervention if children with higher levels of parental involvement are more likely to enroll and complete the program. He suggests that parental involvement, rather than program participation, was the cause of the better outcomes. While we agree with Thompson that parental involvement is independently associated with educational attainment and delinquency, participation in the CPC program has been found to be a major predictor of parental involvement.^{1,2}

We believe that our findings actually underestimate the effect of the CPC. Besides the fact that intervention and comparison groups were reasonably well matched on family risk factors that affect both program participation and outcomes, the entire comparison group participated in an alternative intervention (full-day kindergarten) in which parental involvement also was emphasized. This point is worth underscoring. While all students participated in enriched early childhood programs that encouraged parent involvement, parents of the CPC students had access to much greater resources such as parenting skills workshops and opportunities for educational development that enhanced their involvement in their children's education. Had the comparison group participated in the most common alternative at the time—no intervention or part-day kindergarten—the effect sizes would have been even larger.

Thompson raises the larger issue of the underlying mechanisms of the association between program participation and later outcomes. Our studies suggest several mechanisms of long-term effects.¹⁻³ One is improved family support for children's learning as measured by parental involvement. Improved cognitive development and increased school support through reduced school mobility and attendance in higher quality schools are 2 other mechanisms of effects. Interventions that affect these processes are likely to promote healthy child development. The unique strength of early childhood interventions like the CPC is that they affect all 3 mechanisms.

Arthur J. Reynolds, PhD
Waisman Center on Mental Retardation and Human Development
University of Wisconsin–Madison

Judy A. Temple, PhD
Department of Economics
Northern Illinois University
DeKalb

1. Reynolds AJ. *Success in Early Intervention: The Chicago Child-Parent Centers*. Lincoln: University of Nebraska Press; 2000.
2. Reynolds AJ, Mavrogenes NA, Bezruczko N, Hagemann M. Cognitive and family-support mediators of preschool effectiveness: a confirmatory analysis. *Child Dev*. 1996;67:1119-1146.
3. Reynolds AJ, Chang H, Temple JA. Early childhood intervention and juvenile delinquency: an exploratory analysis of the Chicago Child-Parent Centers. *Eval Rev*. 1998;22:341-372.

Ipriflavone and Osteoporosis

To the Editor: Dr Alexandersen and colleagues¹ found that ipriflavone, which is available as an over-the-counter product, was ineffective at preventing bone loss in postmenopausal white women. We have several concerns about the study's design.

First, each of the women in the study had osteoporosis, with a bone density T score of 0.86 or less. They were each given 500 mg/d of supplemental calcium, which is well below the recommended dose of 1500 mg/d for women with osteoporosis. Also, because there is a wide range of calcium absorption from different available preparations, the specific calcium product must also be known to ensure adequate calcium intake.

Second, women with osteoporosis are typically given vitamin D₃ at 400 IU/d with a calcium supplement. Alexandersen et al do not state whether or not these women were given vitamin D₃. Although the article states that vitamin D₃ levels were measured, these values were not reported.

Third, magnesium supplementation at a calcium-to-magnesium ratio of 2:1 is generally provided to ensure adequate calcium absorption,² but the authors did not mention whether they provided magnesium supplementation. Further rationale for magnesium supplementation is based on reports of women with osteoporosis having low magnesium levels.²

Fourth, the subjects for the study all had a body mass index (BMI) of 30 kg/m² or greater. The authors do not explain their reasons for designing a study restricted to obese women. Estrone, which is the predominant estrogen found in postmenopausal obese women, has been found to be as high or higher than estradiol 17B levels in premenopausal females. The effects of high serum levels of estrone on the activity of ipriflavone needs further study.

Future randomized controlled trials of ipriflavone for the treatment of postmenopausal osteoporosis should include women within a full spectrum of weight ranges. These women should be given calcium, vitamin D₃, and magnesium supplements (dosed in accordance with current guidelines), that allow for bone growth.

Edward P. Schelonka, MD
Alexander Usher, PharmD
Good News Medical Clinic
Belize City, Belize

1. Alexandersen P, Toussaint A, Christiansen C, et al. Ipriflavone in the treatment of postmenopausal osteoporosis: a randomized controlled trial. *JAMA*. 2001;285:1482-1488.

2. Stendig-Lindberg G, Tepper R, Leichter I. Trabecular bone density in a two year controlled trial of peroral magnesium in osteoporosis. *Magnesium Res*. 1993;6:155-163.

In Reply: We provided a daily calcium supplement of 500 mg, but this was in addition to the habitual calcium intake in Denmark of 800 to 1000 mg/d.¹ This gives a total daily calcium intake close to the 1500 mg suggested by Drs Schelonka and Usher to be optimal for women with osteoporosis. A calcium supplement of 500 mg/d is customary in studies of osteoporosis.^{2,3}

The women in our study received no vitamin D supplementation as part of the study. Instead we measured vitamin D levels at enrollment to ensure that none of the subjects had vitamin D deficiency. Some studies³ have included a vitamin D supplement but other studies² have not.

It is not a general practice to include a magnesium supplement in osteoporosis studies. All women had a BMI less than 30, and we apologize for the incorrect text on page 1483 that states the opposite. The average BMIs of the 2 groups can be computed from the height and weight data in Table 1.

The protocol was designed in accord with previous similar studies. The estimation of the effect of an intervention is complicated when more variables are added to the design. Addition of calcium, vitamin D, and magnesium would thus complicate the interpretation of the results. Studies of ipriflavone, or any other study for that matter, should not add more independent variables than absolutely necessary.

Peter Alexandersen, MD
Bente Riis, MD
Center for Clinical and Basic Research
Bellarup, Denmark

1. Nilas L, Christiansen C, Rødbro P. Calcium supplementation and postmenopausal bone loss. *Br Med J*. 1984;289:1103-1106.

2. Ravn P, Clemmesen B, Christiansen C, for the Alendronate Osteoporosis Prevention Study Group. Biochemical markers can predict the response in bone mass during alendronate treatment in early postmenopausal women. *Bone*. 1999;24:237-244.

3. Ettinger B, Black DB, Mitlak BH, et al, for the Multiple Outcomes of Raloxifene Evaluation (MORE) Investigators. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. *JAMA*. 1999;282:637-645.

Economic Consequences of Collective Bargaining by Physicians

To the Editor: I have several concerns about the article by Drs Hellinger and Young¹ on physician antitrust exemption legislation.

First, I suspect that some of the profit reduction achieved by health maintenance organizations (HMOs) in 1999 is attributable not only to physician fees but also to other providers such as hospitals, home care agencies, imaging fees, laboratory fees, and durable medical equipment expenses.

Second, if the balance of power were adjusted slightly in favor of physicians, might that mean that more capital would move from HMOs to physicians without significantly raising the costs to consumers? This assumes that HMOs should be cutting back on inefficient expenditures within their own companies and that some of those savings could be captured by physicians as well as the HMOs and the purchasers of health insurance.

Third, there does not seem to be much of a distinction between federal and new state law/policy, such as the Texas statute.² The Texas law appears to simply codify the federal guidelines. For example, the rule of reason and the federal safety zone guidelines are similar to the Texas criteria, which appear more similar than dissimilar to the federal rules. The Texas legislation "actively supervises" to satisfy the state action immunity

doctrine to such an extent that one could question whether there really is an antitrust exemption at all. Perhaps this is why there have been only 2 applications to collectively negotiate. This supports the authors' conclusion that state legislation is unlikely to be effective.

Finally, one might question the Congressional Budget Office (CBO) assumption that physicians' fees account for one third of health plan cost. Other reports suggested that the number is closer to 10% to 20%.

Perhaps more research needs to be done on what physicians would do with any increased revenue that might result from collective negotiation. In the case of employed physicians, revenue would flow personally to the physicians and to the union in the form of dues. In the case of self-employed physicians some of the augmented revenue would flow to the physicians personally as rising office rents and malpractice insurance premiums would be easier to pay for. A significant amount might also go to overhead expenses including capital improvements (eg, new and modern medical equipment including computers) and to the office staff, which needs at least cost of living adjustments. Thus some of the enhanced economic power of physicians would directly improve the quality and efficiency of care to the patients.

Gary Birnbaum, MD, JD
Case Western University School of Law
Cleveland, Ohio

1. Hellinger FJ, Young GJ. An analysis of physician antitrust exemption legislation: adjusting the balance of power. *JAMA*. 2001;286:83-88.

2. Physician Joint Negotiation. 58 Tex Admin Code §1:3 (West 2000).

To the Editor: Drs Hellinger and Young¹ summarize premium impact estimates developed by Charles River Associates (CR) and by the CBO for federal antitrust exemption legislation. The CR analysis put the impact in the range of 3.6% to 17.7%. In contrast, CBO found only a 1.9% increase. Hellinger and Young indicate that there has been no study of the benefits of the legislation. In fact, we have developed empirical estimates of the costs and benefits of such legislation.²

The CR estimates exceed those from CBO because CR uses numerous unmerited assumptions: managed care will save 13% to 25% of private medical expenditures, all physicians will join bargaining units, and 50% to 100% of all managed care savings will be given back. Managed care savings are generally recognized to be no more than 6% of private health expenditures. Physician participation in bargaining units is unlikely to exceed union participation rates in other sectors—10% for private sector and 38% for public sector unions.³ Moreover, only half of physicians are equity holders in a practice,⁴ so participation will be between 5% and 24%. Finally, to assume that physician bargaining groups could compel dominant national and regional insurers to give up more than half of managed care savings strains credulity. Insurer concessions, if any, would more likely be between 10% and 25%. The net effect of these assumptions is that the CR estimate substantially overstates the cost impact. A more considered cost estimate for physician antitrust exemptions is \$0.6 billion to \$1.4 billion.

Opponents of physician bargaining legislation have ignored existing economic literature that explains benefits from the legislation,⁵ a premise that dates to the 1920s.⁶ Countervailing power theory, described in our study,² suggests that an appropriate “counter” to a monopoly seller or a monopoly buyer will make consumers better off. Mechanisms that allow buyers to offset the power of monopoly sellers can help reduce prices. When a health plan has monopoly power, a purchasing cooperative of employer-buyers can exert pressure to hold down premiums. An analogous lever exists on the other side of plan operations. When a health plan is a monopoly buyer of physician services and has forced reimbursements below competitive levels, collective action can improve consumer welfare. Our simulation of the value of the benefits from collective negotiation estimated the potential gain for consumers at \$1.0 billion to \$1.9 billion through improved access to services.

Negotiations between physician bargaining groups and large insurers could improve the market because balanced power between these parties would permit better checks and balances. Without legislation, collective action by physicians would violate antitrust law. Our analysis² found that many health insurance markets are highly concentrated, meaning insurers have substantial market power. A number of insurers have sufficient market shares to give them monopoly power in the insurance market and monopoly power over physicians and other providers. In these market areas, a limited experiment with countervailing power legislation, like the Campbell Bill, would level the playing field and show whether access to care could be increased while reducing prices.

Stephen Foreman, JD, PhD, MPA
Center for Health Services Research
The Pennsylvania Medical Society
Harrisburg

David Emmons, PhD
Gregory Wozniak, PhD
Center for Health Policy Research
American Medical Association
Chicago, Ill

1. Hellinger FJ, Young GJ. An analysis of physician antitrust exemption legislation: adjusting the balance of power. *JAMA*. 2001;286:83-88.

2. Foreman S. A cost analysis of health care professional negotiating legislation [working paper]. University Park, Pa: Pennsylvania State University; 2000. Available at: <http://www.ama-assn.org/ama/upload/mm/363/costanalysisnegleg.pdf>. Accessibility verified September 20, 2001.

3. Bureau of Labor Statistics, US Department of Labor. *Union Members in 1998*. Washington, DC: US Government Printing Office; 1999. USDL 99-21.

4. Kletke PR, Emmons DW, Gillis KD. Current trends in physicians' practice arrangements: from owners to employees. *JAMA*. 1996;276:555-560.

5. Adama W. Countervailing power. In: Eatwell J, Milgate M, Newman P, eds. *The New Palgrave: A Dictionary of Economics*. London, England: Macmillan Press Ltd; 1998:704-706.

6. Bowley AL. Bilateral monopoly. *Econ J*. 1928;25:51-69.

In Reply: Dr Birnbaum clarifies some of the issues we sought to raise in our article. He states that HMOs form relationships with many types of providers other than physicians and the negotiating strength of those providers also ultimately influences HMO premiums. While it is generally assumed that greater negotiating leverage on the part of providers will translate into higher prices

for consumers, whether and to what degree such price hikes would occur depends on various market dynamics such as the negotiating position of employers vis-a-vis HMOs. We certainly agree with Birnbaum that more research is needed to understand how a shift in the balance of power to providers generally and physicians specifically will affect HMO premiums. The CBO assumption concerning how much physician fees account for health plan costs, is actually one of several possibly questionable assumptions that CBO had to make in estimating the impact of physician antitrust waivers on health care costs. Any effort to estimate the impact of antitrust waivers is particularly limited by the dearth of research on physician market concentration and physician prices.

Birnbaum remarks on the parallels between the Texas waiver mechanism and current federal rules on physician networks. As we stated in our article, although physicians are interested in waivers because many of them are unable to comply with these federal rules for purposes of negotiating collectively, the Texas waiver mechanism itself imposes many requirements on physician applicants that limit its value to physicians. However, the federal waiver bill that was introduced last year would have extended to physicians the opportunity to collectively negotiate with HMOs without the restraints that come with either the current federal rules or the Texas waiver mechanism.

Dr Foreman and colleagues maintain that the estimates of the cost to consumers of implementing federal physician antitrust exemption legislation in the CR report are too high because they use “numerous unmerited assumptions”. Nevertheless, the estimates presented in Foreman’s study also are based on some questionable assumptions.¹ First, Foreman uses a model that explains physician expenditures as a function only of managed care penetration. However, physician expenditures are a function of many other factors including number of physicians, type of physicians, number and size of hospitals, and availability of other types of health care professionals. Second, Foreman asserts that about half of the practicing physicians are “employed physicians” and are not candidates for collective negotiations. He includes physicians employed by professional practices owned by other physicians. However, if physician owners collectively negotiate rates with managed care plans, the negotiated rates will cover services provided by all physicians in the practice (not only the owners). Finally, Foreman states that “we assume that savings give-backs, if any, will range from 10% to 20% of base savings.”¹ In contrast, the CBO report states that, “the CBO estimates that 50% of the utilization savings associated with coalition physicians who contract with managed care plans would be lost as a result of the bill”² and the CR study estimates this figure to be between 50% and 100%.

Fred J. Hellinger, PhD
Center for Organization and Delivery Studies
Agency for Healthcare Research and Quality
Rockville, Md

Gary J. Young, PhD, JD
Department of Veterans Affairs
School of Public Health
Boston University
Boston, Mass

1. Foreman S. A cost analysis of health care professional negotiating legislation [working paper]. University Park, Pa: Pennsylvania State University; 2000. Available at: <http://www.ama-assn.org/ama/upload/mm/363/costanalysisnegleg.pdf>. Accessibility verified September 20, 2001.
2. Congressional Budget Office. *Cost Estimate of HR 1304: Quality Health Care Coalition Act of 2000*. Washington, DC: US Congress; 2000.

RESEARCH LETTER

Coding Changes and Apparent HIV/AIDS Mortality Trends in Florida, 1999

To the Editor: The impact of the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic on morbidity and mortality in Florida and the United States has been profound. In the United States, AIDS deaths peaked in 1995 and then began to decline with the rate of decrease slowing in 1998.¹ The decline in mortality has been attributed to the use of highly active antiretroviral therapy (HAART)²⁻⁴ and prophylaxis against opportunistic infections.⁵ Through 1998, the trend of deaths due to HIV/AIDS in Florida paralleled the national trend of AIDS deaths (TABLE). In 1999, however, when a new coding scheme was introduced, Florida reported 1651 resident HIV/AIDS deaths, an increase of 6.7% compared with 1998.

In view of the declines observed from 1996-1998, this increase was cause for concern. However, the introduction of a new system in 1999 to classify causes of death complicated analysis and interpretation of the 1999 mortality data, both in Florida and nationally. We assessed the impact of this change from the *International Classification of Diseases, Ninth Revision (ICD-9)* to the *10th Revision (ICD-10)* on the apparent reversal of the downward trend in HIV/AIDS mortality in Florida.

Methods. Death certificates for Florida residents with any mention of HIV/AIDS in 1999 and coded using ICD-10 rules were recoded by a certified nosologist using ICD-9 rules. An ICD-10/ICD-9 comparability ratio was computed.

Results. When the 1782 Florida resident death certificates with any mention of HIV/AIDS in 1999 were coded using ICD-9, 1445 (81.1%) were coded with HIV/AIDS as the underlying cause of death. This contrasts with the 1651 (92.6%) deaths coded as HIV/AIDS using ICD-10 ($P < .001$), and yields an ICD-10/ICD-9 comparability ratio of 1.14 (Figure). The 1445 HIV/AIDS deaths (according to ICD-9) in 1999 represent a decline of 6.6% from the comparably coded 1547 HIV/AIDS deaths in 1998.

Comment. Accurate interpretation of HIV/AIDS mortality trends is critical to assist researchers, policy makers, and clinicians in assessing the success of treatment, patterns of competing causes of death in the HIV-infected population, and prioritization of resource allocation. Changes in HIV/AIDS mortality between 1998 and 1999 should be interpreted with caution, because a portion of the change in mortality is directly attrib-

Table. Resident HIV/AIDS Deaths in Florida, 1987-1999*

Year of Death	HIV/AIDS Deaths, No. (% Change)
1987	1095 (NA)
1988	1451 (32.5)
1989	2029 (39.8)
1990	2239 (10.3)
1991	2725 (21.7)
1992	3098 (13.7)
1993	3492 (12.7)
1994	4142 (18.6)
1995	4336 (4.7)
1996	3092 (-28.7)
1997	1879 (-39.2)
1998	1547 (-17.7)
1999	1651 (6.7)

*Mortality coding rules assigned deaths to HIV/AIDS as underlying cause according to ICD-9 codes 042-044 for 1987-1998 and ICD-10 codes B20-B24 for 1999. HIV/AIDS indicates human immunodeficiency virus/acquired immunodeficiency syndrome. Source: Office of Vital Statistics, Florida Department of Health.

utable to changes in coding. The National Center for Health Statistics (NCHS) reports a preliminary, estimated ICD-10/ICD-9 comparability ratio for HIV/AIDS of 1.06 based on double coding of a large sample of death certificates in the United States that were filed in 1996.⁶ The difference between Florida's comparability ratio of 1.14 and the preliminary NCHS ratio of 1.06 suggests that using comparability ratios based on data 2 to 3 years old yields very different results than a direct comparison of coding using the years in question. The NCHS report advised that the estimated comparability ratio of 1.06 might be slightly higher if their recoding was based on 1998 data.⁶ It is possible that the application of NCHS's 1996 ratio to data from later years may result in an inaccurate adjustment to the number of deaths in a disease having the changing dynamics of HIV/AIDS.

Becky Grigg, PhD
Robert G. Brooks, MD
Spencer Lieb, MPH
Meade Grigg, MA
Bureau of HIV/AIDS
Florida Department of Health
Tallahassee

1. HIV and AIDS—United States, 1981-2000. *MMWR Morb Mortal Wkly Rep*. 2001;50:430-434.
2. Palella F, Delaney K, Moorman A, et al. Declining morbidity and mortality among patients with advanced HIV infection. *N Engl J Med*. 1998;338:853-860.
3. Chiasson MA, Berenson L, Li VV, et al. Declining HIV/AIDS mortality in New York City. *J Acquir Immune Defic Syndr*. 1999;21:59-64.
4. Centers for Disease Control and Prevention. *HIV/AIDS Surveillance Report*. Atlanta, Ga: Centers for Disease Control and Prevention; 2000.
5. Selik RM. Trends in fatal infectious diseases among persons dying of HIV infection in the era of HAART [abstract]. Presented at: Seventh Conference on Retroviruses and Opportunistic Infections; January 30-February 2, 2000; San Francisco, Calif. Abstract 462.
6. Anderson RN, Minino AM, Hoyert DL, Rosenberg HM. Comparability of cause of death between ICD-9 and ICD-10: preliminary estimates. *Natl Vital Stat Rep*. 2001;49:1-32.