Correcting Hatch-Waxman

Michael Fernandes

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Letters

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Improve Treatment Of Dual Eligibles

The lack of reporting requirements for Medicare prescription drug plans makes evaluating their success difficult. Richard Frank and Joseph Newhouse (Jan/Feb 08) use creative techniques to provide tantalizing information on the likely impact of the Medicare drug benefit on the costs of prescription drugs, raising doubts about its success on this dimension. They offer particularly convincing information on the population covered by both Medicare and Medicaid (dual eligibles) who used to get drug coverage through Medicaid. Frank and Newhouse found evidence of about an 8 percent increase in the costs of the drugs this group uses over what Medicaid was paying, unnecessarily raising the costs of the program. Applying this statistic to the costs for the 6.2 million dual eligibles suggests that government costs were $1.4 billion higher in 2006 than if these people had been covered by Medicaid.1

This is a key finding, as the drug benefit has not served these beneficiaries well. Dual eligibles are required to enroll in one of the less expensive private plans or be auto-enrolled by the program if they fail to do so. Not all plans offer the drugs these beneficiaries need, and many have had to shift plans from year to year, creating confusion and disruption in services for the sickest and frailest portion of Medicare beneficiaries.

Frank and Newhouse offer a solution that would leave dual eligibles in these plans. Other options should also be considered. What about returning these beneficiaries to Medicaid? In many ways, they were often better off under that system. The biggest gainers from this aspect of the drug benefit are the pharmaceutical companies that are now reaping the advantages of providing drugs at higher prices. The alternative I favor would create a government fallback plan into which Medicaid recipients would be enrolled, which would be available to any other Medicare beneficiaries as well.2

Marilyn Moon
American Institutes for Research
Silver Spring, Maryland

NOTES

Dual Eligibles: The Authors Respond

We are pleased that Marilyn Moon found some of the evidence we present on price changes for prescription drugs under Medicare Part D useful. That evidence suggests that after Part D was implemented, the government was paying more for prescription drugs used by people who are dually eligible for Medicare and Medicaid than it was before.

As Moon notes, there are a number of ways this might be addressed by public policy. She points out that we did not propose moving dually eligible people back to Medicaid. We considered this possibility, but we rejected it because of the distortions created by Medicaid’s “best price” rules for prescription drugs. Because Medicaid prices are—by law—linked to the best private-payer price, private insurers’ bargaining power in dealing with drug manu-
facturers is weakened. As a result, smaller price concessions are granted by manufacturers than would be the case without these “best price” rules. Our proposal seeks to obtain lower prices for drugs used by dually eligible people without distorting private-sector prices. We therefore suggest a targeted set of price controls for the drugs used by dually eligible beneficiaries that are decoupled from private-insurer prices.

Richard G. Frank
Harvard Medical School
Boston, Massachusetts

Joseph P. Newhouse
Harvard University
Cambridge, Massachusetts

NOTE

Happiness And “Human Flourishing”

Adopting a vaguely Aristotelian perspective to comment on Carol Graham’s interesting paper on the economics of happiness (Jan/Feb 08), I’d like to highlight some conceptual differences between her (and her fellow economists’) approach and a nonhedonistic philosophical one.

I wholeheartedly agree with Graham’s comment that “unemployment is one of the most deleterious events as far as happiness is concerned”—but why? A deleterious event is one in which a person is deprived of a good—in this case, not just income, but the good of work. I would argue that work is one of several basic human goods, and jointly these goods make a human life a flourishing one. I could have said that they jointly constitute a “happy” life, but I deliberately chose an alternative term.

The reason is that “happiness,” as used in Graham’s paper, is a subjective state that can be reported only from the perspective of the first-person singular. “I feel happy/unhappy right now” are the reports that happiness studies record and quantify. On the other hand, the classical notion of happiness, the one that scholars today refer to as “human flourishing,” is primarily an objective state that in principle could be ascertained from a third-person perspective. Indeed, there is room for the paradox of the flourishing person who is feeling unhappy.

What, then, is the place of health in the classical idea of happiness defined as human flourishing? Consider Graham’s reference to junk food. Not being able to enjoy junk food wouldn’t decrease the flourishing of any individual, because what counts toward flourishing isn’t raw satisfaction; rather, it’s whether the object in which one finds satisfaction is really good. And junk food isn’t. Health is a good, and the rational thing to do is to pursue it in one’s choices, yet classical ethics doesn’t rank health among the basic human goods. Health, instead, is the proper functioning of any organism (not just a human one); moreover, health is a condition for pursuing the other, more important components of human flourishing.

Alfonso Gómez-Lobo
Georgetown University
Washington, D.C.

Happiness: The Author Responds

Alfonso Gómez-Lobo highlights one of the key unresolved challenges to applying the findings of happiness research to policy: the lack of broad consensus on the definition of happiness. This challenge is highlighted in the concluding section of my paper. Rather ironically, what makes happiness surveys a powerful survey instrument for exploring any number of questions—from the welfare effects of inequality, inflation, and unemployment to the well-being costs of phenomena such as obesity and smoking—is that the definition of happiness is open-ended and up to the respondent, allowing for responses to be compared across hundreds of thousands of individuals across countries and cultures. The results of these surveys show that the basic correlates of happiness demonstrate remarkably similar patterns across countries and cultures. Thus, re-
searchers can find valuable information in the variance of the welfare effects of institutional, environmental, or health-related variables, such as the ones noted earlier in this paragraph.

Yet it is precisely the absence of a definition of happiness that makes it more difficult to directly apply the results of the research to policy (although the results can certainly inform policy). Although happiness defined simply as contentment—for example, “raw satisfaction” as noted by Gómez-Lobo—seems an inappropriate objective for policy, happiness as defined in the Aristotelian sense as human flourishing might be the most appropriate objective of public policy. The junk food example highlights the extent to which resolving the definitional question has implications for the policy conclusions that are inferred.

Carol Graham
Brookings Institution
Washington, D.C.

Look To Behavioral Economics

In their paper on decreasing copayments (Jan/Feb 08), Michael Chernew and colleagues address an important issue about value-based insurance design. Indeed, as health care cost pressures rise, cost-sharing proposals will continue to shift costs to the patient, and proposals need to be designed with value in mind. For value-based benefits, the need is to (1) conduct comparative effectiveness research to identify and quantify the value of effective core treatments, and (2) design an appropriate alignment of incentives for payer, provider, and patient.

Currently some 75 percent of U.S. health care costs are attributed to chronic disease. The dramatic increase in obesity during the past thirty years, the rising risk for diabetes, and the consequences from heart disease and other progressive and chronic diseases will likely contribute to a continuing rise in chronic disease costs. As costs shift onto the patient, so should more personal responsibility, including an added emphasis on health-behavior change and compliance to recommended treatment regimens. Once compliance breaks down, this arguably hastens the onset of chronic disease progression and complications, leading to increased cost pressures in an already overburdened health care system.

A recent U.S. Department of Agriculture study reframes obesity in terms of behavioral economics and sheds light on the irrational choices we make about food. We should ask ourselves whether we can use this knowledge to structure appropriate incentives. Frustrated employers are already beginning to raise insurance copays and alter coverage on the basis of poor health habits. More insight into behavioral economics, with a focus on health behaviors, choices, and decisions made by health care consumers (especially ones surrounding poor health habits and compliance), would add a new perspective. Gaining that insight, while at the same time exploring how to approach and propose realistic solutions and incentives that work within the system we have now, will help effectively reform health care for the future.

Carolyn Sangokoya
Duke University School of Medicine
Durham, North Carolina

NOTE

ADA Guidelines: A Work In Progress

The Americans with Disabilities Act (ADA) has been far-reaching in breaking down the barriers in our communities and hospitals. But as Lisa Iezzoni observed in her Narrative Matters essay (Jan/Feb 08), the text of the ADA does not cover every circumstance.

As a health care architect, however, I have seen that those in my industry—architects, interior designers, planners, and building officials—have embraced the law’s spirit as much as its letter. We work closely with medical equipment planning professionals who rou-
tinely advise clients on appropriate clinical equipment. Patient lifts, either built into the ceiling or portable, are becoming standard equipment in inpatient and outpatient areas. Better patient care, dignity, and efficiency are the rationale and the goal.

Hospital architects are impassioned about improving the health care environment for every single patient, and I hope that the ADA and its accessibility guidelines continue to be updated through public comment and revision.

Helen B. Jeffery
RTKL Associates Inc.
Washington, D.C.

ADA Guidelines: The Author Responds

Helen Jeffery's report of architects, interior designers, planners, and building officials going beyond the letter of the Americans with Disabilities Act (ADA) to embrace the spirit of the law is encouraging. This attitude recognizes that ADA regulatory requirements represent a “floor” (that is, minimum standards) that are often insufficient to ensure that spaces are inclusive and welcoming to people of all abilities. Some states, therefore, mandate additional regulations to improve accessibility of the built environment.

Whether the enthusiasm reported by Jeffery is widely shared remains unclear.1 Anecdotal reports from colleagues nationwide suggest that a more common response involves zeroing in on the bare minimum needed to pass ADA muster. I once spent a half-hour trying to convince architects and designers creating a new clinical space that (1) they should put handrails along a lengthy clinic corridor (which was not required under ADA regulations but would improve safety for patients with walking difficulties, weakness, or fatigue who use walls for support) and (2) they needed to put handrails on both walls (as humans are rarely ambidextrous, individuals would favor one side entering the clinic and the opposite side leaving). It was a tough sell, but the clinic installed the bilateral handrails—and patients use them.

I hope that Jeffery and her colleagues will continue to advocate for health care buildings that meet the spirit of the ADA, which is—at its core—ensuring equity across all users of these spaces. Involving people with disabilities as full partners in design planning, along with the clinicians and other staff members who work in these settings, offers the best chance of achieving universally accessible and workable health care facilities.

Lisa I. Iezzoni
Massachusetts General Hospital
Boston, Massachusetts

NOTE

Yes To “Code Pearl”

We need the “Code Pearl” proposed by Victoria Sweet in her Narrative Matters essay (Jan/Feb 08), because it provides some middle way between full code and Do Not Resuscitate (DNR) medical orders.

I’ve witnessed many deaths, as both family member and nurse practitioner (primary care, home care, and hospice care). I’ve also accompanied many people with life-threatening illnesses who are threading their way through the maze of health care decision making. Few are enabled to choose life in the face of death, as Mrs. D did in the essay. Thanks for telling her story and showing readers the scale of grays between black and white.

Veneta Masson
Washington, D.C.

“Code Pearl” Needed Now

I find myself in full support of Victoria Sweet’s engaging and sensitive Narrative Matters essay (Jan/Feb 08). While serving as an administrator of emergency medical services (EMS) in both prehospital and hospital settings, I often lamented the all-or-nothing approach used with patients and thought that a
level of comfort care should be an option. Many years ago, I also participated in introducing a concept along these lines into the EMS protocols for the state of Iowa, providing a way to give EMS personnel some relief as they endeavored to meet the intent of a Do Not Resuscitate (DNR) order while simultaneously recognizing the need for interim measures. Sweet's essay now offers an especially compelling and sensitive argument for taking this discussion to a more definitive and institutional level.

During the period when I worked for one of the nation's largest academic medical centers, time and again I saw clinicians struggling to find the “Code Pearl” solution that Sweet so elegantly and succinctly describes. Instituting Code Pearl, however, will not be without problems. The nation's health care system is stressed to the breaking point. The poised demographic wave of aging baby boomers mixed with fixed fees and thin operating margins offers a formidable challenge to the Code Pearl concept. Scarcity of resources will be the mantra of resistance.

At the end of the day, doing the right thing will stand the test of time. Sweet and others of similar persuasion have a gift to give that should be on the agenda of every hospital's ethics committee. It is imperative that she be joined by others to remain engaged in bringing broad understanding and support for the Code Pearl option.

JEFFRY W. GAUTHER
Virtuosity Inc.
North Liberty, Iowa

POLST And “Code Pearl”

Victoria Sweet's call for a “Code Pearl” medical code (Jan/Feb 08) has already been answered. The Physician Orders for Life-Sustaining Treatment (POLST) Paradigm is just what this doctor ordered.

The POLST Paradigm, a novel type of advance directive, was developed in Oregon during the 1990s. It takes the form of a physicians’ medical order set that contains instructions governing cardiopulmonary resuscitation, antibiotics, tube feeding, and general intensity of care. Like a conventional advance directive, the POLST form is completed on the basis of a patient's treatment preferences specified in advance of a medical crisis, often while the patient is living at home. The POLST form differs from a conventional advance directive, however, because it is a binding medical order set that follows the patient across treatment settings—and it must be honored by emergency personnel and other medical providers without regard to institutional credentialing requirements. It is currently used in all, or part, of more than twenty U.S. jurisdictions.

The POLST form eliminates the restricted choice described in Sweet's essay and provides the third option she recommends. Susan Hickman and colleagues show that 77 percent of the studied patients used the POLST form to select both “do not resuscitate” status in a category and “more than comfort care” in at least one other category.2 A patient can use the POLST form to choose full treatment up to the point when only resuscitation is needed. It can be the Code Pearl that Sweet calls for.

JASON W. MANNE
University of Pittsburgh
Pittsburgh, Pennsylvania

NOTES
1. For more information, see the POLST home page, http://www.polst.org.

POLST: The Author Responds

I have heard from many practitioners who are enthusiastic about creating a third choice, a “Code Pearl” medical order, including those in the preceding letters. Yet according to Jason Manne, the Physician Orders for Life-Sustain-
The Patient's Code Status: A Poignant Option

Victoria Sweet
University of California, San Francisco

Disappearing Primary Care Physicians?

When pondering Bill Sage’s discussion of legislative reform of delivery systems (Nov/Dec 07), consider that legislative solutions are likely to be a disaster. “Legislating” health care delivery is, in general, a bad idea because legislation, once enacted, is hard to undo. Medical science and delivery systems are rapidly evolving, and what seems like a great idea today (for example, health maintenance organizations or estrogen for postmenopausal women) is likely to seem ill-advised in the near future.

Sage’s paper seems to favor retail clinics. I believe that their proliferation might cause undesirable changes in the health care delivery system. Sage is dismissive of the traditional one doctor/one patient “dyad,” but many patients and doctors prefer it. As retail clinics—which offer convenient care for patients who have one minor problem—continue to proliferate, primary care physicians will see only their chronic, complex patients with multiple diseases. Unfortunately, no one at present seems willing to pay the cost of the intense cognitive effort these patients require. Medicare will not pay for a routine examination in the age group where the advent of disease is likely and that would most benefit from early detection. (The lone exception: the initial “Welcome to Medicare” exam.) In my area, Medicare’s “limiting charge” for a forty-five-minute visit is $91.74. Payment for services usually provided by primary care physicians is being further reduced during 2008.

If the present trends continue, my patients will need to visit an average of three specialists plus a nurse practitioner for minor problems. This fragmented system will be inefficient, expensive, and likely unsatisfying. Primary care physicians will begin to fade from the health care delivery system. It is not as a physician that I fear this change, but rather as a patient that I dread it.

Everest A. Whited
Pflugerville, Texas

Narrow Model

In John Billings and Tod Mijanovich’s paper on care management for high-cost Medicaid patients (Nov/Dec 07), the presented predictive models and business case are predicated on assumptions that severely limit generalizability and thus impede the ability to apply the findings to most Medicaid programs.

First, the cohorts used to construct the models do not represent the general Medicaid...
populations in which disease management (DM) is typically implemented; instead, they consist of the sickest subsets. Further, it appears that the predictive models included only those who had been continuously enrolled in Medicaid for at least four years. Given the high turnover rate in Medicaid eligibility, few Medicaid recipients would be eligible after the “index” admission in the “real time” model to experience the next admission on Medicaid’s dime. This high turnover in the population, coupled with the significant lag in Medicaid medical claims, makes the “archival” model more representative of the real-world experience. As expected, that model has a much lower sensitivity than the “real time” approach (0.230 versus 0.581).

Second, the authors develop a business case on the basis of an intervention targeting only the high-risk group (and using the “real time” model). In reality, DM vendors receive fees for the entire population that is at risk. Because of this, they are responsible for managing the whole population, not just the subset of sickest patients. This only serves to increase fees, making it more difficult to achieve a return on investment.

In summary, this paper presents a model that might be valid in a very narrowly defined group of Medicaid recipients but is unlikely to be useful in a general Medicaid population in which DM typically operates. Further, the authors’ misunderstanding of the standard Medicaid DM contracting model makes the business-case projections overly optimistic. Although a separate discussion should be conducted about optimizing DM strategies for Medicaid, caution is needed in applying these findings to the current approach.

Ariel Linden
Linden Consulting Group
Hillsboro, Oregon

Narrow Model: The Authors Respond

As Ariel Linden suggests, eligibility churning is a major problem for most Medicaid programs, especially among low-income mothers and their children. In this case, however, we focused on adult disabled Medicaid patients, where the rates of turnover are very low. Moreover, we didn’t limit our analysis to patients with continuous eligibility (for example, four years as suggested by Linden); the only criterion for inclusion was an admission (hence eligibility) anytime in 2003. We then looked back three years for previous use regardless of eligibility status (for patients without eligibility, therefore, no use was observed); next we predicted a hospital admission in the next twelve months (again without regard to eligibility during the subsequent twelve months). Had we restricted the analysis to patients with continuous eligibility, the findings on positive predictive value of the algorithm would undoubtedly have been higher (with fewer “false positives”), but the approach would have been inherently less useful, because it wouldn’t have reflected real-world conditions.

Linden is correct that much of “standard” disease management (DM) is done on the basis of an entire population, with the vendor doing its own modeling to identify at-risk patients to target for interventions. We expect that our approach might be useful to these organizations in efforts to target high-risk patients. Other initiatives, however, such as the Medicare Health Support Program, are restricted to high-risk patients, with the funding agency identifying eligible patients. On the basis of patient needs and specific program resources, vendors in this program might use predictive modeling to further target patients assigned for intervention. Similarly, the Medicaid agency in New York has recently issued a request for proposals for a Chronic Illness Demonstration Program (http://www.nyhealth.gov/funding) that uses an algorithm similar to the one we described. It will assign patients that it identifies as being at high risk for future hospital admissions to organized delivery systems to coordinate and manage their care.

John Billings and Tod Mijanovich
New York University
New York, New York
“Godmother” Revisited

In his Nov/Dec 07 review of Regina Herzlinger’s book, *Who Killed Health Care? America’s $2 Trillion Medical Problem—and the Consumer-Driven Cure*, Alan Maynard incorrectly implies that Herzlinger’s ideas are derived from Michael Porter and Elizabeth Teisberg, and even the Jackson Hole Initiative.1 One does not expect everyone to agree with Herzlinger’s proposals, but Maynard should at least be aware of the facts and background behind her work.


Herzlinger has been an important catalyst for change through her best-selling books and tireless work with leaders across the health care system and the government. At the same time, we still have a long way to go in improving health care in this country. We need to encourage innovative, passionate thought leaders such as Herzlinger who are changing the future of health care for the better, not belittle them.

Amy Burroughs Nader
APT Pharmaceuticals
Burlingame, California

**NOTE**


“Godmother” Revisited: The Author Responds

I am most grateful for this elucidation of the antecedents of Regina Herzlinger’s ideas. Herzlinger has clearly been developing and advocating these interesting notions for more than fifteen years. However, Amy Burroughs Nader’s letter fails to clarify why Herzlinger and authors Michael Porter and Elizabeth Teisberg deploy similar arguments but do not cite each other or attribute originality to one of the parties. Given the similarity between their arguments, this practice is unusual.

I agree with Nader that we should encourage innovative policy debate, as the performance of health care systems of the United States and the United Kingdom is deplorably inefficient and inequitable. More than twenty-five years ago, the renowned physician-researcher Archie Cochrane likened the U.K. National Health Service (NHS) to a crematorium, writing: “I once asked a worker in a crematorium, who had a curiously contented look on his face, what he found so satisfying about his work. He replied that what fascinated him was the way in which so much went in and so little came out. I thought of advising him to get a job in the NHS, it might increase his job satisfaction, but decided against it. He probably gets his kicks from the visual demonstration of the gap between input and output. A more statistical demonstration might not have worked so well.”

Until the policy debate takes cognizance of the unproven nature of most health care and...
our ignorance of whether spending billions on it makes patients better, payers will get poor value for money, and patients will be victims of the largely unproven arts of professionals. Consumer-driven health care in this environment might be little more than institutionalized swindles.

Alan Maynard  
University of York  
York, England

NOTE

Vulnerable In More Than One Way
The paper by David Mechanic and Jennifer Tanner about vulnerable populations (Sep/Oct 07) makes an important contribution to the literature by elaborating on major sources of vulnerability across population groups and a society-level strategy for addressing disparities.

Needed further still is an explicit call for researchers, practitioners, and policymakers to recognize that vulnerable populations often share common traits. For example, minority groups (a vulnerability trait) tend to be of lower socioeconomic status (second trait) and are less likely to be insured (third trait). These overlapping traits contribute to gradients in health status and the receipt of health care.

The single-trait approach continues to be the primary mechanism for documenting and addressing health disparities. Only recently have we begun to see vulnerability traits regularly reported in combination. It remains rare, however, that interventions address multiple traits, although this is needed and possible.

Community health centers, for example, have long been reducing barriers to accessing care for vulnerable families. Health centers offer low- or no-cost services (targeting financial barriers), are located in high-need areas (geographic barriers), and provide translation services (language barriers).

With no single intervention available to raise the health of vulnerable populations on a par with the nonvulnerable, our country's future success in resolving disparities might lie in our ability to effectively recognize and intervene simultaneously with multiple, overlapping vulnerability traits.

Gregory D. Stevens, Leiyu Shi, and Pegah Faed  
University of Southern California  
Alhambra, California

NOTES

Correcting Hatch-Waxman
The paper by Ernst Berndt and colleagues (May/Jun 07) about authorized generic (AG) drugs states that AGs don't affect drug prices, while the letter by Donald Moran and colleagues (Jan/Feb 08) suggests that a ban on AGs will increase federal spending. Both groups of authors focus on revenue projections, but they don't distinguish between increased competition and unfair competition.

An AG is a generic version of the brand released by the original “innovator company.” For a generic drug company that produces commodity products, filing an abbreviated new drug application (ANDA) for generic drug approval on an existing drug and a paragraph IV challenge to the patent is a major and risky investment. After approval, if the successful generic drug company needs to compete against the innovator company's AG during the 180-day market exclusivity period, then there is no reward for risk. To major pharmaceutical companies, returns on an AG are minuscule and transient. Could the real reason for AGs be to nullify competition by deinciting generic drug companies? The result
could be more expensive drugs tomorrow.¹

Let’s hope that Congress recognizes and corrects this anticompetitive reality—an unintended consequence of the Hatch-Waxman Act—before analyzing revenue projections. The intent of Hatch-Waxman was procompetition (specifically, encouraging generic companies to challenge patents), and it was correct that economic incentives need to be balanced. For the desired results, however, competition has to be fair, and the 180-day market exclusivity for generic drug companies that are first filers of ANDAs should be truly exclusive—and without exception.

Michael Fernandes
Actimus Biosciences
Chapel Hill, North Carolina
and Visakhapatnam, Andhra Pradesh, India

NOTE

Correcting Hatch-Waxman: An Author Responds

My coauthors and I would like to respond directly to points made by Michael Fernandes about our paper (May/Jun 07). First, the paper does not state that authorized generics (AGs) have no effect on drug prices. Based on data on generic entrants and generic-to-brand price ratios, the paper concludes that in the short run, AGs increase competition and are likely to result in lower prices. Second, the paper concludes that in the long run, an AG is likely to affect prices only if it discourages some generic entry for a drug that would have experienced limited generic entry even in the absence of an AG (for example, a small-revenue drug).

Our paper suggests that it is unlikely that paragraph IV challenges would be deterred by an AG, given the low cost of entry and the substantial revenue potential for generic manufacturers with or without AGs on the market. This latter point is the topic of a follow-up study conducted by three of us. It provides data demonstrating that paragraph IV challenges have continued to increase in recent years, despite the substantial increase in the number of AGs. This working paper, released in April 2007 (while the paper in this journal was being prepared for publication), is available at the Analysis Group Web site.¹

Ernst R. Berndt for the authors
Massachusetts Institute of Technology
Cambridge, Massachusetts

NOTE