

**Comments on FRESH Thinking Papers
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My comments start with my three bottom line beliefs about the connection between regulation and health care reform:

- Health care delivery reform is a precondition to successful health care financing (insurance) reform
- Health care delivery reform can only occur if health care acquires collective public meaning, rather than being seen through a “relational” lens of one patient being cared for by one physician, which requires reorienting substantial amounts of health care regulation.
- Both successful delivery reform and collective meaning require a closer connection between medical care and public health, achieved through a broader range of policies and institutions than at present

This type of “fresh” thinking is only faintly visible in the two papers presented in this session on the role of law and regulation. Why? And what might be done about it? The preliminary comments that follow constitute my sequential reactions to points made in the Jost paper, to which I have added a semblance of organization and incorporated some thoughts on the Noll paper.

Scope and definitions

Why does the FRESH Thinking series artificially (in my view) partition “regulation” from the substantive discussion of coverage and competition? Is there really a case for a “deregulated” health care system? Roger Noll seems to think so, but I can’t imagine it. To me, health care is inevitably regulated, making the terms of regulation (e.g., collective versus relational goals) the core subject for debate.

Tim Jost helpfully identifies four creations or functions of law: principles, institutions, policies, and procedures. Jost’s discussion strikes me as proving the case for the pervasiveness of regulation, while the health reform experience of 1993-94 highlights the perils of partitioning it. During the development of the Health Security Act, President Clinton’s health care czar, Ira Magaziner, seemed to regard legislation as merely a linguistic formality to memorialize policy decisions. Absent from his view was Jost’s insight that law articulates principles, creates institutions, designs structural mechanisms for actualizing policy, and provides procedures for fair enforcement. It is hardly surprising under these circumstances that the bill’s proponents used it primarily to play

budgetary politics while its opponents attributed to it a host of evils associated with managed care that were not part of its language.

Beyond partitioning, both papers limit their scope in response to the FRESH Thinking invitation in ways I find counterproductive. Noll devotes his analysis to a cramped definition of “regulation” based on administrative law, while choosing to ignore the sources of law that are most important to health care and therefore most in need of change: government purchasing through Medicare and Medicaid (which departs from Pentagon-style “procurement” in that government is the buyer but not the user), self-regulation ultimately traceable to the professional prerogatives of physicians, and litigation by individual patients and providers. As Jost notes, command and control regulation is not the norm in health care. The tension between the generally collective orientation of administrative law (constrained by constitutional and statutory process requirements) and the generally relational orientation of the other sources of law is to me at the heart of today’s discussion, but Noll’s paper, responding in textualist fashion to the language of the conference invitation, assumes them away.

Jost truncates his analysis in a different but also unfortunate way, plausibly attributable in a similar fashion to the conference’s expressed mandate. He addresses his legal analysis, which is very sophisticated, to the assigned subject of expanding health coverage. Health care delivery reform becomes an afterthought. This is a conventional way of approaching reform, not a “fresh” one. There seems to be a growing consensus among health policy experts, including many in health law (I suspect Jost among them), that significant improvements in access, cost, and quality require a new approach to delivery system structure, governance, and incentives. But these crucial issues are shunted aside in campaign debates because voters are not accustomed to hearing them, entrenched provider groups will attack them (a point Noll makes), and all that really matters to the political establishment is where candidates stand on tax burden and government spending. I recently heard Len Nichols of the New America Foundation assert the importance of delivery system reform but then decline to “belabor it” in an otherwise detailed presentation. Please, belabor delivery system reform!

Both authors downplay payment policy, in large part as a result of these decisions about the defined scope of their project. Noll considers it “procurement” and therefore off-limits. Jost focuses on coverage and therefore mainly on eligibility and benefit determinations. In fact, administered pricing constitutes the principal form of de facto federal regulation of health care and, in my opinion, bears substantial responsibility for perpetuating the cottage industry-style fragmentation of health care that is largely the source of its high cost, mediocre quality, and shoddy accessibility. Both authors, Noll especially, discuss antitrust law, but both miss the insight that, without Medicare, antitrust law would operate on an unrecognizable competitive landscape because the number, scale, and geographic distribution of health care providers (particularly hospitals) would be so different from what currently exist. Finally, payment policy highlights the near-impossibility of improving health care financing without dramatically changing health care delivery. As Mark Smith has said, in the current system patients and insurers complain of paying too much for what they receive, while physicians and

hospitals complain of being paid too little for what they provide. This is simply an unsustainable model.

Overcoming “relational” bias in favor of collective orientation

As noted above, Jost’s sweeping understanding of law, contrasted with Noll’s self-imposed limitation to non-procurement administrative activity, highlights sources of health care governance that reinforce the one doctor-one patient view of the health care system and retard the system’s ability to articulate and achieve public, collective goals. Much of health law is what Europeans regard as “private law”: contract, tort, and fiduciary obligation. A lot of the rest is self-regulation imposed on the general public by health care providers who serve individual patients. The “public law” of health care is visible only in payment policies (which themselves are often subverted to private ends by their forced mimicry of private health insurance), in tax law (which Jost correctly describes as under-theorized for achieving public purposes), and in the narrow domains of traditional public health.

Federalism traditions in health care reinforce relational bias. Unless and until a substantial body of global public health law develops, or a national crisis of epidemic or bioterrorism occurs, only state law safeguards public health, and typically through an underfunded set of activities poorly connected to the much more lucrative business of insuring and delivering health care to individuals. Federal health regulation is dominated, as noted above, by Medicare payment policies. These are only “collective” in the sense that the macro-politics of taxation and government spending drives their largest expenditures, such as hospital reimbursement (a point made years ago by Bruce Vladeck). In all smaller domains they serve merely to fulfill individual needs for medical services and are nearly always held captive to the parochial interests of health care providers, which serve mainly to freeze in place existing forms of health care delivery.

“Conflict of interest” comes up at a few junctures in Jost’s paper, including both insurance relationships and provider financial relationships. As I have written elsewhere, I think the “conflict of interest” label risks falling into a relational trap, in which problems that really require social consensus regarding optimal incentives structures are incorrectly addressed in terms of loyalty to individual patients or research subjects. For this reason, I like Jost’s instinct to simplify fraud and abuse law, although I am not fully clear on the details of his proposal.

Delivery system reform

Jost correctly identifies Medicare, Medicaid (including, in general terms, SCHIP), and ERISA as the most important legal governance mechanisms in American health care. A core project in health regulatory reform is converting each of these from an obstacle to health care delivery reform to a facilitator of it.

Medicare’s initial political compromise, as Jost notes, was non-interference with the practice of medicine (LBJ’s famous “move the damn bill out” line), which was converted

from a negative to an affirmative pledge through emulation of established forms of insurance administration and payment. Although this pledge has been honored in the breach, nearly all violations have been motivated by reasons other than delivery reform (home health care being the only exception that comes to mind), even in areas such as ESRD and cataract surgery where Medicare is essentially a single payer. Most of Medicare's incursions on medical practice were motivated by government budgetary concerns, a by-product of regulating through payment that also drives the odd incentive structure of federal fraud and abuse law. When not being modified for budgetary purposes, the Medicare-supported delivery system is left alone for political ones, either to avoid provoking providers, especially mobile and well-connected physicians (as in the failure of RBRVS payment to apply a common metric to both primary and specialty care, or in the periodic restructuring and renaming of Medicare's perpetually ineffectual quality review procedures), or to mollify seniors (as when Medicare was left out of the Health Security Act for fear of touching the "third rail" that electrocuted the Medicare Catastrophic Coverage Act in the late 1980s). Pay-for-performance and transparency (especially price transparency) are current Medicare initiatives that have some potential to restructure health care delivery, but their proponents have been tentative so far, vacillating in their insistence on setting goals that require such restructuring and on whether their measures and incentives are intended to help individual consumers or to go beyond facilitative government to articulate truly collective goals. A limiting factor under Republican leadership has been that the most dramatic conceptions of Medicare reform attempt to curtail the program in order to further ideologies of minimal taxation and limited government; these non-health care rationales are unlikely to produce, by happenstance alone, beneficial changes in health care delivery.

Medicaid offers a different set of pathologies, which Jost would be more expert than I in identifying if he examined the program through the lens of delivery system reform. One problem that Jost mentions is how Medicaid's coordinating role on state health investment and coverage policies has been greatly reduced, in essence accidentally, by changes in how the Supreme Court interprets the constitutional underpinnings of our federalist system of government (an analysis completely divorced from the question of which level of government is best equipped to perform a given function for the benefit of the nation). Another problematic aspect of Medicaid is that the federal role is essentially that of banker. How much federal money states seek often reflects the important, but generally not health-related, politics within the state regarding tax burden and ideology of government, with parallel pressures affecting the federal banker itself. At the same time, Medicaid does offer advantages for delivery system reform going forward. If their basic budget needs are met, Medicaid's safety net institutions are primarily concerned with improving access, are oriented to childhood and parenthood and therefore to prevention and public health, and are well connected to other social resources within communities. Medicaid's role as principal funder of long-term care services also provides a vehicle for connecting health policy to aging policy.

ERISA tensions run in yet other directions. The conventional, defined benefit employment-based health insurance system is rightly criticized for catering to the more prosperous in its design implications for health care delivery, and for perpetuating a

regressive tax subsidy from the federal treasury. However, employed groups are natural experiments for pooling health risks and, with recent attention to the costs of chronic disease, of improving collective health behaviors. The managed care organizations and integrated delivery systems with which larger employers contract, moreover, have the potential to help improve the health of communities as a whole, even if that power is somewhat reduced from the early 1990s when it was thought that a few such institutions would dominate the market. Perhaps more importantly, it is the business community (both large and small) that in many parts of the country determines expansions both of care and coverage. Business must be persuaded, by data not rhetoric, that a healthy population is an economically productive one; charitable and compassionate arguments make the marginal case for universal health care, not the modal one. ERISA, conceptually if not in its technicalities, nicely encapsulates these possibilities. On one hand, ERISA gives employers freedom to determine the form and extent of their commitment to health. On the other, ERISA imposes a duty on employers to administer those voluntary commitments for collective benefit, a point the Supreme Court might have discussed in *Pegram v. Herdrich* but did not. In this respect, fear of unfettered private litigation (see below) does constitute an obstacle to reform, in that it diverts the federal courts from engaging deep issues in ERISA preemption cases while also appealing to employers' anti-lawyer instincts whether or not those biases align with their beliefs regarding health care.

Jost presents some novel ideas. I like the idea of regional agreement among states as a bridge between single-state experiments and national commitments. Obesity, for example, hits Southern states the hardest, and a coalition of those states could create new systems of obesity governance that incorporate changes to food, schools, and the built environment as well as to traditional aspects of public health and health care delivery. I am less persuaded by Jost's proposal for a national compendium of coverage recommendations. A technology assessment system that was widely trusted would indeed be "nice" (pun intended), but I fear that a national coding system of this sort would further ossify health care delivery system by creating even more categories to be fiercely protected by entrenched interests.

I am struck by the lack of attention both authors give to the health care workforce beyond the usual criticism of professional licensing. Long-term improvements in health care delivery require short- and medium-term changes in workforce deployment and workforce development, implicating many areas of law and regulation.

Financing reform

I am not suggesting that expanding health insurance coverage is unimportant, or criticizing the authors for devoting attention to it. I do believe, however, that a major expansion of insurance, or even a series of incremental expansions, that are not preceded by serious attention to health care delivery and to public health, will merely accelerate the social unaffordability of our health care system. "Double or nothing" does not strike me as a sensible way to proceed as a nation.

If health care delivery is put at the center of reform, where I think it deserves to be, the regulation-of-financing discussion can be broadened beyond the usual suspects. One productive direction is suggested by the empirical work of Warren, Jacoby, Westbrook and others on the financial burden of illness and its connection to personal bankruptcy filings. In particular, their work documents the recent convergence of health care debt with general consumer debt as health care normalizes its collection practices, and as consumer financing pursues health care as a growth area given its rising cost and the larger percentage of that cost paid at the individual level (especially if consumer-directed health care grows). It used to be that hospital debt was a low priority to pay; it is increasingly the case that hospital debt triggers irreversible consequences for individuals and families who are already living at the financial margin and who have had their economic stress worsened by illness.

Similarly, I think it worth discussing the questionable compatibility between new forms of health care delivery that are arising and existing forms of health care financing. Retail medical clinics, for example, strike me as promising innovations in providing accessible, affordable, and reliable health care services, albeit of limited types. Self-protective regulation favoring physicians over such new competitors is certainly to be avoided. But insidious pressures are being created as more retail clinic services are covered by health insurance, implicating state insurance regulations, private litigation risks, and concerns over conflict of interest and privacy similar to those raised against managed care in the 1990s.

With respect to health savings accounts and consumer-directed health care, my cautionary word is that these initiatives should be debated using hypotheses that connect them to quality and cost-effectiveness in health care delivery. As the Noll paper exemplifies, academics (and policymakers) engage these trends exclusively through insurance theory, testing possible effects on moral hazard and adverse selection.

Overall, I think that health insurance regulatory reform should be directed at discussing, and hopefully generating social consensus on, the appropriate financial response to the unequal burden of illness in any (and especially our) population. Jost devotes much interesting analysis to this issue. I agree wholeheartedly with his observation that it is hard to make a private insurer behave like a social insurer. However, he does not assign the issue singular priority, as I would. In particular, chronic diseases and preventable diseases as well as aging require major public policy attention when planning our long-range financial commitments as a society, and would link the financing discussion productively to public health and health care delivery.

Medical malpractice

Let me offer a postscript on medical malpractice to match Jost's. Jost knows many areas of health law better than I, but I have more experience with liability reform. Early 2006 marked the end of my most recent stint attempting to generate productive reforms from a malpractice insurance crisis. In keeping with the news of that period, I began referring to medical malpractice as the Anna Nichole Smith of health care, particularly for

physicians. It is utterly fascinating, but really not very important. In my view, the progress that can be made involves moving recognition of error and compensation for avoidable injury farther away from the courtroom and closer to the bedside. Error disclosure and early compensation, certainly including voluntary programs such as that used in Colorado by COPIC, is a welcome trend. But it requires mainly cultural change rather than legal change.