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Highlights...

Homeland Security Top Bush Priority For Lame Duck. President Bush wants the lame duck Congress to pass legislation creating a new department of homeland security. (Page 2)

Localities Strained To Limit — But Not Ready — On Bioterror. Local public health agencies are modernizing faster than they have in decades, but most still need more money and more qualified staff to be truly ready for a bioterror attack. (Page 2)

FDA Approves 20-Minute HIV Test. The Food and Drug Administration has approved an easy-to-use HIV/AIDS test that provides results in 20 minutes. Federal officials hope the test will help in deciding who should receive the smallpox vaccine. (Page 3)

QIOs: A 10-Percent Solution For Long-Term Care? Half of the skilled nursing facilities in a 6-state pilot project want intensive help from quality improvement organizations in their quest to do well on performance measures promulgated by the Centers for Medicare and Medicaid Services. However, there's only enough money for ten percent of SNFs to get that kind of help. (Page 3)

FDA Gives Go-Ahead To Generic Prilosec. One of the biggest blockbuster drugs is slated to get some competition, now that the generic company that won patent litigation against Prilosec's manufacturer has reached an agreement with two other generics that lost in the courtroom. (Page 4)

Money No Issue In White House Panel's Report. Two recent reports generally agree that the nation's mental health system needs a dramatic overhaul. But the first, by an independent federal agency, might be titled, "Put Your Money Where Your Mouth Is," while the second, by the President's New Freedom Commission on Mental Health, might be titled, "The Best Things In Life Are Free." (Page 4)

IOM Pushes Quality Standards For Federal Health Programs. An Institute of Medicine report recommends that government health programs use their tremendous power as regulators, purchasers, and providers to promulgate consistent performance measures and encourage development of a health information infrastructure. (Page 5)

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*Congress***HOMELAND SECURITY TOP
BUSH PRIORITY FOR LAME DUCK**

President **George Bush** wants the 107th Congress to pass legislation creating a new department of homeland security before it makes way for the 108th. At a Nov. 7 news conference, Bush labeled this “the single most important item of unfinished business on Capitol Hill” and called on Congress to give him the flexibility he wants regarding labor issues at the new department.

The president, in good humor after Republicans took control of both houses of Congress, called it “imperative” that Congress act on homeland security in the coming “lame duck” session. However, at his Nov. 6 briefing, Senate Majority Leader in waiting **Trent Lott** (R-MS) suggested that final resolution in this area may spill into next year. Lott said he had never been a fan of lame duck sessions and that he wants to keep this one short. Lott’s remarks aren’t sitting too well with the president, the *Associated Press* reported.

The lame ducks may attend to some backlogged legislation, said Lott, but probably not to fiscal year 2003 appropriations for the **Department of Health and Human Services**. Dealing with the 11 outstanding appropriations bills now would eat up lots of time and money, so “the best way ... is to decide on the amount and for how long and to do a continuing resolution over until next year.”

Whenever appropriations are addressed, veteran political analyst and Washington insider **Norm Ornstein** of the **American Enterprise Institute** suggests that Bush may prove more amenable to going beyond the \$131 billion in discretionary spending he requested for HHS and the departments of education and labor.

Before the election, “the president tried to dramatize his role as the fiscal conservative” by focusing on “symbolic amounts that in a \$2 trillion dollar budget weren’t even pocket change ... often at substantial costs to other priorities.” However, with the election over and legislators of both parties pushing for Labor-HHS funding closer to the Senate’s \$136.7 billion figure, Bush “will not want to get bogged down in a fight that will pit a bipartisan coalition against him on a few billion dollars here and there.”

Speaking on a Nov. 5 post-election conference call sponsored by the **American Association of Health Plans**, Ornstein said Bush will “accede to some spending ... and then decide what fights he wants to pick in the next year.”

A short lame duck session may push consideration of Medicare giveback legislation into 2003, but providers still hope for quicker action. For instance, the **American Hospital Association** is urging members to “keep the pressure on their federal lawmakers to commit to passing significant hospital payment relief legislation before the current session ... is over,” *AHA News* reports.

Opponents of giveback money for hospitals are stocking up ammunition, too. For instance, an Oct. 22 congressionally requested analysis by staff of the **Medicare Payment Advisory Commission** found that hospitals had a 4.3 percent seasonally adjusted total margin in the

first two quarters of FY 2002, up from 3.6 percent in the first two quarters of FY 2001. The analysis notes, however, that the rise in margins for all of FY 2002, as compared to all of FY 2001, may be smaller than the increase between first-half FY 2001 and first-half FY 2002.

*Public Health***LOCALITIES STRAINED TO LIMIT —
BUT NOT READY — ON BIOTERROR**

In response to the terror attacks of 2001, local public health agencies may have made greater strides in modernization during the past year than they have in decades. But money and staff to support activities including antiterror efforts still are in short supply, leaving national preparedness in doubt, according to a new survey by the **National Association of County and City Health Officials**. Despite progress, “the nation is not uniformly prepared,” NACCHO concludes from the survey of 1,626 local offices that garnered 342 responses from 44 states. “Much remains to be done and more time and sustained resources are necessary.”

In some cases, localities are building systems from the ground up. “Most of the communities I serve did not have an official public health department” in September 2001, writes a Nebraska official. By mid-2002 “each of the four counties ... appears to have an emergency response plan. However, three of the four counties only have a volunteer or very part-time emergency response coordinator. The development of public health infrastructure is still in its infancy, but it is better than no public health — which was the case on 9/11.”

Increased community collaboration and upgraded electronic technology are the two areas that have seen the biggest gains, although improvement is modest. “Almost half” of respondents reported more community collaboration in the last year, many saying they built relationships for the first time with other first responders such as emergency personnel, NACCHO says. “Before 9/11 we didn’t know our partners. Now we are on their Nextel list,” one Florida official writes.

A quarter of respondents said they’ve improved technology and equipment since Sept. 11, 2001, with the responses illustrating “a wide variety of needs and sophistication,” including improvements to laboratories as well as communications and computer technology, according to NACCHO.

Nevertheless, the future is uncertain. Training staff and obtaining and keeping staff with needed expertise are major ongoing concerns. “Many respondents had not yet conducted any training,” NACCHO’s analysis says.

Maintaining connections with health care partners and the community at large is a challenge, local offices say. “The most overwhelming issue” is “communication: internal, external, with partners, with media, and alternative ways if the system goes down,” a Minnesota official writes.

Staffs are still scanty and are likely to continue so. “Only one-fifth of responding agencies noted that they have hired staff in the last year,” says NACCHO. “Many stated that their current staff size is insufficient” to pursue “bioterrorism preparedness while also main-

taining levels of effort in other areas.” Many agencies report searching hard for qualified staff in needed specialties, including epidemiology and information systems, and not necessarily finding workers with the right resumes. “Smaller rural jurisdictions were particularly concerned about their ability to locate or hire additional experts or specialists to address bioterrorism. Their only option is to train employees they already have.”

Behind most other problems — says NACCHO — “funding, including strains on existing resources, sustainability, and federal funding not reaching the local level.” States and localities have recently imposed new budget cuts, and some local agencies still haven’t “received additional funding and [are] still working with the same limited resources they had prior to Sept. 11,” the group says. “In these cases, new resources for addressing bioterrorism had not been created, but had been taken from already suffering programs. ... A few respondents indicated that they ... may actually be farther behind because of increasing drains on public health resources.”

Local deficiencies could spell trouble for national preparedness on terrorism, **U.S. Department of Health and Human Services** public-health-preparedness chief **Jerry Hauer** told the **Associated Press** Nov. 2. “Our biggest concern is we will get to a location and a state or a city will not be ready,” said Hauer. Federal officials have reported that Florida is the only state currently prepared to receive its allotment from the National Pharmaceutical Stockpile.

HIV/AIDS

FDA APPROVES 20-MINUTE HIV TEST

The **Food and Drug Administration** Nov. 7 approved an HIV test that can provide results within 20 minutes. Current methods take up to two weeks to return results, and **Health and Human Services** Secretary **Tommy Thompson** said 8,000 people annually test positive for HIV but never find out because they don’t return to the testing site to obtain their results. By providing results right away, the new Oraquick Rapid HIV-1 antibody test, made by **OraSure Technologies**, will reduce the number of Americans who unknowingly carry the HIV virus, Thompson predicted at a press conference.

Anthony Fauci, MD, director of the **National Institute of Allergy and Infectious Disease**, said the new test could help doctors quickly determine the HIV-status of a woman in labor, so if necessary they could take steps to prevent mother-to-child virus transmission during delivery. Oraquick could also help health care workers exposed to a patient’s blood decide whether to take prophylactic antiviral drugs, he said.

Bioterror implications also are in the mix, said Fauci. If federal officials decide to administer smallpox vaccine widely, the test could help screen out HIV-positive people, who are advised not to be vaccinated absent an actual outbreak.

However, because Oraquick, like other HIV tests, detects antibodies to HIV rather than the virus itself, there is a 3-month window in which HIV-positive people can still test negative because their bodies have not yet

produced antibodies. Thus, those who test negative but who have been potentially exposed to the virus within that window are advised to repeat the test later.

There is one other rapid HIV test on the market in the United States, but Oraquick is faster and simpler to use because it does not require refrigeration or separation of blood into component parts, said **Murray Lumpkin**, MD, principal FDA deputy commissioner. Lumpkin said Oraquick was also more accurate, providing 99.6 percent positive and negative accuracy.

FDA categorizes the test as “moderate complexity” under the Clinical Laboratory Improvements Amendments of 1988, which means it could be administered in 40,000 CLIA-qualified labs — including some mobile outreach labs — across the country. But Thompson urged the company to apply for a CLIA waiver. If the FDA found that Oraquick was “easy and safe to use,” Thompson said, it “could be given in many more health care settings, perhaps even administered by social workers in HIV counseling centers.”

In an investor teleconference following the HHS press conference, OraSure Chief Executive **Mike Gausling** said the company is already working with the FDA on testing protocols for a CLIA waiver application.

Nursing Home Quality

QIOs: A 10-PERCENT SOLUTION FOR LONG-TERM CARE?

Lack of funding means skilled nursing facilities probably won’t get all the help they want to improve their scores on the standardized quality measures the **Centers for Medicare and Medicaid Services** hopes to begin publicizing nationally this week. Quality improvement organizations in states and territories are the lynchpin of federal efforts to help nursing homes provide better care. But while about 50 percent of SNFs in six states where the initiative was piloted have asked for intensive individual consultations with a QIO, current funding can provide such assistance to only about 10 percent, **American Health Quality Association** Executive Vice President **David Schulke**, MD, told reporters Nov. 7.

QIOs will provide information to all facilities through conferences, mailings, and peer-group collaborations among SNFs, said Schulke. But “we continue to be concerned” about the small number of nursing homes that will get individual help, he said. AHQA continues to call for release of \$80 million in potential federal funding that the White House **Office of Management and Budget** has so far “held back because they weren’t sure this initiative was a good idea.” QIOs in the pilot states have seen big quality improvements in SNFs they worked with closely, Schulke said.

By February, QIOs around the country will need to have enlisted specific facilities they’ll work with individually, and QIOs will later be evaluated on how much those SNFs improve their measures, he explained. Since the White House has said it plans to move to performance-based budgeting, future funding for the technical-assistance initiative likely depends on that evaluation.

So with the initiative’s future potentially riding on how the chosen 10 percent perform, QIOs are picking

partners carefully, with SNFs that demonstrate a long-term commitment to quality improvement being the most likely candidates, according to Schulke.

The pilot project, which began last spring, has produced some refinements to the measures, said Schulke and representatives of the **American Association of Homes and Services for the Aging** and the **American Health Care Association** on hand for the telephone briefing. These include scrapping a weight-loss measure that turned out to be invalid and providing more consumer information about how to interpret and use the measures. "CMS will provide consumers with additional context around the reporting," said AAHSA Senior Vice president **Suzanne Weiss**.

Sen. **Chuck Grassley** (R-IA), soon to resume the chair of the **Senate Finance Committee**, has threatened to demand delay of the planned Nov. 12 launch of nationwide reporting, based at least in part on doubts about whether consumers can understand the measures in their current incarnation. CMS is working to address Grassley's concerns, most of which are touched upon in a **General Accounting Office** report not yet released to the public. Negotiations are understood to be ongoing.

Generic Drugs

FDA GIVES GO-AHEAD TO GENERIC PRILOSEC

The **Food and Drug Administration** gave the final go-ahead Nov. 1 for a generic competitor to Prilosec, **AstraZeneca Plc's** popular anti-ulcer drug. **Kremer Urban Development Company**, a wholly owned American subsidiary of the German company **Schwarz Pharma**, now has the right to offer 10 and 20 milligram versions of omeprazole, the active ingredient in Prilosec.

FDA had earlier granted tentative approval for KudCo's omeprazole products. The agency bestowed final approval after two other makers of omeprazole — **Andrx Pharmaceuticals, Inc.**, and **Genpharm, Inc.** — agreed to relinquish their jointly held right to market generic Prilosec exclusively, without any other generic competitors. In a Nov. 1 statement, the FDA explained that, consequently, "there will be no 180-day exclusivity for any 10 or 20 mg generic omeprazole products."

The six-month market exclusivity, granted under the "Hatch-Waxman" legislation, is designed to give generic drugmakers an incentive to bring their products to market quickly. To compensate Andrx and Genpharm for giving up this right, "KudCo will share a percentage of its profits with each of Andrx and Genpharm," according to a Nov. 1 KudCo statement.

Along with a third firm, **Cheminor Drugs, Lmtd.**, Andrx and Genpharm were blocked from marketing their generic alternatives to Prilosec by the Oct. 11 court decision in *In Re Omeprazole Patent Litigation*. In that case, New York Federal District Court Judge **Barbara Jones** ruled that the versions of omeprazole marketed by these three companies infringed on AstraZeneca's Prilosec patents. KudCo's version, however, did not run afoul of AstraZeneca's intellectual property rights, the judge held.

Mental Health

MONEY NO ISSUE IN WHITE HOUSE PANEL'S REPORT

Two recent government reports on the nation's mental health system conclude there's need for "dramatic" overhaul. But in its September analysis an independent federal agency — the **National Council on Disability** — emphasizes among "root causes" of the crisis inadequate state and federal funding and access disparities in public and private insurance. An Oct. 29 analysis from President Bush's **New Freedom Commission on Mental Health**, on the other hand, has little to say about fiscal matters of any kind, although its authors note that the current system is "incapable of efficiently delivering and financing effective treatments."

Both reports say that fragmentation of service delivery and fragmentation of responsibility for mental health care have worsened as the nation moved over the past five decades to deinstitutionalize mentally ill patients. "The movement away from institutions ... was motivated by reformers' desire to bring services to people in their communities," says the Commission. "The unintended consequence is that responsibility is scattered across levels of government and across multiple agencies."

As is the case in many other parallel sections of the papers, the Council's analysis generally agrees but expands its comments to include the role of financing. "Community mental health services are generally no more expensive than institutional care," says the group. "However, to shift a system from over-reliance on institutions to one that provides more appropriate and more effective community services and supports requires an investment in the community. Start-up costs, along with the need to ensure that people continue to receive care while new community options come on line, have hampered states' ability to ensure that resources follow individuals into the community."

But "far from meeting these obligations" to develop community-based care systems and maintain transitional institution-based care during the change-over, state investments in mental health have decreased over the decades, according to the Council. "State-only appropriations for mental health services are significantly lower today (adjusted for inflation and growth in population) than they were in 1955."

Both reports exhort Americans to end the stigma surrounding mental illness. The Commission analysis quotes President Bush's statement at the panel's April launch: "Americans must understand and send this message: mental disability is not a scandal — it is an illness."

But again, the Council report goes much further, finding that fiscal consequences of stigmatization have created some of the most serious barriers to care. "The underlying stigma surrounding mental illness has led to systemic inequality in all health care delivery. For example, the private sector refuses to insure individuals with a history of any mental health treatment, when they will insure an individual with more severe physical health care needs."

The October report is an interim analysis from the president's Commission. In a concluding statement

the group promises that its final work, due in the first half of 2003, will “propose bold new directions for the mental health service delivery system.”

Quality

IOM PUSHES QUALITY STANDARDS FOR FEDERAL HEALTH PROGRAMS

The federal government should promulgate consistent health care quality standards and pay more to providers who meet them. So says an Oct. 30 report from the **Institute of Medicine**.

The report responds to Congress' request that the IOM review quality enhancement measures in six major government programs: Medicare, Medicaid, the State Children's Health Insurance Program, the **Department of Defense's TRICARE** programs, the **Veterans Health Administration** health programs, and the **Indian Health Service**.

Because these programs together serve almost a third of all Americans, quality improvements are also likely to spill over into the rest of the healthcare system, the report points out.

Each of the six programs has minimum participatory standards, and across all of the programs “there has been a proliferation of performance assessment activities,” the report acknowledges. However, this scattershot approach to quality enhancement “has not closed the quality gap and is unlikely to do so in the future unless changes are made.”

To start more effectively closing the gap, the Secretaries of HHS, DOD, and VA must work together “to establish standardized performance measures across the government programs, as well as public reporting requirements for clinicians, institutional providers, and health plans in each program.” These gauges would apply consistently across different programs and across different financing and delivery options within programs, although each program might implement a different subset of the measures, according to the report.

Specifically, the federal government's **Quality Interagency Coordination Task Force**, in collaboration with private groups like the **Leapfrog Group** and the **National Quality Forum**, “should promulgate standardized sets of performance measures for five common health conditions in fiscal year 2003, and another 10 sets in FY 2004.” By 2007, submitting “audited patient-level data” revealing performance on the 15 metrics would be a requirement for private sector providers wanting to participate in the government health programs, and the government would be expected to produce similar data where it provides services directly.

The government would then, through higher payments, public recognition, and other methods, reward those that provide higher quality care, the report says.

“Computerized clinical data and decision support systems” are a prerequisite to producing this comparative quality information and, for that matter, to providing quality care, the report asserts. Yet, “the health care delivery system has lagged behind other industries in making innovative use of information technology.” Consequently, the report says, Congress should consider

options like tax credits, subsidized loans, and grants “to facilitate rapid development of a national health information infrastructure.” And government health programs should consider both market-based and regulatory methods, perhaps including faster and/or bigger reimbursements, to encourage participating private sector providers to invest in information technology.

The reports say that it was beyond their charge to determine the funding required to build the necessary information technology infrastructure, but additional federal dollars will likely be scarce in today's tight fiscal atmosphere.

Initiatives and Referenda

OREGON REJECTS SINGLE PAYER, DRUG REFORM FARES POORLY

In the broadest health-related ballot question at issue last Tuesday, Oregonians decisively rejected implementing a single-payer health insurance system in that state. Heavily outspent advocates of citizen-developed initiative number 23 were able to muster only just under 175,000 yes votes, against over 680,000 nays.

Voter-initiated efforts to reform and liberalize state drug abuse laws generally fared poorly. Ohio's Issue One, which would have provided for treatment rather than imprisonment for first- and second-time nonviolent drug offenders, went down to a two-to-one defeat, although Washington, D.C., voters easily approved a similar measure. Proposition 203 in Arizona, legalizing medical marijuana use and making other changes in the drug laws, lost as well.

Over 60 percent of Nevada voters opted against a measure that would have decriminalized possession of up to three ounces of marijuana. And South Dakota citizens defeated two measures, one legalizing industrial hemp (cannabis) and another that would have allowed defendants in drug cases and other proceedings to argue openly for “jury nullification,” *i.e.*, acquittal based on an unjust law.

Many have attributed the surprisingly dismal fate of this year's drug reform measures to the “extraordinary” active campaigning against them by White House Drug Czar **John Walters** and **Drug Enforcement Agency** chief **Asa Hutchinson**, observes the **Initiative and Referendum Institute's** post-election report. Litigation against the federal government's involvement in political campaigns may result, notes the Institute, which tracks ballot measures and encourages voter-initiated initiatives.

In the tobacco arena, Florida voters adopted the citizen-initiated Amendment 6, banning smoking in enclosed indoor workplaces. Arizonans more than doubled cigarette taxes, with the proceeds under the legislature-initiated Proposition 203 going to expand smoking cessation programs and health care access. But Missouri voters turned back a citizen-sponsored proposal increasing taxes on tobacco products to fund health initiatives, and Michigan residents by almost two to one rejected a voter-initiated effort, Proposal 02-04, to allocate 90 percent of tobacco settlement revenues to health care purposes and facilities.

Montana's citizen-sponsored Initiative 146, es-

establishing a tobacco use prevention fund with settlement money, was successful, but Oklahomans rejected the legislature-initiated Question 701, designed to ensure steady annual expenditures from tobacco settlement funds.

In Colorado, voters decisively rejected Referendum B, initiated by the legislature, which would have let local governments partner with private enterprises to provide health services.

IN OTHER NEWS

• **Medicare Patients Go Begging For Docs In Colorado, Paper Says.** Only four in 10 primary-care physicians in Colorado are accepting new Medicare patients, and in some areas that ratio is down to one in 10, the *Los Angeles Times* reported Nov. 4.

"For many physicians, the math is fairly simple," says the paper, which recounts tales of state legislators, retired judges and others who were dumped by their long-time physicians and undertook sometimes fruitless quests to find new ones without leaving the state. "In Colorado, private insurers reimburse doctors at rates often 25 percent above what Medicare pays for the same services. Faced with that, individual physicians and group practices have made a business decision that no more than some fixed percentage of their patients can be on Medicare."

Some social service agencies "now count Medicare beneficiaries with the homeless and the uninsured as being 'medically underserved,'" according to the *Times*.

• **Diabetes Hospitalizations Rise, Pennsylvania Finds.** Even as efforts burgeoned to manage diabetic patients better, diabetes-related hospitalizations rose over the past five years, the **Pennsylvania Health Care Cost Containment Council** finds in a new study. Hospitalizations for diabetes-related conditions rose 16.8 percent from 1997 to 2001.

The number and rate of hospitalizations for Type 1 — so-called juvenile onset — diabetes dropped over the period, while hospitalizations for Type 2 diabetes — which is lifestyle-related — have increased steadily. Hospitalizations increased for all age groups, but grew most — by 26.1 percent — for people aged 30 to 39. Hospitalizations for people aged 40 to 49 increased at the second-highest rate — 18.4 percent.

• **Docs Who Napped Less Drowsy In Study.** In a study of 11 emergency department physicians working 24-hour shifts, the subjects showed less physical evidence of drowsiness during nighttime working hours when they'd been offered a four-hour rest during the shift and, especially, if they'd napped during the rest period. The study, published in the October issue of *Critical Care Medicine*, demonstrates that sleep deprivation impairs physician performance and that napping can reverse some of the impairment, its authors say.

Meanwhile, in an article in the Oct. 17 *New England Journal of Medicine*, patient-safety researchers from the **Department of Veterans' Affairs** argue that, even without conclusive clinical evidence that tired doctors harm patients, the potential dangers posed by overtired physicians are obvious in light of the proven fatigue-related dangers in other high-hazard occupations such as piloting airplanes or driving trucks.

To promote harmony with people's natural sleep

cycles, health care facilities should institute shorter shifts, limit high-intensity work to daytime hours, and encourage medical professionals to take a less macho attitude toward fatigue, including, for example, taking a daily nap at a fatigue-vulnerable time, such as the hours between 2 and 4 in the morning, according to **David Gaba, MD**, director of VA's Palo Alto-based **Patient Safety Center of Inquiry**, and his co-authors.

"There's no way you can respond to the issue ... without major changes in the way work gets done. And some of these changes are going to cost a lot of money," warns Gaba.

PEOPLE

Emory University School of Medicine professor of psychiatry **Thomas Insel, MD**, assumes the directorship of the **National Institute of Mental Health** this month. It will be a return to NIMH for Insel, who served there in a variety of posts from 1979 to 1994. At Emory, he's been director of the **Yerkes Regional Primate Research Center** and founding director of the **Center for Behavioral Neuroscience**.

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Medicine & Health Perspectives

COULD MEDICAL-ERROR STUDIES RESHAPE TORT REFORM DEBATE?

This is the second in a series of Perspectives on medical malpractice liability reform. The first appeared in our issue of November 4.

Whenever medical malpractice liability reform is the theme at a gathering of Washington lawmakers and lobbyists, the song is pretty much the same: Doctors and many other providers hope Congress will help trim medical costs — starting with liability-insurance premiums — by capping damage awards and enacting various restrictions that make it harder for plaintiffs to sue, a la California's 1975 Medical Injury Compensation Reform Act (see *M&H Perspectives*, Nov. 4, 2002).

But a wide array of analysts inside and outside the Beltway also are analyzing the malpractice liability system and have their own ideas about what's wrong and how to fix it. Many of them sing quite a different tune from the familiar refrains heard on Capitol Hill.

For starters, scholars point to potential contradictions, hidden facts, and fundamental questions about the current tort liability system for medicine that they say should be brought to light and considered before an overhaul goes forward nationwide. Among the underlying issues are the following:

- **Who's paying those damage awards, anyway?** Clearly, most if not all patients who sue health care providers and collect damages believe that the awards ultimately ding the person that harmed them, thus constituting at least retribution and payback if not a deterrent to future negligent behavior by that provider.

Said one participant at an Oct. 29 forum sponsored by the **American Enterprise Institute-Brookings Joint Center for Regulatory Studies** and the New York City-based legal reform initiative **Common Good**: "Our physicians make a heck of a lot more money than physicians around the world. People look at these guys, and say, 'This guy hurt me. He's gonna pay.'"

The trouble is that a provider who loses in court and is assessed damages isn't really the one who pays, whether or not that provider was at fault in the matter.

It's liability insurance premiums, in the aggregate, that pay the claims, a fact the public generally is unaware of, analysts say.

To hear plaintiffs' lawyers tell it, a court judgment against a doctor is a penalty specifically imposed on "a bad actor," said another Oct. 29 participant. "Insurance is never mentioned," leading injured patients to conclude that when the doctor loses, the doctor pays.

But since liability insurance premiums are spread across whole medical specialties, the doctor patients believe they're punishing really is punished little, if at all, contrary to most plaintiffs' hopes and expectations.

"A gross mismatch between claims made and actual negligence (or even medical injury) blunts specific

safety incentives while generally increasing defensive medicine," writes **Columbia Law School** professor **William Sage**, MD, in the July 11, 2001, *Journal of the American Medical Association*. "Physicians with poor safety records seldom can be identified, and in any event pay no more for liability insurance than their colleagues."

"It's the highest-risk professions that pay the highest premiums," not specialties that include more negligent practitioners or even specialties that are higher paid, one Common Good participant noted. For example, obstetrician-gynecologists — and even much lower-paid nurse-midwives — notoriously pay very high malpractice liability premiums. It's not a reflection on the skills of these practitioners but on the relative riskiness — and scariness — of their specialties. This fact, too, throws cold water on the idea that the current system actually punishes the negligent.

The large premiums paid by specialists in high-risk areas make even some providers skeptical about revisions that leave the current tort system in place but impose damage caps and additional bars to suing. "There needs to be some spread of the costs from obstetrician-gynecologists, neurologists, midwives, and so on to others," said one conference participant. "On the ideal side, I'd like the taxpayer to pay, pay into the system so you have some ownership."

Such highly differential premiums also exacerbate supply-and-demand imbalances in the health care system, some participants said. In a five-person obstetrics-gynecology practice in Pennsylvania, for example, a decade ago all five doctors likely did at least some obstetrics, said one conference attendee. Today, typically only two of the physicians might still deliver babies, regardless of local demand for obstetrical care.

Whatever they'd like to see happen afterwards, unmasking the public myth that successful malpractice claims punish negligent providers financially seems to be a priority for many analysts. But clarifying who's really paying — and who's not — when damage awards are made is only one of many questions that a closer look at malpractice reveals.

For example, said one forum participant: "If we are no longer pretending that the guilty party is coughing up the money — because they don't today — where will the money come from? Who shares the burden? Who is the benefited group? It will always come back to patients. But how do you tell people, 'This is fair, and you've got to pay for it?'"

- **Mathematics or morality: Is that the question?** Thanks — or no thanks — to malpractice insurance, the medical liability system doesn't impose individual financial penalties on providers, whether or not they're at fault.

But how much "mal" is really in malpractice, anyway? Some analysts of the tort system as it applies to health care argue that, in the complex world of modern medicine, it's all but impossible to pin the label of

“negligence” or “provider at fault” on most negative medical outcomes, including the overwhelming majority of those that end up in court.

As with the role of insurance in paying liability claims, many patients may not even be aware that this is in question, some analysts say.

For example, in its 1999 analysis *To Err is Human*, the **Institute of Medicine** declared unequivocally that a less personally punitive atmosphere is needed in health care to diminish the numbers of medical mistakes. But in a **Kaiser Family Foundation** survey taken soon after the highly publicized release of that study, about a third of people stated firmly that the study made the opposite point: that to reduce the incidence of error in health care, penalties against individual practitioners should play a much bigger role.

The highly complex — and often highly invasive — nature of modern medicine may well exacerbate that impression, one forum participant speculated. “Physicians need an aura of infallibility to carve us up and put powerful chemicals in our bodies.” But this very aura may “create the assumption that if it didn’t go right, then the physician” — assumed to have near-magician status — “did something wrong.”

Another under-appreciated fact of modern medicine cuts the other way, however, and likely is more germane to solving the problem, according to **Jeffrey O’Connell**, professor of law at the **University of Virginia**, an architect of no-fault auto insurance and other injury-compensation programs. In another context, **Winston Churchill** observed that he didn’t like to mix mathematics with morality, and that’s exactly what the medical tort system does, said O’Connell.

Given the complexity of contemporary medical interventions and the staggering complexity and individual variation of each human being — a brain has at least 50 billion neurons, for example — “we can’t easily say, ‘Once you start to treat me, this shouldn’t happen.’”

That makes physicians rather “like baseball players — they don’t bat a thousand” — and makes the notion of individual fault essentially inappropriate in most medical-care situations, O’Connell argued. Sheer complexity makes the range of possible medical outcomes enormous and the specific cause of any one such outcome essentially unknowable. In other words, many health-outcomes can’t in fact be predicted and therefore aren’t amenable to fair solution by judicial mechanisms that attempt to find morality in them and award damages accordingly.

In fact, “the problem was solved over 100 years ago, in the first great wave of accidents in the Industrial Age — workplace accidents,” said O’Connell. Very quickly, industrialized societies realized that attempts to litigate about fault in such accidents usually was a fool’s errand and workers’ compensation programs were removed from the tort system.

“No one in this room would even dream of going back after every workplace accident and figuring out who was at fault,” he said. “The fascinating thing is, why did it stop there?”

The country’s newfound focus on medical error as a health care quality issue has not only brought attention to the math versus morality question but largely

settled it on the side of math, pointing to multiple hard-to-disentangle causes rather than individual negligent acts in case after case, analysts say.

“Medicine is a relative latecomer to the science of human mistakes, but previous work in other fields has firmly established their multifactorial nature,” write **Harvard School of Public Health** analyst **David Studdert** and colleagues in the July 11, 2001, *JAMA*. “Investigations of major disasters such as Three Mile Island, Chernobyl, and the Challenger space shuttle demonstrate that ‘latent’ errors in the design of complex systems are an important predictor of accidents. ‘Active’ errors made by frontline operators often play a role, but these are typically in secondary importance in the chain of causation.”

As in industrial settings, they write, “harmful incidents in health systems frequently involve human error, but their causes and consequences cannot be meaningfully understood by examining provider behavior alone.”

As has become evident during debates in Congress and elsewhere, these new notions about the systemic nature of error in complex working environments bring medical-error initiatives into direct conflict with the system of malpractice liability and would do so even if the tort system were overhauled with MICRA-type reforms.

“At its core, malpractice law involves a set of adversarial proceedings, beginning with a patient’s allegation of negligence against an individual provider,” Studdert writes. In diametric opposition to medical-error-prevention initiatives, for malpractice lawyers on both sides of the courtroom “processes of care are relevant only insofar as they may prove or disprove the defendant’s negligence.”

Human psychology combined with complex systems make medical mistakes statistically inevitable, say students of medical error. In his 2002 book *Complications: A Surgeon’s Notes on an Imperfect Science*, **Atul Gawande**, MD, describes it this way, writing of a gallbladder surgery that came within a hair’s breadth of catastrophe: “I may have averted disaster this time, but a statistician would say that, no matter how hard I tried, I was almost certain to make this error at least once in the course of my career.”

If medical-error initiatives continue to gain ground — not at all a sure proposition, of course — those who would reform the medical liability system also may need to follow those initiatives in disentangling ideals of morality from the real mathematics of human error.

Surgeon Gawande suggests this as a guiding principle: “No matter what measures are taken, doctors will sometimes falter, and it isn’t reasonable to ask that we achieve perfection. What is reasonable is to ask that we never cease to aim for it.”

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