



## ***Hearing Aid***

*By Peter J. Pitts*

### ***Okay, take a breath.***

How many times did you hear the words “historic realignment” over the course of this election cycle? How many times did you hear it when President Obama was elected two years ago? How many times when the Democrats took control of Congress four years ago?

We can safely assume that, when it comes to “historic realignment,” the phrase has been overused and is largely rhetorical -- unless you are a fan of the Miami Heat.

But that doesn't mean the midterms are unimportant or unlikely to deliver some real healthcare-related fireworks. *Au contraire.*

When it comes to healthcare reform and a 21<sup>st</sup> century FDA, will the 112<sup>th</sup> Congress be sanguine or sanguinary? Or is there a third way – of bipartisanship?

### ***What does it mean?***

A Republican majority in the House of Representatives means three things:

1. New members – who will need to be educated on many important and arcane policy points;
2. New staff – who will have the power to influence the education of their new masters;
3. New committee and subcommittee chairs – who will have the power to call hearings, select witnesses and wield the power of the gavel over some very exigent issues.

## ***WHAT'S THE IMPACT ON HEALTHCARE REFORM?***

Well, it's complicated but some things are clear.

It's clear that high profile members such as Henry Waxman (Energy and Commerce), Rosa DeLauro (Agriculture and FDA Appropriations) and Pete Stark (Ways & Means Committee) will be moving over to the minority side of the dais. Their inability to set the agenda and call the shots is a game changer when it comes to healthcare reform – and the future of the FDA.

What House hearings we might see – and what are their significance to the future of American healthcare?

Considering the role that healthcare reform played in the midterms, we can expect a series of hearings on the many aspects of the Patient Protection and Affordable Care Act (aka – “ObamaCare”). And many of these will center on the contentious philosophical notion of a cost-centric design versus a patient centric system.

That means hearings featuring the recess-appointed CMS Administrator Don Berwick.

Dr. Berwick, an on-the-record fan of a cost-effectiveness based, single-payer system will face some intense grilling. As Senator John Barrasso (R, WY), an orthopedic surgeon commented when President Obama opted not to send Berwick's nomination for Senate confirmation, “This recess is an insult to the American people. Dr. Berwick is a self-professed supporter of rationing healthcare and he didn't even have to explain his views to the American people in a Congressional hearing.”

Dr. Berwick will certainly face that grilling now – at a time when Britain's NHS has acknowledged that it's reliance on cost-effectiveness via the National Institute for Health and Clinical Excellence (NICE) has failed. The CMS Administrator will have a lot of explaining to do.

Great Britain's decision to denude NICE will feed a call for hearings on a variety rarely discussed (aka “wonky”) but very important codicils of ObamaCare such as the role of the Patient-Centered Outcomes Research Institute (PCORI). Hearings on PCORI will openly debate one of the key under-pinnings of ObamaCare – cost-based care that would empower Uncle Sam, MD to ration care.

Another possible hearing topic is the surprising and unexpected role of the Office of Personnel Management (OPM) in healthcare. OPM is planning a new database that will store health care claims information from three federal programs - the Federal Employees Health Benefits Program, the National Pre-Existing Condition Insurance Program and the forthcoming Multi-State Option Plan.

OPM (in a 10/5 Federal Register notice, says the database will allow OPM to "actively manage all three programs to ensure the best value for the enrollees and taxpayers." The database will be effective Nov. 15 "unless comments are received that would result in a contrary determination."

Information collected will include personal identifying information, address, dependent information, employment information, health care provider details including debarred provider information, health care coverage information, health care diagnosis information and provider changes and reimbursement on the aforementioned coverage, procedures and diagnosis.

OPM? Healthcare “value?” This raises two issues: (1) expertise and (2) mission creep. Are people being hired to do this? Who are they? Who’s choosing them? Transparency is required – if not a Congressional hearing.

Per the FR notice, "the data will be de-identified for specific analysis that provide flexible queries of the data set for general demographic queries, risk-adjusted profiles, and comparison of chronically ill patients and other useful analytics; and engage in econometric modeling of, among other things, health trends, risk adjustment methodologies, pharmacy pricing and negotiation."

Hm – “econometric modeling?” That sounds menacing.

Yes – definitely Congressional hearing material.

And then there’s the Independent Payment Advisory Board (IPAB). ObamaCare restructures the existing federal agency responsible for bringing down Medicare costs — the Medicare Payment Advisory Commission, or MPAC — and turns it into the IPAB.

One of the biggest changes is that the IPAB’s policy recommendation automatically will be instituted unless Congress overrides them.

The IPAB can make drastic changes to Medicare plans, including raising premiums, cutting benefits, and restricting eligibility requirements. IPAB’s recommendations will be implemented automatically unless Congress comes up with its own proposal that meets the same spending cut targets. Congress can also (with 3/5 majority in both houses) pass a resolution rejecting the IPAB proposal, but that can be vetoed by the President and would then be subject to a 2/3 override.

There need to be substantive checks against the IPAB decisions. And seniors need to be guaranteed representation during the policymaking process. It’s likely that a newly empowered Republican House will want to revisit this rarely discussed or debated covenant of ObamaCare.

Hearings are likely on the Medicare Payment Advisory Commission’s recommendation that Medicare to reinstate the option to base Part B drug reimbursement on the least costly alternative (LCA) among products.

Note please, that “least costly” in no way means “best for the patient.”

Recently MedPAC heard two proposals outlined by commission staffer Nancy Ray. The first was that Congress should give CMS authority to apply least costly alternative policies in setting payments for items and services covered under Medicare Parts A and B, and CMS should periodically assess the clinical similarity of Medicare-covered services and apply LCA policies for those services deemed clinically similar.

The second was that Congress should direct CMS to set the payment rate for a newly covered service that lacks evidence demonstrating better outcomes than existing treatment options at a level that is no higher than the LCA.

The policy could end up relying heavily on data from comparative effectiveness research conducted under the auspices of the aforementioned Patient-Centered Outcomes Research Institute, (PCORI).

Ms. Ray can certainly expect to be raising her right hand.

Hearings are also likely to focus on the cost of ObamaCare – and there’s plenty of grist for the mill. According to New York Times economics correspondent David Leonhardt (discussing the Presidential rhetoric used to assuage citizen uncertainty), “Mr. Obama went so far as to suggest there would be no disruptions, saying that people could keep their current plan if they liked it. But that’s not quite right. It is not possible to change a system as huge, and as hugely flawed, as ours without some disruptions.”

The new House majority isn’t going to accept, “It’s gonna get worse before it gets better,” as a go-forward proposition.

Remember all that money that healthcare reform was going to save us? Well, since former Office of Management and Budget (OMB) chief Peter Orszag put that shibboleth to bed (again, in the pages of the New York Times), the debate seems to be about how insurance is going to be made more affordable. One way we’re supposed to achieve this, according to Leonhardt, is that “people will be required to buy insurance, to spread costs among the sick and the healthy.”

Sure – except that this mandate (if it doesn’t turn out to be unconstitutional) (1) doesn’t even kick in until 2014 (the same time the theoretical state exchanges come in to play) and (2) will likely penalize offenders less than even a low-cost health insurance premium.

Specific to the state exchanges that are the foundation of the theory, Leonhardt writes, “the new markets for health insurance, known as exchanges, won’t be up and running until 2014. This timetable has its problems, and the Obama administration will probably need to grant some more temporary exemptions.”

Hearings on this topic will be closely watched as a bell-weather for significant Congressional reform of the Patient Protection and Affordable Care Act. Congressional Budget Office re-scoring will be at the top of the card.

It's also important to note that the healthcare reform repercussions of the midterm elections aren't only on the national front. With more governors and state legislatures likely to take a more strident position on the issue of mandatory insurance coverage, the altered national agenda will also take on a decidedly local flavor.

And nowhere will this manifest itself more than on another foundational issue of ObamaCare – state insurance exchanges.

As state officials implement their plans, Congressional hearings will focus on how to design exchanges don't crowd out free market insurance mechanisms. While the options available on these exchanges will work well for many people; a substantial slice of the patient population will find them unsuitable.

Preserving a vibrant private insurance market in addition to the exchanges will maximize choice and enable people to find the insurance plan that best fits their particular needs. When the President said that people who are happy with their insurance “can keep it,” we should keep him to his word. Choice is crucial and hearings will focus on this core issue.

Exchanges go live in 2014. If a state hasn't started the process of establishing one by 2013, the federal government will take over the responsibility and run the exchange itself. And this will also likely make for interesting hearing fodder.

The healthcare law imposes an array of legal requirements on insurers that participate in the exchanges. Insurers must include a package of to-be-defined “essential” benefits in all plans offered. Insurers are also prohibited from charging deductibles exceeding \$2,000 for individuals and \$4,000 for families.

The exchanges only require insurers to offer two types of coverage. “Silver” plans covering 70 percent of all medical costs. And “Gold” plans covering 80 percent.

Many consumers will benefit from these newfound choices. But not everyone will find them suitable.

There are people who will want even more expansive coverage, say a “Platinum” plan covering 90 percent of costs. And there will be patients who want to risk higher out-of-pocket expenses for lower upfront charges, and are happy with a “Bronze” plan covering just 60 percent of costs.

And still there are other demographic groups who won't find any of these options ideal. The young and healthy typical don't require much medical care, and just want catastrophic coverage in case of an emergency.

As is, the exchanges aren't required to offer these other options. And the federally mandated minimum benefits effectively prohibit the exchanges from offering cheap,

stripped-down plans.

Healthcare coverage isn't one-size-fits-all. House hearings are likely to focus on how an insurance market outside the government exchanges can exist to ensure people with unique plan preferences can get the coverage they want.

Whether or not Speaker Boehner will want hearings on the indoor tanning salon tax remains to be seen.

### ***WHAT ABOUT A 21<sup>ST</sup> CENTURY FDA?***

A Republican House will also be important to the future of the FDA. And at the top of the list are hearings on PDUFA reauthorization.

With Republicans in charge, PDUFA debate will focus not only on what FDA *wants* but what the agency *committed to previously* -- but didn't deliver. Specifically enhanced predictability. New members need to be educated on the many highly technical issues -- but some things just stand out as counterintuitive and will be hard to explain to PDUFA neophytes -- such as when the FDA says that "non-binding advice" could be allowed," but would carry no regulatory weight. Hullo? It will also be interesting to see if the new majority treats Big Pharma with respect in the PDUFA debate. Industry couldn't possibly be treated any worse. Another possible hearing topic is on the unintended consequences of the FDA Amendments Act (FDAAA)-mandate for the agency's early safety signal communications program.

House hearings on PDUFA V will focus not only on the details -- but also on the spirit of user fees -- perhaps resulting in a cleaner reauthorization. That would be a trifecta victory for the FDA, for industry -- and for the public health. It would also be a strong message for all involved that PDUFA needs to get back to first principles.

Then there's the DeLauro factor. With Representative Rosa DeLauro in the minority, her plan to direct the FDA to create an independent Center for Post-Market Drug, Device and Biologics Safety and Effectiveness (via a rider to the appropriations bill) is DOA. This strengthens the hand of FDA Commissioner Peggy Hamburg who believes that "We need to strengthen the integration of safety and efficacy throughout the lifecycle of medical products ... It would be a mistake to further separate and stovepipe safety and efficacy."

What about the FDA's Critical Path initiative and the Reagan/Udall Center? New hearings are most certainly in order to get this crucial FDA initiative out of the state of suspended animation that Ms. DeLauro exiled it to since its inception.

In her perplexing efforts to embog the work of the Reagan/Udall Critical Path Foundation. Ms. DeLauro has demonstrated a remarkable lack of understanding of the science of drug development and the purpose of the Critical Path in general. She has stated: "I believe the Reagan-Udall Foundation has the potential of endorsing the

approval of drugs and devices based on lower standards for safety and efficacy, and without appropriately designed clinical trials. The Foundation could play a significant role in recommending the use of biomarkers and other measures that may not be true measures of efficacy.” This even as the director of the NIH, Dr. Francis Collins, hails biomarkers as the next revolution in medicine.

Progress towards 21<sup>st</sup> century science will be on the new majority’s to-do list. Representative DeLauro was also one of the leading proponents of drug importation. Now that the Democrats are in the minority and Senator Byron Dorgan has retired – the issue of importation will be absent from the national debate for the foreseeable future.

Hearings may also be forthcoming on the safety and manufacturing standards for both generic drugs and follow-on biologics. All is not wine and roses in Hatch/Waxman land. Good manufacturing practices are the silent sisters of post-market safety.

The seemingly endless ritual of House hearings on FDA’s role in direct to consumer advertising is likely to change from “how to stop it” to “how to make it better.” A hearing on how pharmaceutical marketing can be both savvy marketing tactic and potent public health tool would take the vitriol out of the debate and help to create a powerful communications partnership between regulator and regulated. And with Congressman Waxman dislodged from his perch at Oversight and Government Reform, the concept of “more warning letters” as a biomarker for “tougher and more vigilant enforcement” will be largely silenced.

Whether or not this results in fewer warning and untitled letters remains to be seen. One potential topic at a hearing focused on DDMAC missives could be the value of having all correspondence vetted through the Office of Chief Counsel.

In the wake of *Wyeth v. Levine*, House hearings could revisit whether there should be legislation to provide explicit language for federal preemption for pharmaceuticals.

### ***Take another breath.***

Will the 112<sup>th</sup> Congress usher in a new spirit of bipartisanship on healthcare reform and a 21<sup>st</sup> century FDA?

That’s the difference between a hearing aid and a hearing problem.

That’s the difference between addressing policy concerns and playing politics.

Winners and losers (and not to mention “enemies”) aside, we’ve got an opportunity to work together on healthcare, FDA and a plethora of other issues.

Or we can all go down with the (partisan) ship. It’s time for pragmatism.

To paraphrase, "Voters, what have you wrought?"

"An opportunity -- if you can keep it."