Drugmakers' Deal With Obama Said to Be Probed by House

By Drew Armstrong - May 4, 2012 6:25 PM GMT+0200

Pfizer Inc. (PFE) and Merck & Co. (MRK) are being pulled into an expanding congressional investigation about the agreement drugmakers reached with the Obama administration to support the Democrats' overhaul of the U.S. health-care system, according to three people familiar with the talks.

The probe began last year, with Republicans on the House Energy and Commerce Committee seeking documents from an industry trade group, said the people, who aren't authorized to speak publicly. When that group didn't cooperate, the panel decided to target Pfizer, the world's biggest drugmaker, along with Merck, Amgen Inc. (AMGN), Abbott Laboratories (ABT) and AstraZeneca Plc (AZN), said one of the people.

A man walks past Pfizer Inc. headquarters in New York. Photographer: Peter Foley/Bloomberg

The Republicans last month began negotiating directly with the companies in e-mails, calls and meetings demanding documents and information outlining what the industry agreed to with President Barack Obama in 2009 and 2010, when the law was being worked on in Congress. Michael Burgess, a Representative from Texas, said he's been frustrated by a lack of cooperation.

"This has been like pulling teeth, trying to get information," said Burgess, a Republican working on the panel's investigation, in a telephone interview.

A White House spokesman declined to comment about the investigation. Peter O'Toole, a spokesman for New York-based Pfizer, said the company is cooperating, as did Tony Jewell, an AstraZeneca spokesman. Kelly Davenport, a spokeswoman for Thousand Oaks, California-based Amgen, said the drugmaker is aware of the probe.

An 'Inconstant Love'

The investigation is part of a tenuous relationship that has developed between the industry and politicians since passage of a law that expanded health insurance to more than 30 million Americans, said Alec Vachon, a health-care consultant who is president of Hamilton PPB in Washington. The pharmaceutical industry has loosened its ties to Republicans, who were united in voting against the law.

About 54 percent of the industry's political donations in the first quarter of 2012 went to Republicans, down from a 74 percent share in 2002.

"It's an inconstant love," Vachon said by telephone. Past investigations by Republicans have mostly been focused on patient safety or Medicare. This is more political, he said.

Committee Demands

The almost $1 trillion, 10-year plan for overhauling the health-care system passed through Congress without a single

Republican vote in either the House or Senate. The insurance expansion is funded partly by more than $100 billion in taxes and discounts on products the drug industry offered to the White House. In return, the newly insured will be able to buy the drugmakers' pills using their new coverage.

The committee's demands so far have been limited to e-mails and meetings with company lobbyists and lawyers, without subpoenas or formal letters that can be used to push uncooperative targets into compliance, a person familiar said.

"We have been cooperating with the committee on an ongoing basis since the investigation began," said Matt Bennett, a spokesman for the Washington-based Pharmaceutical Research and Manufacturers of America, or PhRMA.

Adelle Infante, an Abbott spokeswoman, and Ron Rogers, a spokesman for Merck, didn't immediately reply to e-mails seeking comment.

'How Dare They'

Drug company executives have said they are worried that providing the committee with a bundle of documents will create more problems than it solves, according to two people familiar with the investigation.

"Any time you disclose documents, you have no idea what rocks you're going to turn over," Vachon said. "There's no upside here."

Parts of the health law expanding insurance coverage have been challenged as unconstitutional by 26 states, which may make this year treacherous for the industry.

PhRMA says that in addition to the $100 billion companies are giving up over a decade to help fund the law, the industry is concerned that its profits will be used by the government to fund future health legislation that could flow out of a Supreme Court ruling against the law.

The trade group cited a potential overhaul of Medicare's payments to doctors, or new health insurance rules.

A Supreme Court ruling that invalidates parts of the law could restart the debate on what to do about health care, said Eli Lilly & Co. (LLY) Chief Executive Officer John Lechleiter.

No Going Back

"There's going to have to be a 'what's next?'", Lechleiter said in an interview from PhRMA's annual meeting in Boston last month. "There's no status quo that any of us could return to."

The court plans to rule on the law's constitutionality in June.

The industry has found little sympathy from Democrats, who say drugmakers still get too good a deal from government health- care programs. A proposal in the Obama administration's fiscal 2013 budget would cut $156 billion over a decade from Medicare and Medicaid spending on the industry's drugs.

Taking more money from drug companies would result in lost jobs and fewer future cures, said John Castellani, CEO of PhRMA.

"I see our critics and their one-dimensional focus on costs, and I say, 'How dare they?'" he said in a speech at the annual meeting last month.

$240 Million Lobby

PhRMA and the rest of the drug and health products lobby, Washington's largest, spent $240 million in 2011 and registered over 1,500 lobbyists, according to the Center for Responsive Politics.

Along with drugmakers, the committee has asked questions of about 10 other groups, including doctors and hospitals. They also demanded that the White House turn over information on negotiations between the health industry and Democrats, and have so far been foiled.

“This is not a beef with anyone in the industry. I’m perfectly OK that they went to the White House and advocated on behalf of the industry, that’s part of the way things are done,” Burgess, the Republican from Texas, said. “What I’ve got a problem with is the door being closed to the rest of us.”

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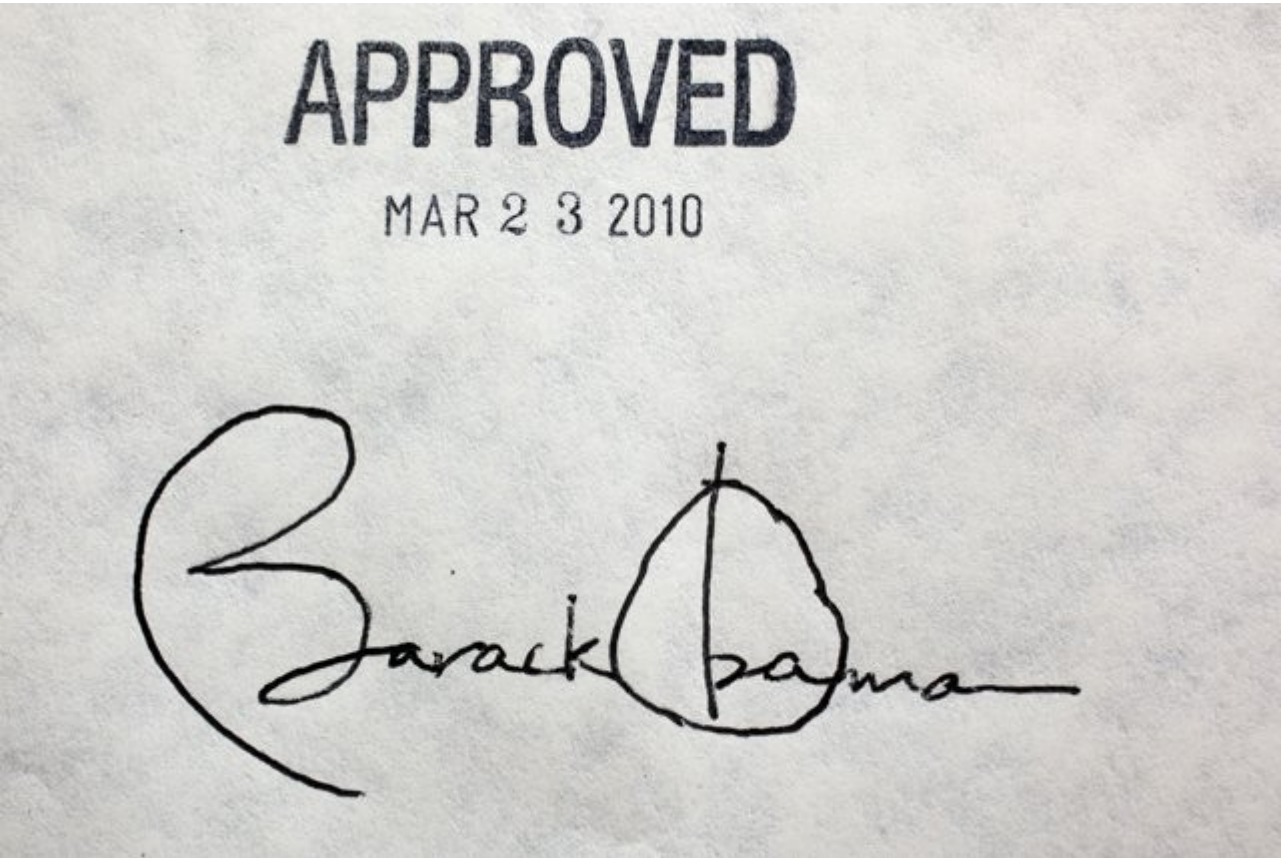


Sunday, January 15, 2012 - Medicine and Politics in America by Adam Frederic Dorin, M.D., MBA

Adam Frederic Dorin, M.D., MBA

Ask me a question.

SAN DIEGO, January 15, 2011–While Big pharmaceutical companies stand to win under Obamacare, this only holds true if the economy improves and local Accountable Care Organizations (ACOs) allow brand prescription drugs to remain on formulary (a formulary is an approved list of medications that physicians can prescribe for their patients under a given insurance/managed care plan).

The average physician, however, loses big under any scenario due to bundled services and decreased, capitated reimbursement. Meanwhile, local physician board members and medical society leaders stand to profit off of their colleagues' misery as they position themselves at the center of ACO 'medical homes'.

The Drug Company Perspective

The pharmaceutical industry recently expressed outrage over an Obamacare/Government practice known as "academic detailing" (or "counter-detailing") wherein government-contracted nurses and pharmacists will meet with doctors to offer the government's point of view on expensive pharmaceutical treatments. Big Pharma is concerned that legislation must address the issue of neutrality and fairness since (unlike their own corporate 'drug reps') the government detailers will not be regulated to insure the accuracy of their information. In 2009, Senator Kohl introduced The Independent Drug Education and Outreach Act to put limits on what detailing programs can receive grant money and what educational materials can be disseminated by these federally-promoted detailers. This legislation never advanced to law. The idea is that the same rules that govern accuracy and other such activity for the pharmaceutical industry should be universally applied to government detailers as well.

Big Pharma signed on to Obamacare back in 2009 after numerous meetings, including some White House secret deals that involved the President and the CEOs of major drug companies. After legislators passed the Patient Protection and Affordable Care Act (PPACA) legislation, however, many in the pharmaceutical industry began to express concern that they had made a bad decision. After all, if Obamacare were to derail the economy, and local 'mini-HMOs' called ACOs took hold, there would be less money for new, expensive (and often superior) brand medications as more emphasis would be placed on generic medicines. The drug industry is now counting on the influx of tens of millions of additional prescription recipients to offset any potential losses incurred in the push for a more 'nationalized'/socialized medical drug delivery system (i.e., one that would push cheaper generics over brand name drugs).

In 2010, nearly 4 million people with Medicare who reached the program's 'Part D' coverage gap received a one-time, tax-free rebate check for $250. (http://www.hhs.gov/news/press/2011pres/03/20110322a.html)

This political gesture caused a net $1 billion increase in Medicare expenditures; this also contributed to the declines in personal out-of-pocket (and private health insurance) prescription drug spending because of the infusion of 'free' taxpayer money into the system. All of this played well with the statistics offered to the public to show that Obamacare was indeed a cost-cutter, because one only had to look to see that patients were paying less for their drugs overall. Of course, this was a shell game, but it played well on some left-leaning media venues.

Healthcare reform reduced Medicaid spending too because Medicaid and the Children's Health Insurance Program (CHIP) grew by only 0.7% in 2010 compared with 6.8% in 2009. Again, be careful not to fall for the political gamesmanship here, because the PPACA increased the Medicaid unit rebate amount and extended rebates to Medicaid managed care plans. Thus, federal expenditures on Medicaid grew by 2.5%

Overall, assuming a healthy economy and fair access to brand drugs at the level of local ACOs, drug companies will win under Obamacare because the new health care law will boost drug spending. CMS projects that annual drug expenditures will double in the next 10 years, to $512.6 billion by 2020.

And, compliments of the PPACA, retail drug spending is projected to grow $35.2 billion (+7.3%) higher in 2020 than it would have been without healthcare reform. (http://www.drugchannels.net/2011/08/cms-bright-future-for-drug-spending-in.html)

The Community Physician Perspective

Some may describe the Obamacare-Medicare Advantage financial scheme as a complex game pitting a select few doctor leaders and hospital/health system administrators against their physician colleagues. Sometimes called 'coding for dollars', Medicare payment schedules and Medical Advantage contracts with physicians can be very complicated and confusing. (http://www.soa.org/files/pdf/2009-toronto-health-collender-27.pdf)

The following piece is a good summary of the Medicare Advantage money stream: http://www.lifehealthpro.com/2011/02/18/cms-unveils-2012-medicare-advantage-payment-propos

It says, essentially, that "The national per capita Medicare Advantage health plan 'growth Percentage' change, or cost trend, will be just 0.7%, but that quality rating bonuses should increase the average actual Medicare Advantage per-capita payment by 1.6%."

Here is Medicare's April 2011 Medicare Advantage report that determines rates for 2012: https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2012.pdf

Basically, community-based 'mini-HMOs' called ACOs or Accountable Care Organizations will survive by managing sick patients in a comprehensive fashion. This will entail having an ethics panel review which patients can have certain surgeries, and have certain plan managers decide if payments to providers should be withheld for 'inadequate' or 'poor' care; it will also involve deciding how much certain specialty doctors will be paid compared to others in an attempt to save the federal government money (compared to historical, actuarial data). If the local ACO/'medical home' is effective at saving money for a given patient/disease state, it will receive bonuses from Uncle Sam; if not, it will get less money.

Monthly capitated rates for Medicare Advantage plans are set by the feds in April the year before, and are based on the local FFS (Fee For Service) Medicare fee schedule. HMOs/IPAs/ACOs may earn more money (i.e., 'double down') by having a higher Risk Adjustment Formula (RAF) number. This number depends on ICD codes and other factors like age. (e.g., 90 year olds are more frail than 70 year olds, and diabetic patients with dementia cost more to take care of than non-diabetic, non-demented patients, etc.).

The Physician vs. ACO Battle

In the short run, physicians are set for further decreases in Medicare reimbursement. The SGR (Sustainable Growth Rate) formula for paying doctors for Medicare services is set for a 27.4% cut in 6 weeks if Congress cannot come up with either a semi-permanent 'fix' or, as they have done for years, simply apply another 2-6 month deferment on the rate decreases. Despite the often misquoted 'rewards' for physicians for the utilization of certain performance criteria, e-prescriptions and the like, doctors will face progressive cuts in Medicare pay (on top of the SGR cuts) starting in 2014 and beyond if they do not comply with every onerous layer of new government mandates in practice guidelines.

Thus, many doctors will not be able to sustain their current level of patient care in the near future. According to the Investor Business Daily poll of September 2009, and several polls by other sources since, upwards of 45% of physicians may stop seeing Medicare patients altogether or simply retire early.

Herein lies the rub for community doctors: Medicare Advantage plans like Secure Horizons may get more money every year for the near future (in contrast to decreasing doctors' pay), but not actually pass these increased revenues along to physicians participating in IPA/ACO/'medical homes'. Remember: SGR cuts are only for Fee For Service (FFS) dollars paid to physicians, not for Medicare Advantage (MA) dollars paid to health systems. If FFS cuts go through, MA plans like Secure Horizons may still receive, for example, $400/month per capitated patient life (plus additional dollars for creative coding for various severe disease states) but then turn around and pay physicians 30% less based on the new fee-for-service/SGR formula.

Until the Medicare Advantage plan dollars are themselves cut in the future, the plans and individuals at the center of the ACO/medical home power structure could be pocketing the difference—potentially millions of dollars essentially picked from the pockets of community doctors. The profits for local and state medical society leaders who may be involved in such schemes could be multiple times what they would earn actually taking care of patients.

Hospital/Health Systems Commit Fraud to Garner Increased Federal Monies

In some cases, hospital systems—not unlike the core of the newly forming, Obamacare-mandated, ACO cost-cutting units—will game the 'coding for dollars' scheme to fraudulently capture more money from a shrinking national pie of health care funds. In the context of struggling community doctors, who will be facing decreasing slices of this pie, this is particularly disturbing. The added funds could be used to pad the pockets of the ACO/health system leaders.

Case in point: http://californiawatch.org/health-and-welfare/prime-hospital-bills-malnutrition-patient-says-she-wasn-t-treated-14055

Here, a "hospital's reimbursement from Medicare increased by more than $6,700 [per patient under their care] – from

$4,708 to $11,463 – by noting kwashiorkor [a rare, third-world country malnutrition problem] on the [patient's] bill, according to a California Watch analysis of billing information obtained under the federal Freedom of Information Act." This fraud was widespread and committed over 1,000 times in one year at just one location.

Conclusion

In the end, in typical big government fashion, the health reform movement made a crucial mistake in placing the power of cost-cutting measures in the hands of those who are not actually delivering direct patient care. Big Pharma made deals with the creators of Obamacare, and these deals may or may not end up being successful for the drug companies themselves. Most notably, consumers could end up losing because if needed new drugs cannot come to market due to restricted brand drug availability in local ACO formularies, resulting in decreased revenues and decreased research and development, then future breakthroughs and patient care innovations may never come to fruition.

Likewise, ACOs will be creating hundreds of community-based managed care power brokers, who will pit a select few potential profiteers (individuals and health systems) against the broader group of medical providers in a local area. If the doctors at the bedside and office setting cannot make ends meet and thus restrict services/access and/or close up shop altogether, the community as a whole will suffer.

The better way to implement health care reform would have been to do what both Hillary-care and Obama-care both failed to do: empower doctors themselves to create new ways to increase access and decrease costs and waste. Since the American Medical Association represents only a minority of community physician members, and has existing conflicts of interest due to tens of millions of dollars annually in federal-protected copyrights on medical billing codes, they were not an honest broker in the 'Act's' creation.

The real danger moving forward with the implementation of Obamacare is that the law could be ruled unconstitutional and repealed, and yet local Accountable Care Organizations could live on. This may very well increase costs and waste by allowing middlemen to control, profit and manipulate community medical care for self-serving—not community-serving--purposes.

Doctor Dorin is a Hopkins-trained, board-certified anesthesiologist, practicing in a large group in San Diego. He is a small business owner, a Commander in the US Navy Reserves, and the Founder/President of America's Medical Society, Inc., (AMS) a non-profit corporation created to serve and educate physicians and the general public in matters of national health-care reform and medical politics

Judicial Watch Press Room

Judicial Watch Files Amicus Curiae Brief with U.S. Supreme Court Challenging Constitutionality of Obamacare

February 14, 2012

HHS "trying to defend a provision in an act passed by Congress that exceeds its enumerated powers."

(Washington, DC) – Judicial Watch, the organization that investigates and fights government corruption, announced today

that it filed an *amicus curiae* brief on February 13, 2012, with the United States Supreme Court challenging the constitutionality of the Patient Protection and Affordable Care Act, also known as Obamacare (*United States Department of Health and Human Services, et al., State of Florida, et al*. (No. 11-398)). The Supreme Court has scheduled oral arguments for the Obamacare case on March 26, 27 and 28, 2012.

With its *amicus curiae* brief Judicial Watch maintains that the "individual mandate" provision of Obamacare, which requires every American citizen to purchase health care insurance or pay a penalty, is unconstitutional, whether considered under Congress' commerce power or taxing power:

Petitioners are trying to defend a provision in an act passed by Congress that exceeds its enumerated powers. Though Congress enacted this provision under the Commerce Clause, Congress' power under the clause is not broad enough to compel Americans to engage in commerce by purchasing a particular product. Though Petitioners try to rescue the provision by arguing that it is valid under Congress' taxing power even if it is invalid under Congress' commerce power, a provision of an act that is not a tax may not be construed as a tax merely to save it from being declared unconstitutional.

Judicial Watch further argues that if the Supreme Court affirms the constitutionality of the so-called individual mandate, "it must be willing to hold that Congress' powers under the Commerce clause are plenary and unlimited, for there remains no principled way to limit Congress' power if it is stretched as far as Petitioners (the Obama administration) ask."

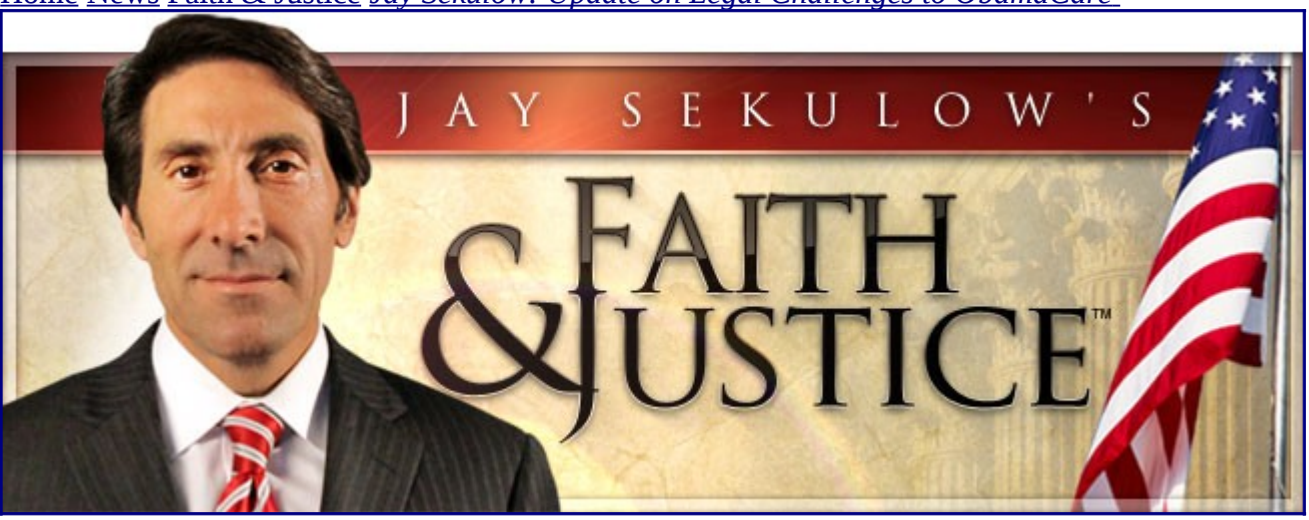
The Judicial Watch *amicus* was filed in support of a challenge to Obamacare by Florida and 25 other states.

Demonstrating the importance of the legal battle over Obamacare, the Supreme Court will hear five-and-a-half hours of oral argument, a rare allotment of time in the court's modern era. The Supreme Court's scrutiny will focus on the constitutionality of the Obamacare individual mandate. The court will also consider whether other components of Obamacare could take effect even if the individual mandate is ruled unconstitutional, among other issues.

In a December 14, 2010, editorial published in *The Washington Post* Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius argued that the individual mandate is essential to Obamacare: "Without an individual responsibility provision (or mandate), controlling costs and ending discrimination against people with preexisting conditions doesn't work."

"The President's socialist healthcare overhaul is an affront to the U.S. Constitution's provisions for limited government," said Judicial Watch President Tom Fitton. "The time has come for the U.S. Supreme Court to put an end to Obamacare once and for all."

Read more about amicus curiae



Jay Sekulow: Update on Legal Challenges to ObamaCare

posted by Jay Sekulow

With a majority of Americans continuing to reject ObamaCare – the government-run, pro-abortion health care law – there's now a new poll that underscores what most Americans want: 70% of Americans favor individual choice over government standards for health insurance.

This comes at a time when the legal challenges to ObamaCare are intensifying with the latest petition filed this week asking the Supreme Court to take a case challenging the flawed health care law.

That development comes just days after the Commonwealth of Virginia filed filed its Petition for Writ of Certiorari with the Supreme Court asking it to take its case and overturn the Fourth Circuit Court of Appeals decision that the Commonwealth lacked standing to sue against ObamaCare.

Virginia's petition asserts, as we have argued in our own suit challenging the law, that the individual mandate of ObamaCare – forcing individuals to buy a particular service against their will – is unconstitutional.

The mandate and penalty are also not supported by the text of the Commerce Clause, which presupposes an activity to regulate. The historical context in which the Commerce Clause was drafted makes it highly unlikely that it included a power to command a citizen to purchase goods or services from another. Certainly there is no tradition or history of the Commerce Clause being used in this way.

As you know, the ACLJ has supported Virginia's challenge to this unconstitutional violation of our personal liberties from the beginning. We filed an amicus brief representing 49 Members of Congress – including House Speaker John Boehner and House Majority Leader Eric Cantor – and over 70,000 Americans from across the country.

As Virginia's petition points out, the number of cases heading to the Supreme Court challenging ObamaCare and the split in the federal circuits, "maximize[s] the likelihood of [the Supreme Court] reaching the merits" and quickly deciding this important constitutional case.

At the same time, we are backing Florida's challenge to ObamaCare. As you may recall, the Obama Administration has asked the U.S. Supreme Court to take the case out of Florida (involving 26 states challenging ObamaCare) and review the decision of a federal appeals court striking the individual mandate of ObamaCare.

We will continue to support these efforts out of Virginia and Florida to overturn this pro-abortion law as we await a decision from a D.C. federal appeals court in our own lawsuit challenging ObamaCare, which we expect to end up at the Supreme Court as well.

Ultimately, the Supreme Court will decide ObamaCare, and I am confident that it will find this law – and its overarching restriction on liberty – unconstitutional.

We will continue to keep you updated as these critical cases progress. You can get the latest information on this and other critical issues by visiting the Jay Sekulow page at our website.

Jay Sekulow

Related Topics: ACLJ, ObamaCare, Supreme Court

Read more: http://blog.beliefnet.com/faithandjustice/2011/10/jay-sekulow-update-on-legal-challenges-to-obamacare.html#ixzz1uMrC7WG6

Arguments On Obamacare Conclude, SCOTUS Decision Due By Late June

Zero Hedge
March 28, 2012

The deliberations on Obamacare have ended. The next catalyst will be late June, when the Supreme Court is expected to rule on whether Obamacare is constitutional or not. If overturned, expect lots of fingerpointing, and even more allegations that it is all Bush's fault, especially if the vote goes down according to party lines.

From Reuters:

> The U.S. Supreme Court on Wednesday ended more than six hours of oral arguments over three days about whether President Barack Obama's signature healthcare law would survive constitutional scrutiny, setting up to deliver a ruling on its fate by late June.
>
> Over the past three days, the nine-member court delved into whether Congress exceeded its authority by requiring most Americans to obtain health insurance by 2014 or face a penalty, along with whether the entire wide-ranging law must be struck down if they found that critical provision to be invalid.

Obamacare reconsidered: a pretty good deal for the drug industry

Matthew Arnold March 26, 2012

As the Supreme Court weighs the constitutionality of the Patient Protection and Affordable Care Act's “Individual Mandate”—and maybe the law itself —a pretty sweet deal for the drug industry hangs in the balance.

“The potential complete demise of Obamacare as written is, as the saying goes, throwing the baby out with the bathwater,” said Peter Pitts of the Center for Medicine in the Public Interest, a caustic critic of some parts of the law. “For pharma, the ACA is a gift, bringing in anywhere between 30-40 million people who could not previously afford pharmaceuticals.”

That's a huge boon at a time when new drugs are few and far between.

The pharma industry was bitterly divided over the law when it passed two years ago after months of acrimonious debate. Billy Tauzin, the longtime Congressional committee baron and fixer extraordinaire, resigned abruptly from his post as head of PhRMA during one rough patch in the legislative process. A number of leading pharmas were unhappy with the deal Tauzin negotiated with the White House, for which the industry had agreed to shell out nearly $100 billion in drug discounts for federal health programs in exchange for a seat at the table, and now it looked like Tauzin had given away the store for nothing.

But in the end, the industry was able to use its leverage to fend off provisions that would have allowed direct price controls and restricted drug marketing. The macro-level tradeoff was this: Smaller profit margins, thanks to those up-front rebates and other cost-control measures built into the law, in exchange for greater volume in the years to come as tens of millions of Americans are insured. Tauzin's pricey gambit bought the industry a law it could live with, for the most part, though PhRMA continues to fight the PCORI and IPAB provisions, which the trade group fears could bring about price controls on prescription drugs and lay the foundations for comparative effectiveness testing, among others. Those parts of the law, in particular, have inspired apocalyptic talk.

“It was the same thing with the Medicare Part D [prescription drug benefit], and you can go all the way back to the ‘90s, with managed care,” said J. D. Kleinke, a medical economist and resident fellow at the American Enterprise Institute. “People said it was going to be the end of pharma, and instead, there was a huge volume increase and it wound up being a good thing.” Kleinke thinks IPAB would focus on surgical interventions in the elderly, and not, with exception to last-dash, long-odds and high cost oncology treatments, on drugs and biologics.

“They've got bigger fish to fry,” said Kleinke.

Few legal observers think the Court would throw out the law altogether. However, the question of whether the Court's conservative/libertarian majority might throw out the Individual Mandate, which requires almost every American to buy health insurance, is anyone's guess. The Obama Administration has asserted that the unpopular provision is not “severable” from the larger law, though this seems more a political position than a legal one. Still, should the Court find the Individual Mandate unconstitutional, many would opt out and the cost of insurance would spike sharply as a result, limiting the volume gains that made the deal a winner for the industry.

“If the insurance mandate is nullified, the impact would be indirect but real,” said John Kamp, executive director of the Coalition for Healthcare Communication (and a former Constitutional law professor). “The insurance mandate provides important financing support for the extension of insurance to the currently uninsured. In short, the ACA needs young, light users of insurance to subsidize the older, heavy users. Without the youth subsidy, the cost pressures on the entire plan are even more immense than already recognized.”

Moreover, while the insurance expansion aspect of the law has gotten most of the attention, much of the ACA consists of various efforts to “bend the curve” of spiraling healthcare costs that threaten to bankrupt federal health programs, including the popular Medicare.

“So if the subsidy dies, policymakers will be looking elsewhere to reduce costs,” said Kamp. “Every cost center—especially hospitals, providers and medicine companies—will be pressured to reduce costs. That will lead to ever more pressure on marketing costs, as well as all other costs faced by medicine companies.”

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