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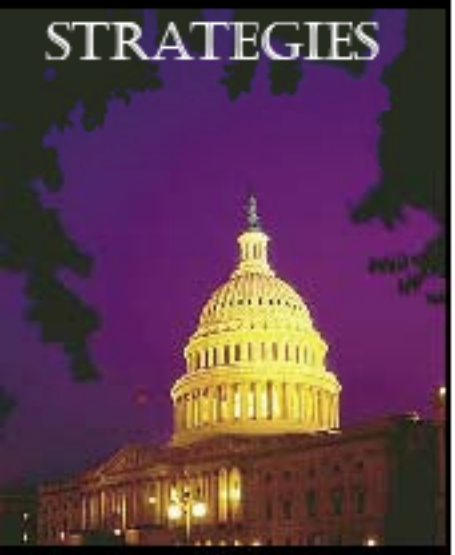

Health Policy Briefing

July 2, 2012

Surprise Supreme Court Decision Upholds PPACA; FDA User Fee Legislation Enacted

Supreme Court Upholds Constitutionality of the PPACA

As described further below, on Thursday the Supreme Court upheld the individual mandate and other contested provisions of the Patient Protection and Affordable Care Act (PPACA). In an unexpected 5-4 decision by **Chief Justice Roberts** and **Justices Breyer, Ginsburg, Kagan and Sotomayor** (the latter appointed by Democratic presidents), the court held that the tax code penalty used to enforce the individual mandate is a "tax" and, thus, the mandate and the related penalty are constitutional. The opinion struck down, however, the Administration's argument that the mandate is constitutional under the commerce clause.

Republican leaders were quick to label the individual mandate enforcement penalty a "tax" on the middle class that the President and congressional Democrats had previously argued was not a "tax." House Republican leadership announced they will hold a vote on July 11th to repeal the entire PPACA. Republicans indicated that repeal efforts on individual parts of the PPACA also are not out of the question this year, at least in the House.

As to House efforts to repeal the law, **Senate Majority Leader Harry Reid** pronounced "The Supreme Court has spoken—the matter is settled…." and said the scheduled House vote to repeal the law is just a "a show vote." Senate Republicans threatened to use budget reconciliation next year (requiring only 51 votes) in an attempt to curtail the law.

On the other hand, **President Obama** reacted to the opinion, favorable to his signature legislative achievement, by stating "Whatever the politics, today's decision was a victory for people all over this country whose lives will be more secure because of this law, and the Supreme Court's decision to uphold it…." He also touted the law's benefits to the 30 million Americans who do not yet have health insurance by offering them in 2014 an array of quality, affordable, private health insurance plans to choose from under new health insurance exchanges.

In a statement disputed by Republicans, the President also maintained that the 250 million Americans who already have health insurance can keep their coverage and that it will be more secure and

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affordable. Republican presidential candidate **Mitt Romney** reacted to the decision by declaring, if elected, he will act to repeal the law on his first day in office in order to avoid adding trillions of dollars to the federal deficit that would burden future generations. He said he will act to replace the law with real reform that would allow people who want to keep their current insurance to do so and protect those with pre-existing conditions from losing their health insurance coverage.

Of note, the Supreme Court decision also clears the way for the federal courts to proceed on numerous other federal cases involving other issues connected to the PPACA, including among other suits: the constitutionality of the Independent Payment Advisory Board; whether First Amendment rights are violated by the PPACA's mandate for religiously affiliated hospitals and other organizations to provide contraception and other services they say violate their religious values; and whether the law unconstitutionally prevents the expansion of doctor owned hospitals. See the Appendix for a summary of the Supreme Court decision in NATIONAL FEDERATION OF INDEPENDENT BUSINESS ET AL. v. SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

Senate and House Send FDA User Fee Bill to President

The Senate voted 92-4 to agree to S. 3187 after the House added the conference agreement on landmark FDA user fee legislation. The bill, which CBO says would reduce direct spending by $307 million but result in deficit reduction of $311 million over ten years, is awaiting **President Obama's** signature to become law. In general, for FY 2013-2017 the bill: reauthorizes the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Authorization (MDUFA); authorizes new generic drug and biosimilars user fee programs; and, among other things, provides new incentives for the development of antibiotics; adds provisions to address drug shortages; adds a new fee program related to rare pediatric diseases; and adds a requirement for the FDA to issue guidance on the use of the internet and social media to promote FDA regulated medical products. Senator Richard Burr (R-NC) lamented how quickly the final bill was pushed through without including "track and trace" provisions to allow for the tracking of drugs after they leave their manufacturers. He said he would pursue legislation on such provisions together with Senator Michael Bennet (D-CO).

Health Pay-fors Avoided under Transportation and Student Loan Bill

Before recessing for the July 4th week, the House and Senate passed legislation (H.R. 4348) that freezes student-loan interest rates at 3.4% for one year and includes offsets to the $6 billion cost by changing pension rules and cutting off subsidized student loans after six years. House and Senate negotiators finalized the legislation without agreeing to health related offsets originally included in the House bill. The compromise omits offsets that would have cut preventive care spending, made adjustments to Medicare tax withholding for selected individuals, placed a limitation on state Medicaid provider taxes, and increased a levy on tax delinquent Medicare providers. However, the final bill includes a new offset for additional Gulf Coast restoration funding with a $651 million cut in Louisiana's Medicaid funds.

Appropriations Issues

The votes to pass the transportation and student loan legislation and charges holding Attorney General Eric Holder in contempt of Congress delayed until after the recess further consideration in the House of the following FY 2013 appropriations bills: Agriculture/FDA (H.R. 5973), Department of Defense (H.R. 5856) and Financial Services (H.R. 6020). The Financial Services bill includes restrictions on PPACA-related funding between HHS and the IRS and restrictions on federal insurance exchanges from using federal funds to pay for administrative costs associated with abortions. Of note, the House Budget Committee passed H.R. 5872, legislation that requires the Administration to provide details on exactly what defense and domestic program cuts will be made in the event Congress does not delay the sequestration cuts enacted as part of the Budget Control Act.

Supreme Court Rules on Individual Mandate

In deciding 5-4 that the individual mandate survives constitutional muster, the Chief Justice wrote that, in considering the mandate under the Constitution's taxing and spending clause, "the mandate is not a legal command to buy insurance." Rather it makes going without insurance just another thing the Government taxes, like buying gasoline or earning income. And if the mandate is in effect just a tax hike on certain taxpayers who do not have health insurance, it may be within Congress's constitutional power to tax." He concluded the penalty complies with the constitutional requirement for taxes, in that "precedent demonstrates that Congress had the power to impose an exaction in the [individual mandate] under the taxing power, and that [the mandate] need not be read to do more than impose a tax. That is sufficient to sustain it." He said it was not the court's role "to forbid it, or to pass on its wisdom or fairness." This ruling came despite the 11th Circuit Court's observation that federal courts "unanimously" viewed the penalty enforcing the individual mandate not to rise to the level of a "tax" for purpose of the taxing and spending clause.

Justices Alito, Kennedy, Scalia and Thomas harshly disagreed with the majority opinion and **Justice Kennedy** stated that the exaction required by the individual mandate is not a tax nor described in the law as such. Of note, the majority also held that the tax anti-injunction act (AIA), which would otherwise bar court consideration of the mandate before an actual monetary extraction occurs in 2014, did not apply because the PPACA did not characterize the "penalty" as a tax for purposes of the AIA. Notwithstanding the above ruling, **Chief Justice Roberts** also made clear that the commerce and the necessary and proper clauses could not be used to justify the individual mandate. In this regard, **Justices Alito, Kennedy, Scalia and Thomas** concurred. However, **Justices Breyer, Ginsburg, Kagan and Sotomayor** disagreed and said that upholding the mandate would be valid under the commerce clause. In holding that a law forcing individuals to participate in an activity cannot be sustained under the commerce clause, **Chief Justice Roberts** argued that Congress had never before attempted to use the commerce clause as justification to "to compel individuals not engaged in commerce to purchase an unwanted product." **Justices Alito, Kennedy, Scalia and Thomas** agreed with **CJ Roberts** that the "….individual mandate, however, does not regulate existing commercial activity," and to rule in favor of the commerce clause argument would open "a new and potentially vast domain to congressional authority." The concurring justices said that the 1942 decision Wickard v. Filburn, in which the court upheld restrictions on farmers growing wheat for personal consumption, represents the outer limit of Congress' commerce clause authority.

Administration Touts Benefits of Health Reform Law

HHS announced that about 12.8 million policyholders will receive over $1.1 billion in rebates from health insurance plans that do not pay out medical claims exceeding the PPACA's minimum loss ratio (MLR) of 80% of premiums in the individual and small group markets and 85% in the large group market. HHS said that only about 67% of covered individuals were in plans that met the MLR. In light of the Supreme Court decision, and in an attempt to further encourage states to establish health insurance exchanges by 2014, HHS announced that all states now will be eligible for grants to help them establish their exchanges by the deadline. The new grant funding announcement expands how resources can be used for "Level One" one-year grants and for "Level Two" three-year grants which must be accompanied by state law authority to establish the exchanges. The amount of the new funding was not made available at the time of the June 29th announcement.

Leading up to the Supreme Court decision last week and since, the President, **HHS Secretary Kathleen Sebelius** and other Democrats have cited the benefits of the PPACA as justification for its "success," including but not limited to: free preventive benefits made available to 54 million Americans in private plans; the elimination of lifetime coverage limitations for 105 million Americans; and allowing 6.6 million young adults up to age 26 to remain on their parents' insurance plan.

States Gain Marginal Win on PPACA Medicaid Challenge

In a 7-2 decision, with regard to whether the PPACA's Medicaid expansion and provisions to withhold existing Medicaid funding for a state's noncompliance constitutes coercion, all but J**ustices Ginsburg and Sotomayor** agreed that the penalty amounting to the loss of existing funding does violate the constitution. **Chief Justice Roberts** said that while Congress can condition the receipt by states of federal Medicaid funding, the states must be given "a genuine choice on whether to accept the offer…." As a result, it appears that a state is free to reject the new federal funding for expanding Medicaid to persons up to 133% of the federal poverty level in 2014 and that the federal government is barred from withholding federal funding for the state's existing Medicaid program. In an attempt to put the best face on the majority ruling from her perspective, Justice Ginsburg said that "Congress' extension of Medicaid remains available to any State that affirms its willingness to participate…." Whether any state will decide to reject the near-term 100% funding of the Medicaid expansion remains to be seen. However, in states that do reject the expansion, those persons who would otherwise become eligible under Medicaid will nonetheless be eligible for federal health insurance subsidies under the health insurance exchanges. With only a handful of states on target to implement their state health insurance exchanges by 2014, it may spur many in Congress to push for a delay in the 2014 effective date. If this action is considered in the post-election lame-duck session, the Obama Administration may not offer great resistance given that the federal government is unlikely to be fully able to implement a federal exchange in numerous states which are unable to meet the 2014 deadline for establishing exchanges. Reacting to this part of the decision, **Rep. Henry Waxman,** ranking member of the House Energy and Commerce Committee, said "In regard to the Medicaid provisions, it should be clear that the court affirmed the constitutionality of providing health care coverage through Medicaid for all persons up to 133% of poverty. It did conclude that no state could lose all of its funds for its current Medicaid program … but the major point is that 100% federal funding remains available to assist states in providing this coverage, and states will seize the opportunity to do so." On the other hand, the Chairman of the Committee, **Fred Upton,** countered that "Today's decision on Medicaid acknowledges at least a small measure of restraint on federal power by rejecting the notion that Congress can cut off all Medicaid funds to a state simply because it chooses not to participate in a massive expansion of the program it cannot afford."

S. 3337 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for the elimination of the Medicare sustainable growth rate (SGR) formula to ensure access to physicians' services for Medicare beneficiaries; PAUL; to the Committee on Finance, June 25.

S. 3338 (MEDICAL IMAGING/ RADIATION THERAPY), to amend the Public Health Service Act and Title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly; WICKER; to the Committee on Health, Education, Labor, and Pensions, June 25.

H. RES. 704 (POLIO), commending Rotary International and others for their efforts to prevent and eradicate polio; MCDERMOTT; to the Committee on Foreign Affairs, June 26.

S. 3345 (PROSTATE CANCER), to provide for research and education to improve screening, detection and diagnosis of prostate cancer; BOXER; to the Committee on Health, Education, Labor, and Pensions, June 27.

S. 3351 (PRIVACY), to amend the American Recovery and Reinvestment Act with respect to the privacy of protected health information; FRANKEN; to the Committee on Health, Education, Labor, and Pensions, June 27.

H.R. 6033 (PROSTATE CANCER), to provide for research and education to improve screening, detection and diagnosis of prostate cancer; CUMMINGS; to the Committee on Energy and Commerce, June 27.

H.R. 6043 (HEALTH INFORMATION TECHNOLOGY), to amend the Public Health Service Act and the Social Security Act to extend health information technology assistance eligibility to behavioral health, mental health, and substance abuse professionals and facilities, and for other purposes; MURPHY of Pennsylvania; jointly, to the committees on Energy and Commerce and Ways and Means, June 27.

Appendix: Summary of PPACA June 28 Supreme Court Decision

Held: The judgment is affirmed in part and reversed in part.
648 F. 3d 1235, affirmed in part and reversed in part.

1. CHIEF JUSTICE ROBERTS delivered the opinion of the Court with respect to Part II, concluding that the Anti-Injunction Act does not bar this suit.
The Anti-Injunction Act provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be main¬tained in any court by any person," 26 U. S. C. §7421(a), so that those subject to a tax must first pay it and then sue for a refund. The pre¬sent challenge seeks to restrain the collection of the shared responsi¬bility payment from those who do not comply with the individual mandate. But Congress did not intend the payment to be treated as a "tax" for purposes of the Anti-Injunction Act. The Affordable Care Act describes the payment as a "penalty," not a "tax." That label cannot control whether the payment is a tax for purposes of the Con¬stitution, but it does determine the application of the Anti-Injunction Act. The Anti-Injunction Act therefore does not bar this suit. Pp. 11–15.

2. CHIEF JUSTICE ROBERTS concluded in Part III–A that the indi¬vidual mandate is not a valid exercise of Congress's power under the Commerce Clause and the Necessary and Proper Clause. Pp. 16–30.

(a) The Constitution grants Congress the power to "regulate Commerce." Art. I, §8, cl. 3 (emphasis added). The power to regulate commerce presupposes the existence of commercial activity to be reg¬ulated. This Court's precedent reflects this understanding: As ex¬pansive as this Court's cases construing the scope of the commerce power have been, they uniformly describe the power as reaching "ac¬tivity." E.g., United States v. Lopez, 514 U. S. 549, 560. The individ-ual mandate, however, does not regulate existing commercial activi¬ty. It instead compels individuals to become active in commerce by purchasing a product, on the ground that their failure to do so affects interstate commerce.
Construing the Commerce Clause to permit Congress to regulate individuals precisely because they are doing nothing would open a new and potentially vast domain to congressional authority. Con¬gress already possesses expansive power to regulate what people do. Upholding the Affordable Care Act under the Commerce Clause would give Congress the same license to regulate what people do not do. The Framers knew the difference between doing something and doing nothing. They gave Congress the power to regulate commerce, not to compel it. Ignoring that distinction would undermine the prin¬ciple that the Federal Government is a government of limited and enumerated powers. The individual mandate thus cannot be sus¬tained under Congress's power to "regulate Commerce." Pp. 16–27.

(b) Nor can the individual mandate be sustained under the Nec¬essary and Proper Clause as an integral part of the Affordable Care Act's other reforms. Each of this Court's prior cases upholding laws under that Clause involved exercises of authority derivative of, and in service to, a granted power. E.g., United States v. Comstock, 560
U. S. ___. The individual mandate, by contrast, vests Congress with the extraordinary ability to create the necessary predicate to the ex¬ercise of an enumerated power and draw within its regulatory scope those who would otherwise be outside of it. Even if the individual mandate is "necessary" to the Affordable Care Act's other reforms, such an expansion of federal power is not a "proper" means for mak¬ing those reforms effective. Pp. 27–30.

3. CHIEF JUSTICE ROBERTS concluded in Part III–B that the individ¬ual mandate must be construed as imposing a tax on those who do not have health insurance, if such a construction is reasonable.
The most straightforward reading of the individual mandate is that it commands individuals to purchase insurance. But, for the reasons explained, the Commerce Clause does not give Congress that power. It is therefore necessary to turn to the Government's alternative ar¬gument: that the mandate may be upheld as within Congress's power to "lay and collect Taxes." Art. I, §8, cl. 1. In pressing its taxing power argument, the Government asks the Court to view the man¬date as imposing a tax on those who do not buy that product. Be¬cause "every reasonable construction must be resorted to, in order to save a statute from

unconstitutionality," Hooper v. California, 155 U. S. 648, 657, the question is whether it is "fairly possible" to inter¬pret the mandate as imposing such a tax, Crowell v. Benson, 285 U. S. 22, 62. Pp. 31–32.

4. CHIEF JUSTICE ROBERTS delivered the opinion of the Court with respect to Part III–C, concluding that the individual mandate may be upheld as within Congress's power under the Taxing Clause. Pp. 33–44.

(a) The Affordable Care Act describes the "[s]hared responsibility payment" as a "penalty," not a "tax." That label is fatal to the appli¬cation of the Anti-Injunction Act. It does not, however, control whether an exaction is within Congress's power to tax. In answering that constitutional question, this Court follows a functional approach,"[d]isregarding the designation of the exaction, and viewing its sub¬stance and application." United States v. Constantine, 296 U. S. 287, 294. Pp. 33–35.

(b) Such an analysis suggests that the shared responsibility payment may for constitutional purposes be considered a tax. The payment is not so high that there is really no choice but to buy health insurance; the payment is not limited to willful violations, as penal¬ties for unlawful acts often are; and the payment is collected solely by the IRS through the normal means of taxation. Cf. Bailey v. Drexel Furniture Co., 259 U. S. 20, 36–37. None of this is to say that pay¬ment is not intended to induce the purchase of health insurance. But the mandate need not be read to declare that failing to do so is un¬lawful. Neither the Affordable Care Act nor any other law attaches negative legal consequences to not buying health insurance, beyond requiring a payment to the IRS. And Congress's choice of language—stating that individuals "shall" obtain insurance or pay a "penalty"—does not require reading §5000A as punishing unlawful conduct. It may also be read as imposing a tax on those who go without insur¬ance. See New York v. United States, 505 U. S. 144, 169–174. Pp. 35–40.

(c) Even if the mandate may reasonably be characterized as a tax, it must still comply with the Direct Tax Clause, which provides: "No Capitation, or other direct, Tax shall be laid, unless in Proportion to the Census or Enumeration herein before directed to be taken." Art. I, §9, cl. 4. A tax on going without health insurance is not like a capitation or other direct tax under this Court's precedents. It there¬fore need not be apportioned so that each State pays in proportion to its population. Pp. 40–41.

5. CHIEF JUSTICE ROBERTS, joined by JUSTICE BREYER and JUSTICE KAGAN, concluded in Part IV that the Medicaid expansion violates the Constitution by threatening States with the loss of their existing Medicaid funding if they decline to comply with the expansion. Pp. 45–58 Syllabus

(a) The Spending Clause grants Congress the power "to pay the Debts and provide for the . . . general Welfare of the United States." Art. I, §8, cl. 1. Congress may use this power to establish cooperative state-federal Spending Clause programs. The legitimacy of Spending Clause legislation, however, depends on whether a State voluntarily and knowingly accepts the terms of such programs. Pennhurst State School and Hospital v. Halderman, 451 U. S. 1, 17. "[T]he Constitu¬tion simply does not give Congress the authority to require the States to regulate." New York v. United States, 505 U. S. 144, 178. When Congress threatens to terminate other grants as a means of pressur¬ing the States to accept a Spending Clause program, the legislation runs counter to this Nation's system of federalism. Cf. South Dakota v. Dole, 483 U. S. 203, 211. Pp. 45–51.

(b) Section 1396c gives the Secretary of Health and Human Ser¬vices the authority to penalize States that choose not to participate in the Medicaid expansion by taking away their existing Medicaid fund¬ing. 42 U. S. C. §1396c. The threatened loss of over 10 percent of a State's overall budget is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion. The Government claims that the expansion is properly viewed as only a modification of the existing program, and that this modification is permissible because Congress reserved the "right to alter, amend, or repeal any provision" of Medicaid. §1304. But the expansion accom¬plishes a shift in kind, not merely degree. The original program was designed to cover medical services for particular categories of vulner¬able individuals. Under the Affordable Care Act, Medicaid is trans¬formed into a program to meet the health care

needs of the entire nonelderly population with income below 133 percent of the poverty level. A State could hardly anticipate that Congress's reservation of the right to "alter" or "amend" the Medicaid program included the power to transform it so dramatically. The Medicaid expansion thus violates the Constitution by threatening States with the loss of their existing Medicaid funding if they decline to comply with the expan¬sion. Pp. 51–55.

(c) The constitutional violation is fully remedied by precluding the Secretary from applying §1396c to withdraw existing Medicaid funds for failure to comply with the requirements set out in the ex¬pansion. See §1303. The other provisions of the Affordable Care Act are not affected. Congress would have wanted the rest of the Act to stand, had it known that States would have a genuine choice whether to participate in the Medicaid expansion. Pp. 55–58.

6. JUSTICE GINSBURG, joined by JUSTICE SOTOMAYOR, is of the view that the Spending Clause does not preclude the Secretary from with¬holding Medicaid funds based on a State's refusal to comply with the expanded Medicaid program. But given the majority view, she agrees with THE CHIEF JUSTICE's conclusion in Part IV–B that the Medicaid Act's severability clause, 42 U. S. C. §1303, determines the appropriate remedy. Because THE CHIEF JUSTICE finds the withhold¬ing—not the granting—of federal funds incompatible with the Spend¬ing Clause, Congress' extension of Medicaid remains available to any State that affirms its willingness to participate. Even absent §1303'scommand, the Court would have no warrant to invalidate the funding offered by the Medicaid expansion, and surely no basis to tear down the ACA in its entirety. When a court confronts an unconstitutional statute, its endeavor must be to conserve, not destroy, the legislation. See, e.g., Ayotte v. Planned Parenthood of Northern New Eng., 546 U. S. 320, 328–330. Pp. 60–61.

ROBERTS, C. J., announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, and III–C, in which GINSBURG, BREYER, SOTOMAYOR, and KAGAN, JJ., joined; an opinion with respect to Part IV, in which BREYER and KAGAN, JJ., joined; and an opinion with respect to Parts III–A, III–B, and III–D. GINSBURG, J., filed an opinion concurring in part, concurring in the judgment in part, and dissenting in part, in which SOTOMAYOR, J., joined, and in which BREYER and KAGAN, JJ., joined as to Parts I, II, III, and IV. SCALIA, KENNEDY, THOMAS, and ALITO, JJ., filed a dissenting opinion. THOMAS, J., filed a dissenting opinion.