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## PLANNED PARENTHOOD

## Republican AGs ask Supreme Court to toss Kansas Planned Parenthood ruling

(Reuters) –The Republican attorneys general of 15 states have asked the U.S. Supreme Court to overturn a ruling that blocked Kansas from cutting off Medicaid funding to Planned Parenthood following the release of controversial videos secretly recorded by an anti-abortion group.

***Andersen v. Planned Parenthood of Kansas and Mid-Missouri et al., No. 17-1340, amici curiae brief filed, 2018 WL 1920635 (U.S. Apr. 23, 2018).***

In an amicus brief filed April 23, the attorneys general urged the justices to hear the appeal by their Republican colleague in Kansas, Derek Schmidt, of a decision by the 10th U.S. Circuit Court of Appeals in February. *Planned Parenthood of Kan. & Mid-Mo. v. Andersen*, 882 F.3d 1205 (10th Cir. 2018).

Indiana Attorney General Curtis Hill's office led the group in filing the brief. Other states involved include Georgia, Idaho, Louisiana, Michigan, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Wisconsin and Wyoming.

The case stems from a 2016 order by Kansas' then-Gov. Sam Brownback, a Republican, following the release of video purporting to show



REUTERS/Lucas Jackson

Planned Parenthood officials negotiating the for-profit sale of fetal body parts.

Planned Parenthood denied the allegation. Two regional Planned Parenthood affiliates and three of their patients sued Kansas, arguing Brownback's order was unconstitutional and violated federal laws including the Medicaid Act.

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## EXPERT ANALYSIS

## 2017 Federal Circuit obviousness decisions in biopharma: 5 takeaways

Patent and intellectual property specialists Jonathan A. Harris, Drew A. Hillier and Ross E. Blau of Axinn, Veltrop & Harkrider survey a host of recent Federal Circuit rulings they say may sway the future of court decisions regarding the possible obviousness of biopharma and related patents.

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# 2017 Federal Circuit obviousness decisions in biopharma: 5 takeaways

By Jonathan A. Harris, Esq., Drew A. Hillier, Esq., and Ross E. Blau, Esq.  
*Axinn, Veltrop & Harkrider*

Obviousness. It is one of the most common defenses invoked in biopharma patent litigation. It is also one of the most complicated. And because Federal Circuit authority on obviousness is highly nuanced, proper presentation of evidence and related expert opinions is critical.

After reviewing the Federal Circuit’s 2017 obviousness opinions for biopharma patents, we believe there are important lessons to be gleaned.

This article seeks to help patent holders and challengers alike remain current on nuanced shifts in Federal Circuit obviousness law — shifts that may mean the difference between success and failure in court.

## TAKEAWAY #1 — INHERENCY AND OBVIOUSNESS

To prove that an inherent, but unknown, property is necessarily present in an obvious combination, one Federal Circuit panel expressly announced the additional requirement that the inherent property is not unexpected in the art.

In 2017, a Federal Circuit panel attempted to reconcile 25 years of precedent concerning inherency and obviousness. To prove an inherent, but unknown property is present in an obvious combination, the panel not only required proof that the property is necessarily present, but also that it was not unexpected in the art.

### Background

The Federal Circuit illustrated this point in *Millennium Pharmaceuticals Inc. v. Sandoz Inc.*<sup>1</sup> And it formally announced it later in *Honeywell International Inc. v. Mexichem Amanco Holding S.A. DE C.V.*<sup>2</sup>

In *Millennium*, the patent covered a compound that combined D-mannitol and a boronate ester of bortezomib. Prior art by Adams taught esters of bortezomib, and that bortezomib rapidly degrades in liquid formulations.

Several experts testified that the general knowledge of a POSA included freeze-drying with mannitol to create non-liquid formulations. The district court thus found

that freeze-drying the bortezomib of Adams with mannitol would inherently produce the claimed D-mannitol boronate ester, which made it obvious.

### Rule

The Federal Circuit reversed. According to the Federal Circuit, regardless of whether freeze-drying with mannitol necessarily produces the claimed compound: “No expert testified that they foresaw, or expected, or would have intended, the reaction between bortezomib and mannitol, or that the resulting ester would have the long-sought properties and advantages.”<sup>3</sup>

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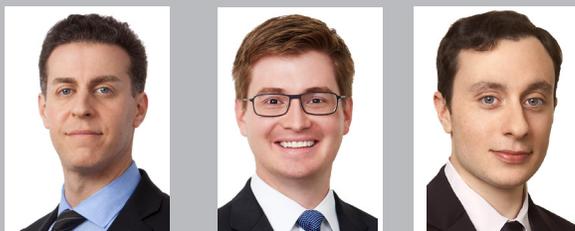
Because Federal Circuit authority on obviousness is highly nuanced, proper presentation of evidence and related expert opinions is critical.

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The Federal Circuit formally announced this rule in *Honeywell*.<sup>4</sup> There, it found the PTAB erred when it held a claimed property was obvious as inherent without addressing whether the property was unpredictable and unexpected.

The *Honeywell* court attempted to reconcile prior Federal Circuit rulings on inherency in the obviousness context, stating “[w]hat is important regarding properties that may be inherent, but unknown, is whether they are unexpected. All properties of a composition are inherent in that composition, but unexpected properties may cause what may appear to be an obvious composition to be nonobvious.”<sup>5</sup>

In 1993, the Federal Circuit broadly stated in *In re Rijckaert* “[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.”<sup>6</sup> Before *Honeywell*, Federal Circuit cases finding



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inherency in the obviousness context had not reconciled *Rijckaert*.<sup>7</sup>

### **In practice**

After *Millennium* and *Honeywell*, it may not be enough to simply assert that an inherent property necessarily results from an allegedly obvious combination without also addressing whether that property is unexpected and unpredictable. Patentees and challengers should pay attention to how their experts characterize prior art teachings surrounding the inherent property.

Experts for patentees should emphasize that the prior art fails to mention the inherent property and provide reasons why skilled artisans would not expect it. Challengers should scour the prior art for teachings suggesting that the inherent property would have been predictable and expected.

### **TAKEAWAY #2 – TEACHING AWAY EVIDENCE**

Absent express criticism of a claim limitation, the success of teaching away arguments hinges upon a prior art showing that pursuing the claimed subject matter would be “unproductive,” as opposed to merely not preferred.

#### **Background**

In *Bayer Pharma AG v. Watson Laboratories Inc.*,<sup>8</sup> the claims covered an orally disintegrating tablet (“ODT”) to treat erectile dysfunction (“ED”) comprising the active vardenafil and at least two sugar alcohols, wherein the tablet disintegrates and immediately releases the active in the mouth. Prior art by Boolell and Fryburg taught formulating vardenafil as an ODT to treat ED.

Prior art by Bauer taught that two sugar alcohols could optimize the properties of a tablet. Tian and Fryburg taught that both immediate and delayed-release ODTs were known.

The district court found the claims non-obvious, holding that the prior art taught away from immediate-release ODTs, because immediately releasing vardenafil in the mouth causes two problems — first, an unpleasant bitter taste and second, higher vardenafil bioavailability, which could trigger heart problems in older patients.

#### **Rule**

The Federal Circuit reversed.<sup>9</sup> A key to the case was the Federal Circuit’s treatment of the

alleged teaching away evidence. The Federal Circuit accepted the district court’s findings on bitter taste and high bioavailability, but disagreed that they qualified as teaching away evidence.<sup>10</sup>

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## Patentees seeking to avoid obviousness based on rationales for combination may wish to investigate whether a known problem or need exists in the prior art.

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According to the Federal Circuit, a prior art reference teaches away when “the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the patentee.”<sup>11</sup>

The problem for the patentee was that its expert did not use the “unproductive” buzz word, opining instead that the bitter taste and high bioavailability of vardenafil would merely lead a POSA to *prefer* a delayed-release formulation (releasing in the stomach), as opposed to the claimed immediate release ODT (releasing in the mouth).<sup>12</sup>

Seizing on this distinction, the Federal Circuit overturned the district court and explained “obviousness does not require that the motivation be the best option, only that it be a suitable option from which the prior art did not teach away.”<sup>13</sup>

The Federal Circuit reached a similar result in *Meiresonne v. Google Inc.*<sup>14</sup> There, it affirmed a PTAB obviousness finding on claims to a computer system for searching the Internet.<sup>15</sup> The sole issue on appeal was whether the prior art taught away from textual descriptions, as claimed, in favor of graphical previews.<sup>16</sup>

Once again characterizing the prior art as merely expressing a preference for one option (graphical previews) over another (textual descriptions), the Federal Circuit refused to find a teaching away.<sup>17</sup>

According to the Federal Circuit “the fact that [prior art by] Finseth describes descriptive text as ‘cursory, if not cryptic’ does not automatically convert the reference to one that teaches away” because “Finseth does not say or imply text descriptions are ‘unreliable,’ ‘misleading,’ ‘wrong’ or ‘inaccurate.’”<sup>18</sup>

### **In practice**

Given the Federal Circuit’s conclusions in these cases, patentee experts would do

well to opine that pursuing the claimed combination in view of the prior art would be “unproductive” or unworkable. Patentees should avoid characterizing alternate prior

art embodiments as merely preferred to the claimed subject matter.

Experts challenging validity, to the extent possible, should characterize the prior art and the opposing expert’s testimony as simply expressing a preference for another option as opposed to the claimed combination.

### **TAKEAWAY #3 – ALTERNATE RATIONALES AND SPECIFIC MOTIVATION**

Federal Circuit judges disagree as to whether the alternate rationales announced in *KSR International Co. v. Teleflex Inc.* require a separate motivation or specific reason to pursue a secondary teaching.

Recent Federal Circuit authority concerning the alternate rationales of *KSR* may have significant implications for the biopharmaceutical industry, where patent claims often recite species of particular compounds or a combination of a known active with a known formulation.

#### **Background**

In *KSR*, the Supreme Court stated “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. ... [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”<sup>19</sup>

This articulation of the standard has led to ambiguity, as some Federal Circuit judges interpret *KSR*’s alternate rationales as constituting the “reason” while others interpret the “reason” as a separate requirement.

In the *en banc* case of *Apple Inc. v. Samsung Electronics Co.*<sup>20</sup> the claims, in relevant part, covered a portable device with a touch-screen that could be unlocked by swiping an

unlock image in a particular direction. This is the general concept of “swipe to unlock” appearing on smart phones today.

Prior art by Neonode taught a mobile device with a touch-sensitive screen where the phone was unlocked by generally “sweeping right.” Neonode therefore disclosed every element of the claim, except the unlock image indicating a particular direction for swiping to unlock, which was taught by Plaisant.

The specific unlock image of Plaisant is more precise than the general “sweeping” of Neonode, and therefore one is less likely to inadvertently unlock the phone. Plaisant, however, taught this feature in connection with a wall-mounted controller for entertainment, security or climate-control systems as opposed to a smartphone.<sup>21</sup>

One key question on appeal was whether invoking the alternate rationales of *KSR* required the challenger to show a specific reason why a POSA would combine a smart phone with features from a wall-mounted screen.

### Rule

Federal Circuit judges disagree on this important issue. Writing for the majority, U.S. Circuit Judge Kimberly A. Moore affirmed the jury’s non-obviousness finding, noting the absence of a specific motivation to add the missing feature.<sup>22</sup>

In a sharply worded dissent, U.S. Circuit Judge Timothy B. Dyk criticized the majority for misinterpreting *KSR*.

According to Judge Dyk, alternate rationales — like combining known elements and simple substitution — do not require a separate reason or motivation to combine or modify.<sup>23</sup> As Judge Dyk explained, “*KSR* also held, contrary to the majority, that evidence of a specific motivation to combine is not required.”<sup>24</sup>

We have not seen much activity on Judge Dyk’s dissent in 2017. In early 2017, a Federal Circuit panel deciding a small molecule patent action noted in dicta that alternate rationales do, in fact, require a separate reason or motivation. See *L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*<sup>25</sup>

In late 2017, a different Federal Circuit panel, including Circuit Judge Dyk, U.S. Circuit Judge Richard G. Taranto and U.S. Circuit Judge Alvin A. Schall echoed Judge Dyk’s

concerns and remanded a non-obviousness finding to the PTAB. See *Microsoft Corp. v. Parallel Networks Licensing LLC*.<sup>26</sup>

### In practice

Given these disparate interpretations, patentees and challengers in the life sciences industry should take heed. Patentees may seek to rely on *Apple* and *L.A. Biomedical* to demand a reason distinct from the alternate rationales, identifying its absence as a fatal hole in a challenger’s case for invalidity.

Challengers may point to *KSR*, other Federal Circuit cases and Judge Dyk’s dissent. But until the Supreme Court clarifies the issue, challengers may also wish to identify a specific reason or motivation for all proposed combinations.

## TAKEAWAY #4 — ROUTINE OPTIMIZATION AND ANALOGOUS ART

In the context of routine optimization, 2017 Federal Circuit case law analyzing whether prior art qualifies as analogous can be read to support opposite results.

### Background

Two contrasting cases make this point.

First, the Federal Circuit held that prior art relating to vitamin B12 administration in routine medical contexts outside cancer was non-analogous and thus inapplicable to methods for treating cancer.<sup>27</sup>

Second, the Federal Circuit held that prior art relating to coatings used with boots, helmets and electrical tape was analogous and thus applicable to vascular drug-eluting stents.<sup>28</sup>

### Rule

In *Lilly*, the claims covered methods for treating cancer comprising pre-administration of (1) about 350 µg to about 1000 µg folic acid and (2) about 500 µg to about 1500 µg vitamin B12, followed by administration of pemetrexed sodium.<sup>29</sup>

The prior art disclosed a correlation between increased pemetrexed toxicity and elevated homocysteine levels, which indicate a folic acid or vitamin B12 deficiency.

The parties disputed whether there was a motivation to select vitamin B12 for treating cancer or pemetrexed toxicity. Putting this issue to the side, the Federal Circuit analyzed whether the dose limitations of about 500 µg to about 1500 µg were subject to routine optimization.

According to the Federal Circuit, vitamin B12 doses and schedules from other “routine” medical contexts were not applicable to the field of oncology, because there was no evidence that a POSA would have applied those doses and schedules to treat cancer with pemetrexed.<sup>30</sup>

In *In re Ethicon Inc.*, the claims were directed to stents comprising the co-polymer VDF:HFP in a 85:15 ratio and at least one pharmaceutical agent intermixed with the co-polymer.<sup>31</sup>

In affirming obviousness, the Federal Circuit relied upon three prior art references. Tuch taught stents comprising a polymer and a drug. Tu taught vascular implants and heart valve leaflets coated with various co-polymers including VDF:HFP. And Lo taught the advantages of a 85:15 ratio for VDF:HFP in coatings for boots, helmets and electrical tape.

Its uses notwithstanding, the Federal Circuit held that Lo is “reasonably pertinent to the particular problem with which the inventor is involved.”<sup>32</sup>

U.S. Circuit Judge Pauline Newman disagreed, noting “none of these uses has any relation to a vascular stent or any biological application.”<sup>33</sup>

### In practice

Given *Lilly*, patentees may wish to take advantage of non-analogous art arguments to defeat routine optimization of result effective variables. The argument is that prior art directed to treating disease states other than those recited by the claimed subject matter is non-analogous and irrelevant.

For their part, challengers should seek out prior art teaching optimization of variables within the context of the claimed disease state. But challengers can also fall back on *Ethicon* to the extent closely analogous art is not available.

## TAKEAWAY #5 — IDENTIFICATION OF A KNOWN PROBLEM OR NEED TO SUPPORT RATIONALES

In cases where identification of a known problem or need is necessary to prove a rationale for combination, the Federal Circuit has liberally interpreted the requirement, relying on prior art references concerning the general state of the art and expert testimony.

### Background

In *Novartis AG v. Noven Pharmaceuticals Inc.*<sup>34</sup> the Federal Circuit affirmed an obviousness decision by the PTAB. The claims covered a

pharmaceutical composition comprising the active rivastigmine, up to about 0.5 percent by weight of an antioxidant and a diluent or carrier.

Enz taught a transdermal patch comprising rivastigmine and an acrylic polymer. Sasaki taught that combining various active compounds with an acrylic polymer tends to reduce any therapeutic effect because the actives break down, and that adding an antioxidant to the combination prevents the drug from breaking down.

The PTAB held Enz in view of Sasaki rendered the claims obvious. Novartis' main argument on appeal was that neither Sasaki nor any other prior art reference actually reported a known oxidation problem with rivastigmine to lead a skilled formulator to add an antioxidant.

### Rule

Certain Federal Circuit cases have held that in the absence of a known problem or need, there is no reason a POSA would seek to improve upon the prior art.<sup>35</sup> Building on this, Novartis argued that a POSA "would only have added an antioxidant when required to address a known oxidative degradation problem," which was simply not reported in the prior art for rivastigmine.<sup>36</sup>

To fill this gap, the PTAB and Federal Circuit relied upon generalized prior art teachings concerning rivastigmine's chemical structure, including its functional groups, to predict reactivity and degradation properties.<sup>37</sup>

There, the petitioner's expert relied upon prior art concerning organic chemistry, chemical kinetics and drug stability to opine that the functional groups in

rivastigmine made it susceptible to oxidative degradation.<sup>38</sup> In finding the claims obvious, the Federal Circuit agreed with petitioner's expert and characterized oxidation as a known problem.<sup>39</sup>

### In practice

Patentees seeking to avoid obviousness based on rationales for combination may wish to investigate whether a known problem or need concerning the claimed subject matter exists in the prior art. Absent a known problem or need, patentees may argue that the required rationale is lacking.

Parties challenging invalidity may take some comfort in *Novartis*, and look to generalized prior art teachings to assist with identification of a problem or need. **WJ**

### NOTES

<sup>1</sup> 862 F.3d 1356 (Fed. Cir. 2017).

<sup>2</sup> 865 F.3d 1348 (Fed. Cir. 2017).

<sup>3</sup> *Millennium Pharm.*, 862 F.3d at 1367.

<sup>4</sup> *Honeywell Int'l*, 865 F.3d 1348.

<sup>5</sup> *Id.* at 1355.

<sup>6</sup> *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

<sup>7</sup> *See, e.g., PAR Pharm. Inc. v. TWI Pharm. Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014).

<sup>8</sup> 874 F.3d 1316 (Fed. Cir. 2017).

<sup>9</sup> *See id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 1328.

<sup>14</sup> 849 F.3d 1379 (Fed. Cir. 2017).

<sup>15</sup> *Id.* at 1380–81.

<sup>16</sup> *Id.* at 1382.

<sup>17</sup> *Id.* at 1383.

<sup>18</sup> *Id.*

<sup>19</sup> 550 U.S. 398, 418 (2007).

<sup>20</sup> 839 F.3d 1034, 1048 (Fed. Cir. 2016), *cert. denied*, 138 S. Ct. 420 (2017).

<sup>21</sup> *Id.* at 1050.

<sup>22</sup> *Id.* at 1051–52.

<sup>23</sup> *Id.* at 1077–78 (Dyk, J., dissenting).

<sup>24</sup> *Id.* at 1077.

<sup>25</sup> 849 F.3d 1049, 1064 (Fed. Cir. 2017) (quoting *KSR*, 550 U.S. at 418).

<sup>26</sup> No. 2016-2515, 2017 WL 5953512, at \*8 (Fed. Cir. Dec. 1, 2017).

<sup>27</sup> *See Eli Lilly & Co. v. Teva Parenteral Meds. Inc.*, 845 F.3d 1357 (Fed. Cir. 2017).

<sup>28</sup> *In re Ethicon Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017) (Newman, J., dissenting).

<sup>29</sup> *Eli Lilly & Co.*, 845 F.3d at 1362.

<sup>30</sup> *Id.* at 1374.

<sup>31</sup> *In re Ethicon*, 844 F.3d at 1353.

<sup>32</sup> *Id.* at 1351.

<sup>33</sup> *Id.* at 1356 (Newman, J., dissenting).

<sup>34</sup> 853 F.3d 1289 (Fed. Cir. 2017).

<sup>35</sup> *See, e.g., Leo Pharm. Prods. Ltd. v. Rea*, 726 F.3d 1346, 1353–56 (Fed. Cir. 2013).

<sup>36</sup> *See Novartis*, 853 F.3d at 1295.

<sup>37</sup> *Id.* at 1295.

<sup>38</sup> *See id.*

<sup>39</sup> *See id.*

# IRS sanction for no health insurance is ‘penalty,’ not tax, bankruptcy judge says

By Michael Nordskog

The “shared responsibility payment” imposed under the Affordable Care Act for failure to obtain health insurance is a government penalty not entitled to priority claim status in a Chapter 13 case, a North Carolina bankruptcy judge has ruled.

***In re Parrish*, No. 17-2341, 2018 WL 1725385 (Bankr. E.D.N.C. Apr. 6, 2018).**

U.S. Bankruptcy Judge Stephani W. Humrickhouse of the Eastern District of North Carolina said the consequences for not paying distinguish the obligation from tax debt, which would be entitled to higher priority in a bankruptcy case.

Judge Humrickhouse granted debtor Angela Parrish’s objection to a priority claim filed by the IRS in her Chapter 13 case and allowed the claim as general unsecured debt.

## ‘INDIVIDUAL SHARED RESPONSIBILITY PAYMENT’

Parrish filed for bankruptcy relief in May 2017.

The debtor disclosed through her 2016 federal tax return that she owed a \$664 “individual shared responsibility payment” for failing to obtain health insurance as required under the so-called individual mandate of the ACA, 26 U.S.C.A. § 5000A(a).

The Internal Revenue Service filed a proof of claim in the bankruptcy, saying the ISRP debt was for an excise tax owed to the government entitled to priority status under Section 507 of the Bankruptcy Code, 11 U.S.C.A. § 507, which governs priority of expenses and claims in bankruptcy cases.

Parrish objected to the claim, saying the debt resulted from a “penalty” that is not a priority debt under Section 507(a)(8).

## PAYMENT IS A PENALTY

Section 507(a)(8)(E) provides for eighth-priority treatment of “allowed unsecured claims of governmental units, only to the extent such claims are for ... an excise tax.”

Judge Humrickhouse rejected the IRS’ position that the U.S. Supreme Court resolved the issue when it rejected a constitutional challenge to the ACA’s individual mandate in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012).

The *Sebelius* court said the financial penalty for failing to obtain insurance “may reasonably be characterized” as a tax, which was all that was needed to establish the law’s constitutionality, Judge Humrickhouse noted.

The decision, however, does not mandate a conclusion that the ISRP is a tax for Bankruptcy Code purposes, she said.

Taxes are enforced contributions for support of government, while a penalty is an exaction imposed to punish an act or omission that is discouraged, the judge said, citing the

bankruptcy priority decision in *United States v. Reorganized CF&I Fabricators of Utah Inc.*, 518 U.S. 213 (1996).

“The most natural reading, for purposes of the Bankruptcy Code, is that the ISRP is a penalty” designed to deter people from living without health insurance coverage, Judge Humrickhouse said, citing *In re Chesteen*, No. 17-11472, 2018 WL 878847 (E.D. La. Feb. 9, 2018).

Failure to pay does not trigger typical consequences for nonpayment of taxes, such as wage garnishments and tax liens, she said, adopting the reasoning of *Chesteen*. Individuals who fail to pay the individual mandate sanction face having the amount exacted from future tax returns, the judge said.

“The nature of the consequences for failure to pay the ISRP distinguish the ISRP from a tax,” Judge Humrickhouse concluded. **WJ**

### Attorneys:

Debtor: William F. Brazier III, Janvier Law Firm PLLC, Raleigh, NC

### Related Filings:

Opinion: 2018 WL 1725385

**See Document Section B (P. 27) for the opinion.**

## Nuns can join case targeting Trump rollback of Obamacare birth control coverage

(Reuters) – A federal appeals court ruled April 24 that an order of Roman Catholic nuns may intervene in a lawsuit by Pennsylvania’s attorney general challenging new Trump administration rules permitting religious and moral exemptions to Obamacare’s contraceptive mandate.

***Pennsylvania v. President of the United States et al.*, No. 17-3679, 2018 WL 1916034 (3d Cir. Apr. 24, 2018).**

The 3rd U.S. Circuit Court of Appeals in Philadelphia said the Little Sisters of the Poor had a significant interest in the lawsuit filed last year by Pennsylvania Attorney General Josh Shapiro.

U.S. District Judge Wendy Beetlestone, who in December issued an injunction preventing enforcement of the rules, had denied the nuns’ motion to intervene and said the federal government would adequately represent its interests in the case. *Pennsylvania v. Trump*, No. 17-cv-4540, 2017 WL 6206133 (E.D. Pa. Dec. 8, 2017).

New rules allow businesses or nonprofits to seek exemptions from Obamacare’s requirement that employers provide contraceptive coverage as part of their health benefits.

The 3rd Circuit disagreed, with U.S. Circuit Judge Thomas Hardiman writing for the three-judge panel that the Little Sisters’ “interest in preserving the religious exemption is concrete and capable of definition.”

Judge Beetlestone’s injunction, which has been stayed pending appeal, was one of two issued by judges nationally in lawsuits filed by Democratic state attorneys general after Republican President Donald Trump’s administration revealed its new rules in October.

The rules allow businesses or nonprofits to seek exemptions on religious or moral grounds from a requirement of 2010’s Affordable Care Act, or Obamacare, that



REUTERS/Mike Blake

employers provide contraceptive coverage as part of their health benefits with no co-payment.

The Little Sisters have since 2013 been active in challenging the mandate. The order opposed an Obama-era religious exemption as too narrow and requiring them to facilitate their employees’ quest to obtain contraceptives elsewhere.

Judge Hardiman said the Pennsylvania litigation had the potential to reopen issues the U.S. Supreme Court chose not to address in an earlier case involving the Little Sisters.

In 2015, the Supreme Court agreed to review a decision by the 10th U.S. Circuit Court of Appeals in a lawsuit by Little Sisters holding the contraceptive mandate did not violate the order’s rights.

But the high court remanded the case the following year after the death of conservative Justice Antonin Scalia left it ideologically deadlocked. *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

Shapiro’s office had argued the Little Sisters did not need to intervene to protect their interest because the nuns and the Trump administration were in “lockstep” in seeking to defend the rules’ validity.

But Judge Hardiman said there was no guarantee the government would sufficiently represent the Little Sisters’ specific interests as it attempts to uphold the rules in their entirety.

Lori Windham, senior counsel at Becket Fund for Religious Liberty, which represents Little Sisters, in a statement welcomed the ruling.

“Women like the Little Sisters of the Poor do not need bureaucrats trying to push them around,” she said. “The appeals court got it right — the Little Sisters should be allowed their day in court to argue for their rights.”

Shapiro’s office had no immediate comment.

**WJ**

(Reporting by Nate Raymond)

**Related Filings:**

Opinion: 2018 WL 1916034

**See Document Section C (P.33) for the opinion.**

## Suit against maker of irregular-heartbeat drug barred, 11th Circuit affirms

By Ethan Kraybill

Alabama's "learned intermediary" doctrine bars a lawsuit alleging off-label use of Sandoz Inc.'s generic heart-rhythm drug amiodarone, the 11th U.S. Circuit Court of Appeals has ruled.

### ***Tutwiler v. Sandoz Inc., No. 17-13985, 2018 WL 1719024 (11th Cir. Apr. 9, 2018).***

Affirming the lower court's dismissal of Barbara Tutwiler's failure-to-warn claim against the pharmaceutical company, the appeals court found she needed to have claimed that her doctor would not have prescribed the drug had Sandoz adequately warned him of the risks.

Simply alleging that Sandoz's warnings to physicians were inadequate was not enough to overcome Alabama's doctrine recognizing physicians' learned-intermediary role between drugmaker and patient.

### **PATIENT NOT WARNED**

In October 2012 Dr. Vance Plumb prescribed Tutwiler amiodarone, a drug of last resort, to treat her non-life-threatening atrial fibrillation, according to the three-judge appellate panel's opinion.

After Tutwiler started taking the drug, she experienced shortness of breath, coughing and tiredness, among other symptoms, the opinion said.

Tutwiler was diagnosed with interstitial lung disease and pulmonary fibrosis in July 2014, according to the opinion.

The FDA's website says amiodarone is "indicated for the management of life-threatening, recurrent ventricular fibrillation ... or ... ventricular tachycardia."

Tutwiler's complaint says the FDA has not approved amiodarone for her non-life-threatening atrial fibrillation.

Nevertheless, the complaint alleges, Sandoz heavily marketed amiodarone for this off-label use.

Tutwiler did not receive a medication guide from her pharmacist and did not realize that her prescription was for an off-label use, according to the opinion.

Tutwiler initially asserted eight causes of action in a complaint filed in the U.S. District Court for the Northern District of Alabama. The court dismissed her failure-to-warn claims as subject to Alabama's learned intermediary doctrine or preempted by federal law.

Tutwiler amended her complaint, repleading three causes of action that included failure to warn under both strict product liability and negligence theories. The District Court dismissed the amended complaint, ruling it contained substantially similar theories or failed to sufficiently describe the claims.

Tutwiler appealed the dismissal of her failure-to-warn claims, arguing that the learned-intermediary doctrine is inapplicable and federal law does not preempt the claims.

### **CAUSATION**

The 11th Circuit found the learned-intermediary doctrine sufficient to decide the appeal and did not rule on preemption.

Under Alabama's learned-intermediary doctrine, once a manufacturer has satisfied its duty to warn a prescribing physician, it holds no duty to warn the patient directly, the court said.

The panel's opinion quoted the Alabama Supreme Court in *Wyeth Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014), saying the adequacy of a manufacturer's warning is "measured by its effect on the physician ... not by its effect on the consumer."

If the warning to the physician is insufficient or misrepresents the risks, the manufacturer may be liable, the court noted.

This requires a showing of causation, however, the court said. Here, Tutwiler was required to plead that "that Dr. Plumb would not have prescribed her amiodarone had he known of its dangers," according to the court.

Tutwiler did assert she would not have taken amiodarone had she known of the risks, the panel said, but she failed to show the warning's impact on Plumb.

The court concluded that Tutwiler failed to plead a causal connection between Sandoz's warnings and Plumb's decision to prescribe amiodarone, meaning the learned-intermediary doctrine barred Tutwiler's claim. **WJ**

### **Attorneys:**

*Plaintiff-appellant:* Edward K. Wood Jr. and Michael E. Gurley Jr., Wood Law Firm LLC, Birmingham, AL

*Defendant-appellee:* Lori G. Cohen, Sara K. Thompson and Christiana C. Jacxsens, Greenberg Traurig LLP, Atlanta, GA

*Defendant-appellee:* Brian P. Kappel and Harlan I. Prater IV, Lightfoot Franklin & White, Birmingham, AL

### **Related Filings:**

Opinion: 2018 WL 1719024  
Tutwiler brief: 2017 WL 5495560  
Sandoz brief: 2017 WL 6508033

# Supreme Court asked to reverse 5th Circuit on False Claims Act evidence

By Jodine Mayberry

Circumstantial evidence should be enough to prove the government was unlawfully billed for drugs prescribed based on “off-label” promotion to doctors, two whistleblowers have told the U.S. Supreme Court.

**United States ex rel. King et al. v. Solvay Pharmaceuticals Inc., No. 17-1370, petition for cert. filed, 2018 WL 1557226 (U.S. Mar. 26, 2018).**

In a March 26 petition, John King and Tammy Drummond ask the high court to revive their 15-year-old False Claims Act suit against Solvay Pharmaceuticals Inc. after the 5th U.S. Circuit Court of Appeals found for the drugmaker in September. *King v. Solvay Pharms. Inc.*, 871 F.3d 318 (5th Cir. 2017).

According to the former Solvay sales reps, the 5th Circuit’s ruling would require direct evidence of specific billings in any off-label-promotion case. That would make future cases nearly impossible to prove, they say in their petition, citing the sophisticated legal strategies employed by drug companies.

“There will almost never be a smoking-gun paper trail of the kind the 5th Circuit hypothesized,” the petition says.

## OFF-LABEL PROMOTION

King and Drummond claim Solvay illegally promoted three drugs: Luvox, a treatment for obsessive-compulsive behavior; Aceon, a hypertension drug; and the synthetic testosterone AndroGel — for off-label uses not approved by the Food and Drug Administration.

In the case of AndroGel, Solvay went as far as to make up the phony disease “andropause,” or male menopause, to market an alleged cure, the petition says.

King and Drummond filed their qui tam suit in 2003, alleging false billing of Medicare and Medicaid.

It took the state and federal governments until 2009 to decline to intervene. The U.S. District Court for the Southern District of Texas then, over a period of years, granted summary judgment to Solvay on each claim.

A 5th Circuit panel affirmed, saying the whistleblowers failed to show a direct

connection between the company’s broader, off-label marketing and false billings for Luvox or Aceon on behalf of specific patients.

The panel also cited the False Claims Act’s public disclosure bar in upholding dismissal of the AndroGel claim. Under the FCA, a plaintiff must be the original source of the information about the alleged misconduct. But in this case, a New Yorker magazine article had described the AndroGel off-label promotion scheme before the whistleblowers filed suit, the appeals court said.

## CIRCUMSTANTIAL EVIDENCE

King and Drummond are seeking Supreme Court review of those two issues: circumstantial evidence and the public disclosure bar.

In their petition, they argue it is virtually impossible to build an off-label-promotion case on direct evidence because only individual doctors know whether they billed off-label prescriptions to the government in response to marketing by Solvay or its sales reps.

The government itself knows how much it paid out for each drug and which doctors prescribed the drugs, so it could investigate further, the petition says.

According to the two whistleblowers, the 5th Circuit rule requiring direct evidence of specific billings would have doomed major off-label enforcement actions that have succeeded in the past.

The 5th Circuit’s ruling also conflicts with Supreme Court decisions on circumstantial evidence and with rulings in other circuits, the petition says. [WJ](#)

### Attorneys:

*Petitioner:* Joel M. Androphy, Sarah M. Frazier, Zenobia H. Bivens and Janis G. Gorton, Berg & Androphy, Houston, TX

### Related Filing:

Petition for certiorari: 2018 WL 1557226

## Planned Parenthood

CONTINUED FROM PAGE 1

The 10th Circuit upheld a lower court judge’s 2016 decision enjoining Kansas from terminating its Medicaid contract with one of the affiliates, Planned Parenthood Great Plains, though remanded for further determination with regard to the other affiliate.

West Virginia Attorney General Patrick Morrisey in a statement said federal law provides states the ability to set the terms of eligibility for each of their Medicaid programs.

“It was not Congress’ intent to allow individual patients or health care providers, such as Planned Parenthood, to make such determinations,” he said.

Planned Parenthood had no immediate comment.

Planned Parenthood has pursued several similar lawsuits challenging state efforts to cut off funding following the release of the videos.

The Republican attorneys general argued in their brief that the so-called Medicaid provider-choice provision of the Medicaid Act did not afford individual patients or medical providers a private right of action they could enforce in court.

The brief said the 10th Circuit’s ruling had deepened a split among the federal appeals courts, in which five circuits in cases largely involving Planned Parenthood have held the provision created a private cause of action while a sixth disagreed.

The single federal appeals court to rule against Planned Parenthood was the 8th Circuit, which in August ruled in favor of Arkansas in holding that the Medicaid law does not unambiguously create a federal right for individual patients that they could enforce in court. *Does v. Gillespie*, 867 F.3d 1034 (8th Cir. 2017). [WJ](#)

(Reporting by Nate Raymond)

### Related Filings:

Petition: 2018 WL 1920635

See Document Section A (P. 19) for the petition.

## Class action blames rising EpiPen costs on pharmacy benefit managers

By Jason Schosler

CVS Health Corp., Express Scripts Inc. and other pharmacy benefit managers breached their fiduciary duties to ERISA-governed health plan participants by failing to negotiate lower prices for EpiPen auto-injectors, according to a consolidated class-action lawsuit.

***In re EpiPen ERISA Litigation, No. 17-cv-1884, consolidated class-action complaint filed, 2018 WL 1702538 (D. Minn. Apr. 2, 2018).***

The complaint, filed in the U.S. District Court for the District of Minnesota, says the managers violated the Employee Retirement Income Security Act, 29 U.S.C.A. § 1132, by contributing to the inflated prices the participants pay for the injectable allergy treatment.

Pharmacy benefit managers oversee lists of prescription drugs that are covered under health plans providing prescription drug benefits, according to the suit.

Other defendants named in the complaint include benefit manager Prime Therapeutics LLC and health insurance giant UnitedHealth Group Inc., which provides manager services through subsidiary and co-defendant OptumRx Inc.

The plaintiffs participated in ERISA-governed health plans that used the defendant managers, the suit says. According to the complaint, the companies account for 81 percent of the pharmacy benefit manager services market.

U.S. District Judge Paul A. Magnuson had granted the plaintiffs' motion to consolidate three lawsuits over the defendants' purported conduct about two months ago. *Klein v. Prime Therapeutics LLC*, No. 17-cv-1884; *Illis v. Optum Inc.*, No. 17-cv-5154; *Brannon v. Express Scripts Holding Co.*, No. 18-cv-18, *consolidation order issued* (D. Minn. Feb. 1, 2018).

In his consolidation order, Judge Magnuson said all future actions filed in or transferred to the District of Minnesota based on the



REUTERS/Jim Bourg

same factual allegations likewise will be consolidated into the case.

### 'SKYROCKETING' COSTS

EpiPens are epinephrine self-injectable devices used on an emergency basis to prevent anaphylaxis, a rapid and potentially fatal respiratory reaction that may occur in people allergic to certain foods, drugs or insect venom.

According to the suit, the EpiPen two-pack price "skyrocketed" from less than \$100 in 2007 to more than \$608 in 2017, coinciding with Mylan's acquisition of EpiPen in 2007.

Mylan is not named as a defendant in the suit.

These price increases are due, at least in part, to the benefit managers' failure to act as effective intermediaries between Mylan and health insurers, the suit says.

Although the managers have the responsibility and authority to negotiate lower drug prices on behalf of ERISA health insurance plans and their plan members, they have failed to do so for EpiPens, the suit says.

Rather than push for lower or stable prices from Mylan, the defendants negotiated for "unprecedented" rebates, or "kickbacks," from the drug manufacturer and kept a significant amount of the rebates for themselves, the complaint says.

This forced Mylan to keep raising benchmark prices for EpiPens, resulting in massive price increases for class members, according to the suit.

"Working with Mylan, defendants put their self-interest above the interests of those to whom they owed fiduciary duties when they leveraged their control over their massive purchasing pool," the suit says.

The complaint claims the defendants' continued solicitation and receipt of rebates from Mylan has caused EpiPen insurance deductible payments to increase nearly 1,600 percent and coinsurance payments to increase by more than 1,500 percent.

In addition to class certification, the plaintiffs seek a ruling that the defendants violated their fiduciary duties to ERISA plan participants and beneficiaries.

They also seek preliminary and injunctive relief, restitution, disgorgement of profits and other unspecified monetary damages.

**WJ**

#### Attorneys:

*Plaintiffs:* Lynn Lincoln Sarko, Gretchen Freeman Cappio, Gretchen S. Obrist, Cari Campen Laufenberg, Matthew M. Gerend, Michael W. Meredith and Laura Zanzig-Wong, Keller Rohrback LLP, Seattle, WA

*Plaintiffs:* Karen Hanson Riebel, David W. Asp, Kristen G. Marttila and Arielle S. Wagner, Lockridge Grindal Nauen PLLP, Minneapolis, MN

#### Related Filings:

Consolidated class-action complaint: 2018 WL 1702538



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## MERGERS

# Cigna gets \$1.5 billion revolver to finance \$67 billion Express Scripts buyout

By Jeremy Abrams

U.S. health insurer Cigna Corp. said it has obtained a \$1.5 billion revolving line of credit backed by a number of lenders to help finance its planned \$67 billion purchase of pharmacy benefits manager Express Scripts Holding Co.

**Cigna Corp. Form 8-K, 2018 WL 01751856 (Apr. 12, 2018).**

The credit limit will increase to \$3.25 billion once the deal closes, according to a Form 8-K Cigna filed with the Securities and Exchange Commission on April 12.

Bloomfield, Connecticut-based Cigna agreed in March to acquire Express Scripts in a cash-and-stock transaction that includes the assumption of about \$15 billion of the St. Louis-based target's debt, according to an earlier SEC filing.

Privately held Express Scripts administers prescription drug programs for health insurance providers and is one of the country's largest pharmacies, serving over 85 million customers, according to its website.

Cigna told investors the acquisition will allow it to cut up to \$600 million in administrative costs and improve the coordination of pharmacy and medical claims.

### CREDIT AGREEMENT

Cigna said it has signed a revolving credit agreement with a lending syndicate that includes Citigroup Global Markets Inc.; Merrill Lynch, Pierce, Fenner & Smith Inc.; and Wells Fargo Securities LLC. JPMorgan Chase Bank NA will act as the loan's administrative agent, according to the Form 8-K.

The credit agreement allows Cigna to borrow \$1.5 billion for general corporate purposes and up to \$3.25 billion upon closing, the

filing said. It also permits Cigna to increase the loan amount by up to \$500 million in the future, according to the Form 8-K.

The credit line is set to expire in 2023 but may be extended for additional one-year periods subject to the lenders' consent, according to the filing.

Cigna said it plans to finance the remainder of the transaction with a combination of cash on hand and new debt.

### POSSIBLE COMPETITION CONCERNS

Cigna's proposed buyout of Express Scripts comes on the heels of its failed attempt last year to acquire fellow insurer Anthem Inc. A federal judge blocked the proposed \$54 billion transaction after concluding the combination would substantially reduce competition in the health insurance market for large employers. *U.S. v. Anthem Inc.*, No. 16-cv-1493, 2017 WL 527923 (D.D.C. Feb. 8, 2017).

The health insurance company could face a similar challenge to its current deal.

In December insurer Aetna Inc. inked an agreement to buy drugstore chain CVS Health Corp. for about \$69 billion. But federal antitrust regulators have requested additional information about that deal, signaling it will face close scrutiny for its potential effects on competition in the health care sector. [WJ](#)

### Related Filings:

Form 8-K: 2018 WL 01751856

## Kindred shareholders approve Humana takeover despite legal challenges

By Jeremy Abrams

The shareholders of Kindred Healthcare Inc. have voted to approve Humana Inc.'s proposed \$4.1 billion purchase of the company, despite a pending shareholder lawsuit challenging the acquisition and the published objections of another shareholder.

### **Kindred Healthcare Inc. Form 8-K, 2018 WL 01632346 (Apr. 5, 2018).**

Over 77 percent of the shareholders approved the acquisition proposal, according to a Form 8-K Kindred filed with the Securities Exchange Commission on April 5. The shareholders separately approved a proposal relating to executive compensation by a similar margin, the filing said.

The companies expect the transaction to close this summer, according to a press statement issued in connection with the Form 8-K.

Louisville, Kentucky-based Kindred is a Fortune 500 health care services company that employs over 85,000 workers and provides health care services in over 2,400 locations across 45 states, according to the statement.

Humana, also based in Louisville, is a broad-based health care services provider that in fiscal year 2017 made over \$53 billion in gross revenue and over \$2.4 billion in net income, according to its website.

### **SHAREHOLDER CHALLENGES**

In February, Kindred shareholder Debra Carter sued the company and its 11 directors in the U.S. District Court for the District of Delaware, alleging the defendants failed

to disclose information the shareholders needed to cast an informed vote on the buyout proposal.

Carter claimed that Kindred's related securities filings omitted crucial information supporting the firm's financial forecasts, including the reconciliation of metrics that did not conform to generally accepted accounting principles.

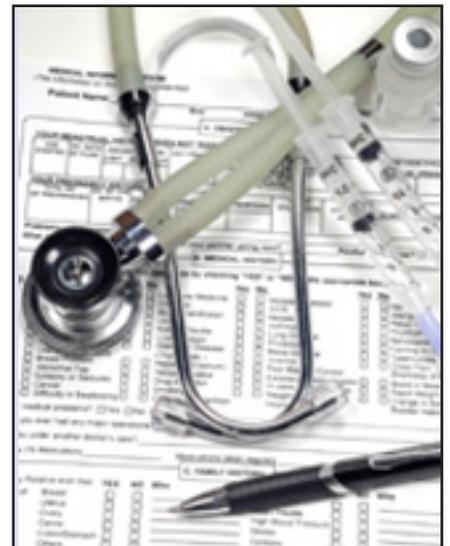
In addition, hedge fund Brigade Capital Management LP, which holds a 5.7 percent stake in Kindred, filed a letter with the SEC in March opposing the deal, according to a Schedule 13D Brigade filed March 21.

Brigade argued that several impediments to growth Kindred factored into its forecasts had been removed, including the cancellation of a proposal by the Centers for Medicare and Medicaid Services to reduce reimbursement rates, and divestiture of Kindred's skilled nursing facilities.

The hedge fund also noted the Tax Cuts and Jobs Act of 2017 was expected to increase Kindred's unleveraged cash flow by up to \$50 million, but Kindred did not factor that into its fairness opinion analysis. **WJ**

#### **Related Filings:**

Form 8-K: 2018 WL 01632346  
Schedule 13D: 2018 WL 01400156



## WESTLAW JOURNAL **HEALTH CARE FRAUD**

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# Seeking full reimbursement, Florida chiropractor files class action against Geico

By Kteba Dunlap, Esq.

Geico has been underpaying certain health care providers in Florida by 20 percent, a proposed class action claims in federal court.

**Rosenberg v. Government Employees Insurance Co. et al., No. 18-cv-60576, complaint filed, 2018 WL 1463869 (S.D. Fla. Mar. 16, 2018).**

In a complaint filed March 16 in the U.S. District Court for the Southern District of Florida, chiropractor Randy Rosenberg says the insurance giant is violating its promise to fully reimburse medical bills that fall below the amount listed on the fee schedule Geico adopted from a state insurance law.

According to the suit, Geico's standard Florida auto policy form says it will fully reimburse bills for less than the "usual and customary" rate reflected in its fee schedule. But the insurer has made a practice of paying only 80 percent of those charges, as it would for doctors billing above the threshold, Rosenberg claims.

Geico has failed to meet the terms of its contracts, and the court should require the insurer to follow its own policies, the suit says.

## 80% OR 100%?

According to the complaint, Florida law, Fla. Stat. Ann. § 627.736, lets insurers limit reimbursement to 80 percent of the reasonable charge for medically necessary treatments.

Geico does that, limiting its payments to doctors billing at or above 80 percent of the reasonable rate in its fee schedule. But the suit says the insurer's policies also promise it will fully reimburse health care providers billing below that level.

Geico is routinely breaching that promise, the complaint says. Calling the practice widespread and ongoing, the suit seeks to certify a class of Florida health care providers that have billed the insurer at the fee-scheduled rate or less.

Instead of damages, Rosenberg seeks a declaration that going forward, Geico must honor the reimbursement practices set forth in its policies.

## A SIMILAR CASE

Rosenberg is represented by Edward H. Zebersky, a class-action attorney who recently won a similar case in the same court. *A&M Gerber Chiropractic v. GEICO Gen. Ins. Co.*, No. 16-cv-62610, 2017 WL 5571353 (S.D. Fla. Nov. 20, 2017).

U.S. District Judge Beth Bloom ruled in November — based on a different but related provision of state law — that Geico must pay in full any claim for less than 200 percent of the amount listed on a certain Medicare Part B fee schedule. [WJ](#)

### Attorneys:

*Plaintiff:* Edward H. Zebersky, Mark Fistos and Michel T. Lewenz, Zebersky Payne, Ft. Lauderdale, FL

### Related Filings:

Complaint: 2018 WL 1463869  
Opinion: 2017 WL 5571353

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# Aetna privacy suit belongs in state court, California federal judge says

By Jason Schossler

A lawsuit claiming Aetna Inc. disclosed confidential HIV-related information in letters to nearly 12,000 patients belongs in state court, a California federal judge has ruled.

***Doe v. Aetna Inc., No. 17-cv-7167, 2018 WL 1614392 (N.D. Cal. Apr. 4, 2018).***

U.S. District Judge Edward M. Chen of the Northern District of California said April 4 that the potential cost of any compensatory damages, injunctive relief and attorney fees likely would fall short of the \$75,000 threshold for federal jurisdiction.

## WINDOWED ENVELOPES

The plaintiff, an Aetna policyholder identified only as “John Doe” sued the insurer last fall in the Contra Costa County Superior Court.

According to his complaint, Doe was a plaintiff in a separate proposed class-action suit that challenged Aetna’s now-defunct policy requiring HIV and AIDS patients to get their specialty medications through a mail-order prescription service.

The class action ultimately settled. Under the settlement agreement Aetna was required to send letters in July 2017 to almost 12,000 individual Aetna policyholders advising them of their right to obtain HIV/AIDS medications from a community pharmacy of their choice, the complaint says.

In his current suit, Doe alleges that Aetna sent the letters in envelopes with an oversized window. The name and address of the recipient was visible in the window, as was a portion of the letter indicating that the recipient had been prescribed HIV medications, according to the complaint.

Doe claims Aetna’s letters were a breach of the settlement terms. His suit also accuses

the insurer of breach of the covenant of good faith and fair dealing and violation of Section 17200 of California’s Business and Professions Code.

He seeks compensatory damages, equitable relief, injunctive relief and attorney fees and other costs.

## COMPENSATORY DAMAGES

Aetna removed the suit from state court to the Northern District of California, arguing the amount in controversy exceeds \$75,000.

In response, Doe moved to remand the case, claiming the amount in controversy falls short of the jurisdictional minimum.

Granting Doe’s motion, Judge Chen noted that Doe’s suit says he has suffered less than \$75,000 in damages.

Although Aetna argued Doe’s compensatory damages could still exceed \$75,000, the judge said such an award was unlikely given that Doe has not alleged any specific injury such as loss of wages or emotional distress.

“Even if Doe had alleged emotional distress, that still would not take the amount in controversy past \$75,000 because emotional distress damages are not typically awarded in breach-of-contract cases,” Judge Chen wrote.

## INJUNCTIVE RELIEF, ATTORNEY FEES

Aetna argued that federal jurisdiction nonetheless is warranted based on Doe’s request for injunctive relief: a requirement



REUTERS/Lucas Jackson

that the insurer use windowless envelopes in its notification mailings.

According to the insurer, the cost of implementing such a policy would exceed \$75,000.

But Judge Chen was not persuaded. The cost of complying with Doe’s request would come nowhere close to that amount, he said, because the plaintiff is asserting only an individual right, rather than a “common and undivided interest” among all letter recipients.

Even if the court did consider the cost of implementing a policy of windowless envelopes for all persons prescribed HIV medications, it is still unlikely that it would add up to more than \$75,000, the judge said.

Lastly, Judge Chen said it is also improbable that the plaintiff’s attorney fees would push the amount in controversy beyond \$75,000 given the fact that Doe is adjudicating only an individual right. **WJ**

### Related Filings:

Order: 2018 WL 1614392

## Becton Dickinson recalls blood-collection tubes over possible chemical interference

Ronald V. Baker

Becton Dickinson & Co. has recalled nearly a billion blood-collection tubes, saying their rubber stoppers contain a chemical that may render certain blood tests results inaccurate.

In a March 23 announcement made through the U.S. Food and Drug Administration, BD said the recall covers all production lots of its BD Vacutainer EDTA tubes with lavender, tan and pink tops as well as its BD Vacutainer Lithium Heparin tubes with green tops.

The tubes, which have been produced and distributed since March 29, 2016, are used to collect venous blood samples so they can be tested in clinical laboratories.

BD said a chemical in the stoppers, thiuram, can release sulfur-containing gases that may

dissolve into the sample and interfere with the accuracy of anodic stripping voltammetry, or ASV, testing methodology. ASV methodology is typically used to check lead levels in blood.

The chemical reaction can produce test results that understate the amount of lead in the blood and hinder proper treatment for lead exposure or poisoning, the company said.

The collection tubes can still be used with non-ASV blood tests, according to the FDA, which has classified the action as a Class I

recall, the most serious of its three recall designations.

BD said it began urgently notifying customers and distributors of the problem March 22, 2018, saying they should continue complying with the FDA's safety instructions on lead testing, assess whether other tests they perform might be affected by thiuram interference and educate their personnel.

BD customers and distributors of the tubes can contact the company at (888) 237-2762 for further recall instructions. [WJ](#)



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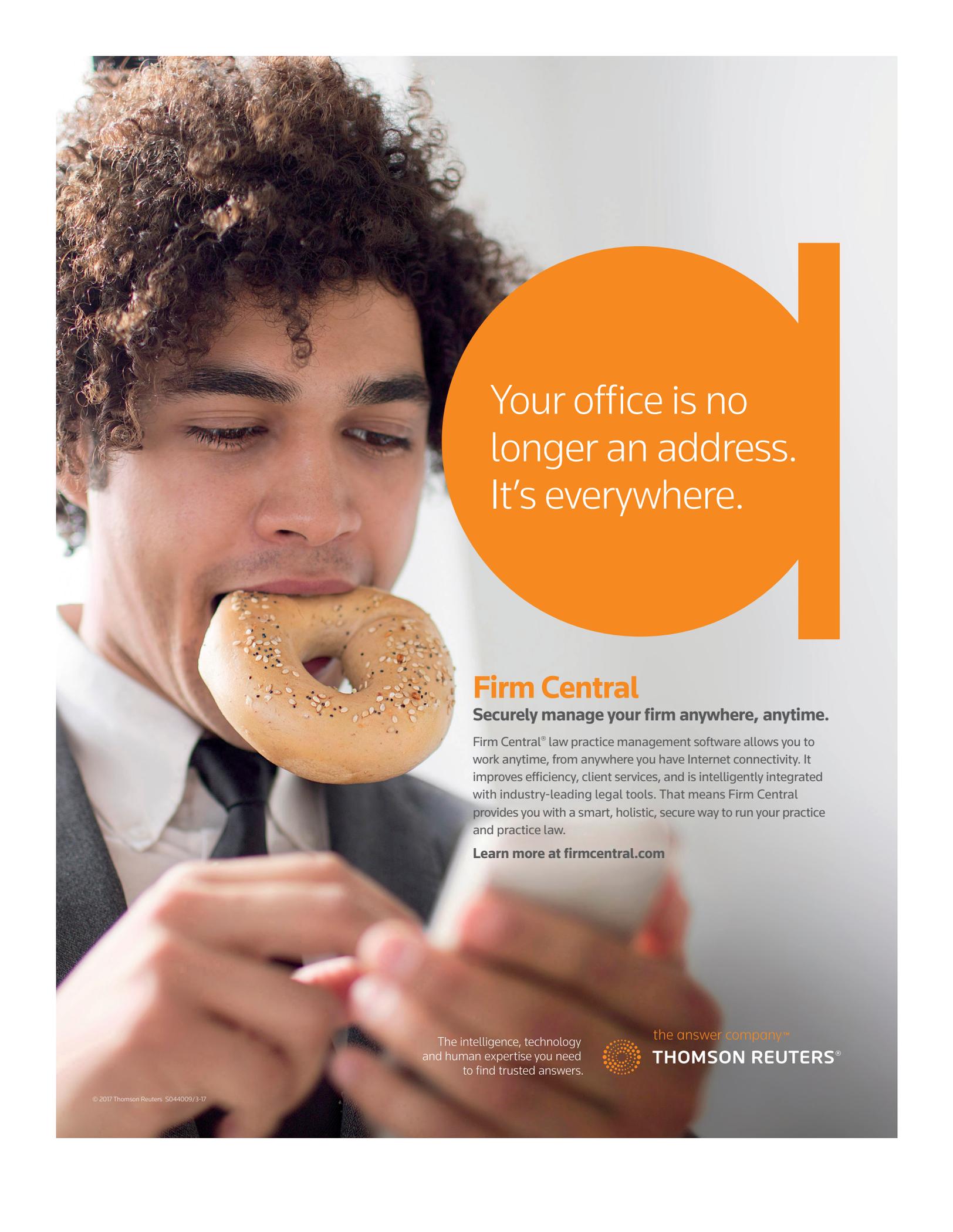
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## CASE AND DOCUMENT INDEX

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A man with curly hair is shown from the chest up, wearing a white shirt and a dark tie. He is holding a sesame seed bagel in his mouth and looking down at a smartphone he is holding in his hands. The background is a plain, light-colored wall.

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# ANDERSON

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2018 WL 1920635 (U.S.) (Appellate Petition, Motion and Filing)  
Supreme Court of the United States.

Jeff ANDERSEN, Secretary, Kansas Department of Health and Environment, Petitioner,  
v.  
PLANNED PARENTHOOD OF KANSAS and Mid-Missouri, et al., Respondents.  
No. 17-1340.  
April 23, 2018.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

**Brief of Indiana, Georgia, Idaho, Louisiana, Michigan, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, Wisconsin, and Wyoming as Amici Curiae in Support of Petitioner**

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## QUESTION PRESENTED

Whether the right-of-action doctrine announced in *Gonzaga University v. Doe*, 536 U.S. 273 (2002), precludes Medicaid providers and patients from suing to enforce the provider-choice Medicaid plan requirement of 42 U.S.C. § 1396a(a)(23).

**\*1 INTEREST OF THE AMICI STATES<sup>1</sup>**

The States of Indiana, Georgia, Idaho, Louisiana, Michigan, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, Wisconsin and Wyoming respectfully submit this brief as *amici curiae* in support of the petitioner. The circuits have split 5-1 on the issue of whether the Medicaid provider-choice provision affords a private right of action under Section 1983 to healthcare providers and their patients whose Medicaid agreements have been terminated by the State. Until this split is resolved, patients in the Fifth, Sixth, Seventh, Ninth, and Tenth Circuits have the right to bring suit in federal court if their preferred provider's agreement is terminated, while patients in the Eighth Circuit do not.

The *amici* States have a strong interest in the proper functioning of the Medicaid system, both in terms of determining which providers are qualified to receive Medicaid funding and in terms of faithfully carrying out their contracts with the federal government. The Petition asserts that thousands of healthcare providers are disqualified by state administrators every year; under the decision below, a patient of any one could sue for reinstatement in federal court. Yet by the terms of the Medicaid Act federal-state contract, the States, not federal courts, are empowered to **\*2** determine the qualifications for eligible healthcare providers. Accordingly, the *amici* States urge the Court to address whether providers or patients have a private right of action under Section 1983 to enforce the Medicaid provider-choice provision.

## SUMMARY OF THE ARGUMENT

While the Court in *Wilder v. Virginia Hospital Ass'n*, 496 U.S. 498 (1990), permitted private enforcement of a Medicaid plan requirement listed in Section 1396a(a), since then the Court has dramatically curtailed the circumstances in which private parties may enforce federal statutes. The Court has never expressly revisited *Wilder*, but its decisions in *Armstrong v. Exceptional Child, Center, Inc.*, 135 S. Ct. 1378 (2015), and *Gonzaga University v. Doe*, 536 U.S. 273 (2002), have cast substantial doubt on its continued vitality and have left it unclear whether the Medicaid Act may be privately enforced. The circuits have split 5-1 on the private enforceability of the Medicaid provider-choice provision alone, and further disagreements exist with respect to other provisions of the Medicaid Act - and the continued significance of *Wilder* more generally.

With this deep division of authority in mind, the Court should grant certiorari and hold that, at the very least, the provider-choice provision of the Medicaid Act is not privately enforceable. Spending Clause legislation such as the Medicaid Act "is much in the nature of a contract: in return for federal funds, the **\*3** States agree to comply with federally imposed conditions." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). In particular, the Medicaid plan requirements - including the provider-choice provision - were intended by Congress as requirements for Medicaid plans to be eligible for federal reimbursement, not as individually enforceable rights. Section 1396a(a) is merely a list of conditions that a State Medicaid plan must meet to be approved by the Secretary of Health and Human Services. It is the role of the HHS Secretary, not individual healthcare providers, to determine in the first instance whether a State Medicaid program is meeting those conditions.

What is more, the meaning of "qualified" provider is found not in the Medicaid Act itself, but in State regulations and State Medicaid plans, which set forth the reasons that a provider's Medicaid agreement may be terminated. For this reason, the proper method of challenging Kansas's determination that Planned Parenthood is not a qualified provider is through administrative review. Only then can the politically accountable bodies of state and federal government properly interpret and apply the entire body of relevant Medicaid statutes, regulations and plan requirements.

**\*4 REASONS FOR GRANTING THE PETITION****I. The Court Should Resolve the Split over Whether the Provider-Choice Provision Is Enforceable via Section 1983**

The Circuits are divided over whether Medicaid beneficiaries have a private right of action to challenge a State's disqualification of a provider under the Medicaid Act. Five circuits have decided that the Medicaid provider-choice provision may be privately enforced under Section 1983, while one has held that it may not. Compare *Planned Parenthood of Kan. & Mid-Mo. v. Andersen*, 882 F.3d 1205 (10th Cir. 2018), *Planned Parenthood of Gulf Coast, Inc. v. Gee (Gee II)*, 862 F.3d 445 (5th Cir. 2017), *Planned Parenthood of Ariz. Inc. v. Betlach*, 727 F.3d 960 (9th Cir. 2013), *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't Health*, 699 F.3d 962 (7th Cir. 2012), and *Harris v. Olszewski*, 442 F.3d 456 (6th Cir. 2006), with *Does v. Gillespie*, 867 F.3d 1034 (8th Cir. 2017).

This split exists because the Court's right-of-action doctrine has changed substantially over the past 25 years. While the circuits

permitting private enforcement of the provider-choice provision have relied on outdated precedents, the Eighth Circuit's rejection of such enforcement properly applied the Court's more recent pronouncements.

**\*5** 1. The Court's older (and now discarded) precedents demonstrated a highly permissive view of private enforcement of federal law. In *Wright v. City of Roanoke Redevelopment & Housing Authority*, the Court held that the Brooke Amendment to the Housing Act of 1937, which limited the amount that tenants of low-income housing projects could be charged for utilities, was privately enforceable under Section 1983. 479 U.S. 418, 419 (1987). In that era, it was sufficient to justify private enforcement that Congress had not "specifically foreclosed a remedy under § 1983." *Id.* at 424 (quoting *Smith v. Robinson*, 468 U.S. 992, 1004-05 & n.9 (1984)). Moreover, the remedial mechanisms provided in the Brooke Amendment were not "sufficiently comprehensive and effective to raise a clear inference that Congress intended to foreclose a § 1983 cause of action for the enforcement of tenants' rights secured by federal law." *Id.* at 425.

A few years later, in *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103 (1989), the Court applied a more systematic - yet still highly permissive - test when it held that the National Labor Relations Act was privately enforceable under Section 1983. In determining that the NLRA created a federal right, the Court considered (1) whether the statute "creates obligations binding on the governmental unit;" (2) whether it is "too vague and amorphous to be beyond the competence of the judiciary to enforce;" and (3) "whether the provision in question was intend[ed] to **\*6** benefit the putative plaintiff." *Id.* at 106 (internal citations omitted).

Once it concluded that a federal right was at issue, the Court also held (a la *Wright*) that Congress had not "specifically foreclosed a remedy under § 1983 ... by providing a comprehensive enforcement mechanis[m] for protection of a federal right." *Id.* (internal citations omitted). The Court further explained that "[t]he availability of administrative mechanisms to protect the plaintiff's interests is not necessarily sufficient to demonstrate that Congress intended to foreclose a § 1983 remedy." *Id.* The question, rather, is whether the statutory framework is such that "[a]llowing a plaintiff to bring a § 1983 action would be inconsistent with Congress' carefully tailored scheme." *Id.* at 107 (internal quotations omitted).

Then, in *Wilder v. Virginia Hospital Ass'n*, the Court considered whether the now-repealed Boren Amendment to the Medicaid Act was enforceable through private action under Section 1983. 496 U.S. 498, 501-02 (1990). The Court applied the same three-part test from *Golden State Transit*: (1) "whether the provision in question was intend[ed] to benefit the putative plaintiff;" (2) whether it reflects "a binding obligation on the governmental unit;" and (3) whether it "is too vague or amorphous such that it is beyond the competence of the judiciary to enforce." *Id.* at 509 (internal citations omitted); see also **\*7** *Blessing v. Freestone*, 520 U.S. 329, 340-41 (1997) (restating the three-part test from *Wilder*). Applying this test, the Court held that a private-right-of-action did exist. *Wilder*, 496 U.S. at 509-10.

2. *Wilder*, however, represents the high water mark of the era where the Court freely found federal statutes to be privately enforceable via Section 1983.

First, in *Alexander v. Sandoval*, the Court held that Title VI of the Civil Rights Act did not "create a freestanding private right of action." 532 U.S. 275, 293 (2001). Rather than requiring defendants to show that Congress had specifically foreclosed private enforcement, as in *Wright* and *Golden State*, the Court required plaintiffs to show that Congress intended "to create not just a private right but also a private remedy." *Id.* at 286. While *Alexander* was not a Section 1983 case, the Court's more restrictive approach to private enforceability of federal statutes took hold.

In particular, the very next year, in *Gonzaga University v. Doe*, 536 U.S. 273, 283-84 (2002), the Court, relying on *Alexander*, cast aside the three-part test used in *Wilder* as it considered "whether a student may sue a private university for damages under [Section 1983] to enforce provisions of the Family Educational Rights and Privacy Act." *Id.* at 276. The Court "reject[ed] the notion that our cases permit anything short of an unambiguously conferred right to support a cause of action brought under § 1983." *Id.* at 283. **\*8** Alluding to *Golden State* and *Wilder*, it then explained that "we fail to see how relations between the branches are served by having courts apply a multifactor balancing test to pick and choose which federal requirements may be enforced by § 1983 and which may not." *Id.* at 286. Because FERPA did not unambiguously confer an individual right, the Court held that it could not be privately enforced under Section 1983. *Id.* at 290.

3. Yet even in the wake of *Gonzaga*, some circuits have continued to apply *Wilder* to permit private enforcement of various provisions of Medicaid using Section 1983.

In particular, after *Gonzaga* and before the Court's decision in *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015), three circuits held that the Medicaid provider-choice provision affords a private right of action to Medicaid recipients under Section 1983. See *Planned Parenthood of Ariz. Inc. v. Betlach*, 727 F.3d 960, 966-68 (9th Cir. 2013); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 972-74 (7th Cir. 2012); *Harris v. Olszewski*, 442 F.3d 456, 461-62 (6th Cir. 2006). Critically, the Sixth and Seventh Circuits relied substantially on *Wilder* because it addressed enforcement of Medicaid and was not directly overruled by *Gonzaga*. See *Planned Parenthood of Ind.*, 699 F.3d at 975-76; *Harris*, 442 F.3d at 461, 463. \*9 Once those decisions came down, the State of Arizona conceded the issue in *Betlach*. 727 F.3d at 966.

4. But in 2015, the Court decided *Armstrong*, where it held that healthcare providers do not have a private right of action under the Supremacy Clause to challenge a State's failure to amend its Medicaid reimbursement rates. 135 S. Ct. at 1387-88. It explained that "the sole remedy Congress provided for a State's failure to comply with Medicaid's requirements ... is the withholding of Medicaid funds by the Secretary of Health and Human Services." *Id.* at 1385. The Court expressly recognized that the provision at issue in *Armstrong* was "parallel" to that interpreted by *Wilder*, yet the Court declined to follow *Wilder's* lead. *Id.* at 1386-87. Instead, the Court applied the more stringent standard of *Gonzaga* to hold that no individual rights were "unambiguously conferred." *Id.* at 1387-88. And while *Armstrong* dealt with a Supremacy Clause claim rather than a Section 1983 claim, the Court made the critical observation that, in all likelihood, the plaintiffs had not asserted a § 1983 action precisely because "our later opinions plainly repudiate the ready implication of a § 1983 action that *Wilder* exemplified." *Id.* at 1386. That passage obviously undercuts the holdings of the Sixth and Seventh Circuits in *Harris* and *Planned Parenthood of Ind.*, which, again, relied on *Wilder* rather than *Gonzaga*.

\*10 Since *Armstrong*, three more circuits have divided - indeed have demonstrated outright confusion - over whether Section 1983 affords a private-right-of-action to Medicaid recipients to enforce the Medicaid provider-choice provision. To begin, the Fifth Circuit in *Planned Parenthood of Gulf Coast, Inc. v. Gee (Gee I)*, 837 F.3d 477 (5th Cir. 2016), held that such a right-of-action exists, only to withdraw its opinion nine months later when one judge changed her position, *Planned Parenthood of Gulf Coast, Inc. v. Gee (Gee II)*, 862 F.3d 445 (5th Cir. 2017). Then, after the Eighth Circuit concluded that no private-right-of-action under the provider-choice provision exists for Medicaid recipients in *Does v. Gillespie*, 867 F.3d 1034 (8th Cir. 2017), the Fifth Circuit denied rehearing en banc for *Gee* in a sharply divided 7-7 vote. *Planned Parenthood of Gulf Coast, Inc. v. Gee (Gee III)*, 876 F.3d 699 (5th Cir. 2017). A Petition for Writ of Certiorari is likely to be filed in *Gee*, as well.

When the Eighth Circuit in *Does* ruled that the Medicaid provider-choice provision is not privately enforceable, it justified its split from other circuits on the grounds of "evolution in the law," namely with reference to "the now-repudiated *Wilder* decision." 867 F.3d at 1043. In *Gonzaga* and *Armstrong*, the Eighth Circuit said, "the Court 'sub silentio overrule[d] cases such as ... *Wilder*,' because the Boren Amendment did not 'clear[ly] and unambiguous[ly] intend enforceability under § 1983'" *Id.* at 1040 (quoting *Gonzaga*, 536 U.S. at 300 n.8 (Stevens, J., dissenting)). The \*11 court concluded that "for purposes of our obligation to apply Supreme Court precedent ... the Court's 'repudiation' of *Wilder* is the functional equivalent of 'overruling.'" *Id.* at 1040 (internal citation omitted).

Even so, in this case the Tenth Circuit - expressly recognizing its split from the Eighth - aligned with the Fifth, Sixth, Seventh, and Ninth Circuits, ruling that the provider-choice provision is privately enforceable. *Planned Parenthood of Kan. & Mid-Mo. v. Andersen*, 882 F.3d 1205 (10th Cir. 2018). Like those other circuits, the Tenth relied heavily on *Wilder*, concluding that it was still binding because *Armstrong* was a plurality decision. *Id.* at 1229.

5. Underscoring the need for Supreme Court review, the Circuits are also divided over private enforcement of the Medicaid Act more generally.

As with the provider-choice provision, most circuits, even after *Armstrong*, continue to rely on *Wilder* to justify private enforcement of various Medicaid provisions by way of Section 1983. Especially illustrative is *BT Bourbonnais Care, LLC v. Norwood*, 866 F.3d 815, 820-21 (7th Cir. 2017), which held that Section 1396a(a)(13)(A) is privately enforceable via Section 1983. While recognizing that *Wilder* "addressed a version of the statute that is now history," the Seventh Circuit also commented that "the Supreme Court has never overruled its decision in *Wilder*." *Id.*

\*12 Other examples include: *Bryson v. Shumway*, 308 F.3d 79, 88-89 (1st Cir. 2002) (citing *Wilder* to establish private enforceability of Section 1396a(a)(8) under Section 1983); *Rabin v. Wilson-Coker*, 362 F.3d 190, 202 (2d Cir. 2004) (finding private right of action under Section 1396r-6); *Sabree ex rel. Sabree v. Richman*, 367 F.3d 180, 192 (3d Cir. 2004) (holding that Medicaid Act sections 1396a(a)(8), 1396a(a)(10) and 1396d(a)(15) are privately enforceable because "the Court has refrained from overruling *Wright* and *Wilder*, which upheld the exercise of individual rights under statutes that contain similar (or, in the case of *Wilder*, identical) provisions to 42 U.S.C.

§ 1396.”); *Doe v. Kidd*, 501 F.3d 348, 356 (4th Cir. 2007) (citing *Wilder* to permit private enforcement of Section 1396a(a)(8) because the “Medicaid Act does not explicitly forbid recourse to § 1983.”); *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 372 (5th Cir. 2018) (deciding the *Armstrong* plurality did not overrule *Wilder*, making Section 1396a(bb) privately enforceable).<sup>2</sup>

Yet, as with the Eighth Circuit in *Does v. Gillespie*, 867 F.3d 1034, 1040 (8th Cir. 2017), the Eleventh Circuit has treated *Wilder* as supplanted by *Gonzaga*. In *Martes v. Chief Executive Officer of South Broward Hospital District*, 683 F.3d 1323 (11th Cir. 2012), the \*13 court did not cite *Wilder* but instead employed *Gonzaga*’s “unambiguously conferred right” test and held that Section 1396a(a)(25) (C) does not confer such rights because it “is formulated as a requirement of a Medicaid State plan as it relates to third party liability for payment of Medicaid patients’ medical expenses.” *Id.* at 1326, 1328-30.

That happens to be the correct (because literal) reading of Section 1396a(a), and yet also the reading expressly rejected by so many other circuits. See *Planned Parenthood of Kan. v. Andersen*, 882 F.3d 1205, 1228-29 (10th Cir. 2018); *Planned Parenthood of Gulf Coast, Inc. v. Gee (Gee II)*, 862 F.3d 445, 46162 (5th Cir. 2017); *Planned, Parenthood of Arizona, Inc. v. Betlach*, 727 F.3d 960, 966-67 (9th Cir. 2013); *Planned Parenthood of Ind., Inc. v. Comm’r of Ind. State Dept. of Health*, 699 F.3d 962, 974-75 (7th Cir. 2012); *Harris v. Olszewski*, 442 F.3d 456, 462-63 (6th Cir. 2006).

Furthermore, the D.C. Court of Appeals also has rejected the vitality of *Wilder*. In *Jones v. District of Columbia*, 996 A.2d 834, 845 (D.C. 2010), the court found no enforceable rights among several sections of the Medicaid Act and rejected plaintiffs’ reliance on *Wilder* because “the Court’s *Gonzaga* decision in 2002 was a game-changer for § 1983 suits.”

To add to the confusion, even when they accept the general proposition that at least some Medicaid plan \*14 requirements might be enforceable, lower courts routinely disagree as to which ones are. Cases listed in an Appendix to this brief demonstrate both the frequency with which such private Medicaid Act claims arise and the need for guidance in addressing them.

\*\*\*

As the multiple divergent circuit decisions demonstrate, the Court’s intervention with respect to private Medicaid Act enforcement is necessary. It should take this case to confirm its repudiation of *Wilder* by holding that the Medicaid Act - or at the very least its plan requirements provision - is not privately enforceable under Section 1983.

## II. Medicaid Act Plan Requirements Govern State-HHS Agreements Without Conferring Individually Enforceable Rights

Selective private enforcement of Medicaid plan requirements through Section 1983 is particularly troublesome because, without the *Wilder* decision as an overlay, no portion of 42 U.S.C. section 1396a(a) can reasonably be read to confer individual rights. The Medicaid Act is not a civil rights statute imposing duties and restraints on States with respect to healthcare financing. Rather, it creates a program that States may elect to use to finance their own healthcare benefits for the poor and disabled. Under the Medicaid model, States may establish healthcare \*15 benefits programs and, if their programs are satisfactory to the Secretary of Health and Human Services, seek federal matching grants.

In particular, Section 1396a(a) establishes conditions under which States may qualify to receive federal funding and begins as follows: “A State plan for medical assistance must ....” 42 U.S.C § 1396a(a). Each subsection then delineates requirements and prohibitions (with varying degrees of specificity) for State plans to qualify for federal matching grants. In context, these provisions say nothing about individual rights, even if some may incidentally yield individually recognizable benefits.

The Medicaid Act provides discretion for States in designing and administering their programs within broad federal guidelines. A few baseline requirements exist, such as providing coverage to “categorically needy” groups for certain basic services. See Barbara S. Klees, Christian J. Wolfe & Catherine A. Curtis, Ctrs. for Medicare & Medicaid Servs., *Brief Summaries of Medicare & Medicaid: Title XVIII & Title XIX of The Social Securities Act 23-27* (Nov. 20, 2017), available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/Medicare MedicaidSummaries2017.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/Medicare%20MedicaidSummaries2017.pdf). In virtually all other matters, however, States can choose the most suitable options. They can, for example, establish eligibility standards, opt to provide coverage for other medical \*16 services, define the amount, duration, and scope of services, and determine the payment methodology and payment rate for services. *Id.* at 23-30. The Secretary determines whether the State has met the requirements of the Act and, if not, whether to dock some or all of a non-conforming State’s funding. See 42 U.S.C. § 1396c; 42 C.F.R. § 430.12(c).

Thus, by its terms, the Medicaid Act imposes legal obligations only on the Secretary, who must ensure that States substantially comply with plan requirements before approving federal matching grants. *See* 42 U.S.C. § 1396c. If the Secretary finds that a state plan “has been so changed that it no longer complies” with the requirements of Section 1396a or that “in the administration of the plan there is a failure to comply substantially with any such provision[,]” then the Secretary “shall notify [the] State [] that further payments will not be made to the State.” *Id.* Payments will be discontinued “until the Secretary is satisfied that there will no longer be any such failure to comply.” *Id.* Or, rather than cutting off payments completely, the Secretary may, in her discretion, “limit payments to categories under or parts of the State plan not affected by [the] failure [to comply].” *Id.*

Critically, States are in no way obligated to implement a Medicaid program in accordance with the conditions required for federal funding. *See, e.g., Harris v. McRae*, 448 U.S. 297, 301 (1980) (“participation in the Medicaid program is entirely optional”). States \*17 participating in Medicaid remain free to amend their programs, even if that means the Secretary will deny federal funding as a consequence. *See* 42 U.S.C. § 1396c; 42 C.F.R. § 430.12(c). Even after a state accepts federal funds, Section 1396c recognizes that state’s continuing prerogative to alter its Medicaid program. Any State that administers a non-compliant program runs the risk that the Secretary will turn off the funding spigot, but this remains a *lawful* option for the State under the statute. “[T]he *sole remedy* Congress provided for a State’s failure to comply with Medicaid’s requirements - for the State’s ‘breach’ of the Spending Clause contract - is the withholding of Medicaid funds by the Secretary of Health and Human Services.” *Armstrong*, 135 S. Ct. at 1385 (emphasis added).

Moreover, allowing a private cause of action to enforce the Medicaid provider-choice provision would disregard the administrative process that Congress envisioned as Medicaid’s primary enforcement mechanism. As the Eighth Circuit recognized in *Does*, federal lawsuits under Section 1983 “would result in a curious system for review of a State’s determination that a Medicaid provider is not ‘qualified.’” 867 F.3d at 1041. The Medicaid Act “requires that when a state terminates a Medicaid provider, the state must afford the provider an opportunity for administrative appeal and judicial review in the state courts.” *Id.* If “individual patients separately could litigate or relitigate the \*18 qualifications of the provider in federal court,” the inevitable result will be “parallel litigation and inconsistent results.” *Id.* at 1041-42.

Allowing a private right of action under the provider-choice provision for Medicaid recipients would frustrate both the federal-state contract that the Medicaid Act creates and the Congressionally-intended enforcement mechanism of state administrative review processes.

### III. The Meaning of “Qualified Provider” Is a Function of the State Medicaid Plan Approved by HHS, Not Simply the Medicaid Act

The decision below illustrates one of the significant structural risks - namely, erosion of political accountability for enforcing the terms of federal-state grant programs - that can arise when private parties bring actions in federal court to enforce their view of the meaning of federal law without an accompanying federal right at stake.

To determine the meaning of “qualified provider” under the Medicaid Act, it is necessary to look not only at the Act itself, but also at the contract that it sets up between states and the federal government. The Medicaid Act provides that “any individual eligible for medical assistance ... may obtain such assistance from any institution ... *qualified* to perform the \*19 service or services required.” 42 U.S.C. § 1396a(a)(23) (emphasis added). The Act does not define “qualified.” However, federal regulations provide that “a State may exclude any individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude the individual or entity from participation” or “for any reason ... authorized by state law.” 42 C.F.R. § 1002.3 (implementing 42 U.S.C. § 1396a(p)(1)). Thus, the definition of a “qualified” healthcare provider must be governed in reference to the State Medicaid plan, which in turn is governed by State and federal statutes and regulations.

The Kansas Administrative Regulations provide a list of reasons for terminating a provider’s Medicaid agreement, including, but not limited to, voluntary withdrawal, non-compliance with state law or its Medicaid provider agreement, and unethical or unprofessional conduct. Kan. Admin. Regs. § 30-5-60(a). Similarly, federal law authorizes exclusion “for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity,” 42 U.S.C. § 1320a-7(b)(5)(B), and for “fail[ing] to grant immediate access ... [to] the State agency, to perform the reviews and surveys required under State plans.” 42 U.S.C. § 1320a-7(b)(12). Kansas’s Medicaid plan, which has been approved by the Secretary of Health and Human Services, sets forth these reasons for terminating a provider’s Medicaid agreement. *See* Kan. Admin. Regs. § 30-5-60(a). \*20 Indeed, when it terminated Planned Parenthood’s provider agreement, Kansas invoked four paragraphs from its regulations: “(2) noncompliance with applicable state laws, administrative regulations, or program issuances concerning medical providers; (3) noncompliance with the terms of a

provider agreement; (9) unethical or unprofessional conduct; and (17) other good cause.” Kan. Admin. Regs. § 30-5-60(a).

In terms of contesting application of the Kansas plan to its situation, Planned Parenthood should have pursued state administrative and judicial review remedies. Kan. Stat. §§ 77-601-31; Kan. Admin. Regs. §§ 30-7-67-68. But in terms of whether Kansas’s Medicaid plan itself violates the terms of the Medicaid Act, it is the responsibility of the federal government to make that determination in the first instance, since, after all, it is federal money that is at stake. *See* 42 U.S.C. § 1396a(b).

The Tenth Circuit purported to accept the Kansas regulations as valid determiners of a healthcare provider’s qualification to receive Medicaid funding, yet disregarded Kansas’s application of those standards. *See Andersen*, 882 F.3d at 1230-31. That decision interferes with the comprehensive planning and review system embodied by federal and State Medicaid statutes, regulations, and plan documents. Ultimately, it vitiates the political accountability that safeguards proper administration of Medicaid. Such structural \*21 risks are a consequence of permitting private plaintiffs to enforce federal statutes that do not confer federal rights.

The Court should grant certiorari and reverse.

### CONCLUSION

The Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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## Footnotes

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<sup>1</sup> Pursuant to Supreme Court Rule 37.2(a), counsel of record for all parties have received notice of the Amici States' intention to file this brief at least 10 days prior to the due date of this brief.

<sup>2</sup> Relatedly, in *Briggs v. Bremby*, 792 F.3d 239, 244 (2d Cir. 2015), the court permitted private enforcement of the Food Stamp Act under Section 1983 by analogizing it to the Medicaid Act and concluding that *Gonzaga* did not undercut *Wilder*.

\* *Counsel of Record*

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# PARRISH

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2018 WL 1725385  
United States Bankruptcy Court, E.D. North Carolina.

IN RE: Angela Boykin PARRISH, Debtor  
CASE NO. 17-02341-5-SWH

|  
SIGNED April 6, 2018

## Attorneys and Law Firms

William F. Braziel, III, William E. Brewer, Jr., Janvier Law Firm, PLLC, Raleigh, NC, for Debtor.

## ORDER ALLOWING OBJECTION TO CLAIM

Stephani W. Humrickhouse, United States Bankruptcy Judge

\*1 The issue before the court is whether the “individual shared responsibility payment” (the “ISRP”) imposed for failure to obtain health insurance under the Affordable Care Act, 26 U.S.C. § 5000 (the “ACA”), is a tax or a penalty for purposes of 11 U.S.C. § 507(a). A hearing took place in Raleigh, North Carolina on February 22, 2018.

## BACKGROUND

Angela Boykin Parrish filed a voluntary petition for relief under chapter 13 of the Bankruptcy Code on May 10, 2017. On her 2016 federal tax return, Ms. Parrish indicated that she owed an ISRP of \$664.00, arising from her failure to obtain health insurance as required by the ACA. Based on the 2016 tax return, the Internal Revenue Service (“IRS”) assessed Ms. Parrish in the amount of \$664.00, and filed a proof of claim in that amount. Claim No. 1-1. The claim indicates that it is for a tax or penalty owed to the government entitled to priority under 11 U.S.C. § 507(a)(8). Claim No. 1-1 at 3, ¶ 12. An attachment to the claim provides that the “Kind of Tax” is “Excise.” *Id.* at 4.

On September 26, 2017, Ms. Parrish filed an objection to the claim filed by the IRS, Dkt. 13, which was amended on October 3, 2017, Dkt. 15. Ms. Parrish contends that the ISRP is not an excise tax, but is instead a penalty that is not entitled to priority under 11 U.S.C. § 507(a)(8). The IRS filed a response on December 4, 2017, Dkt. 27, setting forth the legal basis for its position that the ISRP is a tax. Ms. Parrish submitted a brief on January 21, 2018, Dkt. 32, and a submission in supplemental support on February 21, 2018, Dkt. 36.

## DISCUSSION

Section 507(a)(8) provides for priority treatment of “allowed unsecured claims of governmental units, only to the extent such claims are for—... (E) an excise tax ...; or (G) a penalty related to a claim of a kind specified in this paragraph and in compensation for actual pecuniary loss.” 11 U.S.C. § 523(a)(8). The parties agree that the ISRP is not a penalty as described by (G), but the IRS maintains that the ISRP is either an income tax or an excise tax, while Ms. Parrish contends that it is a penalty that is not entitled to any priority under the Bankruptcy Code. The IRS has the burden of proof to establish that its claim is entitled to priority. *In re Bradford*, 534 B.R. 839, 842 (Bankr. M.D. Ga. 2015) (citing *In re Firearms Imp. & Exp. Corp. v. United Capitol Ins. Co. (In re Firearms Imp. & Exp. Corp.)*, 131 B.R. 1009, 1015 (Bankr. S.D. Fla. 1991).

The ACA established an “individual mandate” requiring most Americans to maintain “minimum essential” health insurance coverage. 26 U.S.C. § 5000A(a).<sup>1</sup> The failure to obtain that insurance results in the ISRP, which is called a “penalty” within the statute. 26 U.S.C. § 5000A(b).<sup>2</sup> However, the parties agree that the label given to an exaction by Congress is not controlling for purposes of determining bankruptcy classification. Instead, courts must look to how that exaction functions. *See United States v. Reorganized CF & I Fabricators of Utah, Inc.*, 518 U.S. 213 (1996) (“On a number of occasions, this Court considered whether a particular exaction, whether or not called a “tax” in the statute creating it, was a tax for purposes of [bankruptcy priority], and in every one of those cases the Court looked behind the label placed on the exaction and rested its answer directly on the operation of the provision using the term in question.”).

**\*2** The IRS maintains that the Supreme Court of the United States, in a binding determination, has already performed a functional analysis and concluded that the ISRP is a tax. Indeed, the Court considered the ISRP in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012), reviewing a constitutional challenge to the ACA as a whole and the ISRP in particular. In *Sebelius*, the Court described the ISRP as follows:

Beginning in 2014, those who do not comply with the mandate must make a “[s]hared responsibility payment” to the Federal Government. § 5000A(b)(1). That payment, which the Act describes as a “penalty,” is calculated as a percentage of household income, subject to a floor based on a specified dollar amount and a ceiling based on the average annual premium the individual would have to pay for qualifying private health insurance. § 5000A(c). In 2016, for example, the penalty will be 2.5 percent of an individual’s household income, but no less than \$695 and no more than the average yearly premium for insurance that covers 60 percent of the cost of 10 specified services (e.g., prescription drugs and hospitalization). *Ibid.*; 42 U.S.C. § 18022. The Act provides that the penalty will be paid to the Internal Revenue Service with an individual’s taxes, and “shall be assessed and collected in the same manner” as tax penalties, such as the penalty for claiming too large an income tax refund. 26 U.S.C. § 5000A(g)(1). The Act, however, bars the IRS from using several of its normal enforcement tools, such as criminal prosecutions and levies. § 5000A(g)(2). And some individuals who are subject to the mandate are nonetheless exempt from the penalty—for example, those with income below a certain threshold and members of Indian tribes. § 5000A(e).

567 U.S. at 539–40.

In its opinion, the Court considered the ISRP in two contexts: first, whether it was barred from reviewing it under the Anti-Injunction Act,<sup>3</sup> and second, whether the ISRP was enacted as part of the taxing authority allocated to Congress under the Constitution. The Court reached two different conclusions. First, the Court determined that the ISRP is a penalty for purposes of the Anti-Injunction Act, 567 U.S. at 546, and second, that the ISRP could reasonably be characterized as a tax for purposes of constitutionality. *Id.*, 567 U.S. at 574. In short, the Court implicitly acknowledged that the same exaction can be construed as a tax for some purposes and a penalty for others. What the Court did not do, however, is construe the ISRP as either a tax or a penalty for purposes of the Bankruptcy Code. Thus, this court must consider whether the determination that the ISRP is a tax for constitutional purposes is necessarily a determination that it is a tax for bankruptcy purposes.

In its consideration of the ISRP, the Court was first required to determine whether it had the authority to review the exaction under the Anti-Injunction Act. That Act would prohibit the review of any *tax*, but not the review of a *penalty*. See *Sebelius*, 567 U.S. at 543 (“The Anti-Injunction Act applies to suits ‘for the purpose of restraining the assessment or collection of any tax.’ [26 U.S.C.] § 7421(a) (emphasis added). Congress, however, chose to describe the ‘[s]hared responsibility payment’ imposed on those who forgo health insurance not as a ‘tax,’ but as a ‘penalty.’ §§ 5000A(b), (g)(2). There is no immediate reason to think that a statute applying to ‘any tax’ would apply to a ‘penalty.’”).

**\*3** The Court concluded that for purposes of the Anti-Injunction Act, the ISRP is a penalty, giving weight to the Congressional decision to label the ISRP as a penalty and not a tax:

Congress’s decision to label this exaction a “penalty” rather than a “tax” is significant because the Affordable Care Act describes many other exactions it creates as “taxes.” See *Thomas More [Law Center v. Obama]*, 651 F.3d [529] at 551 [6th Cir. 2011]. Where Congress uses certain language in one part of a statute and different language in another, it is generally presumed that Congress acts intentionally.

*Sebelius*, 567 U.S. at 544. (citing *Russello v. United States*, 464 U.S. 16, 23 (1983) ). The Court went on to note that “The Anti-Injunction Act and the Affordable Care Act ... are creatures of Congress’s own creation. How they relate to each other is up to Congress, and the best evidence of Congress’s intent is the statutory text.” *Id.*, 567 U.S. at 544. Finally,

In light of the Code’s consistent distinction between the terms “tax” and “assessable penalty,” we must accept the Government’s interpretation: Section 6201(a) instructs the Secretary that his authority to assess taxes includes the authority to assess penalties, but it does not equate assessable penalties to taxes for other purposes.... The Affordable Care Act does not require that the penalty for failing to comply with the individual mandate be treated as a tax for purposes of the Anti-Injunction Act.

*Id.*, 567 U.S. at 546.

However, the Court explained that the same deference is not applied to the chosen term in its analysis of the constitutional authority to impose the ISRP:

It is of course true that the Act describes the payment as a “penalty,” not a “tax.” But while that label is fatal to the application of the Anti-Injunction Act, ... it does not determine whether the payment may be viewed as an exercise of Congress’s taxing power. It is up to Congress whether to apply the Anti-Injunction Act to any particular statute, so it makes sense to be guided by Congress’s choice of label on that question. That choice does not, however, control whether an exaction is within Congress’s constitutional power to tax.

*Id.*, 567 U.S. at 564.

The Court then turned to whether the ISRP could fairly be characterized as a tax. The government maintained that the individual mandate was “not a legal command to buy insurance,” but made “going without insurance just another thing the Government taxes, like buying gasoline or earning income,” that is within Congress’s constitutional power to tax. *Id.*, 567 U.S. at 563. The Court framed its inquiry as follows:

The question is not whether that is the most natural interpretation of the mandate, but only whether it is a “fairly possible” one. *Crowell v. Benson*, 285 U.S. 22, 62, 52 S.Ct. 285, 76 L.Ed. 598 (1932). As we have explained, “every reasonable construction must be resorted to, in order to save a statute from unconstitutionality.” *Hooper v. California*, 155 U.S. 648, 657, 15 S.Ct. 207, 39 L.Ed. 297 (1895). The Government asks us to interpret the mandate as imposing a tax, if it would otherwise violate the Constitution. Granting the Act the full measure of deference owed to federal statutes, it can be so read, for the reasons set forth below.

\*4 *Id.*, 567 U.S. at 563.

The Court then identified some characteristics that made the exaction “look [ ] like a tax:” (1) the ISRP is paid into the Treasury when taxpayers file their tax returns; (2) it does not apply to individuals who do not pay federal income taxes because their income is below the filing threshold; (3) the amount is determined by taxable income, number of dependents, and filing status; (4) the requirement to pay is in the Internal Revenue Code, is enforced by the IRS, and collected in the same manner as taxes; and (5) it produces some revenue for the government. *Id.*, 567 U.S. at 563–64. The Court concluded that “The Affordable Care Act’s requirement that individuals pay a financial penalty for not obtaining health insurance **may reasonably be characterized** as a tax.” *Id.*, 567 U.S. at 574 (emphasis added).

The Court was clear that it did not hold that the ISRP must be construed as a tax, only that it reasonably could be—which is all that is needed to establish its constitutionality.<sup>4</sup> The same conclusion was reached in *In re Bradford*, 534 B.R. 839 (Bankr. M.D. Ga. 2015), which considered whether the “early withdrawal” assessment for retirement accounts was a tax or a penalty for purposes of § 507 of the Bankruptcy Code. After a detailed review of the case law on the tax/penalty distinction including *Sebelius*, that court observed that

... the majority in [*Sebelius*] was applying the most lenient test reasonably possible to construe the characteristics of the ACA to be sufficiently noncriminal to render the ACA supportable as a tax under the Constitution; in doing so, the majority was not looking for the “most natural interpretation” of the ACA’s characteristics, but only “a fairly possible one.” *Id.* [132 S.Ct.] at 2594. Accordingly, the fact that the Court concluded its analysis after examining the characteristics of penalties in *Drexel Furniture* and *CF & I* does not mean that these cases contain an exhaustive list of the characteristics of penalties in the context of the Constitution, and still less § 507 of the Bankruptcy Code.

*Bradford*, 534 B.R. at 856.

Taking *Sebelius* as a whole, the Court found that the same exaction could be considered either a tax or a penalty, depending on the context, and that the ACA does not *require* one reading or the other. Further, the Court did not consider the question for purposes of the Bankruptcy Code, and its determination for purposes of constitutionality is not the end of the analysis for this court. *See also Bradford*, 534 B.R. at 857 (“if the Supreme Court wanted to reshape the definition of ‘tax’ for the purpose of § 507(a)(8), it likely would not do so in such an obtuse manner. For these reasons, [*Sebelius*] cannot be viewed as the Supreme Court merely ‘revisiting’ and applying *CF & I* to the ACA, such that [*Sebelius*] now governs the definition of ‘tax’ in § 507(a)(8) of the Bankruptcy Code.”).

**\*5** Having determined that *Sebelius* does not mandate the conclusion that the ISRP is a tax for purposes of § 507(a), this court returns to the standards previously established to determine whether an exaction is a tax or penalty. In *CF & I*, the Court adopted the general framework from *United States v. La Franca*, 282 U.S. 568, 572 (1931), that “[a] tax is an enforced contribution to provide for the support of government; a penalty, as the word is here used, is an exaction imposed by statute as punishment for an unlawful act” as “sufficient for the decision of this case.” *CF & I*, 518 U.S. at 224.

Locally, in *In re Cespedes*, 393 B.R. 403 (Bankr. E.D.N.C. 2008), this court considered whether “unlawfulness” is a necessary component for an exaction to be a penalty as opposed to a tax, finding that *CF & I* does not mandate that interpretation. In *Cespedes*, the assessment at issue arose from early withdrawal from the debtor’s retirement accounts, an act that is not unlawful. “Because the exaction in question in *CF & I* was related to an unlawful omission, it was not necessary for the Court to consider whether a penalty could also apply to an act or omission that was lawful, but discouraged.” *Cespedes*, 393 B.R. at 408. The *Cespedes* court concluded that nothing in *CF & I* mandated a finding that the early withdrawal assessment was a tax, and held that it was instead a non-priority penalty. *Id.*, 393 B.R. at 409. See also *Bradford*, 534 B.R. 839 (concluding that *CF & I* did not establish a standard requiring an exaction to arise out of *unlawful* activity to constitute a penalty).

Because the action that results in an exaction does not have to be unlawful, the *CF & I* standard can be restated as follows: a “tax is an enforced contribution to provide for the support of government;” while a penalty is an exaction imposed by statute as punishment for an act or omission that is discouraged. Ms. Parrish contends that the primary purpose of the ISRP is not to raise revenue to fund government operations, but to “enhance the goal of obtaining universal health insurance for all Americans,” which is “facilitated by penalizing people who forgo medical insurance.” Debtor’s Brief in Support of Objection to Claim, Dkt. 32 at 9 (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1501(a)(2)(G), 124 Stat. 119, 243 (2010)).<sup>5</sup>

The IRS maintains that the analysis is purely a functional one, and contends that a “primary purpose” inquiry is improper, as it has not been adopted by either the Supreme Court or the Fourth Circuit. The IRS, as the party with the burden of proof, did not present any evidence or provide further detail related to the ISRP other than the statute itself and the analysis in *Sebelius*. Instead, it contends first that *Sebelius* conclusively answers the question by applying a functional analysis and determining that the ISRP is a tax, and second that simply referring to the definitions of income tax and excise tax leads to a finding that the ISRP is a tax entitled to priority under § 507(a)(8). Specifically, the IRS asserts that an “income tax” is calculated based on income, which the ISRP can be, and an excise tax is “any tax imposed on a particular act, event, (non)occurrence, or exercise of a right or privilege.” United States of America’s Response to Debtor’s Objection to IRS Claim, Dkt. 27 at 7 (citing *In re Rizzo*, 741 F.3d 703, 706 (6th Cir. 2014)). “Because the law at times imposes a fixed amount as the shared responsibility payment on individuals who elect not to purchase health insurance coverage, it also functions as an excise tax.” *Id.*

**\*6** Of course, if simple reference to definitions resolved the issue, the complex case history would not exist. Thus, the court returns to the *CF & I* characterizations of funding the government or penalizing an act or omission. Further, many exactions have characteristics of both a tax and a penalty, and the court must use some test to determine whether an exaction is *more like* a tax or more like a penalty. For that reason, the “primary purpose” of the exaction is informative if not determinative.

As summarized above, the *Sebelius* Court identified several factors that make the ISRP “look like” a tax: (1) the ISRP is paid into the Treasury when taxpayers file their tax returns; (2) it does not apply to individuals who do not pay federal income taxes because their income is below the filing threshold; (3) the amount is determined by taxable income, number of dependents, and filing status; (4) the requirement to pay is in the Internal Revenue Code, is enforced by the IRS, and collected in the same manner as taxes; and (5) it produces some revenue for the government. However, even in *Sebelius* items one and four did not *mandate* a finding that the ISRP is a tax, as the Court cited guidance for how the assessment is to be collected as support for its finding that the ISRP is not a tax for purposes of the Anti-Injunction Act:

... “Assessment” and “Collection” are chapters of the Internal Revenue Code providing the Secretary authority to assess and collect taxes, and generally specifying the means by which he shall do so. See § 6201 (assessment authority); § 6301 (collection authority). Section 5000A(g)(1)’s command that the penalty be “assessed and collected in the same manner” as taxes is best read as referring to those chapters and giving the Secretary the same authority and guidance with respect to the penalty. That interpretation is consistent with the remainder of § 5000A(g), which instructs the Secretary on the tools he may use to collect the penalty. See § 5000A(g)(2)(A) (barring criminal prosecutions); § 5000A(g)(2)(B) (prohibiting the Secretary from using notices of lien and levies).

*Sebelius*, 567 U.S. at 545. Similarly, with respect to the revenue-generating component, the Supreme Court noted that “[a]lthough the payment will raise considerable revenue, it is plainly designed to expand health insurance coverage.” *Sebelius*, 567 U.S. at 567.

In February, a Louisiana bankruptcy court described several distinctions between the ISRP and a tax. *In re Chesteen*, No. 17-11472, 2018 WL 878847, at \*3 (E.D. La. Feb. 9, 2018).

Applying the principles of *CF & I* to the case at bar, it is apparent that the ACA individual mandate is a penalty designed to deter citizens from living without health insurance. Under the ACA, if an individual does not maintain health insurance, the “only consequence is that he must make an additional payment to the IRS when he pays his taxes.” [*Bradford*, 534 B.R. at 854.] Failure to make the ACA individual mandate payment does not result in any of the typical consequences that result from non-payment of taxes, e.g. wage garnishments, tax liens, etc. Rather, an individual who fails to make the ACA individual mandate payment is penalized by having the exaction deducted out of future tax returns.

The *Chesteen* court concluded, “Congress’s primary, or dominant, purpose of imposing the individual mandate of the ACA was not to support or fund the government fiscally, but to discourage Americans from living without health insurance coverage. Therefore ... it is not a tax within the meaning of § 507(a)(8).” *Id.*

**\*7** The Supreme Court observed that the question of the nature of the ISRP for purposes of its constitutionality “is not whether that is the most natural interpretation of the mandate, but only whether it is a ‘fairly possible’ one,” *Sebelius*, 567 U.S. at 563, and then found that the ISRP “may reasonably be characterized as a tax.” *Id.*, 567 U.S. at 574. Here, the burden on the IRS is to prove it more than “fairly possible” that the ISRP is a tax, a burden it did not meet.

This court finds that the most natural reading, for purposes of the Bankruptcy Code, is that the ISRP is a penalty. As noted in *Chesteen*, the nature of the consequences for failure to pay the ISRP distinguish the ISRP from a tax. As discussed in *Sebelius*, the collection and assessment by IRS is merely a mechanism to enforce and is not determinative. Further, the fact that the amount of the ISRP is calculated with reference to the debtor’s income does not make it an income tax, as its assessment is not dependent on income, it is dependent upon the failure to purchase health insurance. Finally, the ISRP has a revenue-generating component only if the goal of the ACA—health care coverage for all—fails, such that the revenue impact (while possibly significant) is incidental. Taken together with the primary purpose of the ISRP, to encourage people to buy insurance by penalizing those who do not, the court determines that the ISRP is a penalty for purposes of § 507(a) of the Bankruptcy Code.

## CONCLUSION

Based on the foregoing, the debtor’s objection to the claim filed by the IRS is ALLOWED. The claim of the IRS is not entitled to priority under 11 U.S.C. § 507(a)(8), and but is allowed in the amount of \$664.00 as a general unsecured claim.

### All Citations

Slip Copy, 2018 WL 1725385, 121 A.F.T.R.2d 2018-1413

### Footnotes

- <sup>1</sup> The relevant provision reads: “(a) Requirement to maintain minimum essential coverage.—An applicable individual shall for each month beginning after 2013 ensure that the individual, and any dependent of the individual who is an applicable individual, is covered under minimum essential coverage for such month.” 26 U.S.C. § 5000A(a).
- <sup>2</sup> “(b) Shared responsibility payment.—(1) In general.—If a taxpayer who is an applicable individual ... fails to meet the requirement of subsection (a) for 1 or more months, then, except as provided in subsection (e), there is hereby imposed on the taxpayer a **penalty** with respect to such failures in the amount determined under subsection (c).” 26 U.S.C. § 5000A(b)(1) (emphasis added).
- <sup>3</sup> The Anti-Injunction Act provides that “no suit for the purpose of retraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed.” 26 U.S.C. § 7421(a).

<sup>4</sup> Indeed, if it were the reverse, the Court would have been unable to reach the conclusion that for purposes of the Anti-Injunction Act, the ISRP is a penalty. And, in its analysis under the Anti-Injunction Act, the Court found that the ACA “does not require that the penalty for failing to comply with the individual mandate be treated as a tax for purposes of the Anti-Injunction Act.” *Sibelius*, 567 U.S at 546.

<sup>5</sup> That provision reads,

(G) Under sections 2704 and 2705 of the Public Health Service Act (as added by section 1201 of this Act), if there were no requirement, many individuals would wait to purchase health insurance until they needed care. By significantly increasing health insurance coverage, the requirement, together with the other provisions of this Act, will minimize this adverse selection and broaden the health insurance risk pool to include healthy individuals, which will lower health insurance premiums. The requirement is essential to creating effective health insurance markets in which improved health insurance products that are guaranteed issue and do not exclude coverage of pre-existing conditions can be sold.

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# LITTLE SISTERS

2018 WL 1916034

Only the Westlaw citation is currently available.

United States Court of Appeals, Third Circuit.

COMMONWEALTH OF PENNSYLVANIA

v.

PRESIDENT UNITED STATES OF AMERICA; Acting Secretary of United States Department of Health and Human Services; United States Department of Health and Human Services; Secretary of the Treasury; United States Department of the Treasury; Secretary United States Department of Labor; United States Department of Labor\*Little Sisters of the Poor Saints Peter and Paul Home, Appellant

No. 17-3679

Argued March 23, 2018

(Filed: April 24, 2018)

## Synopsis

**Background:** State brought action challenging interim final rules allowing employers to opt out of providing no-cost contraceptive coverage under Patient Protection and Affordable Care Act (ACA) on basis of sincerely held religious beliefs or moral convictions. Religious nonprofit employer moved to intervene. The United States District Court for the Eastern District of Pennsylvania, No. 2-17-cv-4540, Wendy Beetlestone, J., 2017 WL 6206133, denied motion, and organization appealed.

**Holdings:** The Court of Appeals, Hardiman, Circuit Judge, held that:

- <sup>[1]</sup> employer had sufficient interest in preserving religious exemption;
- <sup>[2]</sup> action posed sufficiently tangible threat to employer's interests; and
- <sup>[3]</sup> employer's interests were not sufficiently represented by federal government.

Reversed and remanded.

West Headnotes (10)

### <sup>[1]</sup> Federal Courts

🔑 Parties and Process

Denial of motion to intervene as of right is final, appealable order. 28 U.S.C.A. § 1291; Fed. R. Civ. P. 24(a).

Cases that cite this headnote

### <sup>[2]</sup> Federal Courts

🔑 Parties

Court of Appeals will overturn district court's order denying motion to intervene as of right only if court has abused its discretion by applying improper legal standard or by reaching conclusion it is confident is incorrect. Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[3] Federal Courts**

🔑 Parties

Court of Appeals reviews orders denying motions for permissive intervention for abuse of discretion, but is reluctant to intrude into such highly discretionary decisions. Fed. R. Civ. P. 24(b).

Cases that cite this headnote

**[4] Federal Civil Procedure**

🔑 Grounds and Factors

Party that has filed timely motion has right to intervene as of right if it can show: (1) sufficient interest in litigation; (2) threat that interest will be impaired or affected, as practical matter, by action's disposition; and (3) that its interest is not adequately represented by existing parties to litigation. Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[5] Federal Civil Procedure**

🔑 Interest of applicant in general

Party seeking intervention as of right must demonstrate that its interest is specific to it, is capable of definition, and will be directly affected in substantially concrete fashion by relief sought. Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[6] Federal Civil Procedure**

🔑 Insurers and insureds

Religious nonprofit employer had sufficient interest in preserving religious exemption to Patient Protection and Affordable Care Act's (ACA) contraceptive mandate to support its motion to intervene as of right in state's action challenging interim final rules (IFR) allowing employers to opt out of providing no-cost contraceptive coverage under Patient Protection and Affordable Care Act (ACA) on basis of sincerely held religious beliefs or moral convictions, where state's action called into question whether new religious exemption was required by Religious Freedom Restoration Act (RFRA) and therefore justified by bypassing notice-and-comment rulemaking to issue IFRs quickly, and employer had litigated for protection conferred by religious exemption IFR for five years. 26 U.S.C.A. § 6033(a)(3)(A)(i), (iii); Religious Freedom Restoration Act of 1993 § 3, 42 U.S.C.A. § 2000bb-1(a); Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[7] Federal Civil Procedure**

🔑 Interest of applicant in general

To meet requirement that putative intervenor's interest be in jeopardy in lawsuit, it must demonstrate that its legal interests may be affected or impaired as practical matter by action's disposition. Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[8] Federal Civil Procedure**

🔑 Insurers and insureds

State's action challenging interim final rules allowing employers to opt out of providing no-cost contraceptive coverage under Patient Protection and Affordable Care Act (ACA) on basis of sincerely held religious beliefs or moral convictions posed sufficiently tangible threat to religious nonprofit employer's interests to support employer's motion to intervene as of right, even though Supreme Court had directed parties in parallel litigation to attempt to arrive at approach that accommodated such employers' religious exercise, and employer had not lost its protection since district court had granted preliminary injunctive relief, where action had potential to declare that exemptions from self-certification accommodation were not required by Religious Freedom Restoration Act (RFRA). 26 U.S.C.A. § 6033(a)(3)(A)(i), (iii); Religious Freedom Restoration Act of 1993 § 3, 42 U.S.C.A. § 2000bb-1(a); Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[9] Federal Civil Procedure**

🔑 Inadequacy of representation of applicant's interest

On motion to intervene as of right, rebuttable presumption of adequacy of representation applies if one party is government entity charged by law with representing interests of applicant for intervention, but even when government is party, burden of establishing inadequacy of representation varies with each case. Fed. R. Civ. P. 24(a).

Cases that cite this headnote

**[10] Federal Civil Procedure**

🔑 Insurers and insureds

For purposes of evaluating religious nonprofit employer's motion to intervene as of right, its interests were not sufficiently represented by federal government in state's action challenging interim final rules (IFR) allowing employers to opt out of Patient Protection and Affordable Care Act's (ACA) contraceptive mandate on basis of sincerely held religious beliefs or moral convictions, where Supreme Court had tasked government with accommodating free exercise rights of religious objectors while protecting broader public interest in access to contraceptive methods and services, and religious and moral interests of entities covered by IFRs were numerous and varied. 26 U.S.C.A. § 6033(a)(3)(A)(i), (iii); Fed. R. Civ. P. 24(a).

Cases that cite this headnote

On Appeal from the United States District Court for the Eastern District of Pennsylvania, (D.C. No. 2-17-cv-4540), District Judge: Honorable Wendy Beetlestone

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Daniel H. Blomberg, Eric C. Rassbach, Mark L. Rienzi, Lori H. Windham [Argued], Becket Fund for Religious Liberty, 1200 New Hampshire Avenue, N.W., Suite 700, Washington, DC 20036, Nicholas M. Centrella, Conrad O'Brien, 1500 Market Street, West Towers, Suite 3900, Philadelphia, PA 19102, Attorneys for Appellant

Before: HARDIMAN, BIBAS, and ROTH, Circuit Judges.

## OPINION OF THE COURT

HARDIMAN, Circuit Judge.

**\*1** In this appeal, we review an order of the United States District Court for the Eastern District of Pennsylvania denying a motion to intervene filed by the Little Sisters of the Poor Saints Peter and Paul Home. The Little Sisters sought to intervene in litigation challenging regulations promulgated under the Patient Protection and Affordable Care Act. The District Court denied the motion, finding that the Little Sisters lacked a significantly protectable interest in the case and that their interests were adequately represented by the federal government. We will reverse.

## I

The Little Sisters of the Poor are an international Roman Catholic congregation whose mission is to serve the elderly poor of all backgrounds. They operate more than 25 homes for the elderly in the United States, all of which adhere to the same religious beliefs. Each home is separately incorporated as a nonprofit but is “operated under the control” of the larger congregation. App. 82.

Appellant in this case is a religious nonprofit corporation that operates a Little Sisters home in Pittsburgh, Pennsylvania. The Little Sisters’ interest in regulations implementing the Affordable Care Act is neither novel nor isolated. Indeed, they have been involved in litigation regarding the Affordable Care Act for years, and their attempt to intervene in this case must be considered in full context. Accordingly, we begin by describing the relevant portions of the Affordable Care Act and its regulatory scheme, along with the pertinent legal challenges filed by the Little Sisters and others.

## A

The Affordable Care Act includes a provision that requires health plans to cover certain forms of preventive care for women without cost sharing, as specified in guidelines issued by an agency of the United States Department of Health & Human Services (HHS) called the Health Resources and Services Administration. See 42 U.S.C. § 300gg-13(a)(4). Preventive care under these guidelines includes: all contraceptive methods approved by the Food & Drug Administration, sterilization procedures, and related counseling and education. Unless an exemption applies, failure to comply with the mandate renders a noncompliant employer subject to a penalty of \$100 “for each day in the noncompliance period with respect to each individual to whom such failure relates.” 26 U.S.C. § 4980D(b)(1). In common parlance, this coverage has come to be known as the “contraceptive mandate.”

In 2011, HHS, along with the United States Departments of Labor and Treasury (collectively, the Departments) promulgated interim final regulations exempting certain religious employers from the contraceptive mandate. 76 Fed. Reg. 46,621 (Aug. 3, 2011). To be eligible, a religious employer had to (1) have the inculcation of religious values as its purpose; (2) primarily employ people who share its religious tenets; (3) primarily provide services to persons who share its religious tenets; and (4) be a church, its integrated auxiliary, a convention or association of a church, or “the exclusively religious activities of any religious order.” *Id.* at 46,623; see also 26 U.S.C. § 6033(a)(3)(A)(i), (iii).

**\*2** Almost two years after the interim final regulations were promulgated, the Departments issued a final rule in response to public input and various legal challenges. 78 Fed. Reg. 39,870 (July 2, 2013). That final rule altered the definition of an eligible religious employer by dropping the first three requirements, *id.* at 39,874, and it also provided an accommodation process for religious nonprofit organizations that did not meet this new definition. Such a religious nonprofit employer could avail itself of the accommodation if it (1) had religious objections to providing coverage for some or all of the required contraceptive services; (2) was “organized and operate[d] as a nonprofit entity;” (3) “[held] itself out as a religious organization;” and (4) “self-certifie[d] that it satisfie[d] the first three criteria.” *Id.* Once an employer made this self-certification to its insurer or third-party administrator, that entity would provide the mandated contraceptive services directly to women covered under the employer’s plan. *Id.* at 39,875. Later, the Departments issued another rule that allowed entities eligible for the accommodation to directly notify HHS of a religious objection. 80 Fed. Reg. 41,318, 41,323 (July 14, 2015).<sup>1</sup> Through these two regulations, the self-certification accommodation sought to ensure that qualifying employers did not need to “contract, arrange, pay, or refer for contraceptive coverage,” but their “plan participants and beneficiaries ... [would] still benefit from separate payments for contraceptive services without cost sharing or other charge,” as required by law. 78 Fed. Reg. at 39,874.

## B

Two months after the final rule was issued in 2013, the Little Sisters of the Poor Home for the Aged, Denver, Colorado and the Little Sisters of the Poor, Baltimore, Inc. filed suit in the United States District Court for the District of Colorado. They claimed the contraceptive mandate was unconstitutional and that it violated the Religious Freedom Restoration Act (RFRA) and the Administrative Procedure Act (APA). See *Little Sisters of the Poor Home for the Aged v. Sebelius*, 6 F.Supp.3d 1225, 1232–33 (D. Colo. 2013). With respect to RFRA, the Little Sisters asserted that the self-certification accommodation would force them to “take actions that directly cause others to provide contraception or appear to participate in the Departments’ delivery scheme,” both of which would violate their religious conviction “that deliberately avoiding reproduction through medical means is immoral.” *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1167–68 (10th Cir. 2015). They sought a preliminary injunction, which the district court denied. The Tenth Circuit affirmed, holding that the regulations did not violate RFRA because they did not substantially burden religious exercise. *Id.* at 1205.

The Little Sisters sought certiorari, and the Supreme Court granted review in order to decide whether the self-certification accommodation violated RFRA. In addition to the Tenth Circuit’s decision, the Court also granted certiorari to review decisions of the Third, Fifth, and D.C. Circuits, which were consolidated as *Zubik v. Burwell*, --- U.S. ----, 136 S.Ct. 1557, 194 L.Ed.2d 696 (2016) (per curiam).

In *Zubik*, the Court did not answer the question “whether petitioners’ religious exercise ha[d] been substantially burdened.” *Id.* at 1560. Instead, it explained that both the petitioners and the government had “confirm[ed]” that “contraceptive coverage could be provided to petitioners’ employees, through petitioners’ insurance companies, without any ... notice from petitioners.” *Id.* at 1559–60. It then vacated the underlying judgments and remanded the cases, directing the parties to attempt “to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health coverage, including contraceptive coverage.” *Id.* at 1560 (internal quotation marks and citation omitted). The Court found its instruction appropriate in light of “the substantial clarification and refinement in the positions of the parties” over the course of the litigation. *Id.* Finally, it “anticipate[d] that the Courts of Appeals [would] allow the parties sufficient time to resolve any outstanding issues between them,” *id.*, and it noted that the litigation sufficed to give the government notice of the petitioners’ objections, such that “the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice,” *id.* at 1561.

## C

**\*3** Two months after *Zubik* was decided, the Departments issued a request for information on “alternative ways ... to obtain an accommodation, while still ensuring that women enrolled in the organizations’ health plans have access to seamless coverage of the full range of ... approved contraceptives without cost sharing.” 81 Fed. Reg. 47,741, 47,741 (July 22, 2016). Six months later, the Departments concluded that no such “feasible approach” existed “at this time.” DEP’T OF LABOR, FAQs About Affordable Care Act Implementation Part 36 at 4 (Jan. 9, 2017), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/ouractivities/resource-center/faqs/aca-part-36.pdf>.

In May 2017, President Trump issued an executive order that directed the Departments to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate.” Exec. Order No. 13,798, 82 Fed. Reg. 21,675, 21,675 (May 4, 2017). In response, the Departments issued two interim final rules (IFRs), one providing for a “religious exemption” and the other providing for a “moral exemption.” Most relevant to this appeal, the “religious exemption” IFR applies to “entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage,” including “for-profit entities that are not closely-held.” 82 Fed. Reg. 47,792, 47,808, 47,810 (Oct. 13, 2017). It also eliminates the need for exempt entities to comply with the self-certification accommodation and imposes no new notice requirements upon them. *Id.* at 47,808. The “moral exemption” IFR allows closely held nonprofit and for-profit entities to claim an exemption based on sincerely held moral beliefs. 82 Fed. Reg. 47,838, 47,849–52 (Oct. 13, 2017).

Five days after the IFRs were promulgated, the Commonwealth of Pennsylvania filed a civil action in the United States District Court for the Eastern District of Pennsylvania, alleging that the IFRs violate the Equal Protection and Establishment Clauses of the Constitution, Title VII of the Civil Rights Act, the Pregnancy Discrimination Act, and procedural and substantive provisions of the APA. Pennsylvania sought a declaratory judgment that both IFRs were unlawful, as well as preliminary and permanent injunctive relief. It claimed that the religious exemption IFR allows employers to opt out of providing no-cost contraceptive coverage, resulting in employees losing the preventive care mandated by the Affordable Care Act.

The Little Sisters moved to intervene either as of right under Rule 24(a) of the Federal Rules of Civil Procedure or alternatively for permissive intervention under Rule 24(b). The District Court denied the motion. It found intervention under Rule 24(a) inappropriate after concluding that the Little Sisters did not have a significantly protectable interest in the litigation and that their interests were adequately represented by the federal government. And it determined that intervention under Rule 24(b) would delay the litigation and “prejudice the interest of the parties in securing an efficient resolution” of the case. *Pennsylvania v. Trump*, 2017 WL 6206133, at \*5 (E.D. Pa. Dec. 8, 2017). The Little Sisters appealed, and a week later the District Court issued an opinion and order granting Pennsylvania’s request for preliminary injunctive relief. The federal government appealed the order granting the preliminary injunction, and this Court stayed that case pending the outcome of our decision in this appeal.

## II<sup>2</sup>

\*4 [1] [2] [3] The District Court had jurisdiction under 28 U.S.C. § 1331. “[W]e have jurisdiction under 28 U.S.C. § 1291 because the denial of a motion to intervene as of right is a final, appealable order.” *Dev. Fin. Corp. v. Alpha Hous. & Health Care, Inc.*, 54 F.3d 156, 158 (3d Cir. 1995). We will overturn a district court’s order denying a motion to intervene as of right only “if the court has abused its discretion by applying an improper legal standard or [by] reaching a conclusion we are confident is incorrect.” *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 969 (3d Cir. 1998). We also review orders denying motions to intervene under Rule 24(b) for abuse of discretion, but “[w]e are more reluctant to intrude” into these “highly discretionary” decisions. *Brody ex rel. Sugzdinis v. Spang*, 957 F.2d 1108, 1115 (3d Cir. 1992).

## III

[4] A party that has filed a timely motion has a right to intervene under Rule 24(a) if it can show three things: (1) a sufficient interest in the litigation; (2) “a threat that the interest will be impaired or affected, as a practical matter, by the disposition of the action”; and (3) that its interest is not adequately represented by the existing parties to the litigation. *Kleissler*, 157 F.3d at 969. Since there is no dispute that the Little Sisters’ motion was timely, we consider these three elements in turn.

## A

[5] Did the Little Sisters demonstrate a sufficient interest in the litigation? To meet this prong, the Supreme Court has held that an applicant must assert an interest that is “significantly protectable.” *Donaldson v. United States*, 400 U.S. 517, 531, 91 S.Ct. 534, 27 L.Ed.2d 580 (1971). We have interpreted this to mean “a cognizable legal interest, and not simply an interest of a general and indefinite character.” *Brody*, 957 F.2d at 1116 (internal quotation marks and citation omitted). An applicant must therefore demonstrate that its interest is “specific to [it], is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought.” *Kleissler*, 157 F.3d at 972. Given these standards, it is not surprising that “[t]he facts assume overwhelming importance in each decision.” *Id.*

The Little Sisters seek to intervene to defend only the portions of the religious exemption IFR that apply to them. See *Benjamin ex rel. Yock v. Dep’t of Pub. Welfare*, 701 F.3d 938, 951 (3d Cir. 2012) (noting that a “proposed intervenor[ ] need not possess an interest in each and every aspect of the litigation” and “[is] entitled to intervene as to specific issues so long as their interest in those issues is significantly protectable” (citation omitted) ). In their motion, the Little Sisters argued that the civil action brought by the Commonwealth would harm them by narrowing or eliminating the protection conferred by the Supreme Court in *Zubik* and by invalidating the regulatory protection afforded to them under the IFR. If those things come to pass, the Little Sisters claim, they will be “forced to choose between violating their faith and paying crippling fines.” ECF 19-1 at 12 (Mem. of Law in Support of Mot. to Intervene).

[6] Contrary to the District Court’s decision, we agree with the Little Sisters that their interest in preserving the religious exemption is concrete and capable of definition. We also agree that the relationships among the various homes run by the Little Sisters of the Poor Congregation, including the two entities that were parties in *Zubik*, confirm that the Little Sisters have a unique interest compared to other religious objectors who might wish to intervene. We therefore conclude that those interests are significantly protectable.

\*5 First, the Little Sisters have a significantly protectable interest in the continued protection afforded by *Zubik*. This litigation has the potential to reopen issues that turn on the meaning of RFRA as it bears on self-certification, potentially influencing any substantive outcome. The Commonwealth’s APA challenge calls into question whether the new religious exemption is required by RFRA and therefore justifies bypassing notice-and-comment rulemaking to issue the IFRs quickly. If this Court were to reach the RFRA issue, we would be answering the very question the Supreme Court chose not to address in *Zubik*, i.e., whether the self-certification process

imposes a substantial burden on the Little Sisters' sincerely held religious beliefs. Answering that question in the negative surely would impair the protection conferred by *Zubik*.

Second, the Little Sisters have a significantly protectable interest in the religious exemption IFR, since it constitutes the very "approach" contemplated by *Zubik*. 82 Fed. Reg. at 47,814 ("These [IFRs] provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year."). The Little Sisters have litigated for the protection conferred by the religious exemption IFR for five years, and the IFR describes the Little Sisters as one impetus for change. *Id.* at 47,798. It stands to reason, then, that the Little Sisters have a significantly protectable interest in whether the approach contemplated by *Zubik*, as manifested in the religious exemption IFR, ultimately prevails.

We faced an analogous scenario in *Kleissler*, where one of the timber companies had won a bid for a contract, and the bid was threatened by an environmental suit against the municipality. 157 F.3d at 973. We granted intervention as of right, reasoning that the accepted bid, while not a contract, amounted to a protectable legal interest. *Id.* The same logic applies here.

For all of these reasons, the Little Sisters have demonstrated that this litigation implicates their legally cognizable interests relating to both the religious exemption IFR and *Zubik*. We are confident the District Court erred in holding otherwise.

## B

<sup>17</sup>Having concluded that the Little Sisters have a sufficient interest in the litigation, we now consider whether that interest "is in jeopardy in the lawsuit." *Brody*, 957 F.2d at 1122. To meet this requirement, an applicant "must demonstrate that [its] legal interests may be affected or impaired[ ] as a practical matter by the disposition of the action." *Id.* (citation omitted). However, "[i]t is not sufficient that the claim be incidentally affected; rather, there must be a tangible threat to the applicant's legal interest." *Id.* at 1123 (internal quotation marks and citation omitted). Because our focus is on the "practical consequences" of the litigation, we "may consider any significant legal effect on the applicant's interest," including a decision's stare decisis effect or a proposed remedy's impact on the applicant for intervention. *Id.* at 1122–23 (citation omitted). We have also stated a "policy preference which, as a matter of judicial economy, favors intervention over subsequent collateral attacks." *Kleissler*, 157 F.3d at 970 (citation omitted).

Thus, we must determine whether the Commonwealth of Pennsylvania's civil action poses a tangible threat to the Little Sisters' interests. In arguing that no threat exists, the Commonwealth claims that the injunctive and declaratory relief it seeks will simply preserve the status quo, under which *Zubik* "fully protect[s]" the Little Sisters from the imposition of fines. Commonwealth Br. 19. To support this argument, Pennsylvania emphasizes that the Little Sisters have not lost their protection under *Zubik* in the months since the District Court granted preliminary injunctive relief, so "no outcome in this case presents a 'tangible threat' to the Little Sisters' 'legally cognizable' interests." *Id.*

\*6 <sup>18</sup>We disagree with this view, which the District Court adopted, and we conclude that the Commonwealth's contentions are based on an incomplete reading of *Zubik*. Far from providing permanent protection, *Zubik* afforded the parties merely "an opportunity" to arrive at a suitable compromise. 136 S.Ct. at 1560. Furthermore, the Supreme Court instructed the courts of appeals to provide the parties with "sufficient time" to settle their differences. *Id.* But what if the parties are unable to settle their differences within what the courts of appeals deem "sufficient time"? In that event, the appellate courts will have no choice but to revisit the merits of the RFRA questions in light of the parties' "significantly clarified" views. *See id.*

As the religious exemption IFR indicates, one court of appeals was close to reaching that point a year ago. In March of 2017, the Seventh Circuit requested "a report of an agreement to resolve the case or detailed reports on the parties' respective positions." 82 Fed. Reg. at 47,814 (quoting ECF 130, *Univ. of Notre Dame v. Sebelius*, 743 F.3d 547 (7th Cir. 2014) (No. 13-3853)).<sup>3</sup> Absent such an agreement by May 1, 2017, the Seventh Circuit "plan[ned] to schedule oral argument on the merits of the case on short notice." *Id.* The Departments subsequently notified the court of the impending rulemaking. *Id.* Though that case was later voluntarily dismissed, the Seventh Circuit's order makes clear that the Supreme Court's decision in *Zubik* lacks the kind of permanency ascribed to it by the Commonwealth here. Should the federal government have to engage in a new rulemaking process, there is no guarantee that the Little Sisters will remain protected under *Zubik*. In this regard, the District Court found that the Little Sisters have recourse through the litigation brought in the Tenth Circuit by their colleagues. However, "[a]n applicant need not ... prove that [it] would be barred from bringing a later action or that intervention constitutes the only possible avenue of relief." *Brody*, 957 F.2d at 1123.

And, as already discussed, the pending litigation poses a tangible threat to the Little Sisters' regulatory protection because it has the potential to declare that exemptions from the self-certification accommodation are not required by RFRA. Such a determination

could affect how the government proceeds in future rulemakings, including whether it provides alternatives to the self-certification accommodation. This, in turn, could affect whether the Little Sisters will remain exempt from the mandate. Accordingly, we conclude that the Little Sisters have demonstrated that they may be “practically disadvantaged by the disposition of the action.” *Benjamin*, 701 F.3d at 951 (citation omitted). They therefore meet the impairment requirement.

## C

Finally, we evaluate whether the Little Sisters have established that their interests are not adequately represented by the federal government. We have held that an applicant’s interests are not adequately represented if they diverge sufficiently from the interests of the existing party, such that “the existing party cannot devote proper attention to the applicant’s interests.” *United States v. Territory of the Virgin Islands*, 748 F.3d 514, 520 (3d Cir. 2014). This burden is generally “treated as minimal” and requires the applicant to show “that representation of his interest ‘may be’ inadequate.” *Mountain Top Condo. Ass’n v. Dave Stabbert Master Builder, Inc.*, 72 F.3d 361, 368 (3d Cir. 1995) (emphasis added) (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10, 92 S.Ct. 630, 30 L.Ed.2d 686 (1972)).

\*7 <sup>[9]</sup>Notwithstanding that minimal burden, a rebuttable presumption of adequacy applies “if one party is a government entity charged by law with representing the interests of the applicant for intervention.” *Virgin Islands*, 748 F.3d at 520 (citation omitted). But even when the government is a party, “[t]he burden of establishing inadequacy of representation ... varies with each case.” *Kleissler*, 157 F.3d at 972. For that reason, the presumption is particularly strong when the governmental and private interests “closely parallel” one another, *id.*, or are “nearly identical,” *Virgin Islands*, 748 F.3d at 525. In those cases, a proposed intervenor will overcome the presumption only with a “compelling showing.” *Id.* at 520 (quoting *Mountain Top*, 72 F.3d at 369). By contrast, “when an agency’s views are necessarily colored by its view of the public welfare rather than the more parochial views of a proposed intervenor whose interest is personal to it, the burden is comparatively light.” *Kleissler*, 157 F.3d at 972. The same holds true when the government is charged with serving “two distinct interests, which are related, but not identical.” *Trbovich*, 404 U.S. at 538, 92 S.Ct. 630.

The parties dispute the degree of divergence between the interests of the Little Sisters on the one hand and those of the federal government on the other. The Commonwealth contends that the Little Sisters and the government are in “lockstep” because they both seek to defend the validity of the IFRs. Commonwealth Br. 16. In support, the Commonwealth relies heavily on *United States v. Territory of the Virgin Islands*, 748 F.3d at 522. In that case, we held that an inmate had no right to intervene in litigation brought by the United States to remedy prison conditions because his interests were “essentially identical” to those of the federal government. *Id.* The Little Sisters respond by citing our decision in *Kleissler v. United States Forest Service*, 157 F.3d at 967, where we recognized the right of timber contractors, municipalities, and school districts to intervene in litigation brought by an environmental public interest group to enjoin logging activities in a national forest. The Little Sisters argue that here, as in *Kleissler*, the government must defend “numerous complex and conflicting interests,” *id.* at 973, including the rights of nonprofit and for-profit religious objectors, moral objectors, and women seeking access to contraceptive services. Without the right to intervene, the Little Sisters contend that their “straightforward” interests “may become lost in [this] thicket of sometimes inconsistent governmental policies.” *Id.* at 973–74.

<sup>[10]</sup>We recognize that the Little Sisters’ situation is not perfectly analogous to *Kleissler* and other cases holding that the government did not adequately represent a private party’s interests. See *Benjamin*, 701 F.3d at 958; *Kleissler*, 157 F.3d at 973–74; *Brody*, 957 F.2d at 1124. Nevertheless, the unique position in which *Zubik* has placed the federal government renders this case sufficiently similar to those decisions for us to conclude that the Little Sisters carry a “comparatively light” burden here and have overcome the presumption. See *Kleissler*, 157 F.3d at 972. First, the Little Sisters’ situation is similar to *Trbovich*, where a statute obligated the Secretary of Labor to uphold the “related[ ] but not identical” interests in enforcing the rights of union members against their union as well as the “public interest” in assuring free and democratic union elections. 404 U.S. at 538–39, 92 S.Ct. 630. *Zubik* likewise tasked the government with serving two related interests that are not identical: accommodating the free exercise rights of religious objectors while protecting the broader public interest in access to contraceptive methods and services. And like *Benjamin*, the *Zubik* compromise must balance the rights of “two groups with quite divergent desires and interests.” 701 F.3d at 958. Finally, as in *Kleissler*, the government must defend “numerous complex and conflicting interests.” 157 F.3d at 973. The religious exemption IFR applies not only to religious nonprofit corporations like the Little Sisters, but also to closely held and publicly traded for-profit corporations. And the moral exemption IFR protects parties for reasons unrelated to religion. The religious and moral interests of these entities are numerous and varied. Accordingly, there is no guarantee that the government will sufficiently attend to the Little Sisters’ specific interests as it attempts to uphold both IFRs in their entirety. See *Kleissler*, 157 F.3d at 967 (concluding that the proposed intervenors had carried their burden by showing “a reasonable doubt whether the government agency would adequately represent [their] concerns”).

\*8 The preceding discussion also demonstrates why our decision in *Virgin Islands* is inapposite. We determined there that the interests of the putative intervenor and the government were “essentially identical,” 748 F.3d at 522, but for reasons that do not apply here. First, the inmate in that case “extensively quote[d]” from the government’s pleadings, *id.* at 521, which the Little Sisters have not done. Second, the United States sought to remedy several allegedly unconstitutional prison conditions, *id.* at 518, which meant that the inmate who moved to intervene was one of “the exact constituents” the government attempted to protect, and both parties shared the same interest in ensuring that any remedy was “strictly enforced,” *id.* at 523. Unlike that situation, here the IFRs protect more than religious nonprofits like the Little Sisters, and the Little Sisters do not share the government’s interest in upholding every aspect of both IFRs. Accordingly, with an eye toward the “elasticity” and “flexibility” that Rule 24 contemplates, *Kleissler*, 157 F.3d at 970, 971, and cognizant of the highly fact-bound nature of requests to intervene under Rule 24(a), we conclude that the Little Sisters’ interests may not be adequately represented by the federal government.<sup>4</sup> Therefore, we must reject the District Court’s contrary holding, which improperly applied our precedent.

## IV

For the reasons stated, we will reverse the District Court’s order denying the Little Sisters’ motion to intervene under Rule 24(a), and we will remand the case to permit intervention for the purpose of defending the portions of the religious exemption IFR that apply to religious nonprofit entities.

**All Citations**

--- F.3d ----, 2018 WL 1916034

## Footnotes

\* Pursuant to Fed. R. App. P. 12(a)

<sup>1</sup> In response to *Burwell v. HobbyLobbyStores, Inc.*, --- U.S. ----, 134 S.Ct. 2751, 189 L.Ed.2d 675 (2014), the Departments also issued rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. 80 Fed. Reg. 41,318, 41,324 (July 14, 2015).

<sup>2</sup> Because the Little Sisters moved to intervene as defendants and seek the same relief as the federal government, they need not demonstrate Article III standing. See *Town of Chester v. Laroe Estates, Inc.*, --- U.S. ----, 137 S.Ct. 1645, 1651, 198 L.Ed.2d 64 (2017); *McConnell v. Fed. Election Comm’n*, 540 U.S. 93, 233, 124 S.Ct. 619, 157 L.Ed.2d 491 (2003) (assuming standing where original defendant had standing and intervenor-defendant sought same relief as that sought by defendant), *overruled on other grounds*, *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 130 S.Ct. 876, 175 L.Ed.2d 753 (2010).

<sup>3</sup> The Supreme Court had previously granted certiorari and vacated the judgment in that case in light of *Zubik*. See *Univ. of Notre Dame v. Burwell*, --- U.S. ----, 136 S.Ct. 2007, 195 L.Ed.2d 210 (2016).

<sup>4</sup> Because we hold that the Little Sisters meet the requirements to intervene as of right, we need not review the District Court’s ruling regarding permissive intervention.

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