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Pepperdine University School of Law Legal Summaries

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Pepperdine University School of Law
Legal Summaries

TABLE OF CASES

UNITED STATES COURTS OF APPEAL

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CENTRAL UNITED LIFE INSURANCE CO. V. BURWELL
827 F.3d 70 (D.C. Cir. 2016)

Synopsis:

Central United Life Insurance Company, and other insurers offering fixed indemnity policies, challenged a regulation by the Health and Human Services (HHS) that tacked on a requirement to provide fixed indemnity plans only to those who had the minimum essential coverage required by the Patient Protection and Affordable Care Act (ACA). The HHS attached this requirement so that the insurance plans would fit the definition of an excepted benefit plan under the Public Health Service Act (PHSA). This rule was found to be arbitrary and capricious by the court.

Facts and Analysis:

The Public Health Service Act[1] (PHSA) provided coverage requirements for health insurance plans, but it did not include requirements for those that are "excepted benefits."[2] Only the insurance health plans listed in the PHSA can qualify as excepted benefits.[3] The benefits that are at issue here are further conditioned by two additional requirements.[4] The excepted benefits list in the PHSA includes a type of insurance called fixed indemnity.[5] When Congress passed the Patient Protection and ACA in 2010, the coverage requirements in the PHSA were updated and mandated that "all applicable individuals maintain 'minimum essential coverage.'"[6]

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[1] 42 U.S.C. § 201 (2012).

[2] Cent. United Life Ins. Co. v. Burwell, 827 F.3d 70, 72 (D.C. Cir. 2016).

[3] *Id.*

[4] *Id.* The specific requirements to be considered for qualification as an excepted benefit insurance are that "the insurance plans must be 'provided under a separate policy, certificate, or contract of insurance,' . . . [and it] 'must be offered as independent, noncoordinated benefits.'" *Id.*

[5] *Id.* The fixed indemnity policies "pay out a fixed amount of cash upon the occurrence of a particular medical event." *Id.*

[6] *Id.*

After the ACA was enacted, individuals favored the fixed indemnity insurance policies over maintaining minimum essential coverage.[7] Because of this trend of individuals migrating over to receive fixed indemnity policies, the HHS decided to change the requirement for fixed indemnity insurance policies to be categorized as an excepted benefit.[8] The HHS tacked on a requirement in addition to the PHSA's already codified requirements which stated that "to be an 'excepted benefit,' the plan may be 'provided only to individuals who have . . . minimum essential coverage.'"[9] With the new amendment, individuals who purchased the fixed indemnity policies instead of choosing the minimum essential coverage now had to satisfy the "PHSA's coverage requirements for non-excepted benefits."[10] However, this new rule completely eliminated "*stand-alone* fixed indemnity plans altogether" because the nature of these policies made it impossible to satisfy the new requirements.[11]

Insurance providers brought an action and challenged the new rule by the HHS stating that this rule was "an impermissible interpretation of the PHSA," and the lower court enjoined the Agency's enforcement under the "*Chevron*"[12] doctrine.[13] According to the *Chevron* two-step test, the court must first determine "whether Congress authorized the agency to act" and if "Congress 'has directly spoken' to . . . the agency's authority, 'the court . . . must give effect to the unambiguously expressed intent of Congress.'"[14] If Congress gave the agency the discretion to interpret and promulgate rules, then the agency's regulation will "be upheld 'as long as the agency

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[7] *Id.* Many individuals favored the fixed indemnity policies over minimum essential coverage because it was more cost effective to choose these policies. *Id.*

[8] Cent. United Life Ins. Co. v. Burwell, 827 F.3d 70, 72–73 (D.C. Cir. 2016).

[9] *Id.* at 73 (quoting Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Fed. Reg. 30240, 30253 (May 27, 2014)).

[10] 827 F.3d 70 at 73.

[11] *Id.* (emphasis in original).

[12] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1983).

[13] Cent. United Life Ins. Co. v. Burwell, 827 F.3d 70, 73 (D.C. Cir. 2016).

[14] *Id.* (quoting Chevron, U.S.A., Inc., v. Nat. Res. Def. Council, Inc., 467 U.S. 837 at 842-43 (1984)).

stay[ed] within that delegation.'"[15] Here, the court analyzed the HHS's rule to reflect an amendment to the "PHSA itself," rather than an amendment in the regulatory criteria.[16] Congress enacted the PHSA to include only two requirements to qualify as an excepted benefit, and the HHS's amendment went against Congress's expressly codified policy.[17] The PHSA does not leave room for the HHS to include additional requirements and the ACA favors the PHSA's definition of excepted benefits—to not include the minimum essential coverage.[18] Enacting the PHSA, Congress carefully and clearly defined the term excepted benefit so that it was not ambiguous, leaving no room for agency interpretation.[19] The HHS made an attempt to regulate individuals "under a provision directed at providers [which confirmed that] the agency's rule was an act of amendment, not interpretation."[20]

Holding:

The court determined that the HHS's action of creating an amendment to the PHSA did not qualify for a Chevron deference—giving discretion to the Agency's interpretation—because the HHS did not interpret the statute but amended it.[21] The court held that the HHS lacked authority to tack on an additional requirement to the PHSA and therefore, the Agency's rule was arbitrary and capricious.[22]

Impact:

By applying the *Chevron* two-step test, the court, once again, clearly defined the limitations of the Agency's authority to interpret and promulgate regulations. The HHS, and all other agencies, must

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[15] *Id.* (quoting Arent v. Shalala, 70 F.3d 610, 615 (D.C. Cir. 1995)).
[16] *Id.*
[17] *Id.*
[18] *Id.* at 73–74.
[19] Cent. United Life Ins. Co. v. Burwell, 827 F.3d 70, 74 (D.C. Cir. 2016).
[20] *Id.* at 74.
[21] *Id.*
[22] *Id.* at 74–75.

follow Congress's delegation of authority because agencies have no power to act unless Congress expressly or impliedly delegates it to them through legislation. Here, Congress was clear and expressly defined terms leaving no ambiguity for the HHS to fill. The court did not allow the HHS to be given any deference because the HHS's proposed rule went beyond the scope and meaning of the statute by amending the meaning of excepted benefits. The Agency's belief that its rule was a mere "interpretation" of the statute was corrected by the court to be considered an amendment of the statute and therefore beyond the meaning of what the statute can bear. The court affirms its view on the importance of agencies to not abuse their power and strictly allowing the agencies to act only under Congress's purview.

COMPETITIVE ENTERPRISE INSTITUTE V. OFFICE OF SCIENCE AND TECHNOLOGY POLICY
827 F.3d 145 (D.C. Cir. 2016)

Synopsis:

The Competitive Enterprise Institute (CEI) brought a Freedom of Information Act (FOIA) action against the Office of Science and Technology Policy (OSTP) because the OSTP refused to search the agency director's private e-mail account for agency records related to the FOIA request. The lower court held against CEI and its FOIA request because the agency, OSTP, had no duty or obligation to search a private e-mail account. The court held that the FOIA request was improperly dismissed because an agency cannot hide the records from search under FOIA by storing the records in a private e-mail account.

Facts and Analysis:

FOIA requires that the agency must "make the records promptly available to any person" upon request.[23] The records disclosure

[23] Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 146 (D.C. Cir. 2016) (quoting 5 U.S.C. § 552(a)(3)(A) (2012)).

"includes the duty to 'search for the records in electronic form or format . . . ."[24] CEI, the appellant, brought a FOIA request for emails using the "jholdren@whrc.org" account (Account), which was a nonofficial account of John Holdren, the Director of OSTP.[25] CEI included this email address account because CEI had knowledge that John Holdren used this particular account in work-related communication.[26] OSTP refused to provide the records from the Account because those records "were in an 'account' that '[was] under the control of the Woods Hole Research Center, a private organization'" and "were 'beyond the reach of FOIA.'"[27] OSTP argued that the contents in the Account were not considered part of the documents required to be disclosed under the FOIA request because the Account was "not under the control of the agency."[28]

FOIA allows an individual to establish the private right of action for the access of the federal records.[29] There are three different requirements that are stated under FOIA, requiring the agency to demonstrate that the agency had "(1) 'improperly'; (2) 'withheld'; (3) 'agency records.'"[30] The main focus of the court was to determine whether the OSTP's action of refusing to provide the records of the Account was considered to be an improper withholding of agency records.[31] OSTP has consistently argued that the contents on a private email account are not in the control of the federal agencies and therefore, not within the scope of FOIA.[32] CEI challenged the idea that the "director of an agency may place his work-related records beyond the reach of FOIA for the simple expedient of using a private email account rather than the official government communications system."[33]

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[24] 827 F.3d at 146 (quoting 5 U.S.C. § 552(a)(3)(C) (2012)).

[25] 827 F.3d at 146.

[26] *Id.*

[27] *Id.* at 146-47.

[28] Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 147 (D.C. Cir. 2016).

[29] *Id.*

[30] *Id.* (quoting Kissinger v. Reporters Comm. for Freedom of the Press, 445 U.S. 136, 150 (1980)).

[31] *Id.*

[32] *Id.*

[33] *Id.*

The court viewed the case, *Ryan v. Department of Justice*,[34] as analogous to OSTP's situation where the FOIA requestor "sought documents from the Department of Justice which were within the exclusive control of the Attorney General."[35] The court did not accept the Department of Justice's argument[36] and held that there was "no basis in the FOIA 'to view the Attorney General as distinct from his department for FOIA purposes.'"[37] The logic was that an agency, like OTSP, "acts through its employees and officials," such as OSTP's Director Holdren and if one of the employees possess agency records, the records "do not lose their agency character just because the official who possesses them takes them out the door or because he is the head of the agency."[38] The court viewed Appellee's argument as defective because their contention was based upon the idea that the contents at issue are in the control of a private entity and not the government.[39] The private entity, Woods Hole Research Center, was the owner of the domain of the Account where Director Holdren fully maintained the Account.[40]

OSTP's argument, also, does not follow the stated purpose of FOIA, which is to serve the citizens and their right to be informed about the action of the government.[41] If the Agency's head official can deprive the citizens of the right to know about the Agency's actions by maintaining Agency emails on a nonofficial account, the purpose of FOIA would be defeated.[42]

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[34] 617 F.2d 781, 786 (D.C. Cir. 1980).

[35] Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149 (D.C. Cir. 2016) (citing Ryan v. Dep't of Justice, 617 F.2d 781, 786 (D.C. Cir. 1980)).

[36] The Department of Justice's (DOJ) argument was that the contents were not under the agency's control because the documents were only in the exclusive control of the agency's head, the Attorney General. *Id.*

[37] *Id.* (quoting Ryan v. Dep't of Justice, 617 F.2d 781, 787 (D.C. Cir. 1980)).

[38] 827 F.3d at 149.

[39] *Id.*

[40] *Id.*

[41] Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 150 (D.C. Cir. 2016).

[42] *Id.* An illustration is given by the Court to help explain its argument: "It would make as much sense to say that the department head could deprive requestors of hard-copy documents by leaving them in a file at his daughter's house and then claiming that they are under her control." *Id.*

Holding:

The court reversed the lower court's decision that dismissed the case in favor of OSTP and further remanded the case to address whether OSTP have other exemptions or if there are any records in the Account.[43] The court emphasized that they are not enforcing disclosure of any Agency documents but that the lower court must re-hear this case in litigation.

Impact:

The court clearly saw the loophole that would allow the agency to abuse their power if an exception, like the one found here for OSTP, was allowed. Just because an agency official or director has the agency records in a separate nonofficial email account, does not mean that the public should be deprived of these records, which violates FOIA. If agencies can hide their records, thereby preventing disclosure to the public, the sole purpose of FOIA would be defeated. Agencies would be given the power to curtail their duties under FOIA and would not be transparent to the public if allowed to exclude records not in the agencies' control over a small technicality—being on a separate private domain outside of the agency domain. This may lead to a high probability of agencies without any checks and balances on their power and will not promote accountability within agencies to enforce compliance with regulations. The court set a precedent that will support the Act, affirm its stance on favoring the agencies to be transparent to the public, and holding agencies accountable for their actions.

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[43] *Id.*

FLORIDA HEALTH SCIENCES CENTER, INC. V. SECRETARY OF HEALTH AND HUMAN SERVICES
830 F.3d 515 (D.C. Cir. 2016)

Synopsis:

Florida Health Sciences Center, Inc. (the Hospital or Tampa General) challenged the Secretary of the Department of Health and Human Services (HHS) in her calculation of the amount of disbursement payment that the Hospital would receive from the Medicare program for uncompensated care. As required by the Affordable Care Act (ACA), the Secretary made an estimate amount to provide federal funding to hospitals like Tampa General that provided medical care to patients who otherwise could not afford treatment. The Hospital challenged the data that the Secretary used to make this estimation. The court held in favor of the HHS and agreed with the lower court's decision stating that judicial review was not permitted on this issue.

Facts and Analysis:

The Hospital served Tampa's low-income population and received compensation for providing healthcare to those who cannot pay through the Disproportionate Share Hospital (DSH) payments, the government's disbursement system.[44] The ACA amended the process for DSH payment calculations, which based the payments mainly on uncompensated care provided by the hospitals.[45] The

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[44] Florida Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs., 830 F.3d 515, 517 (D.C. Cir. 2016).

> [Previously], HHS calculated a hospital's DSH payment based on the number of days per year that the hospital served Medicaid and low-income Medicare patients. This calculation did not factor in the costs to the hospitals of "uncompensated care," which they provide to patients who have no means to pay, whether through federal programs or otherwise.

Id.

[45] *Id.* HHS paid each hospital "25% of the amount it received under the old formula, 42 U.S.C. § 1395ww(r)(1)" then paid an additional amount based partly on the "Secretary's 'estimate' of the percentage of the nation's overall uncompensated care that each hospital provide[d]." *Id.*

Secretary promulgated a final rule in 2014 that described the HHS's method for DSH payment calculations.[46] This rule explained the method where the Secretary used "each hospital's number of *insured* Medicaid and Medicare SSI patients as a proxy for its number of low-income *uninsured* patients."[47] HHS used the March 2013 updates from the annual reports that hospitals submit to them because it was the "most recent data" they received.[48] The HHS did not use any new data submitted past the deadline to calculate the DSH payments for 2014 because of the difficulty of ensuring the accuracy of the data.[49] The Hospital attempted to give new data in April 2013, but the Secretary refused to use this new data.[50] Tampa General brought an action against HHS for not using the recent data they tried provide, which they argued "violated the Administrative Procedure Act" (APA) and the "Medicare statute."[51] The Hospital argued that the April 2013 data showed that they were "entitled to $3 million more than the Secretary originally calculated."[52] Under 42 U.S.C. § 1395ww(r)(3), the lower court dismissed the Hospital's claim because it "prelude[d] judicial review of the Secretary's 'estimate' of a hospital's amount of uncompensated care" and barred the court to review the data used by the Secretary to determine the estimated amount.[53]

The Hospital acknowledged that the Secretary's *estimate* cannot be judicially reviewed but argued for the court to review the "underlying data" that the Secretary relied on, stating that the estimate amount was not the same as the underlying data that was used.[54] However, the court stated that since the Secretary only used the data of Medicaid and Medicare SSI patients as "a proxy for the population of uninsured low-income patients" and no other data to

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[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] Florida Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs., 830 F.3d 515, 517–18 (D.C. Cir. 2016).

[50] *Id.* at 518.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.* at 519.

estimate the amount, challenging the data used would "'eviscerate the bar on judicial review.'"[55] This is because according to a previous case, *Texas Alliance for Home Care Services v. Sebelius*,[56] the data used was integral and "'inextricably intertwined'" with the Secretary's estimate amount of uncompensated care for the Hospital and therefore, the court lacks the jurisdiction to consider this issue.[57]

Tampa General tried to distinguish its claim from *Texas Alliance* in three ways.[58] The Hospital argued that the statutory provision barring judicial review of any period of time that the Secretary selected would serve no purpose if the estimate amount was "interpreted to bar review of anything that affect[ed] the estimate."[59] The court did not agree with the Hospital and said that its interpretation of the estimate did not "deprive the 'period' provision of all meaning and effect."[60] This argument failed because the statute's bar on judicial review of the periods selected by the Secretary had nothing to do with the Secretary's estimate.[61] Next, the Hospital contended under another canon of statutory interpretation that when Congress mentions one thing, Congress reasonably implied the preclusion of other alternatives.[62] In other words, Tampa General argued that the bar of judicial review of the period, "which is one component of the estimate," meant that Congress "left other components of the estimate, like the data, subject to review."[63] Like the first argument, this argument failed as well because the period selected was a component of the estimate in "some provisions of the statute" but it was not a component in other parts of the statute.[64] Therefore, the court concluded that the bar

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[55] Florida Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs., 830 F.3d 515, 519 (D.C. Cir. 2016) (quoting El Paso Nat. Gas Co. v. United States, 632 F.3d 1272, 1278 (D.C. Cir. 2011)).

[56] 681 F.3d 402 (D.C. Cir. 2012).

[57] 830 F.3d at 519.

[58] *Id.* at 520.

[59] *Id.*

[60] *Id.*

[61] Florida Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs., 830 F.3d 515, 520 (D.C. Cir. 2016).

[62] *Id.*

[63] *Id.*

[64] *Id.*

from reviewing the period was not seen as Congress' intent of allowing review of the underlying data and that the period cannot be reviewed under any part of the statutory provisions.[65] Lastly, the Hospital's argument fell short when it erroneously analyzed that a difference between reviewing an ultimate decision and an intermediate decision existed.[66] The issue the Hospital challenged here was not the dispositive issue, rather, it was "whether the challenged data [was] inextricably intertwined with an action that . . . . [was] shielded from review, regardless of where that action [was] in the agency's decision tree."[67]

Finally, Tampa General attempted to change their contention "as an attack on something other than an estimate by the Secretary."[68] The court, relying on its precedent from *Parkview Medical Associates v. Shalala*, reaffirmed that review by the court "is not permitted 'when a procedure is challenged solely in order to reverse an individual . . . decision' that . . . otherwise cannot [be] review[ed]."[69] Tampa General's sole purpose in this action is to change the Secretary's estimate and not to challenge any general rules leading to that estimate.[70]

Holding:

The court was not persuaded by any of the Hospital's arguments that were presented and held against the Hospital, reaffirming the decision from the lower court and from its precedent. The court held that the statute, 42 U.S.C. § 1395ww(r)(3), barred all of Tampa General's contentions and its argument of allowing review of the period selected by the Secretary to form the estimate amount to be compensated to the Hospital.

Impact:

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[65] *Id.*

[66] *Id.* at 521.

[67] Florida Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs., 830 F.3d 515, 521 (D.C. Cir. 2016).

[68] *Id.*

[69] *Id.*

[70] *Id.*

Even though allowing the Agency to determine the compensation amount for all the hospitals by using what they believe to be appropriate and current data seems to be giving the Agency a large amount of control and power, the court placed higher value on Congress' intent. The court, through its decision to reaffirm the bar on judicial review, clarified that it was not willing to accept an arbitrary interpretation by an individual and in turn set a dangerous precedent to review the every single DHS payment application which Congress clearly wanted to prevent from occurring.

RHEA LANA, INC. V. DEPARTMENT OF LABOR
824 F.3d 1023 (D.C. Cir. 2016)

Synopsis:

In *Rhea Lana, Inc. v. Department of Labor*, the Court of Appeals for the District of Columbia Circuit held that an agency letter sent to the plaintiff was a final agency action. Rhea Lana, Inc. (Rhea Lana), a for-profit company, received a letter from the Department of Labor (DOL) indicating that the company's use of volunteer workers violated the Fair Labor Standards Act (FLSA). Rhea Lana filed a suit to seek pre-enforcement declaratory and injunctive relief against the DOL's determination that it was out of compliance. The district court viewed the DOL's letter as merely advisory, and therefore an unreviewable, non-final agency action, and dismissed the suit. The court concluded that the letter was a final agency action because it transmitted legally operative information with legal consequence.

Facts and Analysis:

Rhea Lana, Inc. and Rhea Lana's Franchise Systems, Inc., collectively the plaintiffs, operated and franchised the opportunity to operate semi-annual consignment sales of used children's toys, clothing, and related items.[71] Consignors, otherwise known as "consignor-volunteers," did not receive any compensation from Rhea

[71] Rhea Lana, Inc. v. Dep't of Labor, 824 F.3d 1023, 1025 (D.C. Cir. 2016).

Lana.[72] In January 2013, the DOL investigated Rhea Lana and found that consignor-volunteers were employees under the FLSA and entitled to wages.[73] On August 26, 2013, DOL sent a letter to Rhea Lana stating the following:

> [S]ection 16(e) of the FLSA and Regulations, Part 578 . . . provides for the assessment of a civil money penalty for any repeated or willful violations of [the FLSA's minimum-wage and overtime requirements], in an amount not to exceed $1,100 for each such violation. No penalty is being assessed as a result of this investigation. If at any time in the future your firm is found to have violated the monetary provisions of the FLSA, it will be subject to such penalties.[74]

The DOL explained in the letter to the volunteers that the purpose of the letter was to conclude the matter by "putting the company on notice and taking no 'further action.'"[75] Plaintiffs filed suit[76] and sought "a declaration that those workers are not employees and an injunction barring DOL from further investigations . . . flowing from the agency's determination."[77] The challengers argued that Rhea Lana lacked standing and the letters were not final agency action subject to the APA challenge.[78]

The court reviewed the question at issue in two parts, Part 1 and Part 2: (1) DOL's letter displayed finality of the agency's decision-making on the staffed individuals as employees, and (2) plaintiffs narrowed this finality contention to the agency's August 26, 2013 letter (the Letter).[79] Since the agency has conceded to the first part of

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[72] *Id.*

[73] *Id.*

[74] *Id.* at 1026.

[75] *Id.*

[76] Rhea Lana brought suit under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). *Id.*

[77] Rhea Lana, Inc. v. Dep't of Labor, 824 F.3d 1023, 1026 (D.C. Cir. 2016).

[78] *Id.*

[79] *Id.* at 1027. The agency action must be final before the court may review it according to 5 U.S.C. § 704. Under this section, two conditions must be satisfied: "'First, the action must mark the consummation of the agency's decisionmaking process . . . And second, the action must be one by which rights or obligations have

the issue, the only question before the court reviewed was the second part and whether the Letter "determine[d] rights or obligations or . . . create[d] legal consequences."[80]

Rhea Lana argued that the Letter was the equivalent to the order given by the Environmental Protection Agency (EPA) in *Sackett v. EPA*,[81] where the Supreme Court held the agency action to be final.[82] Concerning Part 1, the court found that the Letter differed from the compliance order in *Sackett*.[83] The Letter was dissimilar to the EPA's order because it created "no new obligation on Rhea Lana that the company did not already bear under the FLSA."[84] The Letter was more advisory, as opposed to a compliance order, used to warn companies of potential violation before enforcements actions.[85] The court concluded that in regards to the first part, the Letter was informal agency advice continuously treated as unreviewable by courts.[86]

The court agreed—only with Part 2—that there were legal consequences resulting from the Letter because Rhea Lana would be "vulnerable to future action for civil penalties."[87] The DOL promulgated a regulation[88] to better define "willful violation" to help

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been determined, or from which legal consequences will flow.'" *Id.* at 1026-27 (quoting Bennett v. Spear, 520 U.S. 154).

[80] *Rhea Lana, Inc.*, 824 F.3d at 1027.

[81] 132 S. Ct. 1367 (2012).

[82] *Rhea Lana, Inc.*, 824 F.3d at 1027. The EPA ordered the Sacketts to take immediate action to restore the property and provide the agency access to the property and records. *Id.* The order determined the "'rights or obligations' by giving the Sacketts the 'legal obligation to restore their property . . . and . . . give the EPA access to their property and to records . . . .'" *Id.* The Supreme Court determined that there were legal consequences that resulted from this order because it imposed double penalties in a future proceeding for the Sacketts. *Id.* at 1028.

[83] *Id.* The EPA's compliance order stated specific actions for the Sacketts to undertake with deadlines and detailed finding of fact. *Id.* There were mandatory terms and immediate requirements in the order. *Id.* The DOL's Letter merely stated that the DOL's view that "employees of for-profit entities are subject to the FLSA's wage-and-hour provisions, and do not qualify for volunteer status." *Id.*

[84] *Id.*

[85] *Rhea Lana, Inc.*, 824 F.3d at 1027.

[86] *Id.*

[87] *Id.*

[88] 29 U.S.C. § 578.3.

when interpreting the FLSA which states—"employers that willfully violate the Act's minimum-wage . . . provisions 'shall be subject to a civil penalty . . . for each such violation.'"[89] The Letter clearly stated that if Rhea Lana continued to not compensate its volunteers after its receipt of the Letter, its conduct will be considered a willful violation.[90] The DOL argued that the penalties described in the Letter are "too contingent to constitute . . . legal consequence necessary to confer finality [of the agency action]."[91] However, the court stated that even if the agency brought an enforcement action for penalties, this may not establish that the administrative order in *Sackett* did not have legal consequences as a result.[92]

Holding:

The court held that the DOL's letter established legal consequences, and therefore, the agency action was final because the DOL determined Rhea Lana may be liable for civil penalties.[93] The court further reasoned that even if the DOL does not bring any enforcement action, the Letter, along with the regulation, may cause Rhea Lana to be "susceptible to civil penalties for violations that, in the absence of the Letter, could be treated as non-willful and ineligible for any such penalties."[94] The court here did not solely focus on the type of communication between the agency and the company but reviewed the Letter's essence and the content that allowed legal consequences to result for the company.

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[89] *Rhea Lana, Inc.*, 824 F.3d at1029. The regulation defines willful violation if the "employer knew that its conduct was prohibited or showed reckless disregard for the requirements of the Act." *Id.* The employer's conduct is considered knowing if the employer received "from a responsible official of the Wage and Hour division . . . that the conduct . . . is not lawful." *Id.*

[90] *Id.* at 1030.

[91] *Id.* at 1032.

[92] *Id.*

[93] *Id.*

[94] *Id.*

SPECTRUM PHARMACEUTICALS, INC. V. BURWELL
824 F.3d 1062 (D.C. Cir. 2016)

Synopsis:

The Court in *Spectrum Pharmaceuticals, Inc. v. Burwell* held in favor of Burwell, the acting Commissioner of the Food and Drug Administration (FDA), concluding that the FDA's action was not arbitrary and capricious and Spectrum Pharmaceuticals, Inc. (Spectrum) was not entitled to notice and an opportunity to be heard from the FDA. Spectrum argued that before the FDA allowed the generic drug manufacturer's drug application to be expedited, they should have been given an opportunity to show that they can meet he market demand. Spectrum, a brand name drug manufacturer, brought suit against the Commissioner to enjoin the FDA to withdraw its approval of the generic drug manufacturer Sandoz, Inc.'s (Sandoz) drug application because the FDA's approval and process to grant the application violated both the Food, Drug, and Cosmetic Act (FDCA) and the Administrative Procedure Act (APA). Spectrum moved for summary judgment, and the generic drug manufacturer, Sandoz, Inc. (Sandoz), cross-moved for summary judgment, which was granted by the lower court.

Facts and Analysis:

In 2008, Spectrum developed a drug to treat cancer called Fusilev that counteracts liver damage caused by a chemotherapy treatment called methotrexate therapy (Methotrexate Indications).[95] Since Spectrum was the first manufacturer to develop Fusilev, the FDCA's Orphan Drug Act (ODA) amendments gave Spectrum the exclusive marketing rights of Fusilev for Methotrexate Indications

[95] Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1064 (D.C. Cir. 2016). Fusilev is the brand name for the drug called Levoleucovorin. *Id.* This cancer drug is also known as an "'orphan drug,' . . . because it is designed to treat a rare disease or condition that historically received little attention from pharmaceutical companies, and hence became 'orphaned' because the comparatively small demand for treatment left little motive for research and development." *Id.*

until 2015.[96] The FDA granted Spectrum approval to market Fusilev for a new purpose in 2011—to manage pain for advanced colorectal cancer (Colorectal Indication).[97] This approval gave Spectrum exclusive marketing rights for the Colorectal Indication, which is set to expire in 2018.[98] When Spectrum's exclusivity rights for Methotrexate Indications ended in 2015, Sandoz received approval to market the generic version of Fusilev for Methotrexate Indications, "having had its application expedited in 2012 to address a drug shortage."[99] Sandoz marketed its generic drug differently from Fusilev's—sold in powder form—by selling it in a "ready-to-use form" and by following the agency's regulations by labeling the generic drug only with Methotrexate Indications—not Colorectal Indication.[100]

Spectrum argued three points in its suit against the FDA's approval of Sandoz's generic drug.[101] The first argument was that Sandoz's intended use of its generic version of Fusilev was for the Colorectal Indication when the label clearly stated its use was for Methotrexate Indications.[102] Spectrum argued that granting Sandoz's application for the generic drug in 2015 was in violation of Spectrum's exclusive marketing rights for Colorectal Indication—rights which do not expire until 2018.[103] The FDA does not grant approval for any generic form of a drug until the exclusivity period

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[96] *Id.* The ODA amendments of the FDCA was created to "increase incentives for companies to develop new orphan drugs" and to give the manufacturer exclusive marketing rights for seven years. *Id*.

[97] *Id.*

[98] *Id*.

[99] *Id.*

[100] Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1064 (D.C. Cir. 2016).

[101] *Id.*

[102] *Id.*

[103] *Id.* The reason Spectrum argued that Sandoz's intended use of the generic drug was contrary to the use labeled on the drug was based on vial size. *Id.* The vial sizes for the two types of indications are drastically different; Methotrexate Indications' standard dose is 7.5 mg, whereas Colorectal Indication's standard dose is 150 mg. *Id.* Sandoz began selling the generic version of Fusilev in 175 mg and 250 mg compared to Spectrum's 50 mg vials. *Id.* This large difference in the vial sizes established Spectrum's argument that Sandoz's generic brand was "intended to treat the Colorectal Indication despite being labeled for only the Methotrexate Indications." *Id.*

ends for the original drug.[104] Under the ODA, the FDA allows a practice called "labeling 'carve-out'"[105] for situations when the pioneer drug has multiple purposes, which are granted exclusivity rights at different times.[106] Generally in the past, the court has held this practice to be "an acceptable interpretation of the FDCA."[107]

The FDA responded to Spectrum's first argument by stating that it did not have to investigate any further than looking at Sandoz's application with the intended use of the drug in order to determine that Sandoz's drug will not violate Spectrum's exclusivity rights.[108] The court determined that the FDA has discretion to look only at the labeling claims to properly determine the drug's intended use.[109] The court viewed the FDA's "interpretation of the ODA reasonable"[110] and was consistent with its own regulations.[111] Therefore, FDA's interpretation is lawful because it is a reasonable interpretation.[112]

In its second argument, Spectrum stated that the Agency's action—approval of Sandoz's generic drug—was arbitrary and capricious because the FDA changed its policy without any justification.[113] Spectrum's argument relied on the FDA's draft guidance document that indicated that "vial sizes 'should be appropriate for the labeled use and dosing of the product.'"[114] Because the FDA failed to justify the reason why it strayed away from its own guidance when the Agency approved Sandoz to sell the

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[104] *Id.* at 1066.

[105] A "labeling 'carve-out' . . . allows producers to sell a generic if they exclude from its label any indication that is still protected by exclusive marketing rights." *Id.*

[106] *Id.* Even with the proper practice of labeling carve-outs, FDA cannot limit a doctor from prescribing the generic drug for another use than the use stated on the label. *Id.*

[107] Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1066 (D.C. Cir. 2016).

[108] *Id.* at 1067.

[109] *Id.* at 1068.

[110] *Id.* at 1067.

[111] *Id.* at 1068-69.

[112] *Id.* at 1069.

[113] Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1064-65 (D.C. Cir. 2016).

[114] *Id.* at 1070.

drug in vials larger than necessary, Spectrum saw this action as arbitrary and capricious.[115]

However, records show that the FDA properly determined that the larger vials were appropriate for Methotrexate Indications and "safe and effective," concluding that "proper labeling would address safety risks."[116] The fact that there was a draft guidance on the large vials as appropriate size for Methotrexate Indications served no purpose in determining the safety and effectiveness.[117] The FDA did not change its position on its policy on the vial size appropriate for Methotrexate Indications, and therefore, its approval was not arbitrary and capricious.[118]

The last contention by Spectrum was that FDA did not meet the requirement to give it "notice and an opportunity to be heard before expediting Sandoz's [application] . . . ."[119] Based on the statute, ODA, the notice requirement is established "only when FDA abrogates a pioneer drug's period of market exclusivity."[120] This notice obligation becomes a requirement for FDA when the agency "makes exceptions to market exclusivity."[121] There are no notice requirements for the FDA to follow if it expedites an application review. Since the FDA did not end Spectrum's exclusivity period, the notice requirement did not apply in this situation.[122]

Holding:

The Court of Appeals affirmed the lower court's order granting summary judgement against Spectrum and held the following: (1) Under the ODA, the FDA was not required to consider the generic drug's "intended off-label uses" to determine approval for the drug application that carved out the exclusive use on its labeling; (2) The

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[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] Spectrum Pharm., Inc. v. Burwell, 824 F.3d 1062, 1071 (D.C. Cir. 2016).
[120] *Id.*
[121] *Id.*
[122] *Id.*

FDA's policy did not change and its action was not arbitrary and capricious; and (3) The FDA was not required, by ODA or any other regulation, to give Spectrum notice or an opportunity to be heard before approving Sandoz's application.[123]

Impact:

By rejecting the pioneer drug manufacturer's arguments for notice and an opportunity to be heard before the FDA's approval of the generic drug manufacturer's application, the court preserved the flexibility of the agency to approve generic drug applications. As a result, the court intended to make it more difficult for pioneer drug manufacturers to block the lower cost generic drug application approval through the addition of procedural hurdles to the approval process. The courts have resisted adding procedural requirements beyond those mandated by the ODA, or the APA to uphold Congress's intent and goal to promote not only drug innovation but also affordable drugs. The added costs of an extended pioneer drug monopoly would be the high price paid by health insurers if those pioneer drug manufactures could slow down the generic drug approval process. With the onset of technology and growth of different types of drugs available to treat rare diseases, the court saw the dangers of the pharmaceutical companies' power to influence and curtail rules set by the agencies and Congress. By setting this precedent, the court clearly defined the agency's discretion and authority to be free from the regulated industry's disadvantaged situations and to be determined by the law and Congress.

WALLAESA V. FEDERAL AVIATION ADMINISTRATION
824 F.3d 1071 (D.C. Cir. 2016)

Synopsis:

The Court in *Wallaesa v. Federal Aviation Administration* held in favor of the Federal Aviation Administration (FAA) and rejected the

[123] *Id.* at 1062.

petitioner's challenge for judicial review.[124] The FAA brought a civil penalty proceeding against the defendant, Brian Wallaesa (Wallaesa) for violating the rule to not interfere with crewmember duties.[125] The Administrative Law Judge (ALJ) overseeing this proceeding imposed a penalty amount of $3,300 against Wallaesa and found him in violation of the fasten-seatbelt rule.[126] Wallaesa appealed the ALJ's determination, and the FAA affirmed the decision, which lead him to petition for judicial review.[127]

Facts, Analysis, and Ruling:

On November 6, 2009, while flying on Southwest Airlines from Baltimore, Maryland to Las Vegas, Nevada, petitioner met a passenger named Jamie T.[128] The flight crew gave safety instructions[129] to all passengers "to keep their seatbelts fastened while the fasten seatbelt sign was illuminated and to follow crewmember instructions."[130] During the flight, Wallaesa switched seats with another passenger to sit next to Jamie, and their conversations "fast became an annoyance."[131] After an inappropriate comment by Wallaesa, Jamie exchanged seats with another passenger across the plane and notified crewmember, Wendy Moorman (Moorman).[132] Moorman then brought Wallaesa to the back of the plane to explain to him that his behavior made Jamie feel uncomfortable and instructed him to take his seat and to not speak to Jamie again.[133] Wallaesa did not listen to Moorman's instructions and soon walked to Jamie's seat to speak to her.[134] This same behavior occurred multiple times and Wallaesa became very agitated

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[124] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1074 (D.C. Cir. 2016).

[125] *Id.*

[126] *Id.*

[127] *Id.* at 1071.

[128] *Id.*

[129] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1074 (D.C. Cir. 2016). For required safety instructions, see 14 C.F.R. § 121.571.

[130] 824 F.3d at 1074.

[131] *Id.*

[132] *Id.* at 1075.

[133] *Id.*

[134] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1075 (D.C. Cir. 2016).

and angry because Moorman continuously intercepted Wallaesa's efforts to bother Jamie; Moorman switched his seat to the other end of the plane.[135] Due to turbulence, the captain of the plane turned on the fasten seatbelt sign following an instruction for everyone, passengers and flight attendants, to stay seated and to fasten their seatbelts.[136] However, Wallaesa did not follow the instructions and "stood up and walked briskly to the front of the aircraft."[137] Moorman and another flight attendant got out of their seats to chase after Wallaesa and instructed him to take his seat, but Wallaesa refused.[138] This standoff occurred steps away from the main cockpit, and, upon Moorman's request, an FBI agent intervened by subduing and handcuffing him.[139]

In February 2010, the FAA held a civil penalty proceeding against Wallaesa and in the Notice of Proposed Civil Penalty, the FAA imposed a $5,500 penalty for the following violations: (1)"[I]nterfering with crewmember duties in violation of 14 C.F.R. § 121.580 (Interference Rule);"[140] (2) "[F]ailing to fasten a seatbelt while the fasten seatbelt sign was illuminated,"[141] and; (3) "[F]ailing to follow crewmember instructions to comply with the fasten-seatbelt rule."[142] Petitioner requested a hearing that lasted one day where the ALJ held that Wallaesa was in violation of all the charges above and his "medical emergency defense was unpersuasive."[143] Wallaesa was issued a penalty amount of $3,300 for violating the Inference Rule and this decision was affirmed after an appeal to the FAA Administrator (Administrator).[144]

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[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.* at 1075-76.

[140] *Id.* at 1076.

[141] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1076 (D.C. Cir. 2016). For statutory language, see 14 C.F.R. § 121.317(f).

[142] 824 F.3d at 1076. For statutory language, see 14 C.F.R. §121.317(k).

[143] 824 F.3d at 1076. Wallaesa did not offer any other evidence of his medical emergency aside from his own testimony, and therefore, the ALJ determined that he fail to meet his burden to prove the defense that his medications caused the "erratic behavior." *Id.*

[144] *Id.*

The court used the arbitrary and capricious standard of review under the Administrative Procedure Act (APA), where "[an] [a]gency['s] findings of fact are conclusive when supported by substantial evidence" and that the decision will only be overturned "if they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'"[145]

Wallaesa argued that the "penalty . . . must be set aside" because the FAA's justification of the charges by using its authority under chapter 447 was not allowed since chapter 447 "does not authorize the regulation of non-violent passenger conduct."[146] The court considered five issues:

> (1) whether the FAA has authority to prohibit passengers from interfering with crewmember duties, and to impose civil penalties on passengers; (2) whether the FAA unlawfully added charges for violating the Seatbelt Rules; (3) whether substantial evidence supported the finding that Wallaesa violated the charges; (4) whether Wallaesa proved an affirmative defense; and (5) whether the penalty amount improperly reflected guidance in an FAA order.[147]

Wallaesa argued that the FAA lacked authority under 49 U.S.C. § 44701(a)(5)[148] to "proscribe the non-violent passenger conduct regulated by the Inference Rule."[149] Under the Federal Aviation Act of 1958, section 601(a)(6) (the Act)[150] the court interpreted

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[145] *Id.* at 1077.

[146] *Id.* Wallaesa argued that chapter 447 applied only to "'requirements of Pilots and Aircraft to Conform to Safety Standards,' not to passengers." *Id.*

[147] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1078 (D.C. Cir. 2016).

[148] This rule states that "the Administrator 'shall promote safe flight of civil aircraft in air commerce by prescribing . . . (5) regulations and minimum standards for other practices, methods, and procedure the Administrator finds necessary for safety in air commerce and national security." *Id*. at 1079 (quoting 49 U.S.C. § 44701(a)(5)).

[149] *Id.*

[150] The Act "transferred to the FAA Administrator the authority to make rules 'necessary to provide adequately for national security and safety in air commerce" and "Congress recodified [this] provision 'without substantive change' at 49 U.S.C. § 44701(a)(5)." 824 F.3d at 1079.

Congress's broad language to allow the Administrator "to promulgate regulations reasonably related to safety in flight."[151] Other cases were also referenced that addressed issues on flights and determined that "passenger interference bears a nexus to flight safety."[152] The court determined that disruptive behavior does not have to involve violence or the threat of violence to interfere with the flight attendant's duties.[153] The FAA cannot provide safety for passengers without enforcing a method of controlling disruptive passenger behavior, and Congress mandated that security and safety be the highest priority in flights.[154] Therefore, the FAA was within its statutory authority, and "proscribing passenger interference with crewmember duties [satisfied] the 'minimum nexus' to safety in flight."[155]

Next, Wallaesa challenged the FAA's authority to impose civil penalties on passengers, and the court began by looking at the statute, which states

> [a]n individual (except an airman serving as an airman) or small business concern is liable to the Government for a civil penalty of not more than $10,000 for violating—(i)… chapter 447. . . or (ii) a regulation prescribed or order issued under any provision to which clause (i) of this paragraph applies.[156]

If Congress did not define a term—such as "individual" in this statute—the term "carries its ordinary meaning, referring to a natural person . . . [and] an airline passenger is a natural person not serving

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[151] *Id.* (quoting Bargmann v. Helms, 715 F.2d 638, 642 (D.C. Cir. 1983).

[152] 824 F.3d at 1080. A previous case stated that disruptive behavior creates "distraction and chaos in an environment where law and order is paramount, potentially preventing the crew from executing emergency procedures or reaching passengers in need." 824 F.3d at 1080. Another case described that the "mundane duties of flight attendants which implicate safety cannot be taken for granted," especially because the "potential for disaster [is] so great." *Id.* (quoting United States v. Hicks, 980 F.2d 963 (5th Cir. 1992).

[153] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1080 (D.C. Cir. 2016).

[154] *Id*. at 1081.

[155] *Id.* at 1082.

[156] *Id.*

as an airman."[157] The court further stated that if the term individual did not include passengers, the penalty provision would hold no effect, and therefore, the "ordinary meaning of 'individual' applie[d] and that passengers naturally fall within that understanding."[158]

Petitioner then challenged the FAA's addition of violations through an amended notice by arguing that he received inadequate notice.[159] However, this challenge also failed because under the Due Process Clause and the APA, the requirement is to provide adequate notice—nothing more.[160] Wallaesa received "an Amended Notice of Proposed Civil Penalty, a Final Notice of Proposed Civil Penalty, and a formal Complaint"—three separate complaints in total for the additional charges.[161] The court determined that Wallaesa had "more than adequate notice" and struck down his notice challenge.[162]

The determination of Wallaesa's violation of the Inference Rule and the Seatbelt Rules would be upheld if the decision is "supported by substantial evidence . . . [defined as] 'relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'"[163] There was substantial evidence to support that Wallaesa had violated the rules, as multiple eyewitnesses testified that he left his seat, did not follow crewmembers' requests, and disregarded the captain's command to remain seated.[164] Therefore, his challenge of the violation, for lack of substantial evidence, failed.

The Administrator correctly found that Wallaesa did not prove an affirmative defense because even though he "bore the burden to prove his affirmative defense[,] . . . [he] failed to introduce any evidence beyond his self-serving, uncorroborated testimony."[165]

Lastly, Wallaesa stated his contention that the civil penalty amount "improperly reflected the FAA's guidance on administrative

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[157] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1083 (D.C. Cir. 2016).
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.* at 1084.
[162] *Id.*
[163] Wallaesa v. Fed. Aviation Admin., 824 F.3d 1071, 1084 (D.C. Cir. 2016).
[164] *Id.*
[165] *Id.*

penalties contained in FAA Order No. 2150.3B" (Order).[166] However, the ALJ did not determine the civil penalty amount based on the Order but rather on "his analysis of sanctions imposed in past cases involving similar violations."[167]

Impact:

This decision strongly affirmed Congress's view on the importance of safety in flights and its delegation of "plenary authority" to the FAA in promulgating safety regulations to ensure the highest level of safety for passengers. [168] The court's decision created a clear and crucial precedent for the FAA to not be swayed by technical challenges regarding the meaning of specific terms in a statute, but to focus on the overall broad picture of the fatal and great danger of flights and the consequence of public harm. The court has incentivized the FAA to be free from limitations on minute details of the statute and to remain focused on promulgating all the regulations necessary to carry out Congress's intent—to uphold safety and security to the highest degree possible.

WEST VIRGINIA V. DEPARTMENT OF HEALTH AND HUMAN SERVICES
827 F.3d 81 (D.C. Cir. 2016)

Synopsis:

The State of West Virginia challenged the Department of Health and Human Services's (HHS) decision to allow the states to enforce the Affordable Care Act's (ACA) minimum coverage requirement. West Virginia claimed that HHS's decision was in violation of the ACA, the Administrative Procedure Act (APA), and the Tenth Amendment. The lower court determined that West Virginia lacked standing because the state did not suffer an injury-in-fact, and the State appealed the decision.

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[166] *Id.*
[167] *Id.*
[168] *Id.* at 1079.

Facts and Analysis:

The Affordable Care Act established a mandate that all health insurance plans must provide a minimum coverage requirement.[169] According to national health care law, "it has been common" to use a "dual federal-state enforcement mechanism" where the state initially enforces the law, "but if the [s]tates decline or fail to enforce, the federal government is a backup enforcer."[170] This method was adopted in the ACA's provisions.[171]

The President stated that the federal government would delay the enforcement of the new statutory requirements by the Affordable Care Act.[172] In response to the President's action, HHS notified the states, including West Virginia, of the "'transitional policy,' allowing health insurers with certain conditions to continue policies that would be outlawed under the statute for a period of a year . . . ."[173] This transitional policy gave states the responsibility to enforce "or not to enforce the very conditions that the federal government determined to abandon for the transitional period."[174] West Virginia made the decision to not enforce the mandate after the agency extended the transitional period from one year to three years.[175]

The State of West Virginia brought action to seek declaratory and injunctive relief, arguing that the transitional policy violated the "plain language of the [ACA], which mandate[d] that the Secretary 'shall' enforce the requirements, when [s]tates do not."[176] West Virginia further argued that HHS was "not at liberty to decline wholesale enforcement of the provisions."[177] The State claimed that

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[169] West Virginia v. U.S. Dep't of Health and Human Servs., 827 F.3d 81, 82 (D.C. Cir. 2016).

[170] *Id.*

[171] *Id.*

[172] *Id.*

[173] *Id.*

[174] *Id.*

[175] West Virginia v. U.S. Dep't of Health and Human Servs., 827 F.3d 81, 82 (D.C. Cir. 2016).

[176] *Id.*

[177] *Id.* at 82-83.

the transitional policy by the HHS was a "substantive and binding rule" that was provided without notice and comment which violated the APA.[178] Lastly, West Virginia brought constitutional claims, stating that the policy both delegated away the federal executive authority to the states and violated the Tenth Amendment by leaving the states with the final decision to enforce the mandates.[179]

Two cases, *Printz v. United States*[180] and *New York v. United States*[181] were used in the State's argument that federal statutes that "compel [s]tates to implement those statutes violate the Constitution."[182] The main conclusion in these cases were that the states were "compelled to act" and the issue of standing was not discussed.[183]

Appellant maintained that it was unconstitutional when the federal government chose to not enforce a federal statute, shifting the enforcement responsibility to the individual states.[184] West Virginia claimed that "the political responsibility of deciding whether or not to implement a federal statute" created an injury-in-fact for them.[185] However, West Virginia's argument lacked support because its injury was—simply put—"nothing more than the [mere] political discomfort in having the responsibility to determine whether to enforce or not . . . annoying some . . . citizens [by its decision]."[186] There is no precedent recognizing political discomfort as an injury-in-fact, and the court does not view the State's claim of injury as a cognizable legal injury.[187] The injury claimed must be concrete according to previous rulings.[188] Even if the agency action breached

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[178] *Id.* at 83.

[179] *Id.*

[180] 521 U.S. 898 (1997).

[181] 505 U.S. 144 (1992).

[182] West Virginia v. U.S. Dep't of Health and Human Servs., 827 F.3d 81, 83 (D.C. Cir. 2016).

[183] *Id.*

[184] *Id.* at 83-84.

[185] *Id.* at 84.

[186] *Id.*

[187] *Id.*

[188] *Id.*

state sovereignty, "West Virginia nevertheless lacks a *concrete* injury-in-fact."[189]

West Virginia's last contention, relying on *Carter v. Carter Coal Co.*,[190] was that any party "has standing to challenge a delegation from the government to carry out a governmental responsibility."[191] However, the case never discussed the issue of standing and therefore cannot be used as precedent for a standing issue.[192]

Holding:

The court held that West Virginia's contentions had no basis of support and relied on cases that did not discuss the issues in this case.[193] The district court's decision to dismiss the case for lack of standing was proper and was affirmed.[194]

Impact:

The court set yet another precedent that the State's injury-in-fact must be concrete and that political discomfort and consequences cannot be the basis for an injury-in-fact. The court solidified its view that the agency should not take responsibility for political accountability and consequences of the state in its decision. States are given the explanation that they cannot turn the blame to the agencies solely because of the fear of political consequences that result from the states' decisions. The court viewed West Virginia's claim to be a policy based dispute. The court's decision was concisely made in hopes to give agencies support when executing their rules and not to be bombarded with unsupported claims of non-concrete injury-in-fact.

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[189] West Virginia v. U.S. Dep't of Health and Human Servs., 827 F.3d 81, 84 (D.C. Cir. 2016) (emphasis in original).

[190] 298 U.S. 238 (1936).

[191] 827 F.3d. at 84.

[192] *Id.*

[193] *Id.*

[194] *Id.*