United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 25, 2022 Decided July 5, 2022

No. 21-5083

JEAN-GABRIEL BERNIER,
APPELLEE

v.

JEFF ALLEN, CHIEF PHYSICIAN, FBOP,
APPELLANT

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-00828)

Edward Himmelfarb, Attorney, U.S. Department of Justice, argued the cause for appellant. With him on the briefs were *Brian M. Boynton*, Acting Assistant Attorney General, and *Barbara L. Herwig*, Attorney.

Theodore A. Howard argued the cause and filed the brief for appellee.

Before: PILLARD and WALKER, *Circuit Judges*, and SILBERMAN, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* PILLARD.

Opinion concurring in the judgment filed by *Senior Circuit Judge* Silberman.

PILLARD, *Circuit Judge*: The Federal Bureau of Prisons cured inmate Jean-Gabriel Bernier's chronic Hepatitis C with pathbreaking and costly drugs. Bernier contends that he should have been treated earlier, within weeks of a new medical consensus recommending the drug even for patients like him in stable and non-life-threatening stages of the disease. He sues Dr. Jeffery Allen, the BOP Medical Director, for damages to compensate for the cruel and unusual punishment Bernier contends Allen inflicted by failing to grant his initial treatment request. Because under the circumstances as alleged Dr. Allen's decision violated no clearly established Eighth Amendment right, we hold that the doctor is entitled to qualified immunity from Bernier's damages claim.

INTRODUCTION

While he was incarcerated in federal prison and suffering from Hepatitis C, Bernier applied in December 2015 to receive treatment with Harvoni, a relatively new direct-acting antiviral drug he alleges "produced amazing results with cure rates nearing 100%" in patients like him. Second Amended Complaint (Complaint) ¶ 14. According to experts Bernier cites, "[a]mong incarcerated individuals, the rate of HCV seroprevalence ranges from 30% to 60%." J.A. 142 (Complaint Exhibit D). Under the treatment protocol then in place at the Federal Bureau of Prisons (BOP or Bureau), however, only Hepatitis C patients with certain indicia of advanced-stage liver disease were deemed "high priority" or "highest priority" and treated with Harvoni. BOP adopted that protocol when the medical consensus favored waiting to "gain experience with the []safety" of the new direct-acting antivirals before approving their broader use for less symptomatic

patients. Complaint ¶ 43. Because Bernier lacked the indicia of advanced-stage liver disease, Dr. Allen denied Bernier's application for treatment with Harvoni.

Bernier did not dispute that as of December 2015 his illness was not at a stage that entitled him to receive Harvoni under BOP's then-operative protocol. But he pointed to the fact that a panel of medical experts had just announced in October 2015 that clinical experience had sufficiently established the safety of Harvoni to justify its broader use. Indeed, in light of the report that Harvoni should be used to treat most Hepatitis C patients, including those like Bernier who were not among the most seriously ill, the BOP updated its protocol while this suit was pending to broaden access to direct-acting antiviral drugs. Pursuant to the revised protocol, the Bureau eventually approved a renewed request on Bernier's behalf. Bernier received treatment and his Hepatitis C has since been cured. Complaint ¶ 25.

His sole remaining claim seeks damages under *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971), from Dr. Allen. He claims that Dr. Allen's initial refusal to approve Harvoni treatment for him in December of 2015 was "a conscious decision to ration the recommended treatment," made solely "to minimize the high cost attending the administration of drugs such as Harvoni, not on the basis of any medical justification." Complaint ¶ 22. The validity or not of the revised BOP treatment protocol for Hepatitis C is not in issue, nor does Bernier make any claim that the Bureau moved too slowly in amending its Hepatitis C treatment protocol in response to the shifting medical consensus. Rather, Bernier contends that, in view of the state of his health at the time and the October shift in the announced medical consensus in favor of broader use of direct-acting antiviral drugs, Dr. Allen's failure two months later to make an

exception from the not-yet-amended protocol to treat Bernier with Harvoni was clearly unconstitutional. In particular, Bernier asserts that his allegation of the high cost of Harvoni suffices to plausibly plead that budgetary concerns displaced medical judgment in Dr. Allen's December 2015 decision. And he argues that, as a legal matter, it is clearly established that a decision based on non-medical reasons like cost to deny treatment for a serious medical need constitutes deliberate indifference in violation of the Eighth Amendment. Complaint ¶¶ 27-49.

The district court denied Dr. Allen's motion to dismiss or for summary judgment based on qualified immunity, and Allen is before us on interlocutory review. We conclude that Bernier fails to state a claim of violation of any Eighth Amendment right that was clearly established at the relevant time. He relies on what he describes as a consensus of authority that prison officials' denial of treatment for a serious medical condition for no reason other than cost violates inmates' clearly established Eighth Amendment rights. The complaint does not plausibly plead that Dr. Allen's December 2015 denial of Harvoni for Bernier's Hepatitis C was solely to save money in reckless disregard of any medical consequences. Nor do any of the precedents on which he relies otherwise recognize an Eighth Amendment violation in circumstances materially similar to his. We accordingly reverse the district court's denial of qualified immunity.

BACKGROUND

A. Factual allegations

Because this appeal arises at the motion to dismiss stage, the relevant facts are drawn from the well-pleaded allegations of Bernier's Second Amended Complaint, with all reasonable factual inferences drawn in his favor. Bernier, a Black man

who was sixty-one years old at the time of his complaint, began his incarceration in June 1990 under the custody of the State of New York Department of Corrections. He was transferred in August 2015 to the Federal Correctional Institution in Allenwood, Pennsylvania (FCI-Allenwood), where he was subjected to the treatment decisions at issue here.

Bernier was first diagnosed with Hepatitis C in state prison in 1999. Hepatitis C is a virus that resides in liver cells and causes progressive liver damage. The disease is typically chronic, and in advanced stages often results in cirrhosis, an inflammation and scarring of liver tissue. As it progresses, Hepatitis C impairs and can even destroy the organ's function. If left untreated, cirrhosis can be fatal.

The complaint identifies several techniques for diagnosing the progression of Hepatitis C and the risk and presence of cirrhosis. Liver biopsies, for example, surgically remove and examine a small piece of liver tissue for damage, with the potential disadvantage that the piece is not a representative sample of the liver's condition. A less invasive alternative is an ultrasound scan, which may be able to detect abnormalities in the liver's structure. Other diagnostic techniques take measurements from blood samples. Measuring liver enzymes in blood to generate an Aspartate aminotransferase-to-Platelet-Ratio-Index (APRI) score tracks the progression of Hepatitis C and development of cirrhosis. A different blood test under the trade name "Fibrosure" measures other blood markers to estimate liver damage.

Shortly after his transfer to FCI-Allenwood, medical staff at the facility examined Bernier. They noted that Bernier had been diagnosed with Hepatitis C and had undergone liver biopsies and Fibrosure tests while in state custody. The liver biopsies showed some tissue scarring that had not yet

progressed to cirrhosis. The Fibrosure results, in contrast, indicated that Bernier already had cirrhosis. The medical staff at Allenwood began regularly measuring Bernier's APRI score, which indicated that some liver damage had occurred but had not risen to the level of cirrhosis.

Bernier wanted to be treated with Harvoni. That relatively new drug had proved highly effective in curing Hepatitis C in patients similar to Bernier. But it came with a high price tag: A full course of treatment with Harvoni at that time cost about $94,000.

Speaking to the initial approval in 2013 to prescribe direct-acting antivirals like Harvoni to treat Hepatitis C, a panel of experts from the American Association for the Study of Liver Disease and the Infectious Diseases Society of America (IDSA/AASLD) noted that "knowledge about how these drugs worked came from clinical trials," and emphasized that the profession "needed to gain experience with their safety before we encouraged all infected persons to initiate therapy." Complaint ¶ 43. In the meantime, the expert panel recommended that the drugs be prescribed only to patients with the most serious need, such as those with severe liver disease who otherwise had dwindling treatment options for grave health conditions. *Id*.

Consistent with the original, more circumscribed recommendation of the IDSA/AASLD expert panel, BOP developed its initial prioritization protocol for treatment with direct-acting antiviral drugs. Under that protocol, patients with Hepatitis C were sorted into categories—Priority 1, 2, 3, or 4, in descending order of severity of their liver damage and other symptoms. *See* J.A. 127-28 (Complaint Exhibit B). BOP institutions were encouraged to submit applications to treat Priority 1 and 2 patients with direct-acting antivirals.

Complaint ¶ 21. Applications would proceed "up the chain of decisional authority" until the relevant BOP medical official approved or denied the treatment. *Id.* ¶ 19.

In December 2015, medical staff at FCI-Allenwood submitted a Non-Formulary Drug Authorization application to the BOP seeking approval to treat Bernier with Harvoni. The application noted that Bernier had chronic Hepatitis C. It included his liver biopsy results and APRI score but—for unknown reasons—did not include his Fibrosure results. *See* J.A. 121 (Complaint Exhibit A). It also observed, based on the biopsy and APRI results, that Bernier appeared to be Priority 3, so not the "highest" or even "high" priority for treatment. *Id.* at 121, 128 (Complaint Exhibits A, B).

Decision on Bernier's application rested with the Chief Physician and Medical Director for BOP, Dr. Jeffery Allen. There is no dispute that Bernier suffered from Hepatitis C, nor that, pursuant to the Bureau of Prisons protocol then in place, patients who did not yet have specified indicia of advanced-stage liver disease placing them in Priority Category 1 or 2 did not qualify for direct-acting antiviral treatment. On December 31, 2015, Allen denied Bernier's application with brief notations that appear to reference BOP's then-applicable prioritization protocol:

> Treatment naive [Hepatitis C] with no evidence for advanced liver disease. Current BOP priority level for treatment are not met. Continue to monitor and manage according to BOP guidelines and resubmit request when BOP priority criteria are met.

J.A. 121 (Complaint Exhibit A). FCI-Allenwood's Clinical Director later elaborated on Allen's reasoning, stating that, "[b]ased on [Bernier's] APRI he is designated as a Priority 3 patient," and that at the time BOP was approving only Priority

1 and Priority 2 patients for treatment with Harvoni. Complaint ¶ 21.

Acting pro se, Bernier filed suit in federal district court here in 2016. As relief for his Eighth Amendment claim of deliberate indifference to his serious medical needs, Bernier sought to enjoin BOP to afford him treatment with Harvoni, and sought damages from Dr. Allen pursuant to *Bivens*. *See Carlson v. Green*, 446 U.S. 14, 17-18 (1980) (recognizing availability of *Bivens* claims for Eighth Amendment violations where prison officials fail to provide adequate medical treatment).

Bernier claimed that the December 2015 treatment denial amounted to deliberate indifference to his serious medical needs in violation of clearly established Eighth Amendment rights. Bernier's complaint cited the latest IDSA/AASLD guidance based on "expanded 'real-world' experience with the tolerability and efficacy of newer [Hepatitis C virus] medications," which supported the use of direct-acting antivirals for "nearly all patients with chronic Hepatitis C." J.A. 130 (Complaint Exhibit C) (formatting altered). The expert panel no longer recommended prioritization only for those patients who were already seriously ill. *Id*. The panel recognized that "[b]ecause of the cost of the new drugs, or regional availability of appropriate health care providers, a practitioner may still need to decide which patients should be treated first," but emphasized that "the goal is to treat all patients as promptly as feasible to improve health and to reduce HCV transmission." *Id.* (internal quotation omitted). And the panel specifically heralded the promise of direct-acting antiviral drugs for prisons, where Hepatitis C is common, noting that "[c]oordinated treatment efforts within prison systems would likely rapidly decrease the prevalence of HCV

infection in this at-risk population . . . ." J.A. 142 (Complaint Exhibit D).

In light of the new IDSA/AASLD guidance, Bernier contended, Allen's December decision could be understood only as unconstitutionally based entirely on cost rather than medical considerations. In support, he recited Harvoni's high cost to assail Dr. Allen's failure to approve his December 2015 treatment request.

Bernier has since received treatment for his Hepatitis C with Zepatier, a direct-acting antiviral drug similar to Harvoni. In October 2016, BOP released an updated protocol that broadened the criteria for Priority 2, making Bernier eligible for treatment with Harvoni or an equivalent. Responding to a renewed application on Bernier's behalf, clinical staff in March 2017 authorized the requested treatment. Bernier's treatment with Zepatier, which began in April 2017, cured his Hepatitis C infection. Complaint ¶¶ 24-25. He now seeks compensation for having suffered the "painful symptoms and physiological harm attributable to his disease, as well as . . . [the] substantial risk of further serious harm" in the interim between his denied application for Harvoni and the commencement of his successful treatment with Zepatier. Complaint ¶ 26.

B. Legal framework

"'Deliberate indifference to serious medical needs of prisoners constitutes the unnecessary and wanton infliction of pain . . . proscribed by the Eighth Amendment,' and this includes 'indifference . . . manifested by prison doctors in their response to the prisoner's needs or by prison guards in intentionally denying or delaying access to medical care.'" *Erickson v. Pardus*, 551 U.S. 89, 90 (2007) (quoting *Estelle v. Gamble*, 429 U.S. 97, 104-05 (1976)) (formatting altered). Deliberate indifference includes subjective and objective

components; an official "must both be aware of facts from which the inference could be drawn that a substantial risk of serious harm exists, and he must also draw the inference." *Farmer v. Brennan*, 511 U.S. 825, 837 (1994). Moreover, not "every claim by a prisoner that he has not received adequate medical treatment states a violation of the Eighth Amendment." *Estelle*, 429 U.S. at 105. Mere inadvertent or negligent failures to provide care do not amount to deliberate indifference. *Id.* at 105-06. A complaint thus "must allege that 'officials had subjective knowledge of the serious medical need and recklessly disregarded the excessive risk to inmate health or safety from that risk.'" *Anderson v. District of Columbia*, 810 F. App'x 4, 6 (D.C. Cir. 2020) (quoting *Baker v. District of Columbia*, 326 F.3d 1302, 1306 (D.C. Cir. 2003)). There is no dispute here that refusal to provide timely, available, and appropriate treatment for a known, serious medical condition posing excessive risk to an inmate's health or safety would be deliberate indifference in violation of the Eighth Amendment.

We assume without deciding that well-pleaded allegations that a treatment decision was based exclusively on nonmedical considerations such as cost or administrative convenience rather than any medical justification can suffice to state an Eighth Amendment deliberate indifference claim. We have not directly spoken to this question, but other courts appear to agree at least that cost or other nonmedical rationale cannot be the only justification for prison officials' treatment decisions—including decisions affecting inmates with Hepatitis C. For example, in evaluating a treatment protocol in the Florida prison system, the Eleventh Circuit held that, while "the Eighth Amendment does not prohibit prison officials from considering cost . . . [,] cost can never be an absolute defense to what the Constitution otherwise requires." *Hoffer v. Sec'y, Fla. Dep't of Corr.*, 973 F.3d 1263, 1277 (11th Cir. 2020). And even before direct-acting antiviral drugs were available, the Seventh

Circuit recognized the viability of a deliberate indifference claim where application of an Illinois protocol regarding older forms of Hepatitis C treatment was motivated by "administrative convenience" and not "any real medical reason." *Roe v. Elyea*, 631 F.3d 843, 860 (7th Cir. 2011) (formatting altered).

As relevant to this appeal, Allen defends based on qualified immunity, which "protects government officials 'from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.'" *Pearson v. Callahan*, 555 U.S. 223, 231 (2009) (quoting *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982)). "[T]he right allegedly violated must be established, 'not as a broad general proposition,' but in a 'particularized' sense so that the 'contours' of the right are clear to a reasonable official." *Reichle v. Howards*, 566 U.S. 658, 665 (2012) (first quoting *Brosseau v. Haugen*, 543 U.S. 194, 198 (2004) (per curiam), then quoting *Anderson v. Creighton*, 483 U.S. 635, 640 (1987)).

To be sufficiently clearly established, a right need not rest on controlling authority directly on point, "but existing precedent must have placed the statutory or constitutional question beyond debate." *Ashcroft v. al-Kidd*, 563 U.S. 731, 741 (2011). Qualified immunity may be unavailable when plaintiffs identify "cases of controlling authority in their jurisdiction at the time of the incident" or "a consensus of cases of persuasive authority such that a reasonable officer could not have believed that his actions were lawful." *Wilson v. Layne*, 526 U.S. 603, 617 (1999).

Because qualified immunity provides "an immunity from suit rather than a mere defense to liability," *Pearson*, 555 U.S.

at 231 (quoting *Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985)), the viability of a duly asserted qualified immunity defense should be resolved "at the earliest possible stage in litigation," *id.* at 232 (quoting *Hunter v. Bryant*, 502 U.S. 224, 227 (1991) (per curiam)). To prevent erroneously subjecting public officials to the burdens of litigation, a defendant with a plausible immunity defense is entitled to an immediate appeal from a district court's order denying it. *See Mitchell*, 472 U.S. at 530.

C. Procedural history

Bernier's initial complaint sought both injunctive relief and damages against Allen and other government officials. Once Bernier's treatment with Zepatier proved successful, the court dismissed the claim for injunctive relief as moot. Meanwhile, over a period of 3 years, the district court struggled to assess the viability of Bernier's damages claim against Dr. Allen in the face of Allen's assertion of qualified immunity. The court considered Allen's three successive motions to dismiss Bernier's twice-amended complaint and Bernier's oppositions thereto, as well as Bernier's motions for reconsideration and to alter or amend the judgment. In the February 2021 order from which Allen appeals, the court decided that Bernier had stated a sufficiently clearly established Eighth Amendment damages claim to surmount Allen's pleading-stage assertion of qualified immunity.

The district court held that Bernier's complaint stated a clearly established Eighth Amendment claim in two distinct ways. The court first considered Bernier's allegations that BOP's protocol served "to minimize the high cost attending the administration of drugs such as Harvoni," and lacked "any medical justification." *Bernier v. Allen* (*Bernier 2020*), No. 16-CV-00828, 2020 WL 4047953, at *5 (D.D.C. July 20, 2020)

(quoting Complaint ¶ 22). Because the district court concluded that the Eighth Amendment clearly prohibits denying necessary treatment "purely for non-medical reasons such as cost," the court allowed Bernier to proceed to discovery to seek to substantiate that theory. *Id.*; *see id.* at *5-*6; *Bernier v. Allen* (*Bernier 2021*), No. 16-CV-00828, 2021 WL 1396375, at *1 (D.D.C. Feb. 8, 2021) (district court reaffirming that conclusion).

The court also noted that Dr. Allen was allegedly aware of Bernier's Fibrosure result showing cirrhosis yet disregarded it when he denied the requested treatment in December 2015. *See Bernier 2020*, 2020 WL 4047953, at *5 (citing Complaint ¶ 21). The court recognized that prison officials with knowledge of an inmate's serious medical needs may exhibit deliberate indifference in violation of the Eighth Amendment when they eschew medically recommended treatment in conscious disregard of excessive health risks. *Id*. at *6-*8 (citing, e.g., *United States v. Fitzgerald*, 466 F.2d 377, 380 n.6 (D.C. Cir. 1972)). If medical records in BOP's hands included test results indicating that Bernier had cirrhosis, the district court reasoned, Allen's disregard of "the BOP's *own* treatment recommendations" in its unamended protocol would amount to deliberate indifference. *Id.* at *6. The court acknowledged that Bernier had not directly asserted that "he was entitled to a higher priority level based on his Fibrosure test result," but granted him "the benefit of the doubt" that he was invoking this second theory in support of his Eighth Amendment claim. *Id.* at *6 n.5; *see also Bernier 2021*, 2021 WL 1396375, at *2 (district court reaffirming that conclusion). Allen timely appealed.

D. Jurisdiction and standard of review

We have jurisdiction to review final decisions of the district court. 28 U.S.C. § 1291. "Provided it 'turns on an issue of law,' . . . a district court's order rejecting qualified immunity at the motion-to-dismiss stage of a proceeding is a 'final decision' within the meaning of § 1291." *Ashcroft v. Iqbal*, 556 U.S. 662, 672 (2009) (quoting *Mitchell*, 472 U.S. at 530). Our review of the district court's decision to deny qualified immunity is *de novo*. *See Youngbey v. March*, 676 F.3d 1114, 1117 (D.C. Cir. 2012).

ANALYSIS

A. We first address the distinct basis for Bernier's Eighth Amendment claim that the district court gleaned but that Bernier himself had not clearly pressed: that Dr. Allen denied the application for Harvoni treatment in knowing disregard of Bernier's Fibrosure test result showing he had cirrhosis. Bernier's complaint alleged that his Fibrosure result indicated cirrhosis. It also alleged that, under BOP policy, medical evidence of cirrhosis might render unnecessary other diagnostic measures of Hepatitis C's progression—like the APRI scores and biopsy results Allen reviewed to conclude that Bernier's Hepatitis was less serious. *See* Complaint ¶¶ 39, 46.

The district court thought it plausible that, if Allen knew of the Fibrosure result, proper consideration of that result might have required him to view Bernier's medical needs as urgent even though other test results indicated otherwise. If a fully informed medical assessment would have concluded that Bernier in fact already had cirrhosis, he should have been placed in the Priority 1 or Priority 2 category even under the initial BOP protocol. Treating him as lower priority might well amount to deliberate indifference to a serious medical

condition. The district court thus decided to give Bernier "the benefit of the doubt" that Dr. Allen was aware of a test result showing that Bernier deserved a "higher priority treatment category" when he denied the application, *Bernier 2020*, 2020 WL 4047953, at *6 n.5, so relied in part on this ground to deny the motion to dismiss.

Bernier has made clear, however, that he is not advancing that distinct theory. Notably, Bernier's complaint did not allege that he was wrongly classified into Priority 3 at the time of his December 2015 request. *See id.* He has since clarified that he is not asserting that he in fact already had cirrhosis, so does not claim that denial of Harvoni before the expert panel released its updated recommendation in October 2015 would have amounted to deliberate indifference. And at oral argument his counsel confirmed that, even were we to credit the allegation that Dr. Allen knew of Bernier's Fibrosure result, Bernier does not claim that he should have been classified as other than Priority 3 (ineligible) under the then-applicable version of BOP's prioritization protocol. *See* Oral Arg. Rec. 42:26-43:59.

B. Bernier's sole theory on appeal, then, is that Dr. Allen was deliberately indifferent in denying the application for Harvoni "in reliance upon a prioritization protocol no longer consistent with accepted professional medical judgment and based entirely upon an intent to minimize costs." Complaint ¶ 46. We conclude that Bernier's allegations fail to plausibly support that inference, and that Allen's decision did not violate clearly established Eighth Amendment law. Accordingly, we hold that qualified immunity shields Allen from Bernier's claim for damages.

We begin with the contention that Dr. Allen's decision to deny the application for Harvoni was entirely cost-based.

Bernier alleges two facts to support that contention: the bare fact that Harvoni was expensive, and the issuance two months earlier of the expert panel report modifying its position to recommend direct-acting antiviral drugs as safe and effective for Hepatitis C patients at all stages of the disease. *See* Appellant Br. 17-22; Complaint ¶¶ 38, 46. But the complaint's Exhibit A belies that contention by providing the decidedly medical reasoning that Dr. Allen gave for his decision to deny Bernier's application for Harvoni.

Allen's written decision reflects an individualized determination about Bernier's circumstances and need. It specifically identifies the nature of Bernier's health issue ("HCV-1a"), his treatment history ("[t]reatment naive"), and the virus's stage of progression ("no evidence for advanced liver disease"). J.A. 121 (Complaint Exhibit A). The decision's express invocation of medical considerations significantly undermines the plausibility of inferring that Allen denied Bernier's application solely because of Harvoni's high cost.

Bernier insists, however, that Dr. Allen acted with deliberate indifference because he referenced BOP's unamended prioritization protocol. Specifically, he argues that, once the medical consensus shifted in October 2015 and effectively updated the standard of care for patients with Hepatitis C, Allen's continued reference to the existing protocol's treatment categories constituted deliberate indifference. *See* Complaint ¶¶ 46-47. In Bernier's view, Allen should have immediately approved the application for Harvoni in accordance with the October 2015 IDSA/AASLD panel report's recommendation that all Hepatitis C patients receive treatment with direct-acting antivirals. Bernier asserts that Allen's denial, with reference to the protocol's priority rubric, amounted to a violation of the Eighth Amendment.

In effect, then, Bernier's claim is that he had a constitutional right to treatment with the direct-acting antiviral drug Harvoni at the time of his December 2015 application. Bernier is no longer seeking an injunction requiring the BOP to treat him with Harvoni, and we accordingly do not decide the distinct question how such a claim might be affected by the updated standard of care. Here, Bernier seeks to overcome Dr. Allen's assertion of qualified immunity in pursuit of his damages claim, and his burden is correspondingly higher. His allegations must plausibly establish the inference that Dr. Allen's decision not only violated a right to treatment for a serious medical need, but a clearly established one. *See Iqbal*, 556 U.S. at 673, 682. To defeat Allen's assertion of qualified immunity, Bernier must point to "existing precedent" that places the relevant "constitutional question beyond debate." *al-Kidd*, 563 U.S. at 741 (citation omitted). The relevant question in this case is whether Bernier, as his health stood at the time, was constitutionally entitled to treatment with Harvoni within two months of the medical community deciding it was appropriate for lower-risk patients like him to receive it.

Whatever the right answer is to that question, we cannot conclude that existing law in December 2015 made it clear. Bernier does not identify—and we are not aware of—any controlling precedent from the Supreme Court or our circuit that affirmatively identifies that right "in a particularized sense so that [its contours] are clear to a reasonable official." *Reichle*, 566 U.S. at 665 (internal quotation omitted). Nor is there "a consensus of cases of persuasive authority such that [Dr. Allen] could not have believed that" it was medically appropriate to deny Bernier's application for Harvoni. *Wilson*, 526 U.S. at 617. Indeed, in response to a question at oral argument about how quickly prison medical authorities are required to conform their actions to a new standard of care to avoid Eighth Amendment liability for deliberate indifference, Bernier's

counsel candidly acknowledged that "the case law that has emerged since the direct-acting antiviral medications came to the fore has been quite variable with regard to the views of courts in terms of how quickly implementation should have taken place, so I do not have a definitive answer." Oral Arg. Rec. at 40:43-41:25; *see also* Appellee Br. at 21 (recognizing the expert panel's acknowledgement "that *implementation* of the new [standard of care] might not be instantaneous"). Especially since Bernier acknowledges that he was correctly classified as Priority 3 when his application was denied, the lack of a definitive answer here is dispositive: No clearly established law guaranteed his right to treatment with direct-acting antiviral drugs at the time of his application.

Bernier seeks to meet the requirement that he identify clearly established law that Dr. Allen violated by citing to three out-of-circuit cases, which he argues support the proposition that corrections officials sued under the Eighth Amendment are not entitled to qualified immunity when they deny prisoners Hepatitis C treatment "on the basis of implementation of bureaucratic administrative policies not having a specific basis in governing medical standards." Appellee Br. at 14; *see id.* at 13-14 (citing *Elyea*, 631 F.3d at 858-61; *Johnson v. Wright*, 412 F.3d 398, 404-06 (2d Cir. 2005); *McKenna v. Wright*, 386 F.3d 432, 435-37 (2d Cir. 2004)). But those decisions do not support the type of claim Bernier asserts. Their reasoning thus does not undercut Dr. Allen's assertion of qualified immunity.

In *Roe v. Elyea*, for example, the Seventh Circuit upheld a jury's verdict that the prison medical director's "failure to consider an individual inmate's condition in making treatment decisions" amounted to deliberate indifference to the inmate's advanced liver disease. 631 F.3d at 862. In 2004, Dr. Elyea denied Roe access to testing and a pre-Harvoni form of antiviral therapy for Hepatitis C. *Id.* at 851. The doctor relied

on an Illinois Department of Corrections protocol that rendered inmates with fewer than eighteen months still to serve in prison ineligible for Hepatitis C testing and treatment. *Id.* at 850. Defendants contended the protocol was justified to ensure that inmates who began a course of treatment could complete it. *Id.* Dr. Elyea adhered to that protocol despite knowledge of Roe's advanced-stage liver disease, and even though he knew that patients with Roe's genotype could be treated in half the time. *Id*. at 850-51. Roe died before he was afforded the treatment he sought. *Id*. at 851. In rejecting the qualified immunity defense, the court noted Dr. Elyea's acknowledgement that "there may not have been any real medical reason" for the protocol's uniform approach across genotypes "other than to keep it simple." *Id.* at 863.

The two cases from the Second Circuit similarly held qualified immunity inapplicable where state prison officials' reliance on treatment protocols led them to deny appropriate treatment to Hepatitis C patients in disregard of known, serious health risks. The defendant officials in *Johnson v. Wright* denied treatment pursuant to a New York State Department of Corrections policy forbidding Hepatitis C medication to any patient with evidence of active substance abuse within the preceding two years. 412 F.3d at 400. Based on one urine test a year earlier showing marijuana use, defendants had "reflexively follow[ed] the Guideline's substance abuse policy in the face of the unanimous, express, and repeated recommendations of plaintiff's treating physicians," *id.* at 406, that Johnson needed medication and should receive it "in spite of [the] drug policy," *id.* at 402 (internal quotation omitted). The policy rested on an interest in avoiding potentially toxic interactions between prescribed treatments and abused substances and concerns that patients abusing drugs and alcohol might miss appointments or otherwise fail to adhere to the treatment regimen. *Id.* at 405. But apprehensions about

alcohol or narcotics contributing to liver damage concededly did not apply to Johnson's limited marijuana use. *Id.* And the court held that a jury could have found compliance concerns likewise inapplicable because of Johnson's record of compliance with an earlier treatment regimen. *Id.* at 405-06. The court of appeals thus held summary judgment unwarranted because a jury could reasonably find that the defendants knew of but acted with deliberate indifference to "an excessive risk to Johnson's health." *Id*. at 406.

The Second Circuit in *McKenna* likewise denied prison officials qualified immunity from an Eighth Amendment deliberate-indifference claim. 386 F.3d at 437. Defendants allegedly withheld urgently needed Hepatitis C treatment for which McKenna would otherwise be eligible, relying in part on the possibility that he might be paroled from his four-year sentence before the twelve months of treatment could be completed and thus add to systemic "risk of the development and spread of untreatable HCV." *Id*. (quotations omitted). In denying treatment, the defendants also cited McKenna's failure to enroll in an alcohol and substance abuse treatment program even though they had deemed him ineligible for that very program due to his medical condition, *id*. at 434, and objected that his "cirrhosis was decompensated, *i.e.,* accompanied by various complications," even though they turned down his request for a liver transplant "because the cirrhosis was probably compensated," *id*. The complaint alleged "a series of failures to test for [McKenna's] condition despite known danger signs of his disease, failure to initiate treatment when the need for treatment was apparent, failure to send McKenna for follow-up visits ordered by doctors," as well as "denial of treatment based on inapplicable and flawed policies" occurring over a period of more than four years. *Id*. at 437. By the time defendants authorized the care McKenna sought, "his disease was so advanced that the side effects rendered him too weak to

continue treatment." *Id*. at 435. The district court correctly denied the defendant officials' motion to dismiss because the allegations showed their reliance on prison policies was not objectively reasonable under the circumstances. *Id*. at 437. In particular, the court held that denial of "urgently needed treatment for a serious disease because [the patient] might be released within twelve months of starting the treatment sufficiently alleges deliberate indifference" to overcome qualified immunity. *Id*.

We cannot conclude based on the cases on which Bernier relies that there is any "consensus of cases of persuasive authority" in support of his particular claim. *Wilson*, 526 U.S. at 617. Unlike in those cases, there is no plausible allegation here of any deliberate or reckless delay or any disregard of exacerbating symptoms. Whether a prison official acts with deliberate indifference depends in part on the severity of the inmate's medical needs. *See Estelle*, 429 U.S. at 104. Despite his Fibrosure results, Bernier does not contend that he in fact had cirrhosis when his application was denied. Oral Arg. Rec. at 43:38-59. Bernier's Hepatitis C was then in relatively early stages, and his medical condition was generally stable. Indeed, Bernier acknowledges that in December 2015 he was correctly categorized into Priority 3 under the protocol. *Id.* at 42:26-52. As such, he was at lower "risk for complications or disease progression" and required less "urgent consideration for treatment" than Priority 1 or 2 patients. Complaint ¶ 21; *see also Bernier v. Koenigsmann*, No. 9:17-CV-0254, 2021 WL 2269839, at * 12 (N.D.N.Y. May 13, 2021) (finding in a separate case related to Bernier's incarceration in state prison that the uncontradicted opinion of Bernier's treating physicians was that, as of April 2015, his "condition was stable, and there was no urgent need to rush treatment"). That makes Bernier's situation unlike one where, for example, an inmate's test results revealed the immediate need to forestall grave harm, requiring

speedier action by prison officials like Dr. Allen to approve even a newly recommended treatment.

Nor did any of the cases Bernier cites recognize a clearly established right of a patient under medical management of a serious disease, monitored and apparently stable, immediately to receive the most recently recommended treatment within just a few weeks of its clinical acceptance as appropriate. Rather, the treatment denial in those cases rested on protocols that focused in bluntly categorical ways on public health concerns at the expense of the individual's known, urgent need for treatment for a serious medical condition, or reflected considerations of administrative convenience that directly conflicted with similarly grave individual health needs.

By contrast, the protocol in this case, while just recently outdated in its classification system, expressly instructed BOP medical officials to make "[e]xceptions" to the regular priority system "on an individual basis . . . [,] determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities." J.A. 128 (Complaint Exhibit B). As discussed above, Dr. Allen's decision relying on BOP's protocol here did in fact make an individualized medical determination about Bernier's needs—considering the stable nature and relatively low urgency of Bernier's case—before concluding that treatment with Harvoni was not then warranted. Having done so, "a reasonable officer" in Dr. Allen's position could accordingly "have believed that his actions were lawful," even assuming that he was bound by the three out-of-circuit decisions Bernier cites. *Wilson*, 526 U.S. at 617.

We therefore hold that qualified immunity protects Dr. Allen from personal liability for damages based on his December 2015 treatment decision in Bernier's case.

* * *

Accordingly, we reverse the district court's denial of qualified immunity to Allen.

So ordered.

SILBERMAN, *Senior Circuit Judge*, concurring in the judgment: Like the majority, I would reverse the district court's denial of qualified immunity to Dr. Allen. I write separately because I think it is clear that Bernier has not stated an Eighth Amendment violation, whether or not it is clearly established in the case law.

Bernier's theory on appeal is that Dr. Allen was deliberately indifferent in denying his application for the anti-viral drug, Harvoni. Bernier claims he was constitutionally entitled to Harvoni for his Hepatitis C and that Dr. Allen illegitimately relied entirely on cost to deny the drug promptly. *See* Complaint ¶ 46. As the majority notes, the relevant question here is "whether Bernier, as his health stood at the time, was constitutionally entitled to treatment with Harvoni within two months of the medical community deciding it was appropriate for lower-risk patients like him to receive it." *Supra* at 17. The majority concludes that, "[w]hatever the right answer is to that question," Bernier cannot overcome qualified immunity because the right he articulates is not clearly established. *Supra* at 17–18.

I think that the right answer—and therefore the theoretically clearly established one—to the question the majority raises is clearly 'no' as a matter of law.

The majority states that "[t]here is no dispute here that refusal to provide timely, available, and appropriate treatment for a known, serious medical condition posing excessive risk to an inmate's health or safety would be deliberate indifference in violation of the Eighth Amendment." *Supra* at 10. I do not agree with that statement. I think it's too broad. In the same vein, the majority opinion goes on to say that "[w]e assume without deciding that well-pleaded allegations that a treatment decision was based exclusively on nonmedical considerations such as cost or administrative convenience rather that any medical justification can suffice to state an Eighth Amendment

deliberate indifference claim." *Supra* at 10. I reject that assumption. It is also an overstatement.

We must bear in mind that the constitutional provision we are applying is the Eighth Amendment, which, in relevant part, bans the infliction of "cruel and unusual *punishments*." U.S. CONST. amend. VIII (emphasis added). It does not guarantee state-of-the-art medical care for prisoners. A federal prison is not a Johns Hopkins Hospital. It appears that some of our sister circuits have lost sight of that fundamental concept in their implementation of the deliberate indifference standard first articulated in *Estelle v. Gamble*, 429 U.S. 97, 104–05 (1976). *See, e.g.*, *Abu-Jamal v. Kerestes*, 779 F. App'x 893, 900 (3rd Cir. 2019); *Johnson v. Wright*, 412 F.3d 398, 404–06 (2nd Cir. 2005).

My view is that in any case in which there is an allegation that a federal prisoner has suffered an Eighth Amendment violation because of deliberate indifference to his or her serious medical needs, the issue before the court is a balancing question. The government is entitled to balance administrative considerations, including cost, against medical need. Still, the threshold question is whether there is a *severe* medical need. In the absence of such a need, even minor administrative considerations would suffice to deny treatment.

Indeed, in *Estelle*, Justice Marshall made clear that not "every claim by a prisoner that he has not received adequate medical treatment states a violation of the Eighth Amendment." *Id.* at 105. He carefully distinguished medical malpractice from an Eighth Amendment violation. *Id.* at 105–06. That means that medical treatment of an inmate that could be criticized as merely "inappropriate" does not constitute an Eighth Amendment violation.

I think the Eleventh Circuit got it right in *Hoffer v. Secretary, Florida Department of Corrections*. 973 F.3d 1263 (11th Cir. 2020). It said that medical treatment violates the Eighth Amendment "only when it is so grossly incompetent, inadequate, or excessive as to shock the conscience." *Id.* at 1271 (quotations omitted). In other words, in its view, the Eighth Amendment only requires a minimally adequate level of care. I agree with their "commonsense notion" that "the civilized minimum level of care required by the Eighth Amendment is a function both of objective need and cost." *Id.* at 1276 (quotations omitted). "The more serious and exigent an inmate's need, the more likely it is that 'the civilized minimum' might be deemed to require expensive treatment—and vice versa." *Id.* So, prison officials may consider cost in "determining what type (or level) of medical care inmates should receive." *Id.* at 1277.

Accordingly, as I've indicated, it is too sweeping for the majority to assert that "refusal to provide, timely, available and appropriate treatment for a known, serious medical condition posing excessive risk to an inmate's health or safety" would necessarily constitute deliberate indifference. "Appropriate treatment" is a medical malpractice concept, which exceeds the government's obligation to provide minimally adequate care. Once that standard is met, refusal to provide a particular treatment that is "available and appropriate"—even for a serious condition—is constitutionally permissible. As the Eleventh Circuit stated, "diagnosing, monitoring, and managing conditions—even where a complete cure may be available—will often meet the 'minimally adequate medical care' standard that the Eighth Amendment imposes." *Id.* at 1273.

Moreover, an allegation that a treatment decision was based solely on cost does not by itself suffice to state a

deliberate indifference claim. The majority quotes one sentence in the Eleventh Circuit's opinion for the proposition that, while "the Eighth Amendment does not prohibit prison officials from considering cost . . . [,] cost can never be an absolute defense to what the Constitution otherwise requires," *id.* at 1277, to support its assertion that cost "cannot be the only justification for prison officials' treatment decisions," *supra* at 10. But that sentence alone is quoted out of context. The Eleventh Circuit immediately thereafter stated that, "[p]ut differently, if a particular course of treatment is indeed essential to 'minimally adequate care,' prison authorities can't plead poverty as an excuse for refusing to provide it." *Id.* at 1277. By implication, a federal prison can deny a *particular course* of treatment—i.e. one that exceeds the constitutional minimum—based exclusively on cost, so long as it provides minimally adequate care. Thus, a prisoner must do more than allege that a treatment decision was based exclusively on cost to state a deliberate indifference claim.

In other words, unless an inmate is facing a serious medical problem, almost any administrative or cost considerations can dictate the prison's response. And, even if an inmate does face a serious medical problem, administrative and cost considerations can outweigh his or her entitlement to a particular treatment, so long as the constitutional minimum is met.

It is obvious that Bernier was not constitutionally entitled to the enormously expensive Harvoni within two months of the medical community deciding it was appropriate for lower-risk patients like him. Harvoni is a state-of-the-art direct-acting antiviral drug that completely cures Hepatitis C. Bernier does not plausibly allege deliberate or reckless delay by Dr. Allen or disregard of disease progression. In fact, Bernier does not claim that he has cirrhosis and does not contest his placement

into Priority 3 under the prison's treatment protocol. In sum, Bernier has not met the threshold to trigger the deliberate indifference balancing test; he was not facing a serious medical risk.

Even if he had met the threshold, Bernier was in stable condition, the prison was managing his Hepatitis C, and Dr. Allen was monitoring Bernier's condition and applying a treatment protocol based on risk for complications or disease progression. Dr. Allen even made an individualized medical determination before denying Bernier's request for treatment with Harvoni. Indeed, Dr. Allen's decision would have been justified in these circumstances even if he had relied purely on cost to deny Bernier treatment with Harvoni. Dr. Allen has provided minimally adequate care and the right Bernier claims far exceeds that constitutional minimum. Accordingly, Dr. Allen's conduct does not constitute deliberate indifference.

Because it is so clear that Bernier has not stated a cause of action plausibly alleging an Eighth Amendment violation, we should forthrightly so conclude.[1]

[1] At times the majority opinion seems to veer back and forth between agreeing that there is no violation here and that the right Bernier asserts is not clearly established. *See supra* at 21–23. Indeed, the majority analyzes the facts and allegations in much the same way I do and approaches the same conclusion. Nevertheless, the majority rests its conclusion on the clearly established prong of qualified immunity.