No. 10-99021

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JEFFREY TIMOTHY LANDRIGAN, Plaintiff - Appellee,

vs.

JANICE K. BREWER et al., Defendants - Appellants.

Appeal from United States District Court
for the District of Arizona
Hon. Roslyn O. Silver, District Judge, Presiding
D.C. No. 2:10-cv-2246-PHX-ROS

RESPONSE IN OPPOSITION TO APPELLANTS' MOTION TO LIFT STAY

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The district court issued an order for a temporary restraining order.[1] Appellants have filed a motion to lift the stay. By doing so, Appellants failed to comply with Federal Rule of Civil Procedure 8(a)(1)(A). And they have provided this Court with no reason why it would have been impracticable to ask the district court for a stay. Procedure aside, Appellants' arguments give this Court no reason to disturb the well-reasoned temporary restraining order issued by the United States District Court for the District of Arizona this afternoon.

One day after Landrigan learned that the State of Arizona intended to execute him using sodium thiopental obtained from a unknown foreign source not approved by the United States Food and Drug Administration (FDA), he filed a complaint and motion for temporary restraining order or preliminary injunction in the United States District Court for the District of Arizona. (Dist. Ct. Doc. Nos. 1, 3.) Contrary to Appellants' motion, Landrigan's pending lawsuit does not challenge Arizona's lethal-injection protocol, nor does it seek to compel the federal courts to find that the FDA regulates executions. Rather, Landrigan raises unique and fact-specific claims related

[1]In the district court, Landrigan filed a Motion for Temporary Restraining Order or a Preliminary Injunction. The district court entered its Order Granting Motion for a Temporary Restraining Order. If this Court concludes that the district court's order should be construed as granting only a temporary restraining order, then this matter is not properly before the Court as an interlocutory appeal. *See, e.g.*, *Bennett v. Medtronic, Inc.*, 285 F.3d 801, 804 (9th Cir. 2002) ("Ordinarily, temporary restraining orders, in contrast to preliminary injunctions, are not appealable.").

to Appellants' intended use of sodium thiopental from an unknown and unverified foreign source. Specifically, Landrigan argues that the unknown provenance of the sodium thiopental means that there are no guarantees that the drug is authentic and pure, that it is not a chemical that will cause him harm, or that it is the same formulation as FDA-approved sodium thiopental. These concerns create both a substantial and objectively intolerable risk of harm for which prison officials cannot be subjectively blameless, in violation of his Eighth Amendment right to be free from cruel and unusual punishment.[2]

1. Landrigan did not unreasonably delay in bringing suit against Appellants.

Contrary to Appellants' assertion, Landrigan could not have raised his claims earlier. Landrigan's concerns over the sodium thiopental Appellants intended to use in his execution arose because of a national shortage of the drug. Landrigan has been attempting to obtain information from Appellants regarding its procurement of the sodium thiopental that the Arizona Department of Corrections (ADOC) intends to use in his execution for over a month. It was not until last Wednesday, October 20, that

[2]Landrigan also alleged that Appellants' failure to disclose requested information regarding the acquisition of this drug violates his due process rights under the Fourteenth Amendment to the United States Constitution. (Dist. Ct. Doc. No. 1, ¶¶ 48-49.)

Appellants' counsel admitted that Hospira, Inc., did not manufacture the drug.[3] The very next day, Landrigan filed his complaint, alleging that the ADOC's use of non-FDA approved sodium thiopental obtained from an unknown source violates his right to be free from cruel and unusual punishment. As the district court found, Landrigan "pursued [his claims] aggressively as soon as he viewed them as ripe." (Dist. Ct. Doc. No. 21 at 12) (quoting *Beardslee*, 395 F.3d at 1069).

The district court's finding was not clearly erroneous. Landrigan sent a letter to ADOC on September 24, 2010, asking for information regarding the source of the drugs that it had obtained for use in Landrigan's execution. (Dist. Ct. Doc. No. 1, Exhibit A.) Appellants could have responded to Landrigan's informal request at that time. Instead, they chose not to. Landrigan then asked the Arizona Supreme Court to order Appellants to do so. On questioning at oral argument, Appellants' counsel admitted only that the drug that ADOC had obtained was not Hospira product.

Armed with that information alone, and with his execution a mere five days away, Landrigan turned to the federal courts for relief. Two days after Landrigan filed his complaint, at 7:52 P.M. on October 23, the district court ordered Appellants to disclose information relating to the provenance of the drugs they had acquired.

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[3]As Hospira is the only manufacturer currently approved by the FDA to manufacture thiopental, this disclosure—for the first time—alerted Landrigan to the fact that ADOC intended to use non-FDA approved drugs in his execution.

(Dist. Ct. Doc. No. 11 at 3-4.)[4] Appellants waited 36 hours—until the morning of the day before Landrigan's scheduled execution—to make even a partial effort at compliance, an effort that fell short of the district court's order.

"Timing is everything" in this case, as this Court has recently observed. *Morales v. Cate*, No. 10-99019, 2010 WL 3749394, at *1 (9th Cir. Sept. 27, 2010). The result in this matter should not be driven either by the State of Arizona's choice to schedule an execution date or by Appellants' effort to manipulate the district court's decisional process by delaying compliance with an order to supply information relevant to resolving Landrigan's claims. *See id*. at *3; *see also* Dist. Ct. Doc. No. 21 at 12-13. As a matter of equity, Appellants' dilatory tactics should weigh against them. The district court thus did not clearly err in finding that Landrigan did not unreasonably delay before filing suit. *See also Nelson v. Campbell*, 541 U.S. 637, 650 (2004).

2. The district court did not abuse its discretion to enjoin Appellants from executing Landrigan on October 26, 2010.

This Court reviews a district court's grant of a preliminary injunction for abuse of discretion. *See Alliance for the Wild Rockies v. Cottrell*, No. 09-35756, 2010 WL

[4]Appellants briefly state that the disclosure ordered by the district court is confidential under Arizona Revised Statute section 13-757(C). Appellants present neither compelling nor new arguments to this Court, and they fail explain why the district court erred in its order.

3665149, at *4 (9th Cir. Sept. 22, 2010). An abuse of discretion exists only if the district court relied "on an erroneous legal standard or clearly erroneous finding of fact." *Id.* The Court reviews "conclusions of law *de novo* and findings of fact for clear error." *Id.* This Court should not reverse the grant of the preliminary injunction where the district court "'got the law right,' even if [this Court] 'would have arrived at a different result,' so long as the district court did not clearly err in its factual determinations." *Id.*

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 374 (2008). A plaintiff may also show that there are "serious questions going to the merits and a hardship balance that tips sharply towards the plaintiff," along with a "likelihood of irreparable injury and that the injunction is in the public interest." *Alliance for the Wild Rockies*, 2010 WL 3665149, at *9. Because the district court correctly applied the correct test and did not make clearly erroneous factual determinations along the way, it did not abuse its discretion to enjoin Appellants from executing Landrigan.

A. Landrigan has shown a likelihood of success or serious questions on the merits

The district court correctly decided that Landrigan has made a "factual showing that there are 'serious questions going to the merits.'" (Dist. Ct. Doc. No. 21 at 14) (citation omitted). In fact, the district court recognized that Landrigan has "shown as much likelihood of success as he possibly could given Defendants' obstructive behavior." (Dist. Ct. Doc. No. 21 at 14.) Appellants once again fail to address Landrigan's argument and instead claim that Landrigan asserts that the FDA regulations should govern executions. (Mot. to Lift Stay at 10.)

Landrigan is not seeking to compel the FDA to take enforcement action against the State of Arizona under the FDCA, unlike the Respondent prison inmates in *Heckler v. Chaney*, 470 U.S. 821, 823 (1985). Accordingly, contrary to Appellants' assertions, this case is decidedly *not* about administrative law. It is about one issue, and one issue only: ensuring the efficacy of a drug, the efficacy of which is undisputedly necessary in ensuring that Arizona's three-drug lethal-injection protocol meets Eighth Amendment requirements.[5]

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[5]Appellants also misstate Landrigan's argument by claiming that "mere assertion that the drugs may be from another country does not establish the showing necessary to prevail." (Mot. to Lift Stay at 5.) Landrigan has supported his claims with evidence that a drug manufactured outside of the United States that has not been approved by the FDA raises real concerns as to the drug's safety and efficacy.

As the district court explained:

> the issue here is not simply FDA approval. Instead, the issue is whether there is a sufficient level of confidence that the sodium thiopental Defendants plan on using to sedate Plaintiff does not create a substantial risk of harm. FDA-approval is relevant in that drugs manufactured under FDA-guidelines are likely to perform as expected; drugs manufactured by non-FDA approved sources might not benefit from such a presumption. Without the assurance of FDA-approval, the Court is left to speculate whether the non-FDA approved drug will perform in the exact same manner as an FDA-approved drug and whether the non-FDA approved drug will cause pain and suffering.

Dist. Ct. Doc. No. 21, at 15. Contrary to the situation in *Chaney*, Landrigan has not asked the Court to compel the FDA to act. Instead, he has repeatedly pointed out the fact that FDA approval is significant because the agency relies on scientific expertise, based on "a solid cadre of experienced physicians, toxicologists, chemists, mathematicians . . . ."[6] to "assur[e] that all prescription . . . drugs are *safe and effective*."[7] Because carefully constructed scientific standards exist in this country,

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[6] *See, e.g.*, *Improving Public Health: Promoting Safe and Effective Drug Use*, FDA Publication No. FS 01-3 (emphasis in original), available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM121592.pdf (*last visited* Oct. 25, 2010).

[7] *Id.*; *see also* testimony of Randal W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, Food and Drug Administration, before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources House Committee on Government Reform, Nov. 1, 2005 (noting that "FDA is concerned that the drug supply is under unprecedented attack from a variety of increasingly

and because drugs which are not approved by the FDA have not been shown to meet those scientific standards, Landrigan has raised serious questions regarding the merits of his claims.

Appellants ignore basic objective standards designed to ensure efficacy and safety of drugs used in this country; accordingly, they have created an objectively intolerable risk of harm for which they are not subjectively blameless. *Baze v. Rees*, 535 U.S. 35, 50 (2008) (three-judge plurality). Appellants have steadfastly ignored the basic issues confronting the use of an untested product. They instead merely repeat their mantra that the protocol will somehow protect Landrigan against concerns of unconsciousness. This tactic of Appellants' led the district court to note that "Defendants make *no effort* to rebut Plaintiff's claim that there is a risk the sodium thiopental, if contaminated, could itself cause unnecessary pain and suffering." (Dist. Ct. Doc. No. 21 at 10.)

As Landrigan alleged in the district court, in the United States, sodium thiopental is regulated by the FDA as a prescription medication and is a controlled

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sophisticated threats. This disturbing trend is evident in the increased efforts to introduce counterfeit drugs into the U.S. market[,]" and that "Counterfeit prescription drugs are illegal and unsafe. Many are visually indistinguishable from authentic drugs, and they pose a potentially serious health threat."). http://www.fda.gov/NewsEvents/Testimony/ucm112670.htm (*last visited* Oct. 24, 2010).

substance. (*See* Declaration of John D. Palmer, Ph.D., M.D., dated Oct. 21, 2010 (Dist. Ct. Doc. No. 3-1, Ex. F)) (herein after "Palmer Decl.") According to John D. Palmer, Ph.D., M.D., a medical doctor whose subspecialty is clinical pharmacology, FDA approval of a drug ensures that the product will be "pure and free of potentially harmful contaminants produced in the production of the product." (Palmer Decl. ¶11.) FDA approval also ensures that "the drug product actually contains the amount and concentration of drug as indicated on the label." (Palmer Decl. ¶13.) The FDA standards require "the use of rigorous analytical techniques to ensure the calculation of safe and effective doses." (Palmer Decl. ¶14.) In fact, "[w]ithout FDA approval the product cannot reliably present the important information contained in the product labeling: basic pharmacologic information, indications, contraindications, adverse reactions, precautions warnings, and usual dosage." (Palmer Decl. ¶15.) Dr. Palmer opines that it is so critical that a drug be approved by FDA "that a reasonable and prudent medical practitioner would not use thiopental that has not received FDA approval." (Palmer Decl. ¶16.)

Based on this uncontested information, Landrigan has shown that there is a likelihood of success on the merits and that there are "serious questions going to the merits" of his claims. *Wild Rockies*, 2010 WL 3665149, at *8. The district court had before it an uncontested declaration from Dr. Palmer raising serious concerns that use

of drug from a non-FDA approved source would violate Plaintiff's Eighth Amendment rights. "There is no way to know with reasonable certainty that the product is safe or effective." (Palmer Decl. ¶16.) As the district court correctly found, "the use of sodium thiopental from a non-FDA-approved source raises issues regarding its efficacy and possible side-effects." (Dist. Ct. Doc. No. 21 at 14.) By intending to use this unknown substance in Plaintiff's execution, Defendants simply are not "subjectively blameless" for the "objectively intolerable risk of harm" that they have created. *Baze v. Rees*, 553 U.S. 35, 50 (2008). Thus, Landrigan has demonstrated a reasonable likelihood of success on the merits.

B. Landrigan will suffer irreparable harm and balance of hardships tips sharply in Landrigan's favor

It is unquestionable not only that Landrigan's case would become moot if the Defendants were permitted to execute him before his claims were resolved on the merits, *see Wainwright v. Booker*, 473 U.S. 935, 936 (1985) (Powell, J., concurring), but also that Landrigan faces execution by an unregulated drug about which he knows virtually nothing, and which comes with no guarantee that it is safe and effective. Landrigan recognizes that the State of Arizona has an interest in seeing finality by imposing his sentence of death quickly; however, the risk of Landrigan facing an unconstitutional execution outweighs the State's interest in carrying out that

execution tomorrow, on October 26, 2010. Executing Landrigan is thus an irreparable harm that counsels in favor of an injunction issued by the district court.

On the other hand, if this Court upheld the injunction, Appellants would suffer little harm. They would simply have to wait until they demonstrate that the obtained drug will be effective and uncontaminated sodium thiopental before carrying out Landrigan's execution. The hardship scale thus tips sharply in Landrigan's favor due to Appellants' actions surrounding his scheduled execution. Appellants have continually failed to provide Landrigan with information regarding the sodium thiopental despite his diligent efforts to discover that information.

C. The injunction is in the public interest

Furthermore, the public interest is advanced by resolving the constitutionality of Appellants' proposed course of action before Landrigan is executed. The public interest is served by protecting Landrigan's constitutional rights. *Preminger v. Principi*, 422 F.3d, 815, 826 (9th Cir. 2005) ("Generally, public interest concerns are implicated when a constitutional right has been violated, because all citizens have a stake in upholding the Constitution."). "The state will get its man in the end. In contrast, if persons are put to death in a manner that is determined to be cruel and unsual, they suffer injury that can never be undone, and the Constitution suffers an injury that can never be repaired." *Gomez v. U.S. Dist. Court*, 966 F.2d 460, 462 (9th

Cir. 1992) (Noonan, J., dissenting).

For all these reasons, Landrigan respectfully asks this Court to deny Appellants pending motion.

Respectfully submitted: October 25, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2010, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/Michelle L. Young
Legal Secretary
Capital Habeas Unit