

**FOR PUBLICATION**

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

DANIELS SHARPSMART, INC., a  
Delaware corporation,  
*Plaintiff-Appellee,*

v.

KAREN SMITH, Director of the  
California Department of Public  
Health, in her official capacity;  
RICHARD PILORIN, Chief of the  
Emergency, Restoration and Waste  
Management Section of the  
California Department of Public  
Health, in his personal capacity;  
ALISON DABNEY, Chief Senior  
Environmental Scientist for the  
Medical Waste Management  
Program of the California  
Department of Public Health, in her  
personal capacity; GINGER HILTON,  
Environmental Scientist for the  
Medical Waste Management  
Program of the California  
Department of Public Health, in her  
personal capacity,  
*Defendants-Appellants.*

No. 17-16424

D.C. No.  
1:17-cv-00403-  
LJO-SAB

OPINION

Appeal from the United States District Court  
for the Eastern District of California  
Lawrence J. O'Neill, Chief District Judge, Presiding

Argued and Submitted April 11, 2018  
San Francisco, California

Filed May 2, 2018

Before: Sidney R. Thomas, Chief Judge, Ferdinand F.  
Fernandez and Ronald M. Gould, Circuit Judges.

Opinion by Judge Fernandez

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## SUMMARY\*

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### **Preliminary Injunction / Qualified Immunity**

The panel affirmed the district court's grant of a preliminary injunction enjoining California Department of Public Health officials from enforcing the California Medical Waste Management Act ("MWMA") against Daniels Sharpsmart, Inc., and reversed the denial of Department officials' motion to dismiss on the basis of qualified immunity.

The panel held that Daniels will likely succeed on the merits of its claim that the Department officials' application of the MWMA constituted a *per se* violation of the dormant

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\* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

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Commerce Clause. The panel affirmed the district court's decision that Daniels was likely to succeed on its claim that California cannot reach out and impose its notions of the proper way to dispose of medical waste upon those who are conducting disposal activities in other states in accordance with the laws of those states. The panel concluded that the district court did not abuse its discretion when it issued the preliminary injunction.

The panel held that the doctrine of qualified immunity protected Department officials Richard Pilorin, Alison Dabney, and Ginger Hilton from damages liability where Daniels' constitutional rights under the dormant Commerce Clause were not clearly established at the time of the violation.

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### COUNSEL

Renu R. George (argued) and Karli Eisenberg, Deputy Attorneys General; Ismael A. Castro, Supervising Deputy Attorney General; Julie Weng-Guetierrez, Senior Assistant Attorney General; Xavier Becerra, Attorney General; Office of the Attorney General, Sacramento, California; for Defendants-Appellants.

Jason Levin (argued), Steptoe & Johnson LLP, Los Angeles, California; Douglas D. Janicik, Phoenix, Arizona; for Plaintiff-Appellee.

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**OPINION**

FERNANDEZ, Circuit Judge:

California Department of Public Health<sup>1</sup> officials, Karen Smith,<sup>2</sup> Richard Pilorin,<sup>3</sup> Alison Dabney,<sup>4</sup> and Ginger Hilton<sup>5</sup> (collectively “the Department officials”) appeal the district court’s grant of a preliminary injunction against them in favor of Daniels Sharpsmart, Inc. (“Daniels”) and the denial of their motion to dismiss on the basis of qualified immunity.<sup>6</sup> The preliminary injunction enjoined the Department officials from enforcing the California Medical Waste Management Act (“MWMA”)<sup>7</sup> against Daniels for the manner in which it disposed of medical waste at facilities outside of the State of California. In its action against the Department officials,<sup>8</sup> Daniels alleged that they violated its constitutional rights

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<sup>1</sup> Hereafter, “the Department.”

<sup>2</sup> Karen Smith was the Director of the Department.

<sup>3</sup> Richard Pilorin was the Chief of the Department’s Emergency, Restoration, and Waste Management Section.

<sup>4</sup> Alison Dabney was the Chief Senior Environmental Scientist for the Department’s Medical Waste Management Program.

<sup>5</sup> Ginger Hilton was an Environmental Scientist for the Department’s Medical Waste Management Program.

<sup>6</sup> Karen Smith was sued in her official capacity. All other Defendants were sued in their personal capacities.

<sup>7</sup> *See* Cal. Health & Safety Code §§ 117600–118360.

<sup>8</sup> 42 U.S.C. § 1983.

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under the dormant Commerce Clause<sup>9</sup> when they engaged in extraterritorial enforcement of the MWMA. The Department officials also appeal the district court’s denial of their motion to dismiss on the basis of qualified immunity. We affirm the grant of the preliminary injunction, but reverse the denial of qualified immunity.

## BACKGROUND

Daniels is an Illinois based corporation that designs, develops, manufactures, markets, and sells reusable sharps container systems for the disposal of needle-inclusive biohazardous medical products. Those medical products include waste syringes, blood collection devices, and IVs. Daniels also handles the transport and treatment of the medical waste. In California, that waste is handled by Daniels’ Medical Waste Treatment Facility and Transfer Station in Fresno. As a medical waste treatment facility in California, it is subject to regulation under California’s MWMA. Therefore, when it received its medical waste treatment facility and transfer station permit from the Department, Daniels agreed to “comply with all applicable provisions of the Medical Waste Management Act.” Daniels also agreed to operate its facility in conformance with the plans approved by the Department.

In general, under the MWMA, California-generated medical waste must be incinerated. *See* Cal. Health & Safety Code § 118215(a)(1)(A), (a)(3)(A). Furthermore, “[m]edical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state.” *Id.* § 118000(c).

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<sup>9</sup> U.S. Const. art. I, § 8, cl. 3.

As of 2014, there were no locations within the State of California that had incinerators to treat Daniels' biohazardous medical waste.<sup>10</sup> Consequently, Daniels transported the waste from the Fresno facility to other states. For some time, Daniels had the waste incinerated at a facility in Baltimore, Maryland.

However, in 2014, Daniels decided to transport its medical waste to locations in Kentucky and Indiana, where the waste would be treated by means other than incineration which were consistent with those states' regulations. In Kentucky, the waste was treated by a method called autoclave, while in Indiana the waste was treated by a technique known as thermal deactivation. Treating the waste in Indiana and Kentucky was more cost effective for Daniels than having the waste incinerated in some other state. From September 11, 2014, to December 1, 2014, Daniels transported roughly 320,000 pounds of medical waste to facilities in Indiana and Kentucky. After a November 20, 2014, inspection of Daniels' facility in Fresno, California, the Department, through Hilton, told Daniels that all biohazardous medical waste originating in California must be treated by incineration, even if the law of another state permitted an alternative method. The Department further indicated that Daniels would be penalized if it did not incinerate all of its biohazardous medical waste. Daniels responded that the Department could not dictate the method by which Daniels treated the waste outside of California.

On April 10, 2015, the Department conducted another inspection of Daniels' facility, and Daniels received a letter

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<sup>10</sup> That medical waste contained trace chemotherapy, pathology, and pharmaceutical waste.

from Hilton, which stated that California law governed Daniels' treatment of medical waste in other states. Then, on August 10, 2015, the Department issued a notice of violation to Daniels for using methods other than incineration to treat its biohazardous medical waste outside of California. The notice imposed a \$618,000 penalty for the 618 violations of law it identified. In order to avoid further penalties, Daniels began transporting its medical waste to incinerators located in other states, at a significantly higher cost to Daniels.

In addition, Daniels filed a complaint in the district court, and alleged that the Department officials violated the dormant Commerce Clause by their extraterritorial application of the MWMA. Daniels then filed a motion for preliminary injunction, and the Department officials, claiming entitlement to qualified immunity, filed a motion to dismiss.

The district court granted Daniels' motion for a preliminary injunction and denied the Department officials' motion to dismiss. This appeal followed.

## JURISDICTION AND STANDARDS OF REVIEW

“We have jurisdiction to review the district court’s grant of a preliminary injunction.” *Meredith v. Oregon*, 321 F.3d 807, 811 (9th Cir. 2003); *see also* 28 U.S.C. § 1292(a)(1). Furthermore, “an order denying qualified immunity is immediately appealable.” *Wilkinson v. Torres*, 610 F.3d 546, 549–50 (9th Cir. 2010). “Our jurisdiction to review an interlocutory appeal of a denial of qualified immunity, however, is limited exclusively to questions of law.” *Id.* at 550.

We review the district court’s decision to grant a preliminary injunction for abuse of discretion. *Associated Press v. Otter*, 682 F.3d 821, 824 (9th Cir. 2012). Moreover:

In deciding whether the district court has abused its discretion, we employ a two-part test: first, we “determine de novo whether the trial court identified the correct legal rule to apply to the relief requested”; second, we determine “if the district court’s application of the correct legal standard was . . . illogical, . . . implausible, or . . . without support in inferences that may be drawn from the facts in the record.”

*Id.* (citation omitted); *see also United States v. Hinkson*, 585 F.3d 1247, 1261–63 (9th Cir. 2009) (en banc). A district court abuses its discretion if it bases a decision “on an erroneous legal standard or a clearly erroneous finding of fact.” *Associated Press*, 682 F.3d at 824 (citation omitted). “We review a denial of qualified immunity de novo.” *Wilkinson*, 610 F.3d at 550.

## DISCUSSION

Daniels asserts that the Department officials, not content with exercising their authority in California, have reached out in an attempt to control how other states handle and allow the disposal of medical waste within their borders. The district court agreed with that assessment, as do we. If permitted, that kind of action would attack the cement that holds this nation together. As the Supreme Court has said:



The Commerce Clause provides that “[t]he Congress shall have Power . . . [t]o regulate Commerce . . . among the several States.” Though phrased as a grant of regulatory power to Congress, the Clause has long been understood to have a “negative” aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce. The Framers granted Congress plenary authority over interstate commerce in “the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” “This principle that our economic unit is the Nation, which alone has the gamut of powers necessary to control of the economy, . . . has as its corollary that the states are not separable economic units.”

*Or. Waste Sys., Inc. v. Dep’t of Envtl. Quality of State of Or.*, 511 U.S. 93, 98–99, 114 S. Ct. 1345, 1349, 128 L. Ed. 2d 13 (1994) (alterations in the original) (citations omitted).

The negative aspect—commonly known as the dormant Commerce Clause—has at least two emanations. The Court has pointed out that “[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579, 106 S. Ct. 2080, 2084,

90 L. Ed. 2d 552 (1986). While many cases deal with the discrimination emanation,<sup>11</sup> this case deals with the direct regulation emanation. “Direct regulation occurs when a state law directly affects transactions that take place across state lines or entirely outside of the state’s borders.” *S.D. Myers, Inc. v. City & County of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001) (citation omitted). As the Court has put it: “the ‘Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.’” *Healy v. Beer Inst.*, 491 U.S. 324, 336, 109 S. Ct. 2491, 2499, 105 L. Ed. 2d 275 (1989). Indeed,

[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.

*Id.* Moreover, the Court further pointed out that:

[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if

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<sup>11</sup> See, e.g., *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38, 128 S. Ct. 1801, 1808, 170 L. Ed. 2d 685 (2008).

not one, but many or every, State adopted similar legislation.

*Id.*

We will apply these general principles to the issues raised in this case.

A. *The Preliminary Injunction*

“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. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20, 129 S. Ct. 365, 374, 172 L. Ed. 2d 249 (2008). We have explained that the first and third of the factors interact so that “‘serious questions going to the merits’ and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest.” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). The Department officials do not contest the district court’s determinations regarding the balance of equities, irreparable injury, and public interest factors, but do insist that Daniels is not likely to succeed on the merits. In short, they essentially state that because it is plain that there was no redressable constitutional violation, Daniels cannot succeed. In that they are plainly incorrect.

The parties do not dispute that a Commerce Clause action can be brought by an individual pursuant to 42 U.S.C. § 1983. *See Dennis v. Higgins*, 498 U.S. 439, 446–47, 111 S. Ct. 865,

870–71, 112 L. Ed. 2d 969 (1991). Thus, we need only consider whether Daniels is likely to succeed on the merits under the facts and circumstances of this case. It is. We are not concerned here with an attempt by the Department officials to protect California and its residents by applying the MWMA to products that are brought into or are otherwise within the borders of the State. *See, e.g., Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1103–04 (9th Cir. 2013); *Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris*, 729 F.3d 937, 949 (9th Cir. 2013); *Valley Bank of Nev. v. Plus Sys., Inc.*, 914 F.2d 1186, 1192–93 (9th Cir. 1990). Rather, we are faced with an attempt to reach beyond the borders of California and control transactions that occur wholly outside of the State after the material in question—medical waste—has been removed from the State.

The mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions. For example, an attempt by California to regulate the terms and conditions of sales of artworks outside of California simply because the seller resided in California was a violation of the dormant Commerce Clause. *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1322 (9th Cir. 2015) (en banc). As we said, the statute in question “directly regulates the conduct of the seller or the seller’s agent for a transaction that occurs wholly outside the State.” *Id.* at 1324. That could not be countenanced and “[w]e easily conclude[d] that the royalty requirement, as applied to out-of-state sales by California residents, violates the dormant Commerce Clause.” *Id.* at 1323. One state cannot be permitted to dictate what other states must do within their own borders.

Over twenty years earlier, we reached a similar conclusion in a quite different factual setting, but for the

selfsame reasons. See *NCAA v. Miller*, 10 F.3d 633, 635 (9th Cir. 1993). There, the State of Nevada sought to impose rules of procedure that would in effect control proceedings in other states, even if those states did not impose the same restrictions on procedures and could even prescribe other rules. *Id.* at 639. As we then declared: “the Statute could control the regulation of the integrity of a product in interstate commerce that occurs wholly outside Nevada’s borders. That sort of extraterritorial effect is forbidden by the Commerce Clause.” *Id.* Moreover, the Nevada statute could have had the baleful effect of subjecting businesses to conflicting requirements. *Id.*; see also *Healy*, 491 U.S. at 336–37, 109 S. Ct. at 2499 (“[T]he Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.”).

This case is little different from *Sam Francis* and *NCAA*, for here there can be no doubt that the Department officials sought to punish Daniels for disposing of medical waste in a manner that was perfectly legal in the states in which Daniels had effectuated disposal. The transactions in delivering and paying for disposal took place within those states and, from all that appears in the record, in accordance with their laws. There is nothing to indicate that the transactions had any effect whatsoever in California. See *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572–73, 116 S. Ct. 1589, 1597, 134 L. Ed. 2d 809 (1996). Rather, California has attempted to regulate waste treatment everywhere in the country, just as it tried to regulate art sales<sup>12</sup> and Nevada tried to regulate rules

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<sup>12</sup> See *Sam Francis*, 784 F.3d at 1324.

violations procedures<sup>13</sup> everywhere in the country. Of course, that could also have the effect of requiring Daniels to run afoul of other states’ regulation of medical waste disposal within their jurisdictions, if California law directed something different from their requirements. *See NCAA*, 10 F.3d at 639.

Therefore, Daniels will likely succeed on its claim that the Department officials’ application of the MWMA constitutes a “per se violation of the Commerce Clause.” *Id.* at 640. Were it otherwise, California could purport to regulate the use or disposal of any item—product or refuse—everywhere in the country if it had its origin in California.<sup>14</sup> The district court did not abuse its discretion when it determined that Daniels was likely to succeed on the merits and enjoined the Department officials from “enforcing the MWMA against Daniels’s out-of-state waste disposal.”

### B. *Qualified Immunity*

The Department officials sought dismissal of the action on the basis of the defense of qualified immunity. While the parties do not make any distinctions among the Department officials, as the district court noted, Smith was sued in her official capacity only and is therefore not entitled to qualified immunity. *See Eng v. Cooley*, 552 F.3d 1062, 1064 n.1 (9th Cir. 2009). Moreover, qualified immunity applies only to liability for money damages—not injunctive or declaratory

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<sup>13</sup> *See NCAA*, 10 F.3d at 639.

<sup>14</sup> We note that even if a law intended to protect the environment is involved, the dormant Commerce Clause applies. *See C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 393, 114 S. Ct. 1677, 1683, 128 L. Ed. 2d 399 (1994).

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relief. *See Hydrick v. Hunter*, 669 F.3d 937, 939–40 (9th Cir. 2012).

That said, the doctrine of “[q]ualified immunity ‘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.’” *Sjurset v. Button*, 810 F.3d 609, 614 (9th Cir. 2015). “Qualified immunity gives government officials breathing room to make reasonable but mistaken judgments about open legal questions. When properly applied, it protects ‘all but the plainly incompetent or those who knowingly violate the law.’” *Ashcroft v. al-Kidd*, 563 U.S. 731, 743, 131 S. Ct. 2074, 2085, 179 L. Ed. 2d 1149 (2011). In determining whether qualified immunity applies, courts “must determine whether: (1) the facts adduced constitute the violation of a constitutional right; and (2) the constitutional right was clearly established at the time of the alleged violation.” *Mitchell v. Washington*, 818 F.3d 436, 443 (9th Cir. 2016).

As we have already noted, it is likely that Daniels will succeed on its claim that the Department officials’ application of the MWMA violated the dormant Commerce Clause. Thus, we will consider the question of whether Daniels’ constitutional rights under the clause were clearly established for this purpose. We think not.

In deciding if a constitutional right was clearly established “at the relevant time, the key question is whether the defendants should have known that their specific actions were unconstitutional given the specific facts under review.” *Hamby v. Hammond*, 821 F.3d 1085, 1090 (9th Cir. 2016). In other words, the “right must be sufficiently clear that

every reasonable official would have understood that *what he is doing* violates that right.” *Id.* (emphases in original). However, the Court has insisted that the “‘clearly established law’ should not be defined ‘at a high level of generality.’” *White v. Pauly*, \_\_\_ U.S. \_\_\_, \_\_\_, 137 S. Ct. 548, 552, 196 L. Ed. 2d 463 (2017) (per curiam); *see also Kisela v. Hughes*, \_\_\_ U.S. \_\_\_, \_\_\_, 138 S. Ct. 1148, 1152, \_\_\_ L. Ed. 2d \_\_\_ (2018) (per curiam); *Hamby*, 821 F.3d at 1090. It is that rock upon which the district court’s qualified immunity decision founders.

The district court was satisfied that, as it said, “[t]he extraterritoriality doctrine has been clearly established for decades.” No doubt that is so, but that is far from deciding that it was clearly established that application of the MWMA violated the doctrine. *See White*, \_\_\_ U.S. at \_\_\_, 137 S. Ct. at 552. Certainly, the Department officials could not look at a decision dealing with the MWMA itself, and that statute at least injected some ambiguity into the equation when it declared that “[m]edical waste transported out of [California] shall be consigned to a permitted medical waste treatment facility in the receiving state.” Cal. Health & Safety Code § 118000(c). Of course, that does not say who must issue the permit to the facility, and a reasonable official, who is not knowledgeable about the arcane considerations lurking within dormant Commerce Clause doctrine, could reasonably, if erroneously, believe that the Department could control what was done with California waste in another state.<sup>15</sup> As we see

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<sup>15</sup> Perhaps the MWMA was intended to reach transactions outside of California. *But see Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 1207, 254 P.3d 237, 248, 127 Cal. Rptr. 3d 185, 198 (2011); *N. Alaska Salmon Co. v. Pillsbury*, 174 Cal. 1, 4, 162 P. 93, 94 (1916). If so, that would not change the result but would further support according qualified immunity



it, this area is complex and murky enough that it was improper to decide that Pilorin, Dabney, and Hilton could be mulcted with damages for their error. The district court erred in holding that they could be.

### CONCLUSION

We affirm the district court's decision that Daniels is likely to succeed on its claim that California cannot reach out and impose its notions of the proper way to dispose of medical waste upon those who are conducting disposal activities in other states in accordance with the laws of those states. Thus, the district court did not abuse its discretion when it issued the preliminary injunction. However, we also hold that the doctrine of qualified immunity does protect Pilorin, Dabney, and Hilton from damages liability.

**AFFIRMED** in part, **REVERSED** in part, and **REMANDED**. The parties shall bear their own costs on appeal.

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to the Department officials. See *Acosta v. City of Costa Mesa*, 718 F.3d 800, 824 (9th Cir. 2013) (per curiam); *Grossman v. City of Portland*, 33 F.3d 1200, 1209 (9th Cir. 1994).