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**UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA**

Joseph Rudolph Wood, et al.,

Plaintiffs,

-vs-

Charles L. Ryan, et al.,

Defendants.

CV 14-1447-PHX-NVW-JFM

**MOTION TO DISMISS
COMPLAINT PURSUANT TO
RULE 12(B)(6)**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants move this Court to dismiss Plaintiffs' Complaint for failure to state a claim upon which relief can be granted. In seeking injunctive relief under 42 U.S.C. § 1983, Plaintiffs assert three claims, two based on the First Amendment and one on the Supremacy Clause of the United States Constitution. Neither the First Amendment nor the Supremacy Clause creates an individually enforceable right that the Plaintiffs have been denied and there is no likelihood of substantial and immediate irreparable injury. The three claims are not plausible. This motion is supported by the following Memorandum of Points and Authorities.

MEMORANDUM OF POINTS AND AUTHORITIES

1
2 Plaintiffs filed suit under 42 U.S.C. § 1983, alleging that Defendants' failure
3 to disclose information regarding the source of drugs to be used in their executions,
4 information regarding the qualifications of personnel involved in the execution
5 process, and information regarding development of the lethal injection protocol
6 violates their First Amendment right to petition the government for redress of
7 grievances and First Amendment right of access to governmental proceedings.
8 They also allege that Defendants' failure to submit their lethal injection protocol to
9 the Food and Drug Administration ("FDA") for review violates the Food, Drug,
10 and Cosmetics Act ("FDCA") in contravention of the Supremacy Clause of the
11 United States Constitution.

12 Plaintiffs seek temporary, preliminary, and permanent injunctive relief
13 enjoining the Defendants from concealing the requested information and enjoining
14 their executions, including the execution of Plaintiff Joseph Wood, scheduled for
15 July 23, 2014. To be entitled to this equitable remedy, Plaintiffs must allege a
16 likelihood of substantial and immediate irreparable injury resulting from the
17 alleged violation of the Constitution or federal law. *See City of Los Angeles v.*
18 *Lyons*, 461 U.S. 95, 111 (1983); *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974).
19 "The Supreme Court has repeatedly cautioned that, absent a threat of immediate
20 and irreparable harm, the federal courts should not enjoin a state to conduct its
21 business in a particular way." *Hodger-Durgin v. de la Vina*, 199 F.3d 1037, 1042
22 (9th Cir. 1999) (*en banc*) (citing Supreme Court cases). The proper balance
23 between state and federal authority requires restraint in issuing injunctions against
24 state officers engaged in administering the States' criminal laws in the absence of
25 immediate and substantial irreparable injury. *O'Shea*, 414 U.S. at 499; *Hodger-*
26 *Durgin*, 199 F.3d at 1042. Even if Plaintiffs' requested injunction was not aimed at
27 stopping their executions, the last stage of their criminal proceedings, the
28 "principles of equity nonetheless militate heavily against the grant of an injunction

1 except in the most extraordinary circumstances.” *Rizzo v. Goode*, 423 U.S. 362,
2 379 (1976); *Hodger-Durgin*, 199 F.3d at 1042. Here the Plaintiffs have not offered
3 any plausible immediate and irreparable harm that is a direct result of the alleged
4 violations of the First Amendment and Supremacy Clause. Balanced against this
5 void is the “well-established rule that the Government has traditionally been
6 granted the widest latitude in the ‘dispatch of its own internal affairs.’” *Hodger-*
7 *Durgin*, 199 F.3d at 1043 (quoting *Rizzo*, 423 U.S. 378–79).

8 This Court should summarily reject Plaintiffs’ requests for injunctive relief
9 and should dismiss the Complaint for failure to state a claim upon which relief may
10 be granted. *See* Fed. R. Civ. P. 12(b)(6).

11 **I. APPLICABLE LEGAL STANDARDS.**

12 A Rule 12(b)(6) motion “tests the legal sufficiency of a claim.” *Navarro v.*
13 *Block*, 250 F.3d 729, 732 (9th Cir. 2001). A claim is subject to dismissal only if “it
14 appears beyond doubt that the plaintiff can prove no set of facts in support of his
15 claim which would entitle him to relief.” *Conley v. Gibson*, 355 U.S. 41, 45–46
16 (1957); *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 338 (9th Cir. 1996). To
17 survive a motion to dismiss, a complaint must contain sufficient factual matter to
18 “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S.662,
19 678 (2009); *Cook v. Brewer*, 637 F.3d 1002, 1004 (9th Cir. 2011). “A claim has
20 facial plausibility when the pleaded factual content allows the court to draw the
21 reasonable inference that the defendant is liable for the misconduct alleged.”
22 *Iqbal*, 556 U.S. at 678. This standard “asks for more than a sheer possibility that a
23 defendant has acted unlawfully.” *Id.* “Threadbare recitals of the elements of a
24 cause of action, supported by mere conclusory statements, do not suffice.” *Id.*
25 “Factual allegations must be enough to raise a right to relief above the speculative
26 level.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The Complaint
27 must do more than create “a suspicion [of] a cognizable right of action.” *Id.*
28 (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235–

1 236 (3d ed. 2004)).

2 For purposes of a 12(b)(6) motion, the court must take all the factual
3 allegations in the complaint as true; however, the court is not bound to accept as
4 true a legal conclusion couched as a factual allegation. *Iqbal*, 556 U.S. at 678
5 (citing *Bell Atlantic*, 550 U.S. at 555). In other words, “the tenet that a court must
6 accept as true all of the allegations contained in a complaint is inapplicable to legal
7 conclusions.” *Id.* A complaint must allege a plausible claim for relief to survive a
8 motion for dismissal. *Id.* at 679. This Court may “draw on its judicial experience
9 and common sense” in deciding whether a claim is plausible. *Id.* Dismissal is thus
10 appropriate where the plaintiff’s complaint lacks a cognizable legal theory, or lacks
11 sufficient facts alleged under a cognizable legal theory. See *Balistreri v. Pacifica*
12 *Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1988).

13 An action instituted pursuant to 42 U.S.C. § 1983 challenges a State’s
14 “deprivation of any rights . . . secured by the Constitution and laws.” See also
15 *Gibson v. United States*, 781 F.2d 1334, 1338 (9th Cir. 1986) (plaintiffs must show
16 that defendants acted under state law and deprived plaintiffs of rights secured by
17 Constitution or federal statutes). “Section 1983 is not itself a source of substantive
18 rights, but merely provides a method for vindicating federal rights elsewhere
19 conferred. The first step in any such claim is to identify the specific constitutional
20 right allegedly infringed.” *Albright v. Oliver*, 510 U.S. 266, 271 (1994) (plurality)
21 (citation and internal quotation marks omitted). “[I]t is only violations of *rights*,
22 not *laws*, which give rise to § 1983 actions.” *Gonzaga University v. Doe*, 536 U.S.
23 273, 283 (2002) (emphasis original) (citing *Blessing v. Freestone*, 520 U.S. 329,
24 340 (1997)). Section 1983 “merely provides a mechanism for enforcing individual
25 rights ‘secured’ elsewhere[.]” *Gonzaga*, 536 U.S. at 285. “[A]nything short of an
26 unambiguously conferred right” does not support an individual right of action
27 under § 1983. *Id.* at 283.

28 Furthermore, “one cannot go into court and claim a ‘violation of § 1983’—

1 for § 1983 by itself does not protect anyone against anything.” *Id.* (quoting
2 *Chapman v. Houston Welfare Rights Organization*, 441 U.S. 600, 617 (1979); *Save*
3 *Our Valley v. Sound Transit*, 335 F.3d 932, 936 (9th Cir. 2003). Thus, for Plaintiffs
4 to succeed there first must be some federal right applicable to the inmates, and
5 second, there must be a plausible showing that the State has or will violate that
6 right. *See Haygood v. Younger*, 769 F.2d 1350, 1354 (9th Cir. 1985) (en banc).

7 None of the Plaintiffs’ three claims allege a plausible violation of any
8 constitutional or federal right.

9 **II. APPLICATION OF LAW TO PLAINTIFFS’ CLAIMS.**

10 **A. Claim One.**

11 Plaintiffs assert that Defendants’ denial of certain information regarding the
12 source of drugs to be used in their executions, qualifications of personnel involved
13 in their executions, and development of the lethal injection protocol deprives
14 Plaintiffs of their First Amendment right to petition the government for redress of
15 grievances. *See* Complaint, ¶¶ 141–49. Specifically, Plaintiffs claim that
16 Defendants have created a condition that frustrates their ability to litigate their
17 claims by “deliberately concealing information about the specific drugs the State
18 intends to use to execute Plaintiffs.” *Id.* at ¶ 147.

19 Courts across the country have rejected similar claims. The Eleventh Circuit
20 recently held that the Eighth Amendment did not entitle a death row inmate to
21 information he argued was necessary to determine whether the state’s lethal
22 injection procedure was cruel and unusual, and that neither the Fifth, Fourteenth,
23 nor First Amendments afford the inmate “the broad right” to know the source and
24 manufacturer of lethal injection drugs or the qualifications of the persons who
25 would manufacture the drugs or participate in the lethal injection process. *Wellons*
26 *v. Comm’r, Ga. Dep’t of Corr.*, ___ F.3d ___, 2014 WL 2748316, at *3–6 (11th Cir.
27 June 17, 2014) (per curiam). Within the last year, the Fifth Circuit found that
28 Louisiana’s refusal to provide details regarding its execution protocol was not a

1 constitutional violation:

2 There is no violation of the Due Process Clause from the uncertainty
3 that Louisiana has imposed on Sepulvado by withholding the details
4 of its execution protocol. Perhaps the state’s secrecy masks “a
5 substantial risk of serious harm,” but it does not create one. Having
6 failed to identify an enforceable right that a preliminary injunction
7 might safeguard, Sepulvado cannot prevail on the merits.

7 *Sepulvado v. Jindal*, 729 F.3d 413, 420 (5th Cir. 2013); *see also Sells v. Livingston*,
8 750 F.3d 478, 481 (5th Cir 2014) (“the assertion of a necessity for disclosure does
9 not substitute for the identification of a cognizable liberty interest”).

10 Similarly, the Eighth Circuit has held that a death row inmate’s argument
11 grounded in an inability to *discover* potential claims fails to state a plausible due
12 process claim because the inability to discover claims does not constitute a due
13 process violation, *see Williams v. Hobbs*, 658 F.3d 842, 852 (8th Cir. 2011), and
14 that the Eighth Amendment does not entitle a death row inmate to information
15 about the physician, pharmacy, and laboratory involved in the execution process
16 absent plausible allegations of a feasible and more humane alternate method of
17 execution or purposeful design by the State to inflict unnecessary pain. *In re*
18 *Lombardi*, 741 F.3d 888, 895–96 (8th Cir. 2014) (en banc); *see also Whitaker v.*
19 *Livingston*, 732 F.3d 465, 467 (5th Cir. 2013) (rejecting Fourteenth Amendment,
20 Supremacy Clause, and access-to-the-courts claims challenging state’s failure to
21 disclosure information regarding the method of execution in a timely manner
22 absent a plausible Eighth Amendment claim). And the Georgia Supreme Court
23 recently rejected an inmate’s claim under the First Amendment challenging a
24 statute protecting the source of lethal injection drugs, stating that “[t]o the extent
25 that [a death row inmate] s[ought] to turn the First Amendment into an Open
26 Records Act for information relating to executions, his claim clearly fail[ed].”
27 *Owens v. Hill*, ___ S.E.2d ___, 2014 WL 2025129, at *9 (Ga. May 19, 2014). As
28 these courts’ holdings demonstrate, the constitution simply does not provide

1 Plaintiffs with a right to the information they seek.

2 Nor do First Amendment principles establish that Plaintiffs' are
3 constitutionally entitled to the information they seek. "Among other rights
4 essential to freedom, the First Amendment protects 'the right of the people . . . to
5 petition the Government for a redress of grievances.'" *Borough of Duryea, Pa. v.*
6 *Guarnieri*, __ U.S. __, 131 S. Ct. 2488, 2491 (2011) (quoting U.S. CONST., Amdt.
7 1). There is no question that "prisoners retain the constitutional right to petition
8 the government for the redress of grievances." *Turner v. Safley*, 482 U.S. 78, 84
9 (1987). The right to petition the government "includes a reasonable right of access
10 to the courts." *Hudson v. Palmer*, 468 U.S. 517, 523 (1984). But, the right of
11 access to the courts is not an unlimited one; it assures only "meaningful access to
12 the courts." *Bounds v. Smith*, 430 U.S. 817, 823 (1977). The right of access is
13 "ancillary to the underlying claim, without which a plaintiff cannot have suffered
14 injury by being shut out of court." *Christopher v. Harbury*, 536 U.S. 403, 415
15 (2002). In other words, the right of access to the courts is tied to and limited by a
16 prisoner's right to "vindication for a separate and distinct right to seek judicial
17 relief for some wrong." *Id.* Additionally, the Supreme Court has held that the
18 guarantee of access to the courts is one of access only, and does not encompass a
19 right to "discover" information. *Lewis v. Casey*, 518 U.S. 343, 354 (1996) (access
20 to the court requires the ability to bring grievances to court, not to discover
21 grievances or litigate effectively once in court).

22 To state a claim for relief, a prisoner must allege that prison officials actively
23 interfered with his freedom to invoke the judicial process, *Blaisdell v. Frappiea*,
24 729 F.3d 1237, 1243 (9th Cir. 2013), or that prison officials retaliated against him
25 for invoking the judicial process, *Rhodes v. Robinson*, 408 F.3d 559, 567–68 (9th
26 Cir. 2005). In this case, Plaintiffs have not shown—and cannot show—active
27 interference with their right to invoke the judicial process, nor have they alleged
28 any evidence of retaliation for invoking the judicial process.

1 Petitioning the government for a redress of grievances and forcing the
2 government to turn over information within its control are two very different
3 things. The First Amendment right to petition does not include a right to
4 “discover” information. *See Lewis*, 518 U.S. at 354. In this case, Defendants’
5 refusal to provide Plaintiffs with the requested information does not restrict
6 Plaintiffs’ First Amendment right to petition the government. In fact, all of the
7 named Plaintiffs have had numerous opportunities to access the courts without any
8 interference from Defendants. The complaint in this case serves as a clear example
9 of Plaintiffs’ unhampered ability to petition for a redress of grievances. *See*
10 *Antonelli v. Sheahan*, 81 F.3d 1422, 1430–31 (7th Cir. 1996) (“Moreover, Mr.
11 Antonelli’s invocation of the judicial process indicates that the prison has not
12 infringed his First Amendment right to petition the government for a redress of
13 grievances.”).

14 To establish a denial of meaningful access to the courts, a plaintiff must
15 establish an “actual injury” as a result of the defendant’s actions. *Lewis*, 518 U.S.
16 at 348. For there to be an actual injury with respect to the planned or existing
17 litigation, the State must cause an inability, such as to meet a filing deadline or to
18 present a claim. *Id.* Here, Plaintiffs’ access to the courts has not been hindered.
19 Plaintiffs do not allege that Defendants have retaliated against them or interfered
20 with their access to the courts. Instead, they merely claim that Defendants have
21 refused to provide certain information. *See* Complaint ¶¶ 39-43. But as the
22 Supreme Court has stated, and courts have found, the State has no obligation under
23 the right-to-access-to-the-courts cases to enable a prisoner to discover grievances
24 and to litigate effectively. *Lewis*, 518 U.S. at 354; *Whitaker*, 732 F.3d at 467;
25 *Owens*, 2014 WL 2025129, at * 8–9. Plaintiffs have therefore failed to allege a
26 plausible First Amendment right-of-access claim and Claim One of the complaint

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28

1 should be dismissed.

2 **B. Claim Two.**¹

3 In this claim, Plaintiffs assert that Defendants' denial of the requested
4 information violates their First Amendment right of access to governmental
5 proceedings. *See* Complaint, ¶¶ 150–52. Plaintiffs have failed to state a claim for
6 relief because there is no affirmative constitutional duty requiring the government
7 to *disclose information* within its possession, and Plaintiffs have no First
8 Amendment right to receive information within the government's control. *See* Fed.
9 R. Civ. P. 12(b)(6).

10 As stated above, courts have rejected the contention that the First
11 Amendment entitles a death row inmate to information such as the source of lethal
12 injection drugs or execution personnel. *See Wellons*, 2014 WL 2748316, at *6 (no
13 Fifth, Fourteenth, or First Amendment right to the source and manufacturer of
14 lethal injection drugs or the qualifications of the persons who would manufacture
15 the drugs or participate in the lethal injection process); *Owens*, 2014 WL 2025129,
16 at *9–10 (First Amendment does not compel state to disclose names and other
17 identifying information of persons and entities involved in executions, including
18 those who manufacture drugs to be used).

19 These decisions rejecting similar claims by death row inmates are consistent
20 with the general principle that the First Amendment does not include the right to
21 information in the government's possession. "The Constitution itself is neither a
22 Freedom of Information Act nor an Official Secrets Act." *Houchins v. KQED*, 438
23 U.S. 1, 15 (1978) (plurality opinion). "Neither the First Amendment nor the
24 Fourteenth Amendment mandates a right of access to government information or

25 _____
26 ¹ Plaintiff Wood relied solely on this argument to support his request for a
27 temporary restraining order and preliminary injunction. (Doc. 11.) In addition to
28 the argument presented here, Defendants rely on the arguments made in their
response to Wood's motion. (Doc. 15.)

1 sources of information within the government’s control.” *Id.*; *see also* *McBurney v.*
2 *Young*, ___ U.S. ___, 133 S. Ct. 1709, 1718 (2013) (“This Court has repeatedly made
3 clear that there is no constitutional right to obtain all the information provided by
4 FOIA laws.”). “As a general rule, citizens have no first amendment right of access
5 to traditionally nonpublic government information.” *McGehee v. Casey*, 718 F.2d
6 1137, 1147 (D.C. Cir. 1983). For example, even in a criminal prosecution, there is
7 no general federal constitutional right to discover information. *Weatherford v.*
8 *Burse*, 429 U.S. 545, 559 (1977).

9 The First Amendment states that “Congress shall make no law . . . abridging
10 the freedom of speech, or of the press.” U.S. CONST. amend. I. “In accord with its
11 plain language, the First Amendment broadly protects the freedom of individuals
12 and the press to speak or publish. It does not expressly address the right of the
13 public to receive information.” *Center for Nat. Sec. Studies v. U.S. Dep’t of*
14 *Justice*, 331 F.3d 918, 934 (D.C. Cir. 2003). “By contrast, it requires some
15 straining of the text to construe the Amendment’s explicit preclusion of
16 government interference as conferring upon each citizen a presumptive right of
17 access to any government-held information which may interest him or her.”
18 *Capital Cities Media, Inc. v. Chester*, 797 F.2d 1164, 1168 (3d Cir. 1986) (en
19 banc). “It simply does not seem reasonable to suppose that the free speech clause
20 would speak, as it does, solely to government interference if the drafters had
21 thereby intended to create a right to know and a concomitant governmental duty to
22 disclose.” *Id.*

23 In contrast, the Supreme Court has recognized a First Amendment right of
24 access to certain government proceedings. *See Press-Enter. Co. v. Superior Court*,
25 478 U.S. 1, 8–14 (1986) (right to transcripts of criminal preliminary hearing)
26 (*Press-Enter. II*); *Press-Enter. Co. v. Superior Court*, 464 U.S. 501, 510–11 (1984)
27 (voir dire) (*Press-Enter. I*); *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596,
28 603–11 (1982) (testimony of child victim in sex offense prosecution); *Richmond*

1 *Newspapers, Inc. v. Virginia*, 448 U.S. 555, 579 (1980) (criminal trial). Yet the
2 Court has also recognized that even when a right of access attaches, it is not
3 absolute. *See Press-Enterprise II*, 478 U.S. at 8–9; *see also El Vocero de Puerto*
4 *Rico v. Puerto Rico*, 508 U.S. 147, 148–51 (1993) (per curiam). Here, however,
5 Plaintiffs are not seeking access to a criminal proceeding, but rather information in
6 the government’s possession. Illustrating this basic distinction, in *Nixon v. Warner*
7 *Communications Inc.*, 435 U.S. 589, 609 (1978), the Supreme Court, while
8 recognizing the press and public’s First Amendment right to attend a criminal trial,
9 concluded that this right does not create a right of access to exhibits and materials
10 displayed in open court. *See also Radio & Television News Ass’n of So. Calif. v.*
11 *Dist. Ct. for Cent. Dist. of Calif.*, 781 F.3d 1443, 1447 (9th Cir. 1986) (“[T]he
12 media’s ‘right to gather information’ during a criminal trial is no more than a right
13 to attend the trial and report on their observations.”).

14 To be clear, “[t]here is no constitutional right to have access to particular
15 government information, or to require openness from the bureaucracy.” *Houchins*,
16 438 U.S. at 14; *see also LAPD v. United Reporting*, 528 U.S. 32, 40 (1999)
17 (“[W]hat we have before us is nothing more than a governmental denial of access
18 to information in its possession. California could decide not to give out arrestee
19 information at all without violating the First Amendment.”). “[T]he right to
20 receive information cannot be stretched to the point of creating a First Amendment
21 right allowing the public to *compel* disclosure of all government-held information.
22 In other words, there is no affirmative constitutional duty requiring the government
23 to disclose non-public information within its possession.” *United States v. Miami*
24 *University*, 91 F. Supp. 2d 1132, 1154 (S.D. Ohio 2000) (emphasis in original).

25 The First Amendment does not compel the disclosure of the information
26 sought by Plaintiffs. If this Court were to adopt Plaintiffs’ view of the First
27 Amendment, there would be no need for Arizona’s public records law or the
28 Freedom of Information Act. Plaintiffs’ reading of the First Amendment is

1 contrary to every Supreme Court case discussing access to government information
2 and Plaintiffs' view of the First Amendment would seem to require both federal
3 and state governments to turn over any information within their possession. The
4 state officials named as Defendants in the complaint have no constitutional duty
5 disclose information under the First Amendment. Likewise, Plaintiffs have no
6 First Amendment right to receive information within Defendants' control. There is
7 simply no First Amendment right to the information which Plaintiffs seek.
8 Accordingly, Plaintiffs have failed to state a claim upon which relief can be
9 granted and Claim Two should be dismissed

10 **C. Claim Three.**

11 Plaintiffs assert that Defendants' failure to submit their lethal injection
12 protocol to the FDA for review violates the FDCA, in contravention of the
13 Supremacy Clause. *See* Complaint, ¶¶ 153–59. Specifically, Plaintiffs argue that
14 Defendants' lethal injection protocol constitutes a “clinical investigation” under the
15 FDCA, protocols for clinical investigations must be submitted to the FDA for
16 review absent an applicable exception, and the FDCA does not contain an
17 exception for drugs used in executions. *See* Complaint, ¶¶ 154–56. They contend
18 that because Defendants did not submit their lethal injection protocol to the FDA
19 for approval, they are in violation of the FDCA. *Id.* at ¶ 157. This failure to
20 comply with the FDCA, they allege, violates the Supremacy Clause, and therefore
21 Plaintiffs' right to be executed in a manner consistent with federal law and the
22 United States Constitution. *Id.* at ¶¶ 158–59. But neither the FDCA nor, under
23 these circumstances, the Supremacy Clause, can support an action under 42 U.S.C.
24 § 1983. Because these contentions do not state a cognizable legal theory under §
25 1983, *Balistreri*, 901 F.2d at 699, Plaintiffs fail to state a claim upon which relief
26 can be granted. *See* Fed. R. Civ. P. 12(b)(6).

27 The first flaw in Plaintiffs' argument is that the FDCA confers no
28 individualized federal right enforceable under 42 U.S.C. § 1983. *See Gonzaga*,

1 536 U.S. at 283–84. When bringing a § 1983 claim pursuant to a federal statute, “a
2 plaintiff must assert the violation of a federal *right*, not merely a violation of
3 federal *law*.” *Blessing v. Freestone*, 520 U.S. 329, 340 (1997) (emphasis in
4 original). “[A]nything short of an unambiguously conferred right” does not
5 support an individual right of action under § 1983. *Gonzaga*, 536 U.S. at 283;
6 *AlohaCare v. Hawaii, Dep’t of Human Services*, 572 F.3d 740, 745–46 (9th Cir.
7 2009) (statute lacked the specific articulation of entitlements required to create an
8 individual, enforceable right remediable under § 1983); *see also Lankford v.*
9 *Sherman*, 451 F.3d 496, 508–09 (8th Cir. 2006) (to confer an individual right
10 enforceable under § 1983, a “statute must focus on an individual entitlement to the
11 asserted federal right, rather than on the aggregate practices or policies of a
12 regulated entity, like the state”).

13 Congress has specifically forbidden private enforcement of the FDCA,
14 stating that “all such proceedings for the enforcement, or to restrain violations, of
15 this [Act] shall be by and in the name of the United States.” *PhotoMedex, Inc. v.*
16 *Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (quoting 21 U.S.C. § 337(a)); *see also,*
17 *e.g., Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 811 (1986)
18 (“Congress did not intend a private federal remedy for violations of the [FDCA].”).
19 “The FDCA leaves no doubt that it is the Federal Government rather than private
20 litigants who are authorized to file suit for noncompliance with the medical device
21 provisions.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.4
22 (2001) (citing 21 U.S.C. § 337(a)); *see also In re Orthopedic Bone Screw Prods.*
23 *Liab. Litig.*, 193 F.3d 781, 788 (3rd Cir. 1999) (“It is well settled . . . that the
24 FDCA creates no private right of action.”).

25 Rather than conferring any “enforceable rights” upon individuals, the FDCA
26 charges the FDA with investigating potential violations, 21 U.S.C. § 372, and
27 provides that agency with enforcement remedies it may pursue. *See Buckman*, 531
28 U.S. at 349; *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). And rather than give

1 individuals the right to sue under the FDCA, the Act permits individuals to petition
2 the FDA to take administrative action.² 21 C.F.R. §§ 10.25(a), 10.30.

3 Because Congress explicitly foreclosed private enforcement of the FDCA and
4 it confers no individual rights, § 1983 is not available to enforce its provisions. *See*
5 *Gonzaga*, 536 U.S. at 283; *AlohaCare*, 572 F.3d at 745–46. Accordingly, the
6 federal courts have consistently rejected § 1983 actions based on alleged FDCA
7 violations. *See Foli v. Metropolitan Water Dist. of So. Cal.*, No. 11CV1765, 2012
8 WL 1192763, at *2–3 (S.D. Cal. April 10, 2012) (“By suing under 42 U.S.C. §
9 1983, Plaintiffs attempt to circumvent FDCA’s limitation on who may sue to
10 enforce the Act.”); *Robertson ex rel. Robertson v. McGee*, No. 01CV60, 2002 WL
11 535045, at *3 (N.D. Okla. January 28, 2002) (“Because there is no private right of
12 action under the federal regulations in question, § 1983 cannot be used to create a
13 private right of action which otherwise does not exist.”); *Murphy v. Cuomo*, 913
14 F.Supp. 671, 679 (N.D.N.Y. 1996) (“To the extent plaintiff’s First Cause of Action
15 [under § 1983] is based on the FDCA, defendant Zarc argues that summary
16 judgment should be granted in its favor because the FDCA creates no private
17 causes of action. Even a cursory review of the applicable caselaw reveals that
18 defendant is correct.”).

19 Even if Congress had not specifically foreclosed private enforcement of the
20 FDCA, it still could not support a section 1983 action because Congress created a
21 comprehensive enforcement scheme that is incompatible with the individual
22 enforcement under § 1983. *See Blessing*, 520 U.S. at 341; *see also Heckler*, 470
23 U.S. at 835 (describing FDCA’s comprehensive enforcement scheme for its

24
25 ² Decades ago, death row prisoners petitioned the FDA claiming that states’ use of
26 drugs in lethal injections violated several FDCA provisions. *Heckler*, 470 U.S. at
27 823. The FDA refused to investigate or take enforcement action and the United
28 States Supreme Court found that the FDA’s discretionary decision was not subject
to judicial review under the Administrative Procedure Act. *Id.* at 838.

1 substantive provisions); *Cottrell, Ltd. v. Biotrol Intern., Inc.*, 191 F.3d 1248, 1254–
2 55 (10th Cir. 1999) (“Moreover, claims that require direct interpretation and
3 application of the FDCA are not properly recognized because such matters are
4 more appropriately addressed by the FDA, especially in light of Congress’s
5 intention to repose in that body the task of enforcing the FDCA.”) (quoting with
6 approval *Braintree Labs, Inc., v. Nephro-Tech, Inc.*, No. 96–2459–JWL, 1997 WL
7 94237, at *6 (D. Kan. Feb. 26, 1997)) (denying plaintiff’s ability to bringing
8 Lanham Act claim based upon alleged FDCA violation). Thus, even without the
9 FDCA’s explicit prohibition on individual enforcement, the Act’s comprehensive
10 enforcement scheme would still foreclose a § 1983 action to enforce its provisions.

11 Because the FDCA cannot support a § 1983 action, Plaintiffs have failed to
12 state a claim upon which relief can be granted, and Claim Three should be
13 dismissed. *See O’Bryan v. McKaskle*, 729 F.2d 991, 993 n.2 (5th Cir. 1984) (court
14 “unable to identify the legal footing for [plaintiff’s] present effort to enforce [the
15 FDCA’s] detailed federal administrative scheme” in a § 1983 action).

16 Plaintiffs’ attempt to root Claim Three in the Supremacy Clause fares no
17 better. “[T]he Supremacy Clause, of its own force, does not create rights
18 enforceable under § 1983.” *See Golden State Transit Corp. v. City of L.A.*, 493
19 U.S. 103, 107 (1989); *White Mountain Apache Tribe v. Williams*, 810 F.2d 844, 848
20 (9th Cir. 1985), (“[T]he Supremacy Clause, standing alone . . . does not create
21 individual rights, nor does it ‘secure’ such rights within the meaning of § 1983.”).
22 Consequently, “a Supremacy Clause claim based on a statutory violation is
23 enforceable under § 1983 only when the statute creates ‘rights privileges, or
24 immunities’ in the particular plaintiff.” *Golden State Transit*, 493 U.S. at 107 n.4;
25 *see also Whitaker*, 732 F.3d at 467 (rejecting Supremacy Clause as a basis for
26 obtaining information about the method of execution). As demonstrated above,
27 the FDCA creates no “rights, privileges, or immunities” in any individual,
28 including Plaintiffs. Consequently, a § 1983 claim is unavailable for an alleged

1 violation of the FDCA and the Supremacy Clause. Claim Three does not state a
2 “plausible claim for relief,” and should be dismissed pursuant to Rule 12(b)(6).
3 *See Iqbal*, 556 U.S. at 679.

4 **III. CONCLUSION.**

5 Plaintiffs have failed to state an actionable First Amendment claim because
6 there is no First Amendment right to obtain the information they seek and because
7 a refusal to provide the confidential information they have requested does not limit
8 their ability to petition the government for a redress of grievances. Additionally,
9 Plaintiffs have failed to state a claim for relief under the Supremacy Clause or
10 FDCA because the FDCA expressly prohibits private enforcement, confers no
11 individual rights, and contains a comprehensive enforcement scheme. Lacking a
12 viable Section 1983 claim, the complaint must be dismissed pursuant to Rule
13 12(b)(6) of the Federal Rules of Civil Procedure.

14 **CONCLUSION**

15 Defendants request that this Court dismiss the Complaint for failure to state
16 a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6).

17 RESPECTFULLY SUBMITTED this 10th day of July, 2014.

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1 I hereby certify that on July 10, 2014, I electronically transmitted the
2 attached document to the Clerk's Office using the ECF System for filing and
transmittal of a Notice of Electronic Filing to the following ECF registrant:

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