APPENDIX

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APPENDIX A

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 19-2816

[Filed: February 11, 2021]

ELIAS KARKALAS,
Appellant

v.

LINDA MARKS, Esquire; KIMBERLY BRILL; UNITED STATES OF AMERICA

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civ. No. 2-19-cv-00948)
District Judge: Honorable Mark A. Kearney

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
March 12, 2020

Before: McKEE, AMBRO, and PHIPPS, *Circuit Judges*

(Filed: February 11, 2021)

OPINION[*]

PHIPPS, *Circuit Judge*.

For over thirty years, Dr. Elias Karkalas was a family practice physician in a Philadelphia suburb. He also had an interest in cyber medicine, and in 2005, he responded to a recruiter's advertisement seeking doctors to review online prescription requests for an internet pharmacy company, Rx Limited. At that time, Rx Limited was operated by Paul Calder Le Roux, who would later plead guilty to several criminal charges related to the company's practices. Karkalas began working for Rx Limited, and between 2005 and 2012, he approved online prescriptions for several drugs. As he did so, he understood that federal law required an in-person encounter to prescribe a controlled substance. *See* 21 U.S.C. §§ 829(b), (e); 21 C.F.R. § 1306.04(a).

One drug that Karkalas prescribed online was Fioricet – a combination drug used to treat tension headaches. Although Fioricet is not expressly listed as a controlled substance, it contains butalbital, a derivative of barbituric acid, which *is* listed as a controlled substance. 21 U.S.C. § 812, Sch. III(b)(1) (designating "[a]ny substance which contains any quantity of a derivative of barbituric acid" as a Schedule III controlled substance); 21 C.F.R. § 1308.13(c)(3) (same). Nevertheless, the *Physicians' Desk Reference*, a reference manual for prescribers, did

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[*] This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

not designate Fioricet as a controlled substance during the years in which Karkalas prescribed it.[1]

Karkalas's online approval of Fioricet prescriptions caught the attention of a diversion investigator at the Drug Enforcement Administration and a federal prosecutor who were investigating Rx Limited. They both believed that, under federal law, Fioricet constituted a controlled substance because it contained butalbital. Through an undercover investigation, they learned that Karkalas was prescribing Fioricet online not just for tension headaches but also for other maladies such as knee pain and hemorrhoids.

In 2013, a federal grand jury in Minnesota returned an 85-count indictment related to Rx Limited against eleven defendants. It named Karkalas in 38 counts. Many of those counts related to the illegal distribution of Fioricet, *see* 21 U.S.C. §§ 841(a)(1), (b)(1)(E), (h)(1), (h)(4), but the indictment also charged Karkalas with conspiracy, wire fraud, mail fraud, and introducing misbranded drugs into interstate commerce. Karkalas was arrested at his office and detained pretrial for six months, including four-and-a-half months in detention centers in multiple states and six weeks in a halfway house. He was later released to home confinement with an ankle monitor.

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[1] The *Physicians' Desk Reference* currently identifies Fioricet as a Schedule III controlled substance. *See* Fioricet Capsules Drug Summary, Prescribers' Digital Reference, https://www.pdr.net/drug-summary/Fioricet-Capsules-acetaminophen-butalbital-caffeine-3284.2260 (last visited Feb. 9, 2021).

Throughout the pretrial period, Karkalas asserted that Fioricet was not a controlled substance. He emailed and called the prosecutor and investigator, and he even voluntarily traveled to Washington, D.C. to meet with them, but they were unconvinced. Karkalas also filed motions in the Minnesota trial court to dismiss the Fioricet charges and to exclude evidence of his distribution of Fioricet. But that court denied both motions, concluding that Fioricet – because it contains butalbital – is a Schedule III controlled substance. *See United States v. Oz*, 2017 WL 342069, at *2, *3–5 (D. Minn. Jan. 23, 2017) (citing 21 U.S.C. § 812, Sch. III(b)(1)); *United States v. Oz*, 2016 WL 1183041, at *2, *4–6 (D. Minn. Mar. 28, 2016). Despite prevailing on those motions, the United States voluntarily dismissed ten of the charges against Karkalas related to his distribution of Fioricet.

The case against Karkalas and three other defendants proceeded to a jury trial, and there it continued to turn in his favor. In the middle of its case-in-chief, the United States dropped the remaining charges related to the distribution of Fioricet. And in returning its verdict, the jury acquitted Karkalas and the other defendants of all other charges.

To vindicate himself beyond that acquittal, Karkalas filed this two-count civil lawsuit in the Eastern District of Pennsylvania. In Count One of the complaint, Karkalas asserts that the prosecutor and investigator violated his Fourth and Fifth Amendment rights by knowingly presenting false and misleading testimony and by prosecuting him without probable cause, leading to his unlawful pretrial detention. In

Count Two, Karkalas sues the United States for malicious prosecution under the Federal Tort Claims Act.

The defendants moved to dismiss the counts against them – the prosecutor and investigator pursuant to Federal Rules of Civil Procedure 12(b)(2), 12(b)(3), and 12(b)(6), and the United States pursuant to Rules 12(b)(1) and 12(b)(6). The District Court granted those motions on several alternative grounds and dismissed Karkalas's amended complaint with prejudice. In doing so, the District Court exercised subject-matter jurisdiction over the federal questions in Count One, *see* 28 U.S.C. § 1331, but determined that it lacked personal jurisdiction over the individual defendants. In addition, the District Court determined that no *Bivens* cause of action could be implied against those defendants, who were also shielded from suit due to qualified immunity (and the prosecutor further protected by absolute immunity). On Count Two, the District Court concluded that it lacked jurisdiction due to the United States' sovereign immunity for discretionary functions and for intentional torts (the latter as to only the conduct of the prosecutor). *See id.* §§ 1346(b)(1), 2674, 2680(a), (h).

Karkalas timely appealed, bringing the case within this Court's appellate jurisdiction. *See* 28 U.S.C. § 1291. The individual defendants no longer press the personal jurisdiction defense, *see* Appellees' Br. 15 n.3, thereby consenting to such jurisdiction. *See Danziger & De Llano, LLP v. Morgan Verkamp LLC*, 948 F.3d 124, 129 (3d Cir. 2020) ("A defendant may . . . consent to personal jurisdiction by waiving any objection to it."

(citing *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 703 (1982))). They have preserved and presented their other defenses. In reviewing the dismissal of the complaint *de novo*, *see Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006), we will affirm the District Court's judgment.

I.

In Count One, Karkalas sues the prosecutor and the investigator in their individual capacities, seeking to recover damages. He does so through a judicially implied cause of action, a *Bivens* claim, which permits a damages remedy for a person whose constitutional rights have been violated by agents of the federal government. *See Ziglar v. Abbasi*, 137 S. Ct. 1843, 1854 (2017). *See generally Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971). In response, the individual defendants argue that a *Bivens* action is unavailable in this context, that the prosecutor qualifies for absolute immunity, and that both defendants are entitled to qualified immunity. The last of those arguments – qualified immunity – is the most natural starting place because it is common to both individual defendants and because it proves dispositive.

Qualified immunity shields government officials from liability for civil damages so long as "their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known." *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982); *see also District of Columbia v. Wesby*, 138 S. Ct. 577, 589 (2018); *El v. City of Pittsburgh*, 975

F.3d 327, 334 (3d Cir. 2020). At the motion-to-dismiss stage, courts evaluate qualified immunity for a constitutional claim by examining (i) whether the complaint contains plausible allegations of a constitutional violation and (ii) whether the asserted constitutional right is clearly established. *See Wood v. Moss*, 572 U.S. 744, 757 (2014) (citing *Ashcroft v. al-Kidd*, 563 U.S. 731, 735 (2011)); *see also Conn v. Gabbert*, 526 U.S. 286, 290 (1999) (explaining that the qualified immunity inquiry requires "a court [to] determine whether the plaintiff has alleged the deprivation of an actual constitutional right at all").

To evaluate the first prong of qualified immunity on a motion to dismiss, this Court follows a three-step plausibility inquiry. *See Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016); *see also Pearson v. Callahan*, 555 U.S. 223, 236 (2009) (noting that "it is often beneficial" for courts to address the two prongs of the qualified immunity analysis in order, even though it is no longer mandatory). The first step involves an articulation of the elements of the claim. *See Connelly*, 809 F.3d at 787 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). The second step scrutinizes the complaint to identify and disregard any "'formulaic recitation of the elements of a . . . claim' or other legal conclusion," *id.* at 789 (quoting *Iqbal*, 556 U.S. at 681), as well as allegations that "while not stating ultimate legal conclusions, are nevertheless so threadbare or speculative that they fail to cross the line between the conclusory and the factual," *id.* at 790 (quoting *Peñalbert-Rosa v. Fortuño-Burset*, 631 F.3d 592, 595 (1st Cir. 2011)). The third step evaluates the plausibility of the remaining allegations – after first

assuming their veracity, construing them in the light most favorable to the plaintiff, and drawing all reasonable inferences in the plaintiff's favor. *See id.* at 787, 790; *see also Iqbal*, 556 U.S. at 679; *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009). At that point, if a complaint alleges "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of" the necessary elements of a claim, then it plausibly pleads a claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). But if "a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted) (quoting *Twombly*, 550 U.S. at 557).

As set forth below, under this plausibility analysis, Karkalas fails to state a claim for a constitutional violation under Count One. And because the complaint fails to plausibly allege that the prosecutor or investigator violated Karkalas's constitutional rights, those individual defendants are entitled to qualified immunity. That conclusion renders unnecessary an analysis of the second prong of qualified immunity, as well as the other defenses related to absolute immunity and the unavailability of a *Bivens* action in this context. *See Wood*, 572 U.S. at 757 (assuming without deciding that a *Bivens* cause of action is available and resolving based on qualified immunity); *Hui v. Castaneda*, 559 U.S. 799, 807 (2010) ("Even in circumstances in which a *Bivens* remedy is generally

available, an action under *Bivens* will be defeated if the defendant is immune from suit.").

A.

Karkalas first brings a Fourth Amendment malicious prosecution claim against the individual defendants. *See Manuel v. City of Joliet*, 137 S. Ct. 911, 919 (2017) ("If the complaint is that a form of legal process resulted in pretrial detention unsupported by probable cause, then the right allegedly infringed lies in the Fourth Amendment."). Under the three-step plausibility inquiry, he fails to allege a violation of the Fourth Amendment.

1. Articulation of the elements. A claim for Fourth Amendment malicious prosecution consists of the following elements:

(1) the defendant initiated a criminal proceeding;

(2) without probable cause;

(3) maliciously or for a purpose other than bringing the plaintiff to justice;

(4) causing the plaintiff to suffer a deprivation of liberty consistent with the concept of seizure; and

(5) the outcome of the criminal proceeding favored the plaintiff.

See Harvard v. Cesnalis, 973 F.3d 190, 203 (3d Cir. 2020) (citation omitted); *see also Black v. Montgomery*

County, 835 F.3d 358, 364 (3d Cir. 2016) (citation omitted).

2. Identification of deficient allegations. Several of Karkalas's conclusory allegations should be disregarded. In particular, Karkalas alleges that the individual defendants made "knowingly false presentations" to the grand jury, namely, (i) that Fioricet is a controlled medication, (ii) that Karkalas knew so, and (iii) that he would continue to prescribe it. First Amended Complaint ¶ 86 (App. 77). But grand jury proceedings are shrouded in secrecy. *See* Fed. R. Crim. P. 6(e)(2)(B); *see also Rehberg v. Paulk*, 566 U.S. 356, 374 (2012) ("We consistently have recognized that the proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings." (citations omitted)); *United States v. Smith*, 123 F.3d 140, 148 (3d Cir. 1997) ("Fed. R. Crim. P. 6(e) is intended to preserve the tradition of grand jury secrecy, creating a general rule of confidentiality for all 'matters occurring before the grand jury.'"). And the complaint nowhere indicates how Karkalas became privy to this secret information. *See* District Ct. Op. 32 (App. 32) ("Given the secrecy of the grand jury proceeding, we question how Dr. Karkalas knows what [the prosecutor and investigator] told the grand jury . . . ."). Without providing a factual basis for his purported knowledge of the grand jury proceedings, Karkalas's allegations that the individual defendants made false statements to the grand jury are "speculative" and "threadbare." *Connelly*, 809 F.3d at 790; *see also Oliver v. Roquet*, 858 F.3d 180, 192 (3d Cir. 2017) ("[A] plaintiff's allegations 'must be enough to raise a right to relief above the speculative level,'

and must reflect 'more than a sheer possibility that a defendant has acted unlawfully.'" (quoting *Twombly*, 550 U.S. at 555, and *Iqbal*, 556 U.S. at 678)); *Peñalbert-Rosa*, 631 F.3d at 595–96 ("[S]ometimes a threadbare factual allegation bears insignia of its speculative character and, absent greater concreteness, invites an early challenge."). As such, those allegations must be excluded from the plausibility analysis.

Similarly, the complaint alleges that the prosecutor and investigator acted "with malice" in initiating the criminal proceeding against Karkalas. First Amended Complaint ¶ 88 (App. 78). But without supporting factual allegations, that is nothing more than a conclusory reformulation of the malice element of a Fourth Amendment malicious prosecution claim, which should be disregarded. *See Twombly*, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." (alteration in original) (citation omitted)).

3. Evaluation of the remaining allegations. Without crediting the deficient allegations, Karkalas has failed to plausibly allege two essential elements of a Fourth Amendment malicious prosecution claim: lack of probable cause and malice. A federal indictment triggers a rebuttable presumption of probable cause to prosecute. *See Goodwin v. Conway*, 836 F.3d 321, 329 (3d Cir. 2016); *Rose v. Bartle*, 871 F.2d 331, 353 (3d Cir. 1989); *see also Kaley v. United States*, 571 U.S. 320, 328 (2014) ("[A]n indictment fair upon its face and returned by a properly constituted grand jury . . . conclusively

determines the existence of probable cause to believe the defendant perpetrated the offense alleged." (citations and internal quotation marks omitted)). And without the allegations concerning the individual defendants' statements to the grand jury, the remainder of the complaint does not rebut that presumption. *See Rose*, 871 F.2d at 353 (explaining that the presumption of probable cause "may be rebutted by evidence that the [indictment] was procured by fraud, perjury or other corrupt means"). Likewise, without the excluded conclusory allegation of malice, the remaining allegations – which do not reflect a prosecution motivated by "ill will" or "spite" or some "extraneous improper purpose," *Lippay v. Christos*, 996 F.2d 1490, 1502 (3d Cir. 1993) (citation omitted) – do not plausibly suggest that the prosecutor or the investigator acted maliciously.

Karkalas has therefore failed to state a Fourth Amendment malicious prosecution claim, as the complaint does not plausibly allege two necessary elements. Accordingly, the individual defendants are entitled to qualified immunity for this claim. *See Bennett v. Murphy*, 274 F.3d 133, 136 (3d Cir. 2001) ("If the plaintiff fails to make out a constitutional violation, the qualified immunity inquiry is at an end; the officer is entitled to immunity.").

B.

Karkalas also sues the individual defendants for using fabricated evidence against him in violation of the Fifth Amendment. *See Halsey v. Pfeiffer*, 750 F.3d 273, 289 (3d Cir. 2014) ("When falsified evidence is used as a basis to initiate the prosecution of a

defendant, . . . the defendant has been injured regardless of whether the totality of the evidence, excluding the fabricated evidence, would have given the state actor a probable cause defense in a malicious prosecution action . . . ."). The plausibility analysis for this claim proceeds along the same lines as above, yielding a similar result: Karkalas does not state a plausible claim for a violation of the Fifth Amendment.

1. Articulation of the elements. For an acquitted criminal defendant, a due process fabricated evidence claim consists of the following elements:

(1) a government actor's production or introduction of evidence or testimony;

(2) at any point before or during a criminal proceeding;

(3) that the government actor knew to be;

(4) false; and

(5) without that fabricated evidence, there is a reasonable likelihood that the defendant would not have been criminally charged.

See Black, 835 F.3d at 370–72; *Halsey*, 750 F.3d at 294–95; *see also Caldwell v. City & County of San Francisco*, 889 F.3d 1105, 1112, 1115 (9th Cir. 2018); *Zahrey v. Coffey*, 221 F.3d 342, 348–49, 355 (2d Cir. 2000).

2. Identification of deficient allegations. As before, Karkalas's allegations as to the statements made to the grand jury are too speculative for inclusion in the plausibility analysis.

3. Evaluation of the remaining allegations. Without the disregarded allegations, Karkalas does not plausibly allege *any* element of a fabricated evidence claim. He attempts to compensate for this shortcoming by referencing statements that the prosecutor made before the Magistrate Judge at the pretrial detention hearing. Those statements include the assertions that Karkalas was involved with an international drug cartel, that his actions resulted in several drug related deaths, that the evidence against him was overwhelming, and that he presented a flight risk. But the prosecutor made those statements not through testimony or the admission of evidence, but rather through advocacy – arguing that Karkalas should be detained pursuant to a statutory presumption against release based on the nature of his charges, *see* 18 U.S.C. § 3142(e)(3)(A). Beyond the dispositive facts that those statements were not evidence and were made *after* Karkalas was charged, the complaint still lacks any non-conclusory allegations that the prosecutor knew her statements to be false when she made them. *See Halsey*, 750 F.3d at 295 ("[T]estimony that is incorrect or simply disputed should not be treated as fabricated merely because it turns out to have been wrong."). Absent plausible allegations stating a fabricated evidence claim, the individual defendants are entitled to qualified immunity. *See id.* at 295 ("[W]e expect that it will be an unusual case in which a police officer cannot obtain a summary judgment in a civil action charging him with having fabricated evidence used in an earlier criminal case.").

II.

In Count Two, Karkalas sues the United States for the state-law tort of malicious prosecution under the Federal Tort Claims Act. The FTCA exposes the United States to tort liability by waiving its sovereign immunity for certain claims. *See* 28 U.S.C. §§ 1346(b)(1), 2674. But that waiver is limited by several exceptions, and the United States invokes two of those jurisdictional defenses here: the discretionary function exception, *id.* § 2680(a), and the intentional tort exception, *id.* § 2680(h). As explained below, the discretionary function exception bars Karkalas's malicious prosecution claim, making it unnecessary to evaluate the United States' remaining defenses.

The discretionary function exception is aptly named. It bars suits against the United States that challenge "the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of . . . an employee of the Government, whether or not the discretion involved be abused." *Id.* § 2680(a). It applies when the challenged acts (i) "involve[d] an element of judgment or choice," and (ii) were "based on considerations of public policy." *United States v. Gaubert*, 499 U.S. 315, 322–23 (1991) (quoting *Berkovitz v. United States*, 486 U.S. 531, 536–37 (1988)); *see also Merando v. United States*, 517 F.3d 160, 164–65 (3d Cir. 2008). Although the exception is "jurisdictional on its face," *S.R.P. ex rel. Abunabba v. United States*, 676 F.3d 329, 333 n.2 (3d Cir. 2012), the United States "has the burden of proving the applicability of the discretionary function exception," *Merando*, 517 F.3d at 164 (citations omitted). Here,

where the challenged acts involve the investigation and prosecution of Karkalas, the United States has met that burden.

Both the investigation and the prosecution of Karkalas satisfy the first element of the discretionary function exception. Investigation and prosecution involve judgment or choice. *See Pooler v. United States*, 787 F.2d 868, 871 (3d Cir. 1986) ("Prosecutorial decisions as to whether, when and against whom to initiate prosecution are quintessential examples of governmental discretion in enforcing the criminal law." (citations omitted)), *abrogated on other grounds by Millbrook v. United States*, 569 U.S. 50 (2013); *Bernitsky v. United* States, 620 F.2d 948, 955 (3d Cir. 1980) ("Decision making as to investigation and enforcement, particularly when there are different types of enforcement action available, are discretionary judgments.").

Similarly, those actions satisfy the second element. Investigatory and prosecutorial decisions are "susceptible to policy analysis." *Gaubert*, 499 U.S. at 325; *see Bond v. United States*, 572 U.S. 844, 865 (2014) ("Prosecutorial discretion involves carefully weighing the benefits of a prosecution against the evidence needed to convict, the resources of the public fisc, and the public policy of the State."); *Baer v. United States*, 722 F.3d 168, 175 (3d Cir. 2013) ("Whether to pursue a lead, to request a document, or to assign additional examiners to an investigation are all discretionary decisions, which necessarily involve considerations of . . . resource allocation and opportunity costs.").

Karkalas does not challenge those straightforward conclusions directly. Rather, he contends that, even with the government's broad discretion to investigate and prosecute crimes, "there is no discretion to violate the Constitution." Appellant's Br. 22; *see also Pooler*, 787 F.2d at 871 (stating in dicta that "federal officials do not possess discretion" to violate "constitutional rights or federal statutes"). But this case does not present an opportunity to evaluate that legal theory because, as explained above, Karkalas does not allege plausible violations of the Constitution. Without such allegations, "all of the challenged actions . . . involved the exercise of discretion in furtherance of public policy goals," *Gaubert*, 499 U.S. at 334, and the United States thus retains its sovereign immunity for this claim.

* * *

In sum, the District Court properly dismissed the *Bivens* claims against the prosecutor and the investigator as well as the FTCA claim against the United States. We will affirm.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. 19-948

[Filed: July 31, 2019]

ELIAS KARKALAS, M.D.	)
	)
v.	)
	)
LINDA MARKS, ESQUIRE, *et al.*	)
	)

MEMORANDUM

KEARNEY, J. **July 31, 2019**

We entrust our federal investigators and prosecutors with substantial power to interrupt lives to challenge conduct they believe violates the law. They must balance their enforcement vigor with seasoned discretion. As presented today, being indicted, arrested, incarcerated and tried is undoubtedly a traumatic series of events for a Pennsylvania medical doctor who believes approving internet prescriptions for Fioricet did not violate the Controlled Substances Act. After spending time in a Philadelphia jail before trial, the United States tried the doctor and co-defendants in the District of Minnesota but then voluntarily dismissed

the Controlled Substances Act charges during the trial. The Minnesota federal jury found the United States did not prove its case and acquitted the doctor and his co-defendants of all remaining charges. Rather than seek remedies provided by Congress like one of his co-defendants, the doctor now sues the United States, its Washington D.C. prosecutor, and the Drug Enforcement Agency's investigator from Minnesota alleging they deprived him of civil rights under the Fourth Amendment. Unlike civil rights claims against state officials, claims against federal officials and the United States are allowed only in strictly limited instances and, as directed by Supreme Court, we may not extend these remedies against federal officials beyond those already recognized.

The United States did not prove the doctor's guilt at trial and the doctor is not incarcerated. He seeks redress. But we lack personal jurisdiction over the Washington D.C. prosecutor and Minnesota investigator in Pennsylvania. Even if we could exercise personal jurisdiction over the Washington prosecutor and Minnesota investigator, the doctor cannot plead the prosecutor and investigator deprived him of his constitutional rights in pursuing charges relating to prescribing Fioricet which some (but not all) courts have recognized. Our elected representatives in Congress defined the remedies and we may not expand those remedies. They are also entitled to immunity. The doctor also fails to plead claims against the United States under the Federal Tort Claims Act or a malicious prosecution theory. We grant the United States' and its officials' Motions to dismiss in the accompanying Order.

I. Alleged facts.

Dr. Elias Karkalas served as medical director at Independence Blue Cross of Pennsylvania while managing a private practice in King of Prussia, Pennsylvania.[1] Before 2013, Dr. Karkalas began working with Rx Limited, an online pharmacy company, approving requests on the internet for prescription medications.[2] He insisted Rx Limited did not sell controlled substances.[3]

Dr. Karkalas approved requests for the drug Fioricet.[4] Fioricet contains butalbital, a Schedule III controlled substance under the Controlled Substances Act, along with caffeine and acetaminophen.[5] Dr. Karkalas did not believe Fioricet is a controlled substance, nor had the Food and Drug Administration designated Fioricet a controlled substance.[6] Dr. Karkalas used the Physician's Desk Reference, an authoritative source for doctors, to determine Fioricet is a non-controlled medication.[7]

The Drug Enforcement Agency investigated the diversion of prescription drugs into illegal markets.[8] Diversion Investigator Kimberly Brill, a Minnesota citizen, believed Rx Limited prescribed controlled substances without a doctor-patient relationship in violation of the Controlled Substances Act.[9] Although Investigator Brill believed Fioricet is a controlled substance, she discovered during her investigations the Food and Drug Administration had not designated Fioricet a controlled substance.[10]

Investigator Brill brought her investigation concerning Rx Limited to the United States Attorney's

Office in Minneapolis, but the Office declined to prosecute.[11] Investigator Brill then brought the case to Attorney Linda Marks, a citizen of Washington, D.C., in the Department of Justice's Consumer Protection Branch.[12] Attorney Marks agreed to prosecute.[13] Investigator Brill and Attorney Marks alleged Rx Limited constituted an "international conspiracy" to illegally sell controlled substances online.[14]

On November 13, 2013, a grand jury in the United States District Court of Minnesota indicted Dr. Karkalas and ten other defendants involved with Rx Limited on thirty-eight counts of violating the Controlled Substances Act, mail and wire fraud, and conspiring to launder money.[15] The grand jury indicted Dr. Karkalas under several provisions of the Controlled Substances Act: Section 841(a) prohibiting distribution of a controlled substance, Section 841(h) prohibiting distribution of controlled substances on the internet, and Section 831 requiring an online pharmacy display certain licensure information on its homepage.[16] Attorney Marks and Investigator Brill allegedly told the grand jury: (1) Fioricet is a "controlled medication"; (2) Dr. Karkalas "was aware that Fioricet was a controlled medication"; and, (3) Dr. Karkalas "would continue to prescribe [Fioricet] in the same manner that he had."[17]

Upon issuance of a warrant following the indictment, unnamed officials arrested Dr. Karkalas at his King of Prussia office.[18] The United States held him in the Federal Detention Center in Philadelphia for two months.[19] He then spent two weeks in an Oklahoma facility and two months in a federally-contracted jail in

Minnesota.[20] He spent the six weeks before trial in a halfway house.[21]

The United States did not apprehend three of the indicted defendants. Three of the eleven defendants plead guilty and five defendants—including Dr. Karkalas—went to trial.[22]

In meetings and interviews before trial, Dr. Karkalas unsuccessfully tried to persuade Attorney Marks and Investigator Brill Fioricet is not a controlled substance.[23] Attorney Marks "sought to intimidate witnesses" like Dr. Karkalas's nurse and office manager to testify against him.[24]

Attorney Marks tried the five defendants together in the District of Minnesota for conspiracy to distribute Fioricet online without valid prescriptions under the Controlled Substances Act, mail and wire fraud, and money laundering.[25] Attorney Marks dropped the Controlled Substances Act charges midway through trial.[26] On March 17, 2017, a jury acquitted Dr. Karkalas and the other four defendants on all remaining counts.[27] Following acquittal, one of Dr. Karkalas's co-defendants moved for an award of attorney's fees under the Hyde Amendment arguing bad-faith prosecution.[28] The trial court held, while the prosecution made mistakes during trial, Dr. Karkalas's co-defendant failed to show "frivolous, vexatious, or bad faith conduct."[29] Dr. Karkalas decided not to move for attorneys' fees.

He instead decided to sue Attorney Marks, Investigator Brill, and the United States for prosecuting him and detaining him before trial. He

alleges Attorney Marks and Investigator Brill presented "false and misleading evidence and testimony to the Grand Jury" to secure an indictment.[30] He alleges Fioricet is not a controlled substance under the Act, and Attorney Marks and Investigator Brill knew Fioricet is not a controlled substance but still prosecuted him. Dr. Karkalas also alleges Attorney Marks and Investigator Brill had no evidence Dr. Karkalas knew Fioricet is a controlled substance. He alleges Attorney Marks's dismissal of the Controlled Substance Act charges during trial signaled "the case was a sham from the beginning and should have never been initiated."[31]

Dr. Karkalas sues Attorney Marks and Investigator Brill for unlawful prosecution and pretrial detention under the Fourth Amendment alleging "malicious prosecution and knowing presentation of false and misleading testimony, and evidence to the Grand Jury."[32] He sues the United States under the Federal Tort Claims Act alleging "malicious prosecution committed by investigative or law enforcement officers of the United States, acting within the scope of their employment."[33]

II. Analysis.[34]

Attorney Marks and Investigator Brill move to dismiss Dr. Karkalas's First Amended Complaint arguing (1) we lack personal jurisdiction over them, (2) venue is improper in the Eastern District of Pennsylvania, (3) we should not imply a constitutional remedy against federal officials under these circumstances, and (4) absolute and qualified immunity bars Dr. Karkalas's claims.[35]

The United States separately move to dismiss the First Amended Complaint arguing (1) Attorney Marks and Investigator Brill are not "investigative or law enforcement officers" under the Federal Tort Claims Act, (2) the discretionary function exception bars Dr. Karkalas's claims, and (3) Dr. Karkalas fails to state a claim for malicious prosecution.[36]

We lack personal jurisdiction over Attorney Marks and Investigator Brill. Venue over them and the United States is proper. But we still dismiss the case as Dr. Karkalas cannot state claims against Attorney Marks, Investigator Brill or the United States.

A. We dismiss Dr. Karkalas's claims for unlawful prosecution and pretrial detention against Attorney Marks and Investigator Brill.

1. We lack personal jurisdiction over Attorney Marks and Investigator Brill.

Attorney Marks and Investigator Brill argue we lack personal jurisdiction over them because they are nonresident defendants lacking minimum contacts with Pennsylvania. We analyze personal jurisdiction based on Pennsylvania law.[37] The Pennsylvania General Assembly allows personal jurisdiction "to the fullest extent allowed under the Constitution of the United States and may be based on the most minimum contact with this Commonwealth allowed under the Constitution of the United States."[38] Under the Due Process Clause, we have personal jurisdiction provided Attorney Marks and Investigator Brill have "certain

minimum contacts with . . . [Pennsylvania] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice."[39]

Attorney Marks and Investigator Brill argue they lack "minimum contacts" with Pennsylvania. The Supreme Court instructs we focus on "the relationship among the defendant, the forum, and the litigation" to determine whether "minimum contacts" exist.[40] The relationship must arise from contacts the "'defendant **himself**' creates with the forum State."[41] We focus on "the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there."[42] "The plaintiff cannot be the only link between the defendant and the forum," and the defendant's conduct "must form the necessary connection with the forum State that is the basis for its jurisdiction over him."[43] "[A] defendant's relationship with a plaintiff or third party, standing alone, is an insufficient basis for jurisdiction."[44] We may only exercise jurisdiction over a defendant "based on [the defendant's] own affiliation with the State, not based on the 'random, fortuitous, or attenuated' contacts he makes by interacting with other persons affiliated with the State."[45]

In *Walden v. Fiore,* a Drug Enforcement Agency officer seized cash from an airplane passenger in Atlanta while the passenger waited for a flight home to Las Vegas.[46] After the passenger returned to Las Vegas, his attorney requested return of the cash. The passenger alleged the officer falsified a probable cause affidavit seeking forfeiture of the money, but the United States never filed a forfeiture complaint and the Drug Enforcement Agency returned the money. The

passenger sued the officer, a Georgia resident, in the District of Nevada alleging illegal seizure. The district court dismissed for lack of personal jurisdiction, but the Court of Appeals for the Ninth Circuit reversed explaining the officer submitted a falsified affidavit in Georgia knowing it would affect the passenger having "significant connection" to Nevada.[47]

The Supreme Court reversed the court of appeals and held the district court lacked personal jurisdiction over the officer.[48] The Supreme Court explained the court of appeals improperly focused on the passenger's connection with Nevada, not the officer's connections.[49] While the officer directed his conduct at the passenger, because he knew the passenger had a connection to Nevada, the officer's conduct had nothing to do with Nevada independent of the passenger. Had the passenger lived in California or Mississippi, the officer would have no connection to Nevada. The Supreme Court explained "the defendant, not the plaintiff or third parties . . . must create contacts with the forum State" to establish personal jurisdiction.50

Dr. Karkalas responds Attorney Marks and Investigator Brill "appeared in the Eastern District of Pennsylvania to investigate the claims, [met] with witnesses, and secured the pre-trial detention of Dr. Karkalas from U.S. Magistrate Judge Jacob Hart of the Eastern District of Pennsylvania."[51] He alleges Attorney Marks interviewed Dr. Karkalas in Pennsylvania and used information she obtained in prosecuting him.[52] Attorney Marks admits she came to Pennsylvania for Dr. Karkalas' s pretrial hearing.[53] Dr. Karkalas alleges Investigator Brill investigated his

Pennsylvania conduct in support of presenting the United States' criminal case.[54] He further alleges their conduct caused his pre-trial custody in a Pennsylvania jail for months.

Dr. Karkalas is "the only link between the defendant[s] and the forum."[55] Attorney Marks and Investigator Brill did not themselves create a contact with Pennsylvania independent of Dr. Karkalas. Attorney Marks appeared for Dr. Karkalas's detention hearing in Philadelphia. She created a contact with the justice system in Pennsylvania. She used the federal court and jail in Pennsylvania to move forward on the Minnesota trial. There is no plead nexus between Investigator Brill and Pennsylvania. Like *Walden,* the individuals' conduct affected Pennsylvania only through the link with Dr. Karkalas. Had the United States arrested and detained Dr. Karkalas in New Jersey, Attorney Marks and Investigator Brill would have no contact with Pennsylvania.

Personal jurisdiction would seem to be a close call based on the conduct directed at Dr. Karkalas's Pennsylvania practice, detention hearing, and jail time in a Pennsylvania prison. But under *Walden,* the challenged conduct is related only to Dr. Karkalas. This nexus is insufficient for personal jurisdiction. Dr. Karkalas fails to articulate a credible basis for Pennsylvania's personal jurisdiction over Attorney Marks and Investigator Brill. We dismiss Attorney Marks and Investigator Brill without prejudice for lack of personal jurisdiction.

2. Venue is proper.

Investigator Brill and Attorney Marks alternatively argue venue is improper because they do not reside in Pennsylvania and no events giving rise to the claim occurred in Pennsylvania. But if we found personal jurisdiction over them, we would enjoy proper venue over them as we do for the claims the United States.

Under 28 U.S.C. § 1391(b), Dr. Karkalas may sue in:

> (1) a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located;
>
> (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated; or
>
> (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action.[56]

Dr. Karkalas admits Attorney Marks and Investigator Brill do not reside in Pennsylvania. He instead alleges "acts giving rise" to his claims occurred in this forum.[57] Under § 1391(b)(2), our Court of Appeals explained the test for venue is "not the defendant's 'contacts' with a particular district, but rather the location of those 'events or omissions giving rise to the claim[.]'"[58] To determine whether the events are "substantial," we must look at "the nature of the

dispute."[59] Dr. Karkalas need not show our District is "the locus of the majority of the events or omissions."[60] But "events or omissions that might only have some tangential connection with the dispute in litigation are not enough" to establish venue under § 1391(b)(2).[61]

Attorney Marks and Investigator Brill argue venue is improper because "[Dr.] Karkalas was prosecuted in Minnesota."[62] But Dr. Karkalas sues for unlawful prosecution and pretrial detention under the Fourth Amendment. He alleges his arrest in this District at his King of Prussia office and unlawful pretrial detainment at the Federal Detention Center in Philadelphia for two months.[63] He alleges Attorney Marks appeared in the Eastern District of Pennsylvania to secure his pretrial detention before United States Magistrate Judge Jacob Hart of the Eastern District of Pennsylvania.[64] He more fundamentally alleges his prescribing medicine from his office in King of Prussia gave rise to the investigation, detention, and prosecution. These events bear more than a "tangential connection" with his claims as the alleged unlawful detention occurred in our District and his prosecution stemmed from his arrest and conduct in this District. Dr. Karkalas shows a substantial part of the events giving rise to his claims occurred in the Eastern District of Pennsylvania.

Assuming we could find personal jurisdiction, we disagree with Attorney Marks and Investigator Brill and would hold venue is proper in our District.

3. We do not imply a *Bivens* cause of action against Attorney Marks and Investigator Brill.

Even assuming we enjoyed personal jurisdiction over Attorney Marks and Investigator Brill, Dr. Karkalas cannot state a claims for unlawful seizure and prosecution by them under *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics.*[65] While Congress established a damages remedy under 42 U.S.C. § 1983 against state officials for constitutional violations, it did not create an analogous statute for damages against federal officials.[66] But in *Bivens,* the Supreme Court implied a damages remedy under the Constitution against federal officials despite Congress's inaction.[67]

In *Bivens,* federal agents entered a man's house without a warrant, arrested and handcuffed him, and searched his house for drugs.[68] The man sued the federal agents for damages under the Fourth Amendment alleging a warrantless search and unreasonable seizure.[69] The district court dismissed his case and the court of appeals affirmed.[70] But the Supreme Court recognized an implied private cause of action for damages for a federal officer's violation of a person's Fourth Amendment rights.[71] The Supreme Court explained while Congress had not created a private cause of action against federal official for damages, the Supreme Court had the power to "adjust . . . remedies so as to grant the necessary relief" to protect a constitutional right.[72]

Since *Bivens,* the Supreme Court only recognized an implied private cause of action under the Constitution

against federal officials in certain instances and discouraged extending its holding. The Supreme Court explained it "has repeatedly refused to extend *Bivens* actions beyond the specific clauses of the specific amendments [of the Constitution] for which a cause of action has already been implied, or even to other classes of defendants facing liability under those same clauses."[73] In *Ziglar v. Abbasi,* the United States held hundreds of noncitizens on immigration charges under an executive policy following the September 11 terrorist attacks.[74] The noncitizens sued alleging executive officials responsible for the policy detained them longer than necessary under harsh conditions. They sued the wardens of the detention facilities for unlawful detention and unconstitutional conditions of confinement under *Bivens* alleging Fourth and Fifth Amendment violations.[75]

The Supreme Court explained expanding the *Bivens* remedy is now a S"disfavored" judicial activity.[76] The Supreme Court recognized an implied action against federal officials in three cases: (1) *Bivens* itself—"a claim against FBI agents for handcuffing a man in his own home without a warrant" under the Fourth Amendment;[77] (2) "a claim against a Congressman for firing his female secretary" under the Fifth Amendment;[78] and, (3) "a claim against prison officials for failure to treat an inmate's asthma" under the Eighth Amendment.[79] But beyond these three cases, the Supreme Court refused to extend *Bivens* "to any new context or new category of defendants."[80] The Supreme Court found noncitizens' claims for unlawful detainment and unconstitutional conditions of confinement following a major terrorist attack did not

resemble the three recognized *Bivens* claims, thus presenting a "new context" for a *Bivens* action.[81] The Supreme Court found the conditions of confinement claim differed from the claim in *Carlson v. Green,* explaining the noncitizens in *Ziglar* alleged failure to respond to grievances, while the prisoner in *Carlson* alleged failure to provide adequate medical care.[82] The Supreme Court cautioned "even a modest extension [of *Bivens*] is still an extension."[83]

The Supreme Court then explained "special factors" showed the Court should not imply a *Bivens* remedy: (1) a court should not inquire into the "formulation and implementation" of an executive policy and the "discussion and deliberation" leading to the policy[84]; (2) as the United States implemented the policy in response to a terrorist attack, a court in a *Bivens* action would inquire into "sensitive issues of national security"[85]; (3) the noncitizens had alternative remedies, including injunctive relief or writs of habeas corpus.[86] Concerning the conditions of confinement claim, the Supreme Court explained with the Prison Litigation Reform Act, Congress did not provide a "standalone damages remedy" against federal officials, suggesting Congress did not intend to extend *Bivens.*[87]

The Supreme Court instructed when facing a claim under *Bivens,* we must first determine whether the case presents a new context for a *Bivens* action.[88] We undertake a "rigorous inquiry . . . before implying a *Bivens* cause of action in a new context or against a new category of defendants."[89] A *Bivens* case presents a new context "[i]f the case is different in a meaningful way from previous *Bivens* cases decided by [the

Supreme] Court[.]"[90] The Supreme Court gave examples of differences showing a case presents a new context including:

> the rank of the officers involved; the constitutional right at issue; the generality or specificity of the official action; the extent of judicial guidance as to how an officer should respond to the problem or emergency to be confronted; the statutory or other legal mandate under which the officer was operating; the risk of disruptive intrusion by the Judiciary into the functioning of other branches; or the presence of potential special factors that previous *Bivens* cases did not consider.[91]

If the case presents a new context, we proceed with two separate inquires. We ask whether there is any "'alternative, existing process' capable of protecting the constitutional interests at stake."[92] A Congressionally-created "alternative remedial structure" limits our ability to imply a *Bivens* action.[93]

We also ask whether there are "special factors counseling hesitation" in extending *Bivens* to a new context.[94] We ask whether these factors show creating a damages action is a "decision for the Congress to make, not the courts."[95]

In *Lane v. Schade,* the District Court for the District of New Jersey applied the Supreme Court's holding in *Ziglar* and refused to extend *Bivens* to a malicious prosecution claim against federal officials.[96] A national park ranger arrested Mr. Lane suspecting public intoxication.[97] Mr. Lane argued the park ranger lacked

probable cause for the arrest. The park ranger then searched Mr. Lane's car and found prescription drugs. In a bench trial, a United States prosecutor tried Mr. Lane for unlawful possession of drugs. The judge found the government "failed to sustain its burden of proof" and acquitted Mr. Lane.[98] Mr. Lane sued the United States prosecutor for malicious prosecution. The district court, citing *Ziglar,* explained the claim for malicious prosecution presented a new context for a *Bivens* action since it "d[id] not resemble the claims the Court has previously approved."[99] The court refused to recognize a *Bivens* action for Mr. Lane's malicious prosecution claim but did not ask whether an alternative remedy exists or whether special factors counseled against extending *Bivens.*[100]

The United States District Court for the Western District of Pennsylvania also refused to imply a *Bivens* action alleging a federal agent coerced a confession violating the prisoner's Fifth Amendment right.[101] The court found the prisoner had no alternative remedy besides a *Bivens* action but dismissed the claim holding special factors counseled against extending *Bivens*. The court explained Congress addressed coerced confessions in 18 U.S.C. § 3501 governing the admissibility of confessions.[102] But while Congress prohibited the United States from using coerced confessions in criminal cases, it did not create a private right of action for criminal defendants.[103] The court also explained implying a *Bivens* remedy in the criminal process context would "flood the federal courts with constitutional damage claims by the many criminal defendants who leave the criminal process convinced

that they have been prosecuted and convicted unfairly."[104]

We use the template in *Ziglar* to determine whether to imply a *Bivens* action for Dr. Karkalas's claims against Attorney Marks and Investigator Brill. We ask (1) whether Dr. Karkalas's case presents a "new context" for a *Bivens* actions; (2) if so, whether Congress created an "alternative, existing process for protecting [Dr. Karkalas's] interest"; and, (3) whether "special factors [exist] counselling hesitation in the absence of affirmative action by Congress."[105]

a. Dr. Karkalas's claim presents a new context to imply a *Bivens* action.

Attorney Marks and Investigator Brill argue Dr. Karkalas's claim presents a *Bivens* action in a new context. We agree. Dr. Karkalas seeks relief for an unlawful prosecution and pretrial detention following allegedly false and misleading statements to a grand jury to secure an indictment for violations of the Controlled Substances Act.[106] His case most closely resembles *Bivens* itself, where a citizen sued federal agents for searching his house without a warrant and arresting him without probable cause.[107] But Attorney Marks and Investigator Brill argue Dr. Karkalas complains of illegal prosecution and pretrial detention following an indictment, not warrantless search and arrest. Unlike *Bivens,* resolution of Dr. Karkalas's claim necessitates an inquiry into the grand jury proceedings since he alleges false testimony before the grand jury. Such conduct presents a different context than the conduct in *Bivens.*[108]

Dr. Karkalas argues his case does not present a new context because *Bivens* involved Fourth Amendment claims.[109] But the Supreme Court in *Ziglar* explained a case can present a new context despite arising under an amendment in one of the three recognized *Bivens* claims.[110] The Supreme Court found the detainees' cases presented a new context despite the claims arising under the Fourth and Fifth Amendments—amendments in two of the three recognized *Bivens* actions.[111] The Supreme Court instructed the correct test for determining whether a case presents a new context involves determining whether "the case is different in a meaningful way from previous *Bivens* cases decided by this Court."[112]

Dr. Karkalas also argues his case does not present a "new context" because the Supreme Court in *Manuel v. City of Joliet* recognized unlawful pretrial detention violated an individual's Fourth Amendment rights.[113] In *Manuel,* police officers tested a bottle of vitamins from Mr. Manuel's car and found they did not contain illegal drugs.[114] The police officers nonetheless arrested Mr. Manuel. A lab technician tested the pills and falsely reported the pills contained ecstasy. Mr. Manuel's pretrial detention and prosecution stemmed from the false arrest and report. Mr. Manuel sued the police officers and the City under § 1983 alleging unlawful detention and prosecution. The Supreme Court held Mr. Manuel could pursue a § 1983 claim against the police and the City for unlawful pretrial detention under the Fourth Amendment.[115]

Dr. Karkalas ignores the test in *Ziglar* for determining whether a case presents a new context:

whether "the case is different in a meaningful way from previous *Bivens* cases decided by this Court."[116] The Supreme Court held Mr. Manuel could pursue a § 1983 action against state officials under the Fourth Amendment.[117] *Manuel* is a § 1983 case, not a *Bivens* case. Dr. Karkalas cannot rely on the Supreme Court's decision in *Manuel* to defeat the argument his case presents a "new context" for a *Bivens* action.

Dr. Karkalas' s claims for unlawful prosecution and pretrial detention present a new context for a *Bivens* action. He is asking us to extend a damages remedy against federal officials for alleged false statements in the grand jury leading to a false indictment, arrest, detention and trial. His claim rests upon his belief someone gave false testimony in a sealed grand jury proceeding. He does not show us a case extending *Bivens* in this context.

b. Attorney Marks and Investigator Brill show an "alternative remedial structure" exists to protect Dr. Karkalas's interests.

In next determining whether to imply a *Bivens* action in a new context, we ask whether there is "any alternative, existing process for protecting the [injured party's] interest[.]"[118] An alternative remedial process provides "a convincing reason for the Judicial Branch to refrain from providing a new and freestanding remedy in damages."[119] A statutory remedy for a federal official's constitutional violation obviates the need for a *Bivens* action.[120]

Attorney Marks and Investigator Brill argue two processes exist to protect Dr. Karkalas's interest: (1) the grand jury proceeding and (2) a criminal defendant's ability to challenge the indictment or the prosecution. They argue Dr. Karkalas took advantage of these processes by moving to dismiss the indictment. The District Court for the District of Minnesota denied his motion finding the Drug Enforcement Agency did not exempt the sale of Fioricet without a prescription from criminal penalties under the Controlled Substances Act.[121]

Attorney Marks and Investigator Brill also argue Congress created an alternative remedial structure with the Hyde Amendment and the Unjust Conviction and Imprisonment Law. Under the Hyde Amendment, a criminal defendant acquitted on all charges may petition for attorneys' fees provided the United States prosecuted the defendant in bad faith.[122] Under the Unjust Conviction law, a criminal defendant can recover damages from the United States if he can prove a court "reversed or set aside [his conviction] on the ground that he is not guilty of the offense of which he was convicted."123 If a criminal defendant can prove he is not guilty, he can recover up to $50,000 for each twelve-month period of wrongful incarceration.[124]

The Court of Appeals for the Eighth Circuit found the Hyde Amendment and Unjust Conviction law provide an "alternative remedy" weighing against implying a *Bivens* action for malicious prosecution.[125] In *Farah v. Weyker,* a grand jury indicted Mr. Farah for his involvement in a sex-trafficking conspiracy.[126] Like Dr. Karkalas, Mr. Farah alleged an investigating

officer presented false testimony to the grand jury to secure the indictment.[127] The United States detained Mr. Farah before trial and a jury acquitted Mr. Farah. He sued the investigating officer under the Fourth Amendment for illegal prosecution and pretrial detention. Citing the Supreme Court's holding in *Ziglar,* the court of appeals refused to imply a *Bivens* action for Mr. Farah's claims. The court found the Hyde Amendment and the Unjust Conviction law constituted an "alternative remedial structure" and found implying a *Bivens* remedy would upset the structure.[128] The court of appeals explained with the Hyde Amendment, Congress intended to grant criminal defendants some relief by awarding attorneys' fees when the United States initiates bad-faith or frivolous prosecution.[129] With the Unjust Conviction law, Congress provided relief to criminal defendants wrongfully convicted.[130] Congress addressed relief for the charged defendant's alleged injuries with these two statutes.[131]

Mr. Farah argued he could not qualify for these remedies because (1) he had appointed counsel and (2) a jury acquitted, not wrongfully convicted, him—like Dr. Karkalas. But the court of appeals explained these factors cut against implying a *Bivens* action. The court explained if Mr. Farah had been wrongfully convicted or retained counsel, he would be eligible for relief. Congress chose to provide a remedy "for some victims of this particular type of injury, but not for others, suggest[ing] that it considered the issue and made a deliberate choice."[132] Extending remedies to someone like Mr. Farah would "upset the existing 'remedial structure'" Congress created.[133]

Mr. Farah also argued even if he did qualify under the Hyde Amendment or the Unjust Conviction law, these remedies failed to offer similar compensation as an award of damages. But the court explained the alternative remedies need not equate to damages. The court explained the Supreme Court held non-monetary "alternative remedies" like injunctions and habeas relief triggered the rule "when alternative methods of relief are available, a *Bivens* remedy usually is not."[134]

Dr. Karkalas makes the same arguments as Mr. Farah. He argues the alternative remedies under the Hyde Amendment and the Unjust Conviction law are "wholly inadequate" for the pain and suffering he experienced.[135] While we understand his frustration, we agree with the Court of Appeals for the Eighth Circuit Congress contemplated remedies for criminal defendants like Dr. Karkalas complaining of improper prosecution. Congress designed a remedial structure offering relief for wrongfully convicted criminal defendants and defendants with retained counsel against whom the United States pursued bad faith or frivolous litigation. For example, Dr. Karkalas's co-defendant moved for fees under the Hyde Amendment and the trial court found the co-defendant failed to show "frivolous, vexatious, or bad faith conduct" by Attorney Marks allowing an award of fees.[136]

Dr. Karkalas also alleges "bad faith prosecution" but he failed to move for fees under the Hyde Amendment.[137] Attorney's fees do not equate to damages, and a jury acquitted Dr. Karkalas making him ineligible for relief under the Unjust Conviction law. Congress nevertheless created a remedial

structure and we should not upset the structure by implying a *Bivens* action here.

c. Special factors exist counseling against implying a *Bivens* action for Dr. Karkalas's claims.

We also ask whether there are "special factors counselling hesitation in the absence of affirmative action by Congress."[138] In doing so, we "weigh[ ] reasons for and against the creation of a new cause of action, the way common law judges have always done."[139] We ask the critical question "'who should decide' whether to provide for a damages remedy, Congress or the courts?"[140] We should not imply a *Bivens* remedy "if there are sound reasons to think Congress might doubt the efficacy or necessity of a damages remedy as part of the system for enforcing the law and correcting a wrong[.]"[141]

Attorney Marks and Investigator Brill argue several factors counsel against implying a *Bivens* action: (1) grand jury proceedings are secret, (2) Investigator Brill is not a traditional law enforcement officer, and (3) Congress expressly refused to provide a private cause of action and immunized the United States and its employees under a section of the Controlled Substances Act.

i. The secrecy of grand jury proceedings counsels against implying a *Bivens* action.

Attorney Marks and Investigator Brill argue the secrecy of grand jury proceedings counsels against implying a *Bivens* action here. In *Farah,* the Court of

Appeals for the Eighth Circuit found the secrecy of grand jury proceedings constituted a "special factor" counseling against a *Bivens* action.[142] The court explained Mr. Farah's claims alleging false information presented to the grand jury would require the court to determine "whether there was probable cause to charge the plaintiffs with a crime that would have justified their detention pending trial."[143] The court explained to determine whether the grand jury had probable cause to indict Mr. Farah, the court would necessarily have to (1) look at the grand jury record to see if probable cause existed and (2) interview grand jury members to determine whether the allegedly false testimony influenced grand jury members in returning an indictment.[144]

Dr. Karkalas argues the secrecy of the grand jury proceeding does not counsel against recognizing a *Bivens* action for malicious prosecution because courts recognize malicious prosecution claims under § 1983. But the court in *Farah* explained Congress in passing § 1983 recognized the encroachment into grand jury proceedings for actions against state officials and determined "the potential encroachment is worth it."[145] The court would not say the same for an action against federal officials "without any congressional guidance."[146]

We agree with the Court of Appeals for the Eighth Circuit the secrecy of grand jury proceeding counsels against recognizing a *Bivens* action for Dr. Karkalas's claims. Dr. Karkalas alleges Attorney Marks and Investigator Brill gave false testimony to the grand jury to secure an indictment against Dr. Karkalas.[147]

His claim will necessarily lead to an inquiry into the grand jury proceeding and the testimony presented. Dr. Karkalas does not deny he sold Fioricet and Fioricet contains butalbital, a controlled substance. Considering the admitted evidence against him, his claim would require whether the alleged false testimony proximately caused his injury. Dr. Karkalas argues courts recognize malicious prosecution claims under § 1983 and such claims involve an inquiry into grand jury proceedings. But as the court of appeals explained in *Farah,* Congress contemplated this distinction in liability of federal and state officials in passing § 1983. It provided no similar remedy against federal officials. Congress must decide whether to provide a remedy.

ii. Investigator Brill's status as a diversion investigator counsels against recognizing a *Bivens* action.

Investigator Brill argues we should not imply a *Bivens* remedy because she is a diversion investigator for the Drug Enforcement Agency and not a typical law enforcement officer. Investigator Brill cites *Vanderklok v. United States.*[148] After going through an airport checkpoint, Mr. Vanderklok threatened to file a complaint against a Transportation Security Administration screener, who then called the police and falsely reported Mr. Vanderklok threatened to bring a bomb on an airplane.[149] A jury acquitted Mr. Vanderklok and he then sued the screener alleging a *Bivens* action for retaliatory prosecution under the First Amendment.[150]

Our Court of Appeals declined to imply a *Bivens* remedy against airport screeners explaining they are not "investigative or law enforcement officers."[151] In deciding whether to imply a remedy, the court looked to the Federal Tort Claims Act and found Congress waived sovereign immunity for tort claims against "investigative or law enforcement officers."[152] The court further explained under Transportation Security Administration regulations, the Administration did not train screeners on probable cause, reasonable suspicion, or other constitutional doctrines governing law enforcement officers.[153] Screeners can only conduct administrative searches rather than criminal ones.[154] The court contrasted screeners with the Administration's designated law enforcement officers whom the Administration authorized to "carry and use firearms" and arrest suspects.[155]

Investigator Brill argues, like airport screeners, Drug Enforcement Agency Diversion Investigators are not traditional law enforcement officers. Under the regulation governing diversion investigators' powers, the Agency did not authorize them to carry firearms or make arrests, only authorizing the following conduct: (1) administering oaths and serving subpoenas; (2) conducting administrative inspections and executing administrative inspection warrants; (3) seizing property incident to compliance and registration inspections and investigations; and (4) seizing or placing controlled substances under seal.[156]

Investigator Brill's status as a diversion investigator constitutes a "special factor" counseling

against implying a *Bivens* action against Investigator Brill. Like the airport screeners in *Vanderklok,* diversion investigators cannot carry firearms or make arrests. Diversion investigators conduct administrative searches and issue administrative warrants. Dr. Karkalas argues diversion investigators can take part in criminal investigations and Investigator Brill did in this case. But like *Vanderklok,* the Drug Enforcement Agency distinguished between "criminal investigators" and "diversion investigators."[157] While Investigator Brill participated in a criminal investigation, we leave to Congress to decide whether to grant a remedy against a class of federal employees the Drug Enforcement Agency failed to classify as "criminal" investigators.

Investigator Brill's status as a diversion investigator counsels against implying a *Bivens* action.

iii. Congress's failure to create a private right of action under the Ryan Haight Act counsels against recognizing a *Bivens* action.

Attorney Marks and Investigator Brill argue we should not imply a *Bivens* action because Congress refused to create a private cause of action under the Ryan Haight Act and immunized the United States and its employees. Congress passed the Ryan Haight Act, an amendment to the Controlled Substances Act, in 2008 to allow states to sue online pharmacy companies for damages and to enjoin the sale of controlled substances on the internet.[158] Congress granted district courts jurisdiction to entertain states' cases against

online pharmacies for damages and injunctive relief.[159] But Congress explained "no private right of action is created under" the Ryan Haight Act.[160] Congress further provided a person may not bring civil action under the Ryan Haight Act against the United States or one of its employees.[161]

Dr. Karkalas declined to oppose this argument. Congress considered whether to create a private right of action under the Controlled Substances Act and chose not to. It also chose to immunize the United States under the Act. While this provision does not address Dr. Karkalas's claims, it shows Congress contemplated remedies for federal officials' violations under the Act. The decision to grant a remedy is better left to Congress.

Under the Supreme Court's guidance in *Ziglar,* Dr. Karkalas cannot pursue a *Bivens* action against Attorney Marks and Investigator Brill for unlawful prosecution and pretrial detention. Dr. Karkalas's claim presents a "new context" for a *Bivens* action. Congress created a remedial structure for criminal defendants like Dr. Karkalas. One of Dr. Karkalas's co-defendants used the remedial structure in moving for attorneys' fees under the Hyde Amendment, but Dr. Karkalas did not. Even though Dr. Karkalas seeks damages rather than attorneys' fees, recognizing a *Bivens* cause of action would upset the existing remedial structure Congress created. Special factors also counsel against a *Bivens* action, including the secrecy of grand jury proceedings, Investigator Brill's status as a diversion investigator for the Drug

Enforcement Agency, and Congress's decision not to create a private cause of action under the Act.

We do not imply a *Bivens* cause of action for Dr. Karkalas's claims against Attorney Marks and Investigator Brill.

4. Prosecutorial immunity bars Dr. Karkalas's claims against Attorney Marks and qualified immunity bars his claims against Attorney Marks and Investigator Brill.

Attorney Marks and Investigator Brill argue even if we imply a *Bivens* cause of action for Dr. Karkalas's case, the doctrines of prosecutorial immunity and qualified immunity bar his claims against them.

a. Prosecutorial immunity bars Dr. Karkalas's *Bivens* claim against Attorney Marks.

Attorney Marks argues prosecutorial immunity bars Dr. Karkalas's claims against her. Absolute immunity bars claims against prosecutors under federal law for acts "'intimately associated with the judicial phase of the criminal process,' such as 'initiating a prosecution and . . . presenting the State's case.'"[162] Prosecutorial immunity applies even when a plaintiff alleges the prosecutor's "knowing use of false testimony before the grand jury and at trial."[163] Prosecutorial immunity also applies to "witness interviews generating evidence for judicial proceedings."[164]

Dr. Karkalas alleges Attorney Marks "interviewed witnesses in this District, met and interviewed Dr.

Karkalas and personally obtained evidence that she would use in the prosecution of Dr. Karkalas."[165] He also alleges Attorney Marks made "false and misleading representations" to the grand jury in seeking an indictment against Dr. Karkalas.[166] He claims Attorney Marks tried to get Dr. Karkalas's nurse and office manager to testify against him.[167] Attorney Marks' alleged conduct involves generating evidence for judicial proceedings and presenting the United States' case.

Dr. Karkalas argues prosecutorial immunity does not apply to Attorney Marks's "administrative duties and those investigatory functions that do not relate to an advocate's preparation for the initiation of a prosecution or for judicial proceedings."[168] But Mr. Karkalas complains of Attorney Marks' generating and presenting evidence in support of prosecution, not unrelated administrative or investigatory duties. Because he complains of Attorney Marks's conduct directed to Dr. Karkalas's prosecution, prosecutorial immunity bars his claims against Attorney Marks.

b. Qualified immunity bars Dr. Karkalas's *Bivens* claim against Attorney Marks and Investigator Brill.

Attorney Marks and Investigator Brill argue even assuming absolute immunity does not apply, qualified immunity bars Dr. Karkalas's claims because Attorney Marks and Investigator Brill reasonably believed they could prosecute him for distributing Fioricet.

We apply a two-step qualified immunity analysis: we ask "(1) whether the plaintiff sufficiently alleged the violation of a constitutional right, and (2) whether the right was 'clearly established' at the time of the official's conduct."[169] Our Supreme Court explained qualified immunity protects "all but the plainly incompetent or those who knowingly violate the law."[170]

To determine whether a right is "clearly established," we ask whether "it would be clear to a reasonable officer that his conduct was unlawful in the situation he confronted."[171] This inquiry requires we look at "the specific context of the case," rather than defining the constitutional right "as a broad general proposition."[172] "'If the officer's mistake as to what the law requires is reasonable,' the officer is entitled to qualified immunity."[173]

i. Attorney Marks and Investigator Brill reasonably believed they could prosecute Dr. Karkalas for selling Fioricet on the internet.

Attorney Marks and Investigator Brill argue they did not violate "clearly established" law because they reasonably believed the Drug Enforcement Agency criminalized the sale of Fioricet based on the law at the time of the indictment. Dr. Karkalas does not deny he distributed Fioricet and Fioricet contains butalbital, a controlled substance. He instead argues Attorney Marks and Investigator Brill unlawfully prosecuted him because Fioricet is not a controlled substance and thus he did not violate the Controlled Substances Act. Attorney Marks and Investigator Brill argue because

several district courts—including the District Court for the District of Minnesota in Dr. Karkalas's criminal case—held the Drug Enforcement Agency did not exempt Fioricet from the criminal provisions of the Controlled Substances Act, they reasonably believed they could prosecute Dr. Karkalas for selling Fioricet.

Attorney Marks and Investigator Brill cite three district court cases—including Dr. Karkalas's own criminal case—denying criminal defendants' motions to dismiss an indictment for the sale of Fioricet.[174] The district court in *United States v. Williams* ruled three years before Dr. Karkalas's 2013 indictment, while the court in *United States v. Riccio* ruled two years before Dr. Karkalas moved to dismiss his indictment. Dr. Karkalas cites a single case in which the district court dismissed an indictment for sale of Fioricet after denial of the motion in Dr. Karkalas's case.[175] Neither party cites authority from the Supreme Court or the court of appeals concerning whether the United States can prosecute for sale of Fioricet under the Controlled Substances Act.

In *Williams,* the District Court for the Western District of Oklahoma upheld an indictment for sale of Fioricet without a valid prescription in 2010, three years before Dr. Karkalas's indictment.[176] The United States charged Mr. Williams with violating the Controlled Substances Act for conspiring to sell Fioricet on the internet without valid prescriptions.[177] Mr. Williams moved to dismiss the indictment arguing Fioricet is not a controlled substance under the Act.

The district court denied Mr. Williams's motion to dismiss. The court explained Fioricet contains

butalbital, a derivative of barbituric acid.[178] Under the Controlled Substances Act, Congress classifies as a Schedule III drug "[a]ny substance which contains any quantity of a derivative of barbituric acid[.]"[179] Under Section 811, the Drug Enforcement Agency may "exempt any compound, mixture, or preparation containing a controlled substance from the application" of the Act.[180] In its Exempting Regulation, the Agency exempted Fioricet from the application of several provisions of the Act "for administrative purposes only."[181] The court explained the Agency did not exempt Fioricet from the criminal provisions of the Act, including the provision under which the United States charged Mr. Williams.[182] The court denied the motion to dismiss the indictment holding the United States could prosecute Mr. Williams for sale of Fioricet without a valid prescription.[183]

In *Riccio,* a grand jury indicted ten defendants for conspiring to sell Fioricet online using an internet pharmacy company.[184] The grand jury returned an indictment against Mr. Lasher under 21 U.S.C. § 841(h), prohibiting a person from "deliver[ing], distribut[ing], or dispens[ing] a controlled substance by means of the Internet."[185] The United States argued Fioricet is a controlled substance because it contains butalbital, a Schedule III controlled substance under the Controlled Substances Act.[186] Mr. Lasher moved to dismiss the indictment arguing the Drug Enforcement Agency exempted Fioricet from the Controlled Substances Act.

The District Court for the Southern District of New York in August 2014 denied Mr. Lasher's motion to

dismiss holding, in agreement with the district court in *Williams,* the Drug Enforcement Agency did not exempt Fioricet from the criminal provisions of the Controlled Substances Act. The court found the decision in *Williams* constituted "the only judicial precedent on point."[187] The court explained Congress defined Schedule III controlled substances under the Act to include "[a]ny substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid."[188] Since Fioricet contains butalbital, a barbituric acid derivative, the district court found "there is no dispute" Fioricet is a Schedule III drug.[189]

The district court further explained Congress under the Act allows the Drug Enforcement Agency to "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of the subchapter of the Controlled Substance Act dealing with Control and Enforcement.[190] The Drug Enforcement Agency exempted Fioricet from certain sections of the Act "for administrative purposes only."[191] But the district court held based on the "plain language" of the Exempting Regulation the Drug Enforcement Agency did not exempt Fioricet from the criminal provisions of the Act.[192] The court explained the statutory and regulatory framework of the Controlled Substance Act shows Congress intended to separate administrative and criminal enforcement of the Act.[193] The Drug Enforcement Agency exempted Fioricet from the Act's administrative regulations concerning "registration, labeling, packaging, record-keeping and security requirements."[194] Because the Drug Enforcement

Agency did not expressly exempt Fioricet from the criminal provision under which the United States charged Mr. Lasher, the court held the Drug Enforcement Agency did not intend to exempt Fioricet from criminal enforcement. The court cited the decision in *Williams* to support its holding.[195] The district court also rejected the defendant's argument for vagueness in the statutory scheme.[196]

In his criminal case, Dr. Karkalas moved to dismiss the indictment against him arguing Fioricet is not a "controlled substance" under the Controlled Substances Act because (1) the Drug Enforcement Agency did not list Fioricet on any schedules and (2) the Drug Enforcement Agency listed Fioricet on the "Exempt Prescription Products List."[197] The District Court for the District of Minnesota held "the plain language of the Exempting Regulation" shows "Fioricet is not exempt from the criminal provisions of the [Controlled Substances Act]."[198] The court explained the Drug Enforcement Agency exempted Fioricet from portions of the Controlled Substances Act "for administrative purposes only."[199] The district court further explained the district courts in *Williams* and *Riccio* also denied motions to dismiss indictments holding the Drug Enforcement Agency only exempted Fioricet from administrative regulations concerning labeling and packaging, but not the criminal provisions of the Controlled Substances Act.[200]

Dr. Karkalas cites a single case in which a district court granted a motion to dismiss holding the Drug Enforcement Agency exempted Fioricet from the criminal provisions of the Controlled Substances Act.[201]

The United States charged the defendant in *United States v. Akinyoyenu* with selling Fioricet without a valid prescription.[202] The district court cited *Riccio, Williams,* and Mr. Karkalas's criminal case and agreed with these courts the Drug Enforcement Agency considers Fioricet a controlled substance.[203] But the court explained the Drug Enforcement Agency exempted Fioricet from the Section 829 of the Act requiring a prescription for sale of a Schedule III controlled substance.[204] Thus, the court explained because the Agency exempted Fioricet from the regulation requiring a prescription to sell a drug, it did not intend to criminalize the sale of Fioricet without a valid prescription.[205] The court believed the Agency accidentally left the phrase "for administrative purposes only" in the Exempting Regulation.[206] The court admitted the scope of regulations concerning Fioricet was "more convoluted than for the usual case[.]"[207]

The district court in *Akinyoyenu* distinguished Dr. Karkalas's criminal case. The court explained unlike the defendant in *Akinyoyenu,* the United States also charged Dr. Karkalas with violating Section 831 of the Act mandating a person selling drugs through an online pharmacy must disclose certain information on the pharmacy's website.[208] The court explained the Drug Enforcement Agency did not exempt Fioricet from Section 831.[209]

Qualified immunity bars Dr. Karkalas' s claims for unlawful prosecution and detention against Attorney Marks and Investigator Brill. District courts at the time of Dr. Karkalas's indictment rejected the

argument the Drug Enforcement Agency exempted Fioricet from criminal provisions of the Controlled Substances Act. Even considering the decision in *Akinyoyenu,* a federal official could not be certain pursuing a conviction for selling Fioricet violated a citizen's Fourth Amendment rights. Qualified immunity bars Dr. Karkalas's claims unless "it would be clear to a reasonable officer" Attorney Marks's and Investigator Brill's conduct "was unlawful in the situation [they] confronted."[210] Other district courts held the Drug Enforcement Agency did not exempt Fioricet from criminal provisions of the Act, including the District Court for the District of Minnesota in Dr. Karkalas's case. We cannot say it would be clear to an officer prosecuting Dr. Karkalas's case "was unlawful." Although Dr. Karkalas argues the Food and Drug Administration did not specifically designate Fioricet a controlled substance, he admits Congress designated butalbital, an ingredient in Fioricet, a controlled substance. On August 30, 2018, the District Court for the Southern District of New York denied a habeas petition for a conviction for selling Fioricet rejecting the argument Fioricet is not a controlled substance.[211]

Dr. Karkalas also argues Fioricet is not a controlled substance because on May 24, 2011, Michele M. Leonhart, the Administrator of the Drug Enforcement Agency testified before the United States Senate "Fioricet was exempt from the purview of the CSA."[212] But on August 30, 2011, Deputy Administrator Joseph T. Rannazzisi clarified Ms. Leonhart did "not intend[] to deviate in any way from 21 C.F.R. 1308.32 [i.e., the Exempting Regulation.]"[213] Rather, Mr. Rannazzisi affirmed "the exemption from certain provisions of the

Controlled Substances Act and [Drug Enforcement Agency] regulations is for administrative purposes only. Any person who unlawfully distributes Fioricet remains subject to criminal liability under the Act."[214]

We do not opine whether Fioricet is a controlled substance. But based on the uncertainty of the law at the time of Mr. Karkalas's trial, we cannot say Attorney Marks and Investigator Brill acted unreasonably in prosecuting Dr. Karkalas for selling Fioricet on the Internet.

ii. Attorney Marks and Investigator Brill reasonably relied on the indictment in establishing probable cause for prosecuting Dr. Karkalas.

Attorney Marks and Investigator Brill also argue they did not violate any clearly established right because they relied on the grand jury's indictment in prosecuting Dr. Karkalas. Dr. Karkalas admits a grand jury indicted him.[215]

To establish a malicious prosecution claim, Dr. Karkalas "must plead sufficient facts to support a reasonable inference that the defendants acted without probable cause and are not entitled to qualified immunity."[216] A person's right "to be free from prosecutions on criminal charges that lack probable cause" is clearly established.[217] But in malicious prosecution actions, "a grand jury indictment or presentment constitutes prima facie evidence of probable cause to prosecute[.]"[218]

In *Cobb v. Truong,* a grand jury indicted Mr. Cobb with various crimes stemming from the plaintiff's alleged involvement with a drug-trafficking conspiracy.[219] The prosecutor took the charges to trial, but a jury acquitted Mr. Cobb on all counts.[220] Mr. Cobb sued the prosecutor for malicious prosecution. Like Dr. Karkalas, Mr. Cobb alleged the prosecutor made false statements to the grand jury and withheld information regarding his role in the conspiracy to obtain an indictment.[221]

The District Court for the Western District of Pennsylvania explained to plead a malicious prosecution claim, the plaintiff "must plead sufficient facts to support a reasonable inference that the defendants acted without probable cause."[222] Noting a grand jury indictment "constitutes prima facie evidence of probable cause to prosecute," the court explained the plaintiff must allege facts showing "the indictment was procured by fraud, perjury or other corrupt means" to overcome the presumption of probable cause.[223] The court held the plaintiff failed to plead facts to overcome the presumption of probable cause.[224] The court held plaintiff's legal conclusions of a lack of probable cause "[did] not supply the factual matter needed to proceed with rebutting the presumption of regularity from the grand jury's return of the indictment."[225]

Dr. Karkalas admits a grand jury indicted him in 2013.[226] But he merely concludes the lack of probable cause because Attorney Marks and Investigator Brill made "knowingly false presentations" to the grand jury.[227] Beyond conclusions, he fails to allege the "false presentations" Attorney Marks and Investigator Brill

made to the grand jury. As the district court explained in *Cobb,* Dr. Karkalas cannot plead lack of probable cause with such bare conclusions.[228] He bases his claim for lack of probable cause on his allegation Attorney Marks and Investigator Brill knew Fioricet is not a controlled substance. But most courts facing this issue—including the district court in Dr. Karkalas's case—held the Drug Enforcement Agency did not exempt Fioricet from criminal provisions of the Controlled Substances Act. We cannot say "it would be clear to a reasonable officer" the conduct here "was unlawful in the situation [they] confronted."

Dr. Karkalas argues Attorney Marks and Investigator Brill prosecuted without probable cause because they lacked evidence Dr. Karkalas knew Fioricet is a controlled substance but told the grand jury Dr. Karkalas knew Fioricet is a controlled substance. He alleges Attorney Marks and Investigator Brill "never had any evidence that Dr. Karkalas knew he was breaking the law, even though violations of the [Controlled Substances Act] have a *mens rea* requirement."[229]

Dr. Karkalas still fails to rebut the presumption of probable cause because he fails to allege facts showing Attorney Marks and Investigator Brill procured the indictment through "fraud, perjury, or other corrupt means."[230] Dr. Karkalas admits he prescribed Fioricet and Fioricet contains butalbital, a controlled substance. The weight of authority at the time of Dr. Karkalas's indictment showed the sale of Fioricet violated the Controlled Substances Act. The district court in his criminal case denied Dr. Karkalas's motion to dismiss

the indictment charging him with the sale of Fioricet.[231] Concerning *mens rea,* the trial court in rulings following Dr. Karkalas's trial explained the United States argued to establish the *mens rea* requirement in the case, the Controlled Substances Act "only requires that [the United States] prove the defendants knowingly distributed Fioricet, not that the defendants knew Fioricet was a controlled substance."[232] The trial court rejected this argument and explained the United States must prove Dr. Karkalas knew he distributed a controlled substance, not merely he knew he distributed Fioricet.[233] The trial court found the United States misinterpreted Supreme Court precedent concerning what the United States must prove for a defendant's state of mind under the Controlled Substances Act.[234] But the district court found even considering the mistake concerning *mens rea* for the Controlled Substances Act charge, the United States did not prosecute without probable cause.[235]

Given the secrecy of the grand jury proceeding, we question how Dr. Karkalas knows what Attorney Marks and Investigator Brill told the grand jury concerning his *mens rea* for the crime, especially considering the trial court in his criminal case explained Attorney Marks based her argument on a different—although mistaken—understanding of the *mens rea* requirement. Even so, the district court explained notwithstanding the mistake concerning the *mens rea* requirement, Attorney Marks did not prosecute without probable cause.[236] Dr. Karkalas alleges Attorney Marks and Investigator Brill knew Dr. Karkalas did not know Fioricet is a controlled substance because he told them. But Attorney Marks

and Investigator Brill need not "accept a suspect's innocent explanation at face value."[237] A prosecutor would never bring a case if a suspect's assertion of innocence negated probable cause.

Attorney Marks and Investigator Brill relied on the grand jury's indictment and Dr. Karkalas fails to allege facts showing they procured the indictment through improper means. Attorney Marks and Investigator Brill did not violate Dr. Karkalas's clearly established rights as they relied on the grand jury's indictment to prosecute Dr. Karkalas. Qualified immunity bars Dr. Karkalas's claims against Attorney Marks and Investigator Brill.

We dismiss Dr. Karkalas's claims against Attorney Marks and Investigator Brill.

B. We dismiss Dr. Karkalas's Federal Tort Claims Act claims against the United States.

Dr. Karkalas sues the United States under the Federal Tort Claims Act for malicious prosecution. The United States argues it has not waived sovereign immunity because (1) Attorney Marks and Investigators are not "investigative or law enforcement officers" under the Act and (2) the discretionary function exception applies. The United States also argues Dr. Karkalas fails to state a claim for malicious prosecution.

1. Attorney Marks is not an investigative or law enforcement officer under 28 U.S.C. § 2680(h).

The United States argues Dr. Karkalas cannot sue under the Federal Tort Claims Act because Attorney Marks and Investigator Brill are not "investigative or law enforcement officers."

"Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit."[238] Congress partially waived sovereign immunity with the Federal Tort Claims Act, the "exclusive waiver of sovereign immunity for actions sounding in tort against the United States, its agencies and officers acting within their official capacity."[239] Under the Act, we have jurisdiction over damage claims against the United States "for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."[240]

Congress did not waive sovereign immunity for claims "arising out of assault, battery, false imprisonment, false arrest, malicious prosecution, abuse of process, libel, slander, misrepresentation, deceit, or interference with contract rights[.]"[241] But the exception to the waiver does not apply to "investigative or law enforcement officers of the United States Government."[242] Dr. Karkalas may sue an "investigative or law enforcement officer" under the

Act. Congress defined "investigative or law enforcement officer" as a United States officer "empowered by law to execute searches, to seize evidence, or to make arrests for violations of Federal law."[243] Prosecutors are not "investigative or law enforcement officers" under the Federal Tort Claims Act.[244]

The United States argues Attorney Marks and Investigator Brill do not qualify as "investigative or law enforcement officers" under section 2680(h) of the Federal Tort Claims Act. Attorney Marks, as a prosecutor, is not an "investigative or law enforcement officer" under the Act. The United States has not waived sovereign immunity for Attorney Marks's conduct.

Investigator Brill is a diversion investigator with the Drug Enforcement Agency. Under its regulations, the Agency authorizes diversion investigators "to administer oaths and serve subpoenas under 21 U.S.C. §§ 875 and 876; to conduct administrative inspections and execute administrative inspection warrants under 21 U.S.C. §§ 878(2) and 880; to seize property incident to compliance and registration inspections and investigations under 21 U.S.C. § 881; and to seize or place controlled substances under seal pursuant to 21 U.S.C. § 824."[245]

Only one court decided whether a Drug Enforcement Agency diversion investigator is an "investigative or law enforcement officer" under the Federal Tort Claims Act.[246] In *Nguyen Estate of Carlisle,* the District Court for the Northern District of Florida held diversion investigators are "investigative

or law enforcement officers" because they "are empowered to seize property" under the Agency's regulations, and one of the three alternative characteristics of an "investigative or law enforcement officer" in Section 2680(h) is the ability to seize evidence.[247] We agree. The Agency authorizes diversion investigators to seize evidence. Investigator Brill is an "investigative or law enforcement officer" under the Federal Tort Claims Act.

We dismiss Dr. Karkalas's claims against the United States to the extent he bases them on Attorney Marks's conduct since Attorney Marks is not an "investigative or law enforcement officer."

2. The discretionary function exception under 28 U.S.C. § 2680(a) bars Dr. Karkalas's claims against the United States.

Attorney Marks and Investigator Brill also argue the discretionary function exception in the Federal Tort Claims Act bars Dr. Karkalas's claims. Under the discretionary function exception, Congress bars suits against the United States challenging "the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."[248]

The Supreme Court developed a two-part test to determine whether the discretionary function exception applies.[249] We first ask whether "the act giving rise to the alleged injury and thus the suit involves an 'element of judgment or choice.'"[250] If so, we ask

"whether that judgment is of the kind that the discretionary function exception was designed to shield."[251] Investigative activity is "precisely the kind of policy-rooted decisionmaking that section 2680(a) was designed to safeguard."[252]

Investigative decisions and decisions to prosecute fall within the discretionary function exception.[253] In *Barbieri v. United States,* an FBI agent investigated an attorney for assisting his client with bankruptcy fraud.[254] Following the investigation, a grand jury indicted the attorney for bankruptcy fraud but a jury later acquitted the attorney.[255] Like Dr. Karkalas, the attorney sued for malicious prosecution under the Federal Tort Claims Act. The attorney alleged the FBI agent commenced a "sham investigation" because the attorney did not provide his client's file to the United States.[256] He also alleged the prosecutor and the FBI agent presented "patently false and misleading information" to the grand jury.[257]

Judge Goldberg in our District found the discretionary function exception barred the attorney's malicious prosecution claims. Under the first element of the two-part test, Judge Goldberg found the investigation and decision to prosecute are "entirely discretionary."[258] Under the second element, Judge Goldberg explained the discretionary exception function shields decisions "grounded in social, economic, and political policy[.]"[259] He explained the discretionary function exception bars the attorney's claims because the investigation and decision to prosecute are "policy-based in nature"—conduct the

discretionary function exception "was designed to shield."[260]

Dr. Karkalas alleges Investigator Brill "focused her investigations on the methods by which prescription drugs are diverted into illegal markets."[261] He alleges Investigator Brill investigated Rx Limited and its online activity involving Fioricet and determined it prescribed Fioricet without a doctor-patient relationship.[262] Investigator Brill brought the case to the U.S. Attorney's Office in Minneapolis and then to the Consumer Protection Branch of the Department of Justice in Washington, D.C.[263] Attorney Marks in the Consumer Protection Branch decided to prosecute the case. Like the attorney in *Barbieri*, Dr. Karkalas alleges Attorney Marks and Investigator Brill launched an "unlawful investigation and prosecution of" him and "knowing[ly] present[ed] . . . false and misleading testimony and evidence to the Grand Jury[.]"[264]

The discretionary function exception shields Investigator Brill's and Attorney Marks's conduct.[265] The investigation and decision to prosecute Dr. Karkalas are discretionary. Investigator Brill's and Attorney Marks's determinations are policy-based, and thus the discretionary function exception shields this conduct from tort liability, even for claims alleging false statements to a grand jury.[266]

Dr. Karkalas argues our Court of Appeals held if a plaintiff alleges a federal official violated his constitutional rights—like Dr. Karkalas does here—a court could not apply the discretionary function exception "since federal officials do not possess discretion to commit such violations."[267] Judge

Goldberg faced the same argument. He persuasively explained the Supreme Court declined to recognize constitutional torts under the Federal Tort Claims Act after our Court of Appeals' holding in *Pooler v. United States*.[268] We agree with Judge Goldberg as the import of the Supreme Court's precedent. Dr. Karkalas's argument fails.

The United States did not waive sovereign immunity for Dr. Karkalas's claims.

3. Dr. Karkalas fails to state a claim for malicious prosecution.

The United States argues even if sovereign immunity does not bar his claim, Dr. Karkalas fails to state a claim for malicious prosecution.

Congress does not provide a cause of action under the Federal Tort Claims Act but rather provides a partial waiver of sovereign immunity for torts against the United States. Thus, Dr. Karkalas's malicious prosecution claim against the United States arises under state law.[269] An essential element of malicious prosecution, under either Minnesota or Pennsylvania law, is a prosecution without probable cause.[270]

Dr. Karkalas bases his claim for malicious prosecution on his assertion Fioricet is not a controlled substance under the Controlled Substances Act. But as we explained in detail, Attorney Marks and Investigator Brill relied on two district court cases, and the district court in Dr. Karkalas's criminal case, holding Fioricet is a controlled substance and the Drug Enforcement Agency did not exempt Fioricet from the criminal provisions of the Controlled Substances Act.

Dr. Karkalas also admits a grand jury indicted him. An indictment provides a rebuttable presumption probable cause existed.[271]

Dr. Karkalas fails to allege facts showing Attorney Marks and Investigator Brill prosecuted him without probable cause. He fails to state a claim for malicious prosecution.

III. Conclusion.

In an accompanying Order, we grant Attorney Marks's and Investigator Brill's motion to dismiss Dr. Karkalas's *Bivens* claim for unlawful prosecution and pretrial detention. We also grant the United States' motion to dismiss Dr. Karkalas's claims for malicious prosecution under the Federal Tort Claims Act.

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[1] ECF Doc. No. 8 ¶ 28

[2] *Id.* at ¶ 31.

[3] *Id.* at ¶ 35.

[4] *Id.* at ¶ 36.

[5] *Id.* at ¶ 45.

[6] *Id.* at ¶ 36.

[7] *Id.* at ¶ 56.

[8] *Id* at ¶ 38.

[9] *Id.* at ¶ 39.

[10] *Id.*

[11] *Id.* at ¶ 40.

[12] *Id.*

[13] *Id.*

[14] *Id.* at ¶ 41.

[15] *Id* at ¶¶ 8, 44.

[16] *United States v. Oz,* No. 13-273, 2016 WL 1183041, at *2 (D. Minn. Mar. 28, 2016).

[17] ECF Doc. No.8 ¶ 45.

[18] *Id.* at ¶ 46.

[19] *Id.* at ¶¶ 46-47.

[20] *Id.* at ¶¶ 48-49.

[21] *Id.* at ¶ 50.

[22] *Id.* at ¶ 66.

[23] *Id.* at ¶ 64.

[24] *Id.* at ¶ 65.

[25] *Id.* at ¶¶ 11, 67.

[26] *Id.* at ¶ 68.

[27] *Id.* at ¶ 69.

[28] *United States v. Oz,* No. 13-273, 2017 WL 3531521, at *1 (D. Minn. Aug. 17, 2017).

[29] *Id.*

[30] ECF Doc. No. 8 ¶ 80.

[31] *Id.* at ¶ 68.

[32] *Id.* at ¶ 11.

[33] *Id.* at ¶ 12.

[34] When considering a motion to dismiss "[w]e accept as true all allegations in the plaintiff's complaint as well as all reasonable inferences that can be drawn from them, and we construe them in a light most favorable to the non-movant." *Tatis v. Allied Interstate, LLC,* 882 F.3d 422, 426 (3d Cir. 2018) (quoting *Sheridan*

v. NGK Metals Corp., 609 F.3d 239, 262 n.27 (3d Cir. 2010)). To survive dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly,* 550 U.S. at 556). Our Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Connelly v. Lane Constr. Corp.,* 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal,* 556 U.S. at 675, 679).

[35] ECF Doc. No. 12.

[36] ECF Doc. No. 14.

[37] Fed. R. Civ. P. 4(k) ("Serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant who is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located[.]").

[38] 42 Pa. C.S. § 5322(b).

[39] *O'Connor v. Sandy Lane Hotel Co.,* 496 F.3d 312, 316 (3d Cir. 2007).

[40] *Walden v. Fiore,* 571 U.S. 277, 284 (2014) (quoting *Keeton v. Hustler Magazine, Inc.,* 465 U.S. 770, 775 (1984)).

[41] *Id.* (emphasis supplied).

[42] *Id.* at 285.

[43] *Id.* at 286.

[44] *Id.*

[45] *Id.* (quoting *Burger King Corp. v. Rudzewicz,* 471 U.S. 462, 475 (1985)).

[46] *Id.* at 284.

[47] *Id.* at 282.

[48] *Id.* at 291.

[49] *Id.* at 288-89.

[50] *Id.* at 291.

[51] ECF Doc. No. 8 ¶ 17.

[52] *Id.* at ¶ 22.

[53] ECF Doc. No. 12-1, at p. 24.

[54] ECF Doc. No. 8 ¶ 17.

[55] *Walden,* 571 U.S. at 286.

[56] 28 U.S.C. § 1391(b).

[57] ECF Doc. No. 8 ¶ 17.

[58] *Cottman Transmission Sys., Inc. v. Martino,* 36 F.3d 291,294 (3d Cir. 1994).

[59] *Id.* at 295.

[60] *RAIT P'ship, L.P. v. Fieldstone Lester Shear & Denberg, LLP,* No. 09-28, 2009 WL 3297310, at *5 (D. Del. Oct. 14, 2009) (citing *Traynor v. Liu,* 495 F. Supp. 2d 444, 450 (D. Del. 2007)).

[61] *Fisher v. King,* No. 15-2081, 2015 WL 7016527, at *2 (M.D. Pa. Nov. 12, 2015) (citing *Cottman,* 36 F.3d at 294).

[62] ECF Doc. No. 12-1, at p. 25.

[63] ECF Doc. No. 8 ¶¶ 46-47.

[64] *Id.* at ¶ 17.

[65] 403 U.S. 388 (1971).

[66] *Turner v. Doe,* No. 15-5942, 2018 WL 2278096, at *3 (D.N.J. May 18, 2018).

[67] *Bivens,* 403 U.S. at 389.

[68] *Id.*

[69] *Id.* at 389-90.

[70] *Id.* at 390.

[71] *Id.* at 397.

[72] *Id.* at 392 (quoting *Bell v. Hood,* 327 U.S. 678, 684 (1946)).

[73] *Bistrian v. Levi,* 912 F.3d 79, 89 (3d Cir. 2018) (quoting *Vanderklok v. United States,* 868 F.3d 189, 200 (3d Cir. 2017)).

[74] 137 S. Ct. 1843, 1853 (2017).

[75] *Ziglar,* 137 S. Ct. at 1853-54.

[76] *Id.* at 1857 (quoting *Ashcroft v. Iqbal,* 556 U.S. 662, 675 (2009)).

[77] *Bivens,* 403 U.S. at 397.

[78] *Davis v. Passman,* 442 U.S. 228, 230 (1979).

[79] *Carlson v. Green,* 446 U.S. 14, 19 (1980).

[80] *Ziglar,* 137 S. Ct. at 1857.

[81] *Id.* at 1860.

[82] *Id.* at 1864.

[83] *Id.*

[84] *Id.* at 1861 (allowing a damages claim in this context would "interfere in an intrusive way with sensitive functions of the Executive Branch").

[85] *Id.*

[86] *Id.* at 1862-63.

[87] *Id.* at 1865.

[88] *Vanderklok,* 868 F.3d at 200 (citing *Ziglar,* 137 S. Ct. at 1856).

[89] *Id.* (citing *Wilkie v. Robbins,* 551 U.S. 537, 550 (2007)).

[90] *Ziglar,* 137 S. Ct. at 1859.

[91] *Id.* at 1860.

[92] *Vanderklok,* 868 F.3d at 200 (quoting *Minneci v. Pollard,* 565 U.S. 118, 126 (2012)).

[93] *Ziglar,* 137 S. Ct. at 1858.

[94] *Vanderklok,* 868 F.3d at 205.

[95] *Ziglar,* 137 S. Ct. at 1860.

[96] *Lane v. Schade,* No. 15-1568, 2018 WL 4571672, at *6 (D.N.J. Sept. 24, 2018).

[97] *Id.* at *2.

[98] *Id.* at *3.

[99] *Id.* at *7.

[100] *Id.* ("[T]he Court will not recognize a *Bivens* remedy for Lane's claims of malicious abuse of process or malicious prosecution.").

[101] *Lee v. Janosko,* No. 18-1297, 2019 WL 2392661, at *4 (W.D. Pa. June 6, 2019).

[102] 18 U.S.C. § 3501.

[103] *Janosko,* 2019 WL 2392661, at *5.

[104] *Id.* (quoting *Vennes v. An Unknown No. of Unidentified Agents of U.S.,* 26 F.3d 1448, 1452 (8th Cir. 1994)).

[105] *Ziglar,* 137 S. Ct. at 1857-58.

[106] ECF Doc. No. 8 ¶ 80 (suing under *Bivens* for "illegal prosecution of Dr. Karkalas, the unlawful seizure of and the presentation of false and misleading evidence and testimony to the Grand Jury regarding Dr. Karkalas' involvement with RXL.").

[107] *Bivens,* 403 U.S. at 389.

[108] *Farah v. Weyker,* 926 F.3d 492, 499 (8th Cir. 2019) (finding a "new context" for a *Bivens* action when plaintiff complained arresting officer presented false information to prosecutors and grand jury explaining "information-gathering and case-building

activities are a different part of police work than the apprehension, detention, and physical searches at issue in *Bivens").*

[109] ECF Doc. No. 15, at p. 7.

[110] *Ziglar,* 137 S. Ct. at 1859 (explaining even when the right at issue and the "mechanism of injury" resemble one of the three *Bivens* cases, the case can still present a "new context").

[111] *Id.* at 1860 (explaining the Court recognized an implied action in *Bivens* under the Fourth Amendment and an action in *Davis* under the Fifth Amendment).

[112] *Id.* at 1859.

[113] ECF Doc. No. 15, at p. 8 (citing *Manuel v. City of Joliet, Ill.,* 137 S. Ct. 911 (2017)).

[114] *Manuel,* 137 S. Ct. at 915.

[115] *Id.* at 919-20.

[116] *Ziglar,* 137 S. Ct. at 1859.

[117] *Manuel,* 137 S. Ct. at 919-20.

[118] *Ziglar,* 137 S. Ct. at 1858.

[119] *Wilkie,* 551 U.S. at 550.

[120] *Brunoehler v. Tarwater,* 743 F. App'x 740, 752 (9th Cir. 2018) (provision providing for civil damages for official's violation of the Wiretap Act counseled against extending *Bivens* to Fourth Amendment claim for illegal wiretap).

[121] *United States v. Oz,* No. 13-273, 2016 WL 1183041, at *7 (D. Minn. Mar. 28, 2016).

[122] 18 U.S.C. § 3006A; *United States v. Manzo,* 712 F.3d 805, 810 (3d Cir. 2013) (explaining a successful criminal defendant can move for attorneys' fees and costs under the Hyde Amendment for a "prosecution brought vexatiously, in bad faith, or so utterly without foundation in law or fact as to be frivolous").

[123] 28 U.S.C. § 2513(a).

[124] *Id.* § 2513(e).

[125] *Farah v. Weyker,* 926 F.3d 492 (8th Cir. 2019).

[126] *Id.* at 496.

[127] *Id.* at 496-97.

[128] *Id.* at 501-02.

[129] *Id.* at 500.

[130] 28 U.S.C. § 2513.

[131] *Farah,* 926 F.3d at 501.

[132] *Id.* at 502.

[133] *Id.* (quoting *Ziglar,* 137 S. Ct. at 1858).

[134] *Id.* (quoting *Ziglar,* 137 S. Ct. at 1863).

[135] ECF Doc. No. 15, at p. 10.

[136] *Oz,* 2017 WL 3531521, at *l.

[137] ECF Doc. No. 8 ¶ 70.

[138] *Ziglar,* 137 S. Ct. at 1857 (quoting *Carlson,* 446 U.S. at 18).

[139] *Vanderklok,* 868 F.3d at 206 (quoting *Wilkie,* 551 U.S. at 554).

[140] *Id.* (quoting *Ziglar,* 137 S. Ct. at 1858).

[141] *Ziglar,* 137 S. Ct. at 1858.

[142] *Farah,* 926 F.3d at 499.

[143] *Id.* at 500.

[144] *Id.*

[145] *Id.* at 501.

[146] *Id.*

[147] ECF Doc. No. 8 ¶ 80 (suing Attorney Marks and Investigator Brill for the "illegal prosecution of Dr. Karkalas, the unlawful seizure of and the presentation of false and misleading evidence and testimony to the Grand Jury regarding Dr. Karkalas' involvement with RXL").

[148] *Vanderklok,* 868 F.3d at **189.**

[149] *Id.* at 194.

[150] *Id.* at 195.

[151] *Id.* at 208.

[152] *Id.* at 203 (citing 28 U.S.C. § 2680(h)).

[153] *Id.* at 208.

[154] *Id.* at 209.

[155] 49 U.S.C. § 44903(a)(2) (defining "law enforcement personnel" under the Aviation and Transportation Security Act).

[156] 28 C.F.R. § Pt. 0, Subpt. R, App.§ 3(b) (regulation governing delegation of functions to officers and employees of the Drug Enforcement Agency).

[157] *Id.* at §§ 3(a)-(b).

[158] *See* 21 U.S.C. § 882.

[159] *Id.* § 882(a).

[160] *Id.* § 882(c)(5).

[161] *Id.* § 882(c)(6)(C).

[162] *McLaughlin v. Henry,* No. 19-9451, 2019 WL 2588758, at *4 (D.N.J. June 24, 2019) (quoting *Yarris v. Cty. of Delaware,* 465 F.3d 129, 135 (3d Cir. 2006)).

[163] *Burns v. Reed,* 500 U.S. 478, 485 (1991).

[164] *Newsome v. City of Newark,* No. 13-06234, 2014 WL 4798783, at *3 (D.N.J. Sept. 25, 2014) (citing *Rose v. Bartle,* 871 F.2d 331, 344 (3d Cir. 1989) (explaining solicitation of false testimony for presentation to the grand jury encompassed within "the preparation necessary to present a case" and therefore immunized)).

[165] ECF Doc. No. 8 ¶ 22.

[166] *Id.* at ¶ 45.

[167] *Id.* at ¶ 65.

[168] ECF Doc. No. 15, at p. 16 (quoting *Yarris,* 465 F.3d at 135).

[169] *L.R. v. Sch. Dist. of Philadelphia,* 836 F.3d 235, 241 (3d Cir. 2016) (quoting *Pearson v. Callahan,* 555 U.S. 223, 232 (2009)); *see also D.C. v. Wesby,* 138 S. Ct. 577, 589 (2018).

[170] *Ziglar,* 137 S. Ct. at 1867 (quoting *Malley v. Briggs,* 475 U.S. 335, 341 (1986)).

[171] *Couden v. Duffy,* 446 F.3d 483, 492 (3d Cir. 2006) (quoting *Saucier v. Katz,* 533 U.S. 194, 202 (2001)).

[172] *Mullenix v. Luna,* 136 S. Ct. 305, 308 (2015).

[173] *Couden,* 446 F.3d at 492 (quoting *Saucier,* 533 U.S. at 205).

[174] *United States v. Oz,* No. 13-273, 2016 WL 1183041 (D. Minn. Mar. 28, 2016); *United States v. Riccio,* 43 F. Supp. 3d 301 (S.D.N.Y. 2014); *United States v. Williams,* No. 10-0216, 2010 WL 4669180 (W.D. Okla. Nov. 9, 2010).

[175] *United States v. Akinyoyenu,* 199 F. Supp. 3d 106 (D.D.C. 2016).

[176] *Williams,* 2010 WL 4669180, at *1.

[177] *Id.*

[178] *Id.* at *1 n.2.

[179] 21 U.S.C. § 812(c) (list of Schedule III drugs).

[180] *Id.* § 811(g)(3).

[181] 21 C.F.R. § 1308.32.

[182] *Williams,* 2010 WL 4669180, at *1.

[183] *Id.* at *1.

[184] *Riccio,* 43 F. Supp. 3d at 304.

[185] 21 U.S.C. § 841(h).

[186] *Riccio,* 43 F. Supp. 3d at 304 (citing 21 U.S.C. § 841(b)(1)(E)).

[187] *Id.* at 305.

[188] *Id.* at 304 (citing 21 U.S.C. § 812, Schedule III, Part (b)(1)).

[189] *Id.*

[190] *Id.* (quoting 21 U.S.C. § 811(g)).

[191] 21 C.F.R. § 1308.32.

[192] *Riccio,* 43 F. Supp. 3d at 305.

[193] 21 C.F.R. § 1301.41 ("Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.").

[194] *Riccio,* 43 F. Supp. 3d at 305.

[195] *Id.* (citing *Williams,* 2010 WL 4669180, at *1 ("The Attorney General/DEA could have exempted Fioricet 'from the application of all' of subchapter I of the [Controlled Substances Act] but did not.")).

[196] *Id.* at 307.

[197] *United States v. Oz,* No. 13-273, 2016 WL 11396496, at *4 (D. Minn. Feb. 1, 2016), *report and recommendation adopted,* No. 13-273, 2016 WL 1183041 (D. Minn. Mar. 28, 2016).

[198] *Oz,* 2016 WL 1183041, at *6.

[199] *Id.* at *4 (quoting 21 C.F.R. § 1308.32).

[200] *Id.* at* 5.

[201] *Akinyoyenu,* 199 F. Supp. 3d at 106.

[202] *Id.* at 108.

[203] *Id.* at 112.

[204] *Id.*

[205] *Id.* at 120.

[206] *Id.* at 117.

[207] *Id.* at 114.

[208] 21 U.S.C. § 831(c) (Internet pharmacy site disclosure information).

[209] *Akinyoyenu,* 199 F. Supp. 3d at 120 (quoting *Oz,* 2016 WL 1183041, at *7).

[210] *Couden,* 446 F.3d at 492 (quoting *Saucier,* 533 U.S. at 202).

[211] *See Lasher v. United States,* No. 12-868, 2018 WL 3979596, at *4 (S.D.N.Y. Aug. 20, 2018). 212 ECF Doc. No. 8 ¶ 58. We may consider public documents like Congressional testimony and Drug Enforcement Agency memoranda as these are matters of public record. *See Buck v. Hampton Twp. Sch. Dist.,* 452 F.3d 256, 260 (3d Cir. 2006) (explaining in deciding a motion to dismiss we may consider "documents that are attached to or submitted with the complaint" and "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case"). Dr. Karkalas relies on Administrator Leonhart's statement in his complaint. Attorney Marks filed Deputy Administrator Rannazzisi's response to Administrator Leonhart on the record in Dr. Karkalas's criminal proceeding.

[213] ECF Doc. No. 12-2, at p. 54.

[214] *Id.*

[215] ECF Doc. No. 8 ¶ 44.

[216] *Spiker v. Whittaker,* 553 F. App'x 275, 278 (3d Cir. 2014).

[217] *Andrews v. Scuilli,* 853 F.3d 690, 705 (3d Cir. 2017).

[218] *Palma v. Atl. Cty.,* 53 F. Supp. 2d 743, 756 (D.N.J. 1999) (quoting *Rose v. Bartle,* 871 F.2d 331, 353 (3d Cir. 1989)); *Goodwin v. Conway,* 836 F.3d 321, 329 (3d Cir. 2016) (reaffirming holding in *Rose* indictment creates "a rebuttable presumption of probable cause").

[219] *Cobb v. Truong,* No. 13-1750, 2015 WL 1405438, at *3 (W.D. Pa. Mar. 26, 2015).

[220] *Id.* at *4.

[221] *Id.* at *8.

[222] *Id.*

[223] *Id.* at *11.

[224] *Id.* at *9 (quoting *Woodyard v. Cty. of Essex,* 514 F. App'x 177, 183 (3d Cir. 2013)).

[225] *Id.* at *10 (*citingAshcroftv. Iqbal*, 556 U.S. 662, 678 (2009)).

[226] ECF Doc. No. 8 ¶ 44.

[227] *Id.* at ¶ 86.

[228] *Cobb,* 2015 WL 1405438, at *10 ("[T]endering only broad and generalized labels and conclusions or naked assertions that are devoid of further factual development will not supply the factual matter needed to proceed with rebutting the presumption of regularity from the grand jury's return of the indictment."); *see also Blassengale v. City of Philadelphia,* No. 11-3006, 2012 WL 4510875, at *6 (E.D. Pa. Sept. 28, 2012) (dismissing malicious prosecution claim explaining plaintiff merely concluded without alleging facts defendant "fabricated evidence or relied heavily on the questionable testimony of a compromised complaining witness to secure a grand jury indictment").

[229] ECF Doc. No. 8 ¶ 71.

[230] *See Outen v. Office of Bergen Cty. Prosecutor,* No. 12-123, 2013 WL 6054586, at *4 (D.N.J. Nov. 14, 2013) ("Mere allegations of wrongful conduct before the grand jury, without specifically identifying evidence that was offered by corrupt means, fails to rebut the presumption of probable cause provided by a grand jury indictment.").

[231] *Oz,* 2016 WL 1183041, at *1.

[232] *Oz,* 2017 WL 3531521, at *4 (co-defendant's post-trial motion for attorneys' fees under the Hyde Amendment).

[233] *Id.*

[234] *Id.* (citing *McFadden v. United States,* 135 S. Ct. 2298 (2015)).

[235] *Id.* at *7.

[236] *Id.* (explaining the government could rely on "circumstantial" evidence—like the "volume of drugs being dispensed"—to establish intent to support probable cause, not necessarily direct evidence).

[237] *Wesby*, 138 S. Ct. at 593.

[238] *Pellegrino v. United States Transportation Sec. Admin., Div. of Dep't of Homeland Sec.,* 896 F.3d 207, 213 (3d Cir.), *reh'g en banc granted sub nom. Pellegrino v. United States of Am. Transportation Sec. Admin.,* 904 F.3d 329 (3d Cir. 2018).

[239] *Wilson v. Rackmill,* No. 87-0456, 1990 WL 63504, at *7 (E.D. Pa. May 11, 1990).

[240] 28 U.S.C. § 1346(b)(1).

[241] *Id.* § 2680(h).

[242] *Id.*

[243] *Id.*

[244] *See Adams v. Boden,* No. 18-4408, 2018 WL 5923448, at *3 (E.D. Pa. Nov. 9, 2018) ("As a prosecutor, Boden does not qualify as an 'investigative or law enforcement officer' within the meaning of § 2680(h)."); *Johnson v. Manzo,* No. 18-2608, 2019 WL 1470991, at *2 (D.D.C. Apr. 2, 2019) (dismissing plaintiff's claim for malicious prosecution alleging prosecutor provided false testimony to grand jury explaining federal prosecutor is not an investigative or law enforcement officer under§ 2680(h)).

[245] 28 C.F.R. § Pt. 0, Subpt. R, App. § 3.

[246] *Nguyen v. Estate of Carlisle,* No. 04-26, 2006 WL 1653371 (N.D. Fla. June 9, 2006), *rev'd sub nom. Nguyen v. United States,* 545 F.3d 1282 (11th Cir. 2008), *opinion superseded on reconsideration,* 556 F.3d 1244 (11th Cir. 2009), *and rev'd sub nom. Nguyen v. United States,* 556 F.3d 1244 (11th Cir. 2009).

[247] *Id.* at *4 (citing 28 U.S.C. § 2680(h)).

[248] 28 U.S.C. § 2680(a).

[249] *United States v. Gaubert,* 499 U.S. 315, 322 (1991).

[250] *Barbieri v. United States,* No. 16-3748, 2017 WL 4310255, at *4 (E.D. Pa. Sept. 28, 2017) (quoting *United States v. Gaubert,* 499 U.S. 315, 322 (1991)).

[251] *Id.* (quoting *Gaubert,* 499 U.S. at 322-23).

[252] *Kelly v. United States,* 924 F.2d 355, 362 (1st Cir. 1991).

[253] *Barbieri,* 2017 WL 4310255, at *6 (citing *Pooler v. United States,* 787 F.2d 868, 870 (3d Cir. 1986)) ("The conduct described in the Amended Complaint relates to the investigation into Mr. Barbieri and the decision to prosecute him, and such decisions are entirely discretionary.").

[254] *Id.* at *2.

[255] *Id.*

[256] *Id.*

[257] *Id.*

[258] *Id.* at *4.

[259] *Id.* at *6.

[260] *Id.*

[261] ECF Doc. No.8 ¶ 38.

[262] *Id.* at ¶ 39.

[263] *Id.* at ¶ 40.

[264] *Id.* at ¶ 23.

[265] *Barbieri,* 2017 WL 4310255, at *6 ("Because an FBI agent's investigatory decisions and a decision to prosecute are determinations that are policy-based in nature, I find that the conduct of AUSA Eve and Agent Cosgriff is the type that the discretionary function exception was designed to shield.").

[266] *Id.*

[267] *Pooler,* 787 F.2d at 871.

[268] *Barbieri,* 2017 WL 4310255, at *6 (citing *F.D.I.C. v. Meyer*, 510 U.S. 471, 477 (1994)).

[269] *Meyer,* 510 U.S. at 478 (explaining for claims under Section 1346(b) of the Act "'law of the place' means law of the State—the source of substantive liability under the FTCA").

[270] *Brawn v. Mercadante,* 687 F. App'x 220, 223 (3d Cir. 2017) (listing elements of malicious prosecution under Pennsylvania

law); *Dunham v. Raer,* 708 N.W.2d 552, 569 (Minn. Ct. App. 2006) (elements for malicious prosecution under Minnesota law). The United States argues Minnesota law applies. Dr. Karkalas does not dispute this, arguing he states a claim under either Minnesota or Pennsylvania law.

[271] *Palma,* 53 F. Supp. 2d at 756 (quoting *Rose,* 871 F.2d at 353); *Goodwin,* 836 F.3d at 329 (reaffirming holding in *Rose* indictment creates "a rebuttable presumption of probable cause").

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CIVIL ACTION
NO. 19-948

[Filed July 31, 2019]

ELIAS KARKALAS, M.D.	)
	)
v.	)
	)
LINDA MARKS, ESQUIRE, *et al.*	)
	)

ORDER

AND NOW, this 31st day of July 2019, upon considering the Defendants' Motions to dismiss (ECF Doc. Nos. 12, 14), Plaintiffs Oppositions (ECF Doc. Nos. 15, 16), the individual Defendants' Reply (ECF Doc. No. 17), and for reasons in the accompanying Memorandum, it is **ORDERED** the Defendants' Motions (ECF Doc. Nos. 12, 14) are **GRANTED**, we **dismiss** the first amended complaint with prejudice, and the Clerk of Court shall **close** this case.

s/_____
KEARNEY, J.

APPENDIX D

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 19-2816
(D.C. Civ. No. 2-19-cv-00948)

[File April 15, 2021]

ELIAS KARKALAS,	)
Appellant,	)
	)
v.	)
	)
LINDA MARKS, Esquire;	)
KIMBERLY BRILL;	)
UNITED STATES OF AMERICA	)
	)

SUR PETITION FOR REHEARING

Present: SMITH, Chief Judge, McKEE, AMBRO, CHAGARES, JORDAN, HARDIMAN, GREENAWAY, JR., SHWARTZ, KRAUSE, RESTREPO, BIBAS, PORTER, MATEY, and PHIPPS, Circuit Judges

The petition for rehearing filed by Appellant in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular

service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

s/ *Peter J. Phipps*
Circuit Judge

Date: April 15, 2021
CLW/cc: David F. McComb, Esq.
Mark B. Stern, Esq.
Daniel Wink Esq.

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

CIVIL ACTION NO.: 2:19-cv-00948

[Filed May 10, 2019]

ELIAS KARKALAS, M.D.
80 Flintlock Lane
Phoenixville, PA 19460

Plaintiff,

vs.

LINDA MARKS, ESQUIRE
c/o U. S. Department of Justice
950 Pennsylvania Ave NW,
Washington, DC 20530;

KIMBERLY BRILL,
c/o U. S. Drug Enforcement
Administration
100 S. Washington Avenue, No.800,
Minneapolis, MN 55401; and

UNITED STATES OF AMERICA)
c/o U. S. Department of Justice)
950 Pennsylvania Ave NW,)
Washington, DC 20530.)
)
Defendants.)
)

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiff, Elias Karkalas, M.D. ("Dr. Karkalas"), by and through his attorneys, brings this First Amended Complaint against defendants, and alleges as follows:

I. PRELIMINARY STATEMENT

1. Dr. Karkalas, an innocent man, was wrongfully charged with thirty-eight (38) felony counts in an eighty-five (85) count indictment returned in the United States District Court for the District of Minnesota for alleged violations of the Controlled Substances Act, 21 U.S.C. §801 *et seq*. ("CSA"), mail and wire fraud, and international money laundering. *See United States of America v. Berkman, et al.* 0:13-cr-00273 (D. Minn.).

2. Over the next four (4) years, Dr. Karkalas was wrongfully imprisoned, lived under a cloud of prosecution, lost friends, family, and his medical practice, and his travel was restricted.

3. The charges, however, were false, malicious, and entirely fabricated. The United States Government ("Government"), with the assistance of defendants

Kimberly Brill ("Brill") and Linda Marks ("Marks"), alleged that Dr. Karkalas was part of a global cartel run by the notorious criminal Paul Calder Le Roux ("Le Roux"), that enabled United States citizens to obtain enormous quantities of potentially addictive prescription drugs from hundreds of linked Internet websites without a valid doctor-patient relationship. The indictment charged eleven (11) people in addition to Dr. Karkalas ("Indictment"). The case was filed in Minnesota for no reason other than that was where Brill worked.

4. Dr. Karkalas' criminal case was the result of an investigation led by defendants Brill and Marks into the online pharmacy known as Rx Limited ("RXL"), which was owned by Le Roux. The Indictment alleged that Dr. Karkalas acted in conspiracy with the other defendants when, in fact, he neither knew them nor ever heard of them.

5. The ringleader of the alleged conspiracy, Le Roux, had admitted to various crimes, including multiple murders, but was not indicted with Dr. Karkalas.

6. Dr. Karkalas was charged with, among other things, prescribing controlled substances without a valid prescription. At no time, however, did Dr. Karkalas issue prescriptions for controlled substances.

7. The criminal trial against Dr. Karkalas and others lasted several weeks and resulted in no trial convictions.

8. Before the Indictment was sought and returned, defendants Marks and Brill either knew or

recklessly disregarded the fact that Dr. Karkalas did not violate the CSA, mail and wire fraud, and international money laundering statutes.

9. Further, defendants Marks and Brill knew or recklessly disregarded the fact that Dr. Karkalas' work with RXL was legitimate and not part of any unlawful scheme.

10. The basis of the prosecution of Dr. Karkalas was false and collapsed by its own wrongful weight, when the jury returned a verdict of not guilty on all counts against him.

11. This action is brought under the United States Constitution pursuant to *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971), for the defendants' malicious prosecution and knowing presentation of false and misleading testimony, and evidence to the Grand Jury, in violation of the Fourth and Fifth Amendments.

12. This action is also brought under the Federal Tort Claims Act, for the tort of malicious prosecution committed by investigative or law enforcement officers of the United States, acting within the scope of their employment, against Dr. Karkalas.

13. Dr. Karkalas requests compensatory damages, punitive damages and attorney's fees for these claims and violations of his rights are secured by the Constitution of the United States.

II. JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this Complaint under the Fourth and Fifth Amendments to the United States Constitution and 28 U.S.C. § 1331 & 28 U.S.C. § 1346(b).

15. Dr. Karkalas also brings his complaint pursuant to 28 U.S.C. § 1332, as the parties are completely diverse in citizenship and the amount in controversy exceeds $75,000, exclusive of interests and costs. Upon information and belief, defendant Marks is a citizen of Washington, D.C., and with an address of 4114 Davis Place NW Apartment 305, Washington, D.C. 20007, and defendant Brill is a citizen of Minnesota with an address of 10218 Karston Court NE, Albertville, MN 55301.

16. On October 9, 2018, Dr. Karkalas, pursuant to the administrative claim procedures of the Federal Tort Claims Act, 28 U.S.C. §2671 *et seq*. ("FTCA"), submitted a Standard Form (SF 95) Administrative Tort Claim to the U.S. Department of Justice, which the Department acknowledged receiving on October 22, 2018. The FTCA provides, at 28 U.S.C. §2675(a), that the failure of the agency to make a final disposition within six months of its filing shall, at the option of the filer, be deemed a final denial of the administrative claim for the purposes of the Act. Accordingly, Dr. Karkalas deems the failure of the agency to make a final disposition to constitute a final denial of his administrative claim, and, therefore, has exhausted all administrative remedies.

17. Venue is properly laid in the Eastern District of Pennsylvania under 28 U.S.C. § 1391(b)(2), 28 U.S.C. § 1391(e)(1) and 28 U.S.C. § 1402(b) as the acts giving rise to these claims took place in the Eastern District of Pennsylvania. Among other things, defendants Marks and Brill appeared in the Eastern District of Pennsylvania to investigate the claims, meet with witnesses, and secured the pre-trial detention of Dr. Karkalas from U.S. Magistrate Judge Jacob Hart of the Eastern District of Pennsylvania.

III. THE PARTIES

18. Dr. Karkalas is a duly-licensed medical doctor and citizen of the Commonwealth of Pennsylvania with a personal address of 80 Flintlock Lane, Phoenixville, PA 19460.

19. Defendant Brill, was at all times relevant to this Complaint, employed by the Drug Enforcement Agency ("DEA") as a Diversion Investigator. Upon information and belief, Brill was stationed out of the DEA field office located at 100 S. Washington Avenue, #800, Minneapolis, Minnesota 55401. Brill is sued in her individual capacity.

20. Defendant Marks was, at all times relevant to this Complaint, employed as an attorney for the Consumer Protection Branch, a section of the U.S. Department of Justice in Washington, D.C. Marks is sued in her individual capacity.

21. At all times relevant to this Complaint, defendants Marks and Brill were acting within the course and scope of their employment with federal investigative and law enforcement agencies.

22. At all times relevant to this Complaint, defendants Marks and Brill were acting as investigative and law enforcement officers. Although Marks served as a prosecutor in this action, the claims against her arise out of the actions she undertook while acting in an investigative capacity rather than her role as a prosecutor or advocate. Among other things, Marks personally interviewed witnesses in this District, met and interviewed Dr. Karkalas and personally obtained evidence that she would use in the prosecution of Dr. Karkalas.

23. Defendant, United States of America, is the appropriate defendant under the FTCA and its investigative or law enforcement officers participated in the unlawful investigation and prosecution of Dr. Karkalas and the knowing presentation of false and misleading testimony and evidence to the Grand Jury, in violation of the Fourth and Fifth Amendments.

IV. FACTUAL ALLEGATIONS

24. Dr. Karkalas is a medical doctor. He never met any of the individuals that were alleged to be his co-conspirators. He does not know any international criminals. Dr. Karkalas was a family practice physician who, in addition to treating patients at his practice in a suburb of Philadelphia, contracted with an Internet pharmacy to review requests for prescription medications. Based on decades of experience as a practicing physician, he approved requests when appropriate, denied the requests when not appropriate, and took the trouble to alert RXL when he suspected that prospective patients were gaming the system or somehow attempting to commit fraud. It was clear from

the outset that Dr. Karkalas had done nothing improper.

25. By way of background, Dr. Karkalas studied biology as an undergraduate at the University of Pennsylvania and microbiology as a graduate student at Temple University School of Medicine. He then earned the degree of Doctor of Medicine from Temple University in 1980.

26. After earning his medical degree, Dr. Karkalas completed a three-year residency in family practice, and shortly thereafter opened his own practice named King of Prussia Family Practice, P.C. In or around 1995, Dr. Karkalas opened Upper Merion Family Practice, P.C.

27. Dr. Karkalas took an interest in the advantages of Internet medicine long before the events that are involved in this case. It was during the 1990s, in the early days of the Internet, that Dr. Karkalas began investigating "cyber medicine."

28. Dr. Karkalas also served as a medical director at Independence Blue Cross of Pennsylvania ("IBC"), where he developed an interest in the growing field of Internet medicine. Dr. Karkalas became a medical director for the insurance company while still managing a multi-physician practice and seeing patients on a full-time basis. He maintained the position with IBC for nine (9) years.

29. As a medical director for an insurer of approximately 4.5 million lives, Dr. Karkalas was involved in policy-making, physician and hospital credentialing, quality assurance, and utilization

review. He had direct and indirect responsibility for approximately 2,500 primary and specialty physicians, and his decisions affected another 2,000 to 3,000 healthcare workers and the IBC hospital network.

30. Moreover, during his tenure as a medical director at IBC, Dr. Karkalas, with others, developed a system that enabled patients to request a prescription directly from the health insurance company without the need to go to their primary care doctor. The patient submitted his/her request with a simple paper questionnaire. It was nearly identical in format and content to the questionnaires that Dr. Karkalas later processed online and were involved in this case. Dr. Karkalas recognized that such practices were advantageous for providing routine medical treatment for patients who lacked ready access to providers.

31. Because of his many years of experience as a practicing physician, as a medical director of IBC, as the innovator of a web-based prescription system, and as an advisor to the IBC fraud and abuse unit, he responded to a recruiter's advertisement seeking doctors to work with an Internet pharmacy company to review requests for prescription medications.

32. Dr. Karkalas responded to the request because he believed that the future of medicine would be positively impacted by the growth of the Internet and he wanted to participate in a venture that was going to do it in way that was beneficial to patients and in accordance with all governing regulations.

33. For example, Dr. Karkalas made certain that all requests processed by the Internet pharmacy would

be filled by brick-and-mortar pharmacies based in the United States, using verifiable wholesalers of medications from approved and legitimate pharmaceutical manufacturers.

34. Dr. Karkalas also participated in the design of the online questionnaires to be used by the Internet pharmacy to ensure: (i) collection of appropriate patient information; and (ii) uniformity to facilitate efficient review by a doctor.

35. Dr. Karkalas further insisted that the Internet pharmacy offer medications listed on a drug formulary that he had approved, and that they not sell any controlled substances. This action took place years before the passage of the Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. 831, which mandated an in-person encounter to obtain a prescription for a controlled substance. In doing so, it was clear that Dr. Karkalas would not participate in a venture that offered controlled substances.

36. That did not present any issues because RXL did not sell any medication that health professionals believed to be controlled. At that time, neither Dr. Karkalas nor any other medical or healthcare practitioner believed that *Fioricet* was a controlled medication. In fact, at no time has *Fioricet* ever been listed as a controlled medication.

37. RXL was registered as a corporation in Delaware.

38. As part of her background, Brill, as a DEA Diversion Investigator, focused her investigations on the methods by which prescription drugs are diverted

into illegal markets. Most of Brill's investigations involved the diversion of prescribed substances away from legitimate avenues of distribution, whether through intentional misconduct or carelessness on the part of physicians or pharmacists. The typical diversion investigation involves an audit of a pharmacy where a Diversion Investigator audits the number of pills of a specific medication ordered, and then looks at how many were prescribed to patients and how many remain in inventory. Such audits are not factually or legally complex.

39. Brill, in association with others at the DEA, was investigating RXL and believed, among other things, that RXL was prescribing controlled substances without the appropriate doctor-patient relationship. One of those medications was *Fioricet*, even though Brill found out during her investigation that *Fioricet* had not been designated as a controlled medication by the Food and Drug Administration.

40. Upon information and belief, Brill brought her investigation to the United States Attorney's office in Minneapolis, which declined to prosecute because of a perceived lack of prosecutorial merit. For reasons that are unclear, Brill then turned to the Consumer Protection Branch, a section of the Department of Justice in Washington, where Brill met with Marks to persuade her to prosecute the case. Upon information and belief, Marks had little or no criminal prosecutorial experience in drug cases and had only brought cases involving consumer protection, such as auto dealers selling cars with odometer rollbacks. Marks agreed to take on the RXL case.

41. After a lengthy investigation, the Government, acting through Brill and Marks, inexplicably alleged that RXL was part of an "international conspiracy" to illegally distribute prescription drugs over the internet. The Government alleged that RXL distributed large amounts of prescription drugs using a series of websites. They stated that: (i) customers filled out medical questionnaires on the websites; (ii) the questionnaires were reviewed; and (iii) the prescriptions were written and filled. The Government further alleged that these practices did not comport with the requirements of various federal statutes – namely, that the customers and doctors did not have the necessary doctor-patient relationship and that a controlled medication, in the form of *Fioricet*, was dispensed through this process without a valid prescription.

42. In fact, RXL was run by Le Roux, a wealthy, self-confessed murderer, international drug dealer, arms trafficker and computer hacker, who oversaw a multi-faceted international criminal enterprise. In 2012, Le Roux was arrested in Liberia and extradited to the United States as part of a sting orchestrated by the DEA. He quickly began to cooperate with the Government, in relevant part, assisting with its ongoing investigation of RXL.

43. Le Roux pled guilty to numerous charges, including misbranding drugs, mail and wire fraud, and conspiracy stemming from his involvement with RXL, on separate indictments in the Southern District of New York. Le Roux was not a defendant in Dr.

Karkalas' criminal matter and the Government did not call him as a witness at trial.

A. The Indictment, Arrest and Detention of Dr. Karkalas.

44. On November 13, 2013, Dr. Karkalas was indicted in the United States District of Minnesota and charged with 38 counts of an 85-count indictment.

45. In presenting the case to the Grand Jury, Brill and Marks made false and misleading representations, stating that *Fioricet* was a controlled medication, that Dr. Karkalas was aware that *Fioricet* was a controlled medication, and that he would continue to prescribe it in the same manner that he had. Much of the prosecution's argument hinged on the idea that *Fioricet* was classified as a controlled medication. While one ingredient in *Fioricet*, namely butalbital, was a Schedule III controlled substance, *Fioricet* itself, which combines butalbital along with caffeine and acetaminophen (Tylenol), was never officially designated by the Food and Drug Administration ("FDA"), which has sole authority to do so, as a controlled medication.

46. Dr. Karkalas was arrested at his office while seeing patients. This was both terrifying and humiliating, and intensely upsetting to him, his patients and staff. Dr. Karkalas was first taken to the Federal Detention Center ("Detention Center") in Philadelphia and held in a prison cell with approximately twenty (20) others. When Dr. Karkalas was asked how he was doing by the Detention Center's

psychologist when assigned a bunk, he said that he was terrified and wanted to kill himself.

47. At this point, Dr. Karkalas was immediately moved to a bare cell with a concrete platform for a bed, had all his clothes taken away, and was forced to wear a canvas smock. The lights were on all day and night. He was then completely ignored for several days and was returned to a two-man cell when he promised that he would not attempt suicide. Dr. Karkalas remained at the Detention Center for approximately two (2) months.

48. Dr. Karkalas was then moved to a federal transfer facility in Oklahoma, and placed in the general population, where he immediately felt physically threatened by other inmates. Within an hour of his arrival, he was moved to another "suicide watch" cell, similar to that in Philadelphia, and then to a two-man cell in "special housing," where his cellmate was a self-described "violent schizophrenic."

49. After two (2) weeks in Oklahoma, Dr. Karkalas was transported to Minnesota in a plane with an estimated 250 others, all the while in wrist and leg shackles. Once in Minnesota, Dr. Karkalas was driven to St. Paul, where he was placed in a federally-contracted county jail. Dr. Karkalas remained in the St. Paul prison for approximately two (2) months. While in St. Paul, he was moved between units' multiple times. Dr. Karkalas later learned this was due to threats of random violence against him, because he was suspected by other inmates of being a "child molester" because of his quiet and retiring demeanor.

50. Upon appeal to Judge Nelson, Dr. Karkalas was then moved to a "half-way house" in St. Paul, over the objections of defendant Marks, who argued that the trial was "imminent". To the contrary, an additional two and a half years elapsed before the Government was prepared to proceed. A GPS monitor was placed on his ankle and he could not leave the premises. After approximately six (6) weeks in the halfway house, Dr. Karkalas was finally able to return home with the GPS device.

51. The GPS device caused Dr. Karkalas great pain, and constant swelling which was documented by the Government. Once the device was removed, the swelling persisted, and Dr. Karkalas was left with neuropathic pain. These symptoms persist to this day.

52. Marks, to further isolate, punish, and harm Dr. Karkalas, also obtained an order from Judge Nelson preventing Dr. Karkalas from contacting family and friends prior to trial, alleging they were to be called as witnesses. In fact, Marks knew that she was never going to have any of Dr. Karkalas' friends and family testify at his trial.

53. Dr. Karkalas was the only physician held in pre-trial detention. At the detention hearing, Marks told the Court that Dr. Karkalas was involved in "an international drug cartel, his actions had resulted in several drug related deaths, the evidence against him was overwhelming, and he presented a flight risk." In fact, none of those statements were true.

54. There were no legitimate reasons to hold Dr. Karkalas in pre-trial detention.

55. Not only was Dr. Karkalas the only physician held in pre-trial detention, he was also the only physician about whom a statement was released to the press by Brill, Marks and others.

B. *Fioricet* Was Not a Controlled Medication.

56. When seeking information about medications, including controlled substances, one of the most authoritative and relied upon sources of information is the Physician's Desk Reference. The Physician's Desk Reference has always listed *Fioricet* as a non-controlled prescription product. Dr. Karkalas regularly and consistently relied upon the Physician's Desk Reference, as well as many other official sources, when performing services as a physician and/or conducting Internet prescription services.

57. In addition, healthcare professionals consistently rely on a manufacturer's FDA-approved package insert for its medications to identify which are controlled, and which are not. *Fioricet* has never been designated as a controlled medication.

58. Finally, various statements and reports from other governmental, legal, and industry sources confirmed that *Fioricet* was not a controlled medication. For example, on May 24, 2011, Michele M. Leonhart, the Administrator of the DEA, testified before the U.S. Senate Subcommittee on Crime and Terrorism that *Fioricet* was exempt from the purview of the CSA.

59. Dr. Karkalas spent many hours every day reviewing requests for medication. He reviewed each request individually and spent a considerable amount

of time throughout the day doing this, routinely denying requests for cause when appropriate because he was aware of the potential for fraud and abuse.

60. Dr. Karkalas was investigated by the Pennsylvania Board of Medicine ("Board") on three (3) separate occasions (at the behest of the DEA) and at no time did the Board take issue with Dr. Karkalas' prescribing activity.

61. During this period of time, other courts concluded without much difficulty that *Fioricet* was not a controlled medication. For example, on August 4, 2016, the Honorable James E. Boasberg of the United States District Court for the District of Columbia dismissed counts against a pharmacist for allegedly violating the CSA in the distribution of *Fioricet* without a valid prescription. Marks was the prosecutor in that matter. *See United States of America v. Titlayo Akintomide Akinyoyenu*, 1:15-cr-00042 (D. D.C.).[1]

62. Judge Boasberg concluded that the CSA authorized the distribution of *Fioricet* as a non-controlled medication, rejected the Government's argument, and noted that it had been "recycled" from another case. This was approximately six (6) months prior to the commencement of Dr. Karkalas' trial, and during the period of his pretrial detention and confinement.

63. Moreover, during this entire period, numerous pharmacists and pharmacies continued to

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[1] https://ecf.dcd.uscourts.gov/doc1/04515714889

fill online requests for *Fioricet* and have done so without interruption or DOJ/DEA question.

C. Dr. Karkalas Attempted to Explain the Status of *Fioricet* to Investigators.

64. At all times during the investigation, Dr. Karkalas was completely open with the authorities. When investigators came to his house and office to conduct searches and seize his computers, he answered their questions about the services he performed and the process he utilized. Moreover, Dr. Karkalas engaged with the agents and prosecutors in other ways, including calling and emailing them. He volunteered to travel to Washington, D.C. to attend a meeting with Marks, Brill, and others. At that meeting, Dr. Karkalas explained what he was doing and wanted to know why they were conducting this investigation. During those interviews, defendants Brill and Marks seemed uninformed of the status of *Fioricet* and disinterested in the subject. In fact, Dr. Karkalas had a discussion with Brill outside his office, in the parking lot, wherein he again told her that *Fioricet* is not a controlled medication and Brill responded, she thought "it should be." At no time did Dr. Karkalas hide anything from the investigators or try to mislead them, nor did Brill or Marks provide Dr. Karkalas with any information suggesting that he was incorrect in his understanding of correct prescribing practices.

65. Marks, presumably knowing she had a weak case, sought to intimidate witnesses such as Dr. Karkalas' nurse and office manager. Marks showed up at their homes in an effort to coerce them to testify against Dr. Karkalas.

66. After the return of the indictments in Minnesota in the RXL case, of the eleven original defendants: (i) three pled guilty; (ii) three remained at large; and (iii) five refused to take plea deals; namely, Moran Oz, Lachlan McConnell, Prabhakara Tumpati, Dr. Karkalas and Babubhai Patel.

67. Defendants Oz, McConnell, Tumpati, and Dr. Karkalas were tried together. Those four defendants were charged with conspiring to distribute prescription drugs over the Internet without valid prescriptions. The Government painted a picture of a conspiracy, with the defendants operating without regard for either the laws of the United States or the safety of the public.

68. At trial, the prosecutors immediately encountered the original challenge that the DEA investigators had faced at the start of the case; namely, that the *Fioricet* sold by RXL was not a controlled medication. Halfway through their own prosecution, the Government gave up on the argument and dropped the charges related to the illegal prescribing of controlled substances, signaling that the case was a sham from the beginning and should have never been initiated by Brill, Marks and others.

69. The jury rejected the Government's case in its entirety and on March 17, 2017, Dr. Karkalas, along with the other defendants, was acquitted on all counts.

70. The bad faith prosecution of Dr. Karkalas by Brill and Marks caused Dr. Karkalas to be removed from his home, kept in detention for six months, and then placed on electronic monitoring. His medical practice of over thirty (30) years and his professional

reputation were completely destroyed. Further, his incarceration prevented him from addressing critical personal and financial issues, thus resulting in the loss of most of his assets, including his medical building, and caused him to suffer related tax issues. He sustained significant nerve damage due to the electronic monitoring. Moreover, it is unlikely that he will ever be hired as a physician due to the negative publicity, the destruction of his professional reputation, and his resultant failing health. Finally, the loss of his medical practice leaves Dr. Karkalas without adequate financial resources to start a new practice.

71. Marks, Brill and the Government never had any evidence that Dr. Karkalas knew he was breaking the law, even though violations of the CSA have a *mens rea* requirement.

72. In ruling on numerous post-trial motions, Judge Nelson, the presiding trial judge, remarked that the prosecution had demonstrated "a complete failure of proof." The flaws in the case were fundamental.

73. In short, after a decade-long investigation, defendants Marks, Brill, and the Government failed to obtain a single conviction in Federal Court beyond the defendants who simply gave up and took a guilty plea, most of them in exchange for avoiding jail time.

74. The prosecution of Dr. Karkalas was widely reported in national and international media and Dr. Karkalas was portrayed as a drug dealer, based on press releases issued by defendants and by the DOJ. This publicity, and the portrayal of Dr. Karkalas as a criminal, compounded the emotional distress that he

suffered and further damaged his respected reputation and medical career.

75. The malicious prosecution and the deprivation of the basic rights of Dr. Karkalas proximately caused harm to his professional pursuits and career and have and will continue to have an adverse impact on his life as a medical practitioner.

76. The malicious prosecution of Dr. Karkalas proximately caused harm to his professional stature and resulted in significant emotional distress.

77. The prosecution and related events prejudiced, and will continue to prejudice, Dr. Karkalas and dramatically reduce his opportunities to obtain further professional advancement in employment, thereby causing harm to his stature and future earnings.

78. The prosecution and related events prejudice and will continue to prejudice Dr. Karkalas with respect to his future opportunities to advance in employment, causing harm to his stature and future earnings. In short, Dr. Karkalas is virtually unemployable as a physician or health care provider and likely never again will work in his chosen profession.

79. As a clear result of the defendants' actions and conduct, Dr. Karkalas suffered from and continues to suffer from excruciating physical pain, severe emotional and physical trauma and distress. His injuries also have manifested themselves physically as clinical depression, with loss of appetite, loss of family and friends, difficulty sleeping, and physical and

mental exhaustion. These injuries are ongoing and continuous and likely will continue until an indefinite time in the future.

V. CLAIMS

COUNT I
Federal Constitutional Claims under *Bivens*

80. The actions of defendants Marks and Brill violated Dr. Karkalas' clearly established due process rights and right to be free from unlawful prosecution and unlawful seizure under the Fourth and Fifth Amendments. This action is brought against defendants under the United States Constitution pursuant to *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971), for the defendants' illegal prosecution of Dr. Karkalas, the unlawful seizure of and the presentation of false and misleading evidence and testimony to the Grand Jury regarding Dr. Karkalas' involvement with RXL.

81. As the lead case agents and investigators, defendants Marks and Brill initiated the prosecution of Dr. Karkalas without probable cause and acted with improper motives and purposes.

82. The charges in the Indictment were entirely false, malicious, and fabricated, and resulted directly from the actions of Brill and Marks, who intentionally, knowingly, and recklessly made false statements and representations to the Grand Jury regarding the actions and state of mind of Dr. Karkalas.

83. The false allegations made in the Indictment were a direct result of defendants' actions in

intentionally, knowingly, and/or recklessly making false statements and representations and material omissions of facts about Dr. Karkalas in reports and other communications with other prosecutors and in testimony and presentation of evidence before the Grand Jury.

84. The endless false statements were at the core of the wrongdoing in the investigation of Dr. Karkalas: their intentional, knowing and/or recklessly false conclusions were all made without any basis to allege that Dr. Karkalas had knowingly violated the CSA.

85. The Fourth Amendment protects "[t]he right of the people to be secure in their persons . . . against unreasonable . . . seizures." The Fourth Amendment further prohibits Government officials from detaining a person in the absence of probable cause. Dr. Karkalas suffered pre-trial detention because of his wrongful prosecution. As previously noted, Dr. Karkalas was found not guilty on all counts.

86. Plaintiff's Fourth Amendment right to be free from unreasonable seizure continued beyond the Government's invocation of legal process because probable cause simply never existed. Dr. Karkalas should never have been indicted because the indictment was obtained upon knowingly false presentations made by defendants to the Grand Jury. Dr. Karkalas should never have been detained pre-trial because the detention order was obtained upon knowingly false representations made by defendants to U.S. Magistrate Judge Hart. The violations of Dr. Karkalas' Fourth Amendment rights and Fifth Amendment due process rights were a continuing

violation that occurred right up until his acquittal and release.

87. Because of the foregoing, Dr. Karkalas was wrongfully detained, was denied fundamental constitutional rights, was publicly embarrassed and humiliated, was caused to suffer severe emotional distress, was forced to incur substantial legal expenses, had his personal and professional reputation destroyed, and lost his livelihood as a medical doctor.

COUNT II
Federal Tort Claims Act – Malicious Prosecution

88. Through their actions, defendants Marks and Brill initiated the prosecution of Dr. Karkalas without probable cause and with malice. This constituted the tort of malicious prosecution under the law of the Commonwealth of Pennsylvania and the law of Minnesota.

89. Under the Federal Tort Claims Act, defendant United States of America is liable for these actions.

WHEREFORE, plaintiff, Dr. Elias Karkalas, respectfully requests that the Court enter judgment in his favor and against defendants and that he be awarded compensatory and punitive damages against defendants, attorney's fees and costs and any other relief that the Court deems just.

Respectfully submitted,

ZARWIN ♦ BAUM ♦ DeVITO
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Dated: May 9, 2019

APPENDIX F

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 19-2816

[File March 25, 2021]

ELIAS KARKALAS,	)
	)
Appellant,	)
	)
V.	)
	)
LINDA MARKS; KIMBERLY BRILL; UNITED STATES OF AMERICA	)
	)

PETITION FOR PANEL REHEARING
AND REHEARING EN BANC

I. INTRODUCTION

Petitioner, Elias Karkalas requests that the Court grant his Petition for Panel Rehearing and Rehearing *En Banc* Under Fed. R. App. P. 35(b) and 40(a).

In support of this petition, counsel represents the following:

I express a belief, based on a reasoned and professional judgment, that the panel's opinion (attached as Addendum I) is contrary to the decisions of the United States Court of Appeals for the Third

Circuit and the Supreme Court of the United States, and that consideration of the full court is necessary to secure and maintain uniformity of decisions in this court, *i.e.*, the panel's decision is contrary to the decision of the United States Supreme Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and this Court in *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008), governing the pleading requirements of a civil rights complaint and that this appeal involves a question of exceptional importance, namely whether properly pleaded facts in a complaint should be considered insufficient or conclusory solely because the plaintiff does not identify the source of his knowledge of those facts.

Here, the panel, *sua sponte*, raised the sufficiency of the complaint allegations regarding grand jury misconduct by Brill and Marks and used that basis to affirm the lower court's dismissal on other grounds of petitioner's claims pursuant to *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971) ("*Bivens*") and the claims against the government pursuant to the Federal Tort Claims Act ("FTCA") without considering plaintiff's right to file an amended pleading.

A. Facts and Procedural History

Dr. Elias Karkalas, a physician, was charged with thirty-eight (38) felony counts in an eighty-five(85) count indictment returned in the United States District Court for the District of Minnesota for alleged violations of the Controlled Substances Act, 21 U.S.C. §801 *et seq*. ("CSA"), mail and wire fraud, and international money laundering. *See United States of*

America v. Berkman, et al. 0:13-cr-00273 (D. Minn.). (A60). Following the indictment, Dr. Karkalas was detained pending trial and then for many months made subject to electronic monitoring which left him with permanent nerve damage.

The charges against Dr. Karkalas, however, were false, malicious, and entirely fabricated. The United States Government ("Government"), acting through defendant Kimberly Brill ("Brill"), a U.S. Drug Enforcement ("DEA") Investigator, and Linda Marks, Esq. ("Marks"), a U.S. Department of Justice attorney, alleged that Dr. Karkalas was part of a "global cartel" that enabled United States citizens to obtain enormous quantities of potentially addictive prescription drugs from hundreds of linked Internet websites without a valid doctor-patient relationship. The indictment charged eleven people in addition to Dr. Karkalas ("Indictment"). (A61). The case was filed in Minnesota for no reason other than that was where Brill worked. (A61).

Dr. Karkalas was charged with, among other things, prescribing controlled substances without a valid prescription. (A61). At no time, however, did Dr. Karkalas issue prescriptions for controlled substances as the medication he prescribed. *Fioricet*, has never been designated a controlled substance. (A61).

The criminal trial against Dr. Karkalas and others lasted several weeks and resulted in no trial convictions. (A61). As set forth in his complaint below, Marks and Brill either knew or recklessly disregarded the fact that Dr. Karkalas did not violate the CSA, mail

and wire fraud, and international money laundering statutes. (A62).

Dr. Karkalas' action against Brill and Marks was brought under a *Bivens* theory for the defendants' malicious prosecution and knowing presentation of false and misleading testimony, and evidence to the grand jury. (A62). His claims under *Bivens* arise out of that conduct in violation of the Fourth and Fifth Amendments. (A62). Thereafter, Dr. Karkalas amended his Complaint to assert claims against the government pursuant to the FTCA after exhausting the statute's administrative claim procedure.

II. DISCUSSION

A. The Panel Misapplied or Ignored the Law in Finding that Karkalas Failed to Plead Facts Sufficient to Sustain His Claims.

The panel should reconsider its opinion in this case because its basis for finding that Dr. Karkalas failed to plead sufficient facts to state a viable cause of action is contrary to the precedent set in *Twombly* and distorts established pleading requirements.

In its opinion, the panel, *sua sponte*, determined that the following allegations from Karkalas' first amended complaint should be disregarded as "conclusory":

"Defendants made knowingly false presentations to the grand jury, namely, (i) that Fioricet is a controlled medication, (ii) that Karkalas knew so, and (iii) that he would continue to prescribe it."*See* Opinion at p. 9,*citing* (A77).

The panel's rationale for finding those allegations conclusory was that "[w]ithout providing a factual basis for his purported knowledge of the grand jury proceedings, Karkalas' allegations that the individual defendants made false statements to the grand jury are "speculative" and threadbare." *See* Opinion at p. 9. The panel then used the purported *Twombly* deficiency as a basis to uphold the individual defendants' qualified immunity to the *Bivens* claims, *id.* at 6-8; and the dismissal of the FTCA claims of malicious prosecution against the government. *Id.* at 13-15.

It is noteworthy that at no point did the district court nor defendants ever raise a *Twombly* challenge, or otherwise contend there was a lack of notice or clarity as to what was alleged by Dr. Karkalas. Moreover, the purported pleading standard described by the panel is contrary to the *Twombly* standard utilized in this Circuit and elsewhere, and neither *Twombly* nor subsequent decisions have ever imposed a requirement that a pleading must specifically identify the basis for the pleader's knowledge of the facts.

According to the panel, however, because grand jury proceedings are secret, Karkalas' allegations in his amended complaint regarding defendants' false presentations to the grand jury were "speculative"and "threadbare,"and thus not plausible. *Id.* at 9-10.

That conclusion is simply wrong. Grand jury secrecy is not absolute and there are many avenues for such testimony to be disclosed. As every federal prosecutor knows, Rule 26.2 of the Federal Rules of Criminal Procedure requires the district court to produce, upon request by the defendant, "any statement of the

witness that is in their possession and that relates to the subject matter of the witness's testimony. . . ." The Rule defines "statement" to include testimony before the grand jury. *See* Fed. R. Crim. P. 26.2(f)(3). Such a request was made here at trial by defendant Karkalas, the district court ordered Brill's grand jury testimony produced to him, and it was no longer secret.[1]

Finally, even if *Twombly* were applicable here - and it is not - this Court has exercised its supervisory authority to direct that when a *Twombly* issue is raised below, the party is granted leave to file an amended pleading to remedy the perceived deficiency. But that did not occur here, and the panel affirmed the dismissal without ever addressing the issue.[2]

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[1] There is nothing in Fed. R. Crim. P. 6 that prevents this grand jury testimony from being disclosed further. In fact,"[n]o obligation of secrecy may be imposed on any person except in accordance with Rule 6(e)(2)(B)." Fed. R. Crim. P. 6(e)(2)(A). The only limitation at issue in this case regarding Brill's grand jury testimony is the protective orders issued in Karkalas' criminal case, which only prohibited the disclosure of personal identifiers and certain financial information not relevant to the instant litigation. Brill's transcripts were redacted consistent with those orders.

[2] The district court's dismissal of petitioner's *Bivens* claims was based on its view that it lacked personal jurisdiction over Brill and Marks, but that conclusion was abandoned on appeal by appellees. On appeal, Brill and Marks advised the Court that they were"not pressing" the jurisdictional issues and did not address them in their brief. *See* Opinion at p.5.

III. ARGUMENT

A. The Panel Misapplied Twombly.

In *Twombly*, "the Supreme Court reaffirmed that Fed. R. Civ. P. 8 'requires only a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests,'" and that this standard does not require "detailed factual allegations.""*Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) *citing Twombly*, 127 S.Ct. at 1964. Importantly, *Twombly* did not "undermine [the] principle" that all reasonable inferences are to be drawn in favor of the plaintiff and reaffirming that "the facts alleged must be taken as true and a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits". *See Id.* at 1964–65, 1969 n.8.

Here, the panel gave no reasonable inferences in favor of Dr. Karkalas and summarily dismissed his allegations in the first amended complaint because of their connection to a grand jury proceeding. While Fed. R. Crim P. 6(e) safeguards the secrecy of grand jury proceedings, there are a number of recognized exceptions to that prohibition. Grand jury proceedings are, of course, transcribed and matters occurring before the grand jury are subject to disclosure in appropriate circumstances, including here where a request for grand jury testimony was made and granted pursuant to Fed. R. Crim. P. 26.2, and the grand jury testimony of Agent Brill and statements by DOJ attorney Marks

were produced to Karkalas and referenced in his first amended complaint .

In prior cases, this Court has recognized the significance of grand jury materials in subsequent litigation. For example, in *Rose v. Bartle*, 871 F.2d 331 (3d Cir. 1989),a decision relied upon by the panel in its opinion, the Court permitted a civil rights claim based on grand jury misconduct to go forward and remanded the matter with the instruction that the district court grant plaintiff leave to file an amended complaint to assert with greater specificity the alleged misconduct that occurred before the grand jury. *Id.* at 355-356.

Moreover, the panel's reliance on the First Circuit's *Penalbert-Rosa* decision makes little sense here, as that court found that "specific information, even if not in the form of admissible evidence, would likely be enough at this stage; pure speculation is not." *Penalbert-Rosa v. Fortuno-Burset*, 631 F.3d 592, 596 (2011).[3] Likewise, the panel's citation at page 6 of its Opinion to *Connelly v. Lane Construction Corp.*, 809 F.3d 780 (3d Cir. 2016), does not in any way support its analysis. In *Connelly*, the Court remanded a discrimination matter where the district court misapplied *Twombly* noting that:

> *Twombly* and *Iqbal* distinguish between legal conclusions, which are discounted in the

[3] In *Penalbert-Rosa* the Court found that "there was nothing in the complaint beyond raw speculation to suggest that the named defendants [the governor of Puerto Rico, his chief of staff, and administrator of governor's mansion] participated—either as perpetrators or accomplices—in the decision to dismiss" appellant. *Id.* at 594-95.

> analysis, and allegations of historical fact, which are assumed to be true even if 'unrealistic or nonsensical,' 'chimerical,' or 'extravagantly fanciful.' *Iqbal,* 556 U.S. at 681, 129 S.Ct. 1937. Put another way, *Twombly* and *Iqbal* expressly declined to exclude even outlandish allegations from a presumption of truth except to the extent they resembled a "formulaic recitation of the elements of a ... claim" or other legal conclusion.

Id. at 789-90.

Here, Dr. Karkalas did not make threadbare and conclusory legal statements of the type criticized by the *Twombly* decisions. Rather, he asserted fact-based, specific allegations relating to statements made to the grand jury by DEA Diversion Investigator Brill and DOJ Attorney Marks that, if proven true, are sufficient to establish Dr. Karkalas' *Bivens* claims and FTCA claims of malicious prosecution.

This Court has never held that the sufficiency of a pleading requires the identification of all sources of the information. Even if the Court were inclined to adopt that view -- notwithstanding the absence of anything in the *Twombly* cases supporting it -- any such deficiency in the pleading should be addressed by directing the filing of an amended complaint, not a dismissal with prejudice. *See, e.g., Grayson. v Mayview State Hospital*, 293 F.3d 103,108 (3d Cir. 2002) (court must inform party of right to amend unless amendment would be inequitable or futile).

B. The Panel Misapplied the Controlled Substances Act.

One of the principal issues raised in the underlying litigation was whether *Fioricet* was a controlled substance that could be prescribed only following an in-person examination by a physician. The Panel's decision is virtually silent on that issue.

By way of background, while some medications, such as *Viagra* and *Propecia*, may be dispensed only when a physician issues a prescription, they are not controlled medications within the meaning of the CSA, and such prescriptions can be issued following an online or telephonic consultation with a physician.

On the other hand, because of the greater possibility for abuse, controlled substances - many of which are narcotic and opiate-based, require an in-person physician examination before a prescription can issue. Controlled substances range from Schedule I for substances like heroin, with no legitimate medical treatment and which never can be prescribed, to Schedule V medications commonly prescribed for pain relief. *See* 21 USC § 812(c).

The distinction is critical. Under the CSA, only the Attorney General is authorized to add a drug to the schedules of controlled substances, and only subject to the approval of the Secretary of Health and Human Services and the FDA. *See* 21 USC § 811(a).[4] That

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[4] The Attorney General may "exempt" prescription drugs containing controlled substances from any part of the CSA if she finds that the drug, by incorporating non-controlled substances,

designation constitutes an important bright line for practitioners, regulators and law enforcement. A medication is designated as a controlled substance - or it is not. DEA agents and prosecutors cannot exercise discretion as to what medications they personally believe *should* be listed as controlled substances. The CSA as well as common sense do not permit such a result. Moreover, a thirty (30) second *Google* search will disclose what substances are controlled and which are not.

For these reasons, it is perplexing that the panel concluded that both individual defendants "believed that, under federal law *Fioricet* constituted a controlled substance because it contained butalbital." *See* Op. at p. 3. The panel does not explain how it reached such a conclusion given that *Fioricet* is not listed as a controlled substance, and the first amended complaint stated that the DEA administrator testified before Congress that *Fioricet* is not a controlled substance. (A73).

Further, the first amended complaint alleges that after Karkalas told Brill that *Fioricet* is not a controlled medication, Brill responded that "it should be.'" (A73).

These allegations set forth an adequate basis, at this stage in the litigation, that Brill knew that *Fioricet* was not, in fact, a controlled substance but nonetheless pursued an investigation and testified falsely that

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"vitiate[s] t he potential for abuse" of the controlled substance. *Id.* § 811(g)(3)(A). Fioricet is exempted as a combination drug, *see* 21 C.F.R. § 1308.32, and https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.

Fioricet was a controlled substance and in doing so obtained an indictment against Karkalas for illegally prescribing a controlled substance. Rehearing is necessary to reconcile this misapplication of the law.

C . The Court Misapprehended the Applicability of Qualified Immunity.

The individual defendants are not entitled to qualified immunity as they knew from their numerous conversations with him that: (1) Dr. Karkalas never had the requisite *mens rea* for a violation of the CSA; and (2) *Fioricet* was never a controlled substance. The CSA has a *mens rea* requirement,[5] and as pleaded in the first amended complaint Karkalas consistently asserted that *Fioricet* was not a controlled substance and that his online prescribing was legal. (A67). By defendants' own admission, Dr. Karkalas voluntarily travelled to Washington D.C. and met with Brill and Marks and asserted his belief that *Fioricet* was not a controlled substance within the meaning of the CSA. (A179).

The panel nevertheless concluded that "testimony that is incorrect or simply disputed should not be treated as fabricated merely because it turns out to have been wrong," in finding that the individual defendants were entitled to qualified immunity. *See* Op. at p. 13.

However, there is no dispute based on the pleadings that Dr. Karkalas believed that his prescribing of

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[5] *See McFadden v. United States*, 576 U.S. 186, 192, 135 S. Ct. 2298, 2304 (2015).

Fioricet was legal. Given Appellant's detailed and well-pleaded allegations demonstrating that he believed his prescribing of *Fioricet* was legal, and individual defendants' knowledge of the same, defendants are not protected by qualified immunity, particularly at this stage of the proceedings. A contrary conclusion is sadly ironic, namely that a federal prosecutor and a DEA Diversion Investigator simply do not know how to determine what substances are controlled, and such a "mistake" by them carries no consequences even when it results in such enormous harm.

IV. CONCLUSION

Appellant, Dr. Elias Karkalas, respectfully requests that the Court grant his petition for rehearing or rehearing *en banc*.

Respectfully Submitted,

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