

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

SOUTHEASTERN PENNSYLVANIA : CIVIL ACTION  
TRANSPORTATION AUTHORITY, et al. :  
 :  
v. :  
 :  
GILEAD SCIENCES, INC. : NO. 14-6978

MEMORANDUM

Dalzell, J.

May 4, 2015

**I. Introduction**

We consider here defendant Gilead Sciences, Inc.’s (“Gilead”) motion to dismiss under Fed. R. Civ. P. 12(b)(6). Plaintiffs -- the Southeastern Pennsylvania Transportation Authority (“SEPTA”), John Doe, and Jane Doe -- are suing Gilead on behalf of themselves and others similarly situated alleging that Gilead’s pricing scheme for the sale of its patented Hepatitis C drugs violates Section 1557(a) of the Patient Protection and Affordable Care Act, constitutes unjust enrichment, breaches the implied duties of good faith and fair dealing, and violates California Business & Professions Code § 17200. Amend. Compl. at ¶¶ 124-61. Gilead moves to dismiss the entire Amended Complaint.

We have jurisdiction over plaintiffs’ federal claim pursuant to 28 U.S.C. § 1331 and supplemental jurisdiction over their state law claims pursuant to 28 U.S.C. § 1367.<sup>1</sup>

**II. Standard of Review**

A defendant moving to dismiss under Fed R. Civ. P. 12(b)(6) bears the burden of proving that the plaintiff has failed to state a claim for relief. See Fed. R. Civ. P. 12(b)(6); see also, e.g.,

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<sup>1</sup> Plaintiffs state that we also have jurisdiction over their putative class action under CAFA pursuant to 28 U.S.C. § 1332. Amend. Compl. at ¶ 18.

Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). To survive a Rule 12(b)(6) motion, the complaint must contain sufficient factual matter, accepted as true, to state a facially plausible claim to relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678.

As the Supreme Court stresses, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action...do not suffice.” Id. Courts “are not bound to accept as true a legal conclusion couched as a factual allegation.” Twombly, 550 U.S. at 555. In the wake of Twombly and Iqbal, our Court of Appeals laid out a two-part test to apply when considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6):

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’

Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (internal citations omitted). In deciding a motion to dismiss, we may consider “the allegations contained in the complaint, exhibits attached to the complaint and matters of public record,” and any “undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document.” Pension Benefits Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993); see also Pryor v. National Collegiate Athletic Ass’n, 388 F.3d 548, 560 (3d Cir. 2002) (explaining that a court may consider a

document not attached to the pleading if its contents are alleged in the complaint and no party questions its authenticity).

We recite the relevant facts as they appear in the Amended Complaint.

### **III. Factual Background**

Defendant Gilead manufactures Sovaldi and Harvoni, two highly effective -- and profitable -- treatments for Hepatitis C. Amend. Compl. at ¶¶ 1-3, 29, 37. Twelve-week courses of Sovaldi and Harvoni cost \$84,000 and \$94,500, respectively. Id. at ¶ 6. Gilead has made billions of dollars from the sale of these drugs. Id. at ¶ 91.

Plaintiff SEPTA is the regional transportation authority for public transit serving Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties in the Commonwealth of Pennsylvania. Id. at ¶ 20. SEPTA maintains an employee health and welfare benefit plan pursuant to which it reimburses and pays for certain of its employees' prescription drug purchases. Id. In 2014, SEPTA paid more than \$2.9 million for Sovaldi and \$850,000 for Harvoni for its employees. Id.

Plaintiff Jane Doe is a resident of Souderton, Pennsylvania, whose insurance company denied her coverage for Sovaldi after she was diagnosed with Hepatitis C, and who Gilead said was ineligible for its Patient Assistance program because of her private insurance. Id. at ¶ 21. Plaintiff John Doe is a resident of Sun City West, Arizona, whose insurance company also denied him coverage for Sovaldi after his Hepatitis C diagnosis. Id. at ¶ 22.

Plaintiffs allege that Gilead sells sofosbuvir -- the active ingredient in Sovaldi and Harvoni -- at much lower prices abroad and has announced plans to license a generic version of its drugs in developing countries at deeply discounted prices. Id. at ¶¶ 7-8, 38-39. Some federal agencies and large prescription benefit managers also receive significant discounts on Sovaldi.

Id. at ¶¶ 7, 41-42, 47. But, as a result of Gilead’s domestic pricing scheme, many consumers -- such as Jane Doe and John Doe -- and government programs have been unable to obtain either Sovaldi or Harvoni. Id. at ¶¶ 10-11. Some health insurers and prescription benefit managers have been rationing, delaying, or limiting the availability of Sovaldi and Harvoni. Id. at ¶¶ 11, 62-63, 65. Plaintiffs allege that Gilead’s pricing scheme “has had a disproportionately adverse impact on racial minorities and those in lower income brackets.” Id. at ¶ 12. State Medicaid programs have also developed strict protocols to limit the provision of Sovaldi and Harvoni to only the sickest patients. Id. Some prescription benefit managers have responded to these high prices by entering into exclusive deals with Gilead or one of its competitors, AbbVie, Inc., in order to obtain Sovaldi and Harvoni at discounted prices. Id. at ¶ 13. Citing to several specific exclusivity contracts Gilead has with Express Scripts, CVS, Anthem, Inc., Prime Therapeutics LLC, and Aetna, plaintiffs argue that such deals demonstrate that Gilead overpriced Sovaldi and Harvoni in 2014. Id. at ¶¶ 49, 51, 53, 55, 58-59.

Plaintiffs also claim that these drugs are overpriced as evidenced by the fact that they are priced more like “orphan drugs” -- drugs for rare conditions (even though Hepatitis C is not a rare disease) -- thereby violating “an unwritten rule in the pharmaceutical industry that orphan drugs would be priced high because of the low number of treatments.” Id. at ¶¶ 86-88. Plaintiffs allege that Gilead’s prices preclude patients from gaining access to Sovaldi or Harvoni and force third party payers, like SEPTA, to pay “exorbitant prices.” Id. at ¶ 16. Plaintiffs also allege that Gilead’s Patient Assistance Program does not “provide meaningful access” to Sovaldi and Harvoni because of bureaucratic hurdles and paperwork requirements. Id. at ¶¶ 72, 74-76.

Gilead justifies its prices based partly on its prediction that the drugs allow patients to avoid future healthcare expenses -- such as liver transplants -- and cure “a horrible disease in a

very rapid time frame.” *Id.* at ¶ 95. Plaintiffs assert that Gilead’s justifications for its high prices are “bogus.” *Id.* at ¶ 96. Plaintiffs also allege that Gilead’s patents might be vulnerable. *Id.* at ¶ 99. Plaintiffs, on behalf of themselves and those similarly situated, are suing Gilead “to stop this unconscionable and unfair conduct, and to secure appropriate relief for consumers and third party payers who have been victimized by Gilead’s price gouging scheme.” *Id.* at ¶ 17.

#### **IV. Discussion**

In Count I, plaintiffs allege unjust enrichment because of Gilead’s “patently unconscionable” “price gouging” and because its prices are “unreasonable, excessive, arbitrary, discriminatory, inflated, exorbitant and inflated.” *Id.* at ¶¶ 127-29. In Count II, plaintiffs Jane Doe and John Doe allege discrimination in violation of Section 1557 of the Patient Protection and Affordable Care Act. *Id.* at ¶¶ 130-39. In Count III, plaintiffs argue Gilead has breached the duty of good faith and fair dealing by “demanding the excessive prices it charged for Sovaldi and Harvoni.” *Id.* at ¶ 143. In Counts IV and V plaintiffs argue that Gilead has violated California Business & Professions Code § 17200 which prohibits unfair competition. *Id.* at ¶¶ 140-54. Plaintiffs also seek class certification and to represent the class as a whole. *Id.* at ¶¶ 117-23.

Gilead moves to dismiss plaintiffs’ entire Amended Complaint. MTD at 2.

We first consider plaintiffs’ federal claim under the Affordable Care Act and then their state law claims.

##### **A. Affordable Care Act Claim**

In Count II, individual plaintiffs Jane Doe and John Doe allege that Gilead has discriminated against them, and similarly situated class members, in violation of Section 1557 of the Affordable Care Act. Amend. Compl. at ¶¶ 137-39. Section 1557 contains an anti-

discrimination provision that “an individual shall not, on [the basis of any protected ground], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.” 42 U.S.C. § 18116. Protected grounds include race, color, national origin, sex, age, and disability. Id. (citing to Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973).

Plaintiffs argue that Gilead’s pricing violates Section 504 of the Rehabilitation Act and Title VI of the Civil Rights Act because it both discriminates against persons with disabilities and “Gilead’s pricing -- while perhaps not intentionally discriminatory -- has had a disparate impact on minorities.” Amend. Compl. at ¶ 133; Pl. Resp. at 17. Plaintiffs’ theory of discrimination on the basis of disability is that the pricing scheme: (1) charges more to people with Hepatitis C in the United States as opposed to abroad, (2) charges more to those with Hepatitis C who are not part of health programs or plans that have entered into contracts for discounts with Gilead, (3) causes health plans and programs to refuse or limit access to the drugs, and (4) denies access because of the “excessive and discriminatory pricing practices, contracts and policies.” Pl. Resp. at 19-20. Plaintiffs’ theory of discrimination on the basis of race is that Gilead has intentionally discriminated against minorities by being deliberately indifferent to the fact that “Hepatitis C victims are disproportionately African Americans” and pricing its drugs “in a manner that would negatively impact racial minorities’ access.” Id. at 33.

Gilead contends that plaintiffs’ claim fails because (1) they have not shown Gilead discriminates on the basis of who has Hepatitis C, (2) a neutral price is not discriminatory, and (3) simply having Hepatitis C is not a disability. MTD at 7. Gilead also argues that plaintiffs

have failed to show that its “conduct adversely affected racial minorities compared to non-minorities.” Def. Reply at 4.

**1. Whether Section 1557 Provides A Private Right Of Action**

There are very few cases interpreting Section 1557 of the Affordable Care Act.<sup>2</sup> As this is a matter of first impression, we begin by inquiring whether Congress created a private right of action when it enacted Section 1557 of the Affordable Care Act.

42 U.S.C. § 18116 – Nondiscrimination provides:

(a) In general

Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

(b) Continued application of laws

Nothing in this title (or an amendment made by this title) shall be construed to invalidate or limit the rights, remedies, procedures, or

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<sup>2</sup> In fact, we were only able to identify one case substantively engaging with Section 1557. See Rumble v. Fairview Health Servs., 2015 WL 1197415, \*1 (D. Minn. Mar. 16, 2015) (Nelson, J.). Other cases touching on Section 1557 have done so in a cursory fashion by dint of a procedural posture or cited the statute for another principle. See, e.g., East v. Blue Cross & Blue Shield of La., 2014 WL 8332136, \*2 n.1 (M.D. La. Feb. 24, 2014) (Jackson, C.J.) (finding in the context of issuing a temporary restraining order that plaintiff made a preliminary showing that he was likely to succeed on the merits of his claim because the Affordable Care Act contained a non-discrimination provision); Russo v. Diocese of Greensburg, 2010 WL 3656579, \*3 (W.D. Pa. Sept. 15, 2010) (Lancaster, C.J.) (citing 42 U.S.C. § 18116 for the proposition that “Federal Financial Assistance” includes subsidies).

legal standards available to individuals aggrieved under [title VI and title VII of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975], or to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a).

(c) Regulations

The Secretary may promulgate regulations to implement this section.

We begin with the plain language of the statute. Lamie v. United States Tr., 540 U.S. 526, 534 (2004) (explaining that “when the statute’s language is plain, the sole function of the courts -- at least where the disposition required by the text is not absurd -- is to enforce it according to its terms”) (citing Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6 (2000) (in turn quoting older cases)). Only in the face of ambiguous statutory text are we permitted to look to the statute’s legislative history or consult the relevant agency’s interpretation of the statute. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984). Congress itself may create -- explicitly or by implication -- any private right of action to enforce federal law. Alexander v. Sandoval, 532 U.S. 275, 286 (2001). We must determine whether the statute manifests an intent to create both a private right and “also a private remedy. Statutory intent on this latter point is determinative. Without it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute.” Id. at 286-87 (internal citations omitted). “For a statute to create such private rights, its text must be ‘phrased in terms of the persons benefitted.’” Gonzaga Univ. v. Doe, 536 U.S. 273, 284 (2002) (quoting Cannon v. University of Chi., 441 U.S. 677, 692 n.13 (1979)). Even if a statute includes “such explicit rights-creating terms, a plaintiff suing under an implied right of action still must show that the statute manifests an intent ‘to create not



just a private right but also a private remedy.” Id. (quoting Sandoval, 532 U.S. at 286 and adding emphases).

Section 1557 expressly incorporates four federal civil rights statutes and includes the kind of rights-creating language found in those statutes. See 42 U.S.C. § 2000d (“No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”); 20 U.S.C. § 1681 (“No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance...”); 42 U.S.C. § 6102 (“[N]o person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.”); 29 U.S.C. § 794 (“No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of her or his disability, be excluded from the participation in, be denied benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance....”).

Section 1557 cross-references these four federal civil rights statutes to provide the classes of those protected by the statute’s non-discrimination provision. The cross-reference to these statutes and the use of similar rights-creating terms manifest Congressional intent to create a private right. See 42 U.S.C. § 18116(a) (“an individual shall not, on the ground prohibited [under the federal civil rights statutes], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under” a variety of programs and activities). Further, 42 U.S.C. § 18116(a) expressly provides that the “enforcement mechanisms provided for and available under

such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.” Such express incorporation of the enforcement mechanisms from those statutes is probative of Congressional intent to provide both a private right and a private remedy for violations of Section 1557.

We therefore find that Congress intended to create a private right of action for alleged violations of Section 1557. Further, Congress’s express incorporation of the enforcement mechanisms from those four federal civil rights statutes, as well as its decision to define the protected classes by reference thereto, manifests an intent to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.<sup>3</sup> We thus consider whether plaintiffs’ complaint alleges sufficient factual matter, accepted as true, to state a violation of Section 1557 given the different statutory schemes for determining whether an individual has been discriminated against on the basis of either a disability or one’s race.

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<sup>3</sup> The district court in Rumble found that Congress “likely intended to create a new right and remedy in a new context without altering existing laws” when it enacted Section 1557 as part of the Affordable Care Act. Rumble, 2015 WL 1197415, \*11 n.6 (citing academic commentary). But we part ways with the district court in Rumble with respect to its interpretation of the precise standards to apply in a Section 1557 claim. We do not find that adopting an interpretation of the statute whereby standards and burdens change based on a plaintiff’s protected class status to be “patently absurd.” Had Congress intended, as the district court in Rumble suggests, “that the same standard and burden of proof apply to a Section 1557 plaintiff, regardless of the plaintiff’s protected class status,” id. at \*12, Congress could have listed the six protected classes without reference to those statutes and expressly provided for a single enforcement mechanism instead of incorporating mechanisms from all four statutes.

We therefore find that while Section 1557 does create a new private right under the Affordable Care Act, the rights of action and corresponding remedies, including all of their limitations, are to be drawn from the four federal civil rights statutes listed in 42 U.S.C. § 18116(a) and applied depending upon the nature of the discrimination alleged by a putative Section 1557 plaintiff.

## 2. Section 1557 And Disability

The Rehabilitation Act adopts the scheme of “remedies, procedures, and rights set forth in Title VI of the Civil Rights Act of 1964...to remedy alleged violations of Section 504 by recipients of federal funding.” A.W. v. Jersey City Pub. Schs., 486 F.3d 791, 803-04 (3d Cir. 2007) (citing 29 U.S.C. § 794a(a)(2)). While Title VI does not have an express right of action, the Supreme Court found an implied right of action and Congress acknowledged that right via amendment to the statute. Id. at 804. Congress has essentially provided a right of action under Section 504 by incorporating Title VI’s remedies, procedures, and rights into the statute. Id. (quoting Three Rivers Ctr. for Indep. Living v. Housing Auth. of Pittsburgh, 382 F.3d 412, 425-26 (3d Cir. 2004)).<sup>4</sup>

To state a claim under Section 504, a plaintiff must demonstrate that she is (1) a qualified individual with a disability (2) who was denied the benefits of a program or activity which receives federal funds (3) on the basis of her disability. Calloway v. Boro of Glassboro Dep’t of Police, 89 F. Supp. 2d 543, 551 (D.N.J. 2000); see also Pl. Resp. at 17 (providing this test as the appropriate one to determine whether there has been a violation of the Affordable Care Act based on the Rehabilitation Act).

We must determine whether the individual plaintiffs are qualified individuals with disabilities who have been denied the benefits of a program or activity which receives federal

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<sup>4</sup> Notwithstanding the incorporation of Title VI into the Rehabilitation Act, the two statutes are not co-extensive. The Supreme Court has “assume[d] without deciding that [Section 504 of the Rehabilitation Act] reaches at least some conduct that has an unjustifiable disparate impact upon the handicapped.” Alexander v. Choate, 469 U.S. 287, 299 (1985) (explaining that “just as there is reason to question whether Congress intended § 504 to reach only intentional discrimination, there is similarly reason to question whether Congress intended § 504 to embrace all claims of disparate-impact discrimination.”). But the Supreme Court has clearly held that § 601 of Title VI prohibits only intentional discrimination, and there is no private right of action to enforce disparate impact regulations promulgated under § 602 of Title VI. Sandoval, 532 U.S. at 280, 293.

funds<sup>5</sup> on the basis of their disabilities. Jane Doe has Hepatitis C and, although her doctor has recommended that she take Sovaldi, her insurance company has told her “that Sovaldi was not an available drug on her formulary.” Amend. Compl. at ¶ 21. Gilead told Jane Doe that she was ineligible for its Patient Assistance Program because she had private insurance. *Id.* Jane Doe alleges that “[b]ut for the high price of Sovaldi, she would be able to afford this much needed drug.” *Id.* John Doe, who also has a Hepatitis C diagnosis and a doctor’s recommendation that he take Sovaldi, was denied coverage for Sovaldi by his insurance company because of its high price. *Id.* at ¶ 22.

Plaintiffs’ claim fails to state a viable cause of action under the Affordable Care Act on the basis of Section 504 of the Rehabilitation Act. Plaintiffs’ claim -- by their own admission -- is that Gilead charges too much for drugs that are quite effective at treating a disease that when left untreated, can cause cirrhosis, liver cancer, and death. *Id.* at ¶ 27. None of the plaintiffs’ theories connecting the high price of Gilead’s drugs to Jane Doe and John Doe’s inability to obtain those drugs states a viable claim under either the Rehabilitation Act or the Affordable Care Act. There are no allegations that Gilead changes the prices of its drugs depending upon whether the potential consumer has Hepatitis C. While obviously only patients with a Hepatitis C diagnosis would try to acquire these drugs in the first place, that type of obvious barrier is an example of the Supreme Court’s concern in Alexander v. Choate about interpreting Section 504 so as to reach all claims of disparate impact discrimination. Plaintiffs’ other theories of discrimination similarly fail to demonstrate that Gilead is excluding individual plaintiffs from purchasing its drugs on the basis of membership in a protected class. The Rehabilitation Act protects individuals from discrimination on the basis of disability. Plaintiffs’ theories of

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<sup>5</sup> Gilead has not contested that it is a covered entity under 42 U.S.C. § 18116.

discrimination are a hodgepodge of complaints about the unfairness of how pharmaceutical companies adjust pricing to accommodate international markets or bulk purchasers that do not implicate discrimination on the basis of disability. As articulated, none of these theories would support a class action claim.

We also note that plaintiffs' allegations do not establish that Jane Doe and John Doe are disabled, but rather only that they have been diagnosed with Hepatitis C. A disability is a physical or mental impairment that substantially limits one or more major life activities. 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102(1)(A). Plaintiffs' statement in Paragraph 132 of the Amended Complaint that all persons with Hepatitis C are disabled within the meaning of Section 504 of the Rehabilitation Act is a legal -- not factual -- assertion, and therefore we may disregard it. There are no allegations in the Amended Complaint that Hepatitis C substantially limits one or more major life activities for either individual plaintiff. See Amend. Compl. at ¶ 21-22 (notably omitting any assertions regarding how Hepatitis C substantially limits one or more of Jane Doe or John Doe's major life activities). Merely having Hepatitis C is not a disability. See Ellis v. Mohenis Servs., Inc., 1998 WL 564478, \*3 (E.D. Pa. Aug. 24, 1998) (Gawthrop, J.) (citing extensive case authority for the proposition that "not every illness is considered a disability, even if the disease is life-threatening or ultimately terminal."). See also Amos v. Correctional Med. Servs., Inc., 2009 WL 1884142, \*6 (D.N.J. June 30, 2009) (Hillman, J.) (explaining that "numerous courts have held that [Hepatitis C] alone", absent a demonstration of how it limits a major life activity is not enough to qualify as a disability); Shultz v. Potter, 142 F. App'x 598, 599-600 (3d Cir. 2005) (non-precedential) (citing with approval to Supreme Court dictum that merely having diabetes -- a chronic illness -- without additional impairment is not a disability). However, because of the fatal defects in plaintiffs' allegations regarding causation -- that is, their

failure to show how Gilead's actions discriminate on the basis of disability -- we will not permit the plaintiffs to again amend their complaint to cure this second pleading defect, as such amendment would be futile with respect to reviving the claim itself.

### 3. Section 1557 And Race

To state a claim under Title VI of the Civil Rights Act, a plaintiff must show that he or she (1) was a member of a protected class, (2) qualified for the benefit or program at issue, (3) suffered an adverse action, and (4) the adverse action occurred under circumstances giving rise to an inference of discrimination. Blunt v. Lower Merion Sch. Dist., 767 F.3d 247, 274-75 (3d Cir. 2014); see also Pl. Resp. at 31 (providing this test). Private rights of action under Title VI itself are available only for allegations of intentional discrimination and not disparate impact. Sandoval, 532 U.S. at 281-82. Plaintiffs suing under Title VI may show intentional discrimination with evidence demonstrating either discriminatory animus or deliberate indifference. Blunt, 767 F.3d at 272 (extending the deliberate indifference standard to claims under Title VI as well as claims under the Rehabilitation Act). Discriminatory animus requires plaintiff establish prejudice, spite, or ill will. S.H. ex rel. Durrell v. Lower Merion Sch. Dist., 729 F.3d 248, 263 (3d Cir. 2013). To establish deliberate indifference, a plaintiff must show that a defendant (1) knew that a harm to a federally protected right was substantially likely and (2) failed to act. Id. at 263.

Plaintiffs' claim fails to state a viable cause of action under the Affordable Care Act on the basis of Title VI. Plaintiffs have not alleged that either of the individual plaintiffs is a member of a protected class on the basis of their race, and plaintiffs have not brought a class action on behalf of racial minorities. See Amend. Compl. at ¶¶ 117-123 (neglecting to mention any allegations of racial discrimination). Plaintiffs have failed to explain how, other than by

virtue of their Hepatitis C diagnosis, they "qualify" for Gilead's patented drugs. Plaintiffs have not defined with precision of what adverse action they complain. While the individual plaintiffs' insurance carriers denied coverage for Gilead's drugs, and Gilead denied Jane Doe the benefits of its Patient Assistance Program, the class action portion of the Amended Complaint seeks to represent a class of persons who have either purchased or paid for Gilead's drugs at an exorbitant price, or been unable to purchase or obtain such drugs.

Even if the plaintiffs had decided on a particular adverse action on which to hang their hat, they fail to allege how these adverse actions occurred under circumstances giving rise to an inference of discrimination. Plaintiffs have not shown Gilead has any prejudice, spite, or ill will toward racial minorities, nor have they shown that Gilead was deliberately indifferent to any substantial likelihood that its actions would violate a federally protected right. Gilead setting high prices for its drugs -- despite knowing that setting high prices would make it difficult for consumers without means or insurance coverage to acquire those drugs -- is not the type of failure to act that Title VI reaches. Hepatitis C may indeed infect different segments of the population at different rates, but plaintiffs' sweeping claim that Gilead is somehow discriminating on the basis of race because Hepatitis C infects a higher proportion of racial minorities and Gilead sells those drugs that treat Hepatitis C at a high price is facially unavailing.

Plaintiffs' Amended Complaint does not state a claim under the Affordable Care Act. Plaintiffs have not pled sufficient factual matter, accepted as true, to sustain a facially plausible claim that Gilead discriminates on either the basis of disability or race. Plaintiffs make no colorable allegations that Gilead is intentionally pricing out members of any protected class on the basis of their protected status.

We will therefore dismiss Count II of the Amended Complaint.

**B. State Law Claims**

Plaintiffs bring Counts IV and V under California Business & Professions Code § 17200, but their Amended Complaint does not state under what law they allege unjust enrichment (Count I) or a breach of the duty of good faith and fair dealing (Count II). Gilead argues that plaintiffs' state law claims fail because they are preempted by federal patent law and without merit. MTD at 12; Def. Reply at 5, 7.

**1. Preemption**

Gilead argues that plaintiffs' state law claims are preempted by federal patent law. MTD at 12. Specifically, Gilead argues that plaintiffs are attempting to use state law to regulate or reduce the price of Gilead's patent-protected drugs Sovaldi and Harvoni. *Id.* at 12; Def. Reply at 5. Plaintiffs respond that while Gilead can use patent law to exclude others from making an infringing product, it "cannot exploit its patent rights by charging exorbitant prices." Pl. Resp. at 38.

Federal Circuit law governs whether federal patent protections preempt a state law claim. Ultra Precision Mfg., Ltd. v. Ford Motor Co., 411 F.3d 1369, 1376 (Fed. Cir. 2005); accord IMCS, Inc. v. D.P. Tech. Corp., 264 F. Supp. 2d 193, 196 n.5 (E.D. Pa. 2003). While state laws regulating unfair competition and trade secret protections may be consistent with federal patent law, states may not "second-guess" Congress when "it is clear how the patent laws" resolve the "tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152, 166 (1989).



For example, in Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), the Federal Circuit held that the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 was preempted by federal patent law because the "underlying determination about the proper balance between innovators' profit and consumer access to medication... is exclusively one for Congress to make." Id. at 1374. The Court observed that "general state power must yield to specific Congressional enactment," and the "present patent system reflects the result of Congress's deliberations...that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." Id. at 1373. Because the Act stood "as an obstacle to the federal patent law's balance of objectives," federal patent law preempted it. Id. at 1374.

Gilead argues that "[g]iven that it is beyond the authority of a legislature to determine that a pharmaceutical price is 'excessive,' it is a fortiori beyond the authority of a court applying a vague state law of general application to achieve the same result." MTD at 13. Plaintiffs respond that they "do not seek to have this Court set prices for Gilead's drugs," but rather anticipate presenting "related pricing data to the Court through expert testimony in order to establish non-discriminatory prices for the Class." Pl. Resp. at 30.

To the extent that plaintiffs seek to use state law to challenge Gilead's exercise of its exclusive patent rights<sup>6</sup> to make pricing decisions, plaintiffs' claims are preempted. Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs. Plaintiffs have attempted to parry Gilead's preemption argument by

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<sup>6</sup> Plaintiffs also believe that Gilead's patents may be invalid on the basis of certain pending lawsuits. Amend. Compl. at ¶ 99. Patents are presumed valid. 35 U.S.C. § 282(a). Pending suits do not change that presumption.

suggesting that Gilead is attempting to “shift the Court’s attention to the damages methodology” and away from the merits of their claims. Pl. Sur-Reply at 2. While the thrust of Gilead’s preemption argument is devastating, we will also discuss the merits of plaintiffs’ claims because federal preemption is intimately related to why plaintiffs’ state law claims are substantively unavailing.

## 2. **Unjust Enrichment**

Plaintiffs’ Amended Complaint does not state under what law they bring their claim in Count I for unjust enrichment. On this basis alone their claim fails, as unjust enrichment “is not a catch-all claim existing within the narrow scope of federal common law.” In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 167 (E.D. Pa. 2009) (citing Woodward Governor Co. v. Curtiss Wright Flight Sys., Inc., 164 F.3d 123, 129-30 (2d Cir. 1999)). After noting plaintiffs’ failure to provide a state statute to support its unjust enrichment claim, Gilead elected to treat the claim as being brought under California law. MTD at 11. Plaintiffs responded by defending their claim under California, Pennsylvania, and Arizona laws. Pl. Resp. at 46.

Plaintiffs cannot amend their Amended Complaint through their pleadings in response to Gilead’s motion to dismiss. See Frederico v. Home Depot, 507 F.3d 188, 201-02 (3d Cir. 2007) (explaining that the court does not consider after-the-fact allegations to determine the sufficiency of a complaint under Rule 12(b)(6) because a complaint may not be amended by the briefs in opposition to a motion to dismiss). But we will consider their arguments in anticipation of their desire to cure this defect through amendment.

California courts appear to be split on whether unjust enrichment is an independent claim or merely an equitable remedy. Baggett v. Hewlett-Packard Co., 582 F. Supp. 2d 1261, 1270 (C.D. Cal. 2007) (quoting Falk v. General Motors Corp., 496 F. Supp. 2d 1088, 1099 (C.D. Cal.

2007)). Compare Melchior v. New Line Prods., Inc., 106 Cal.App. 4th 779, 793 (Cal. Ct. App. 2003) (explaining that unjust enrichment is not a remedy itself, but rather a general principle underlying legal doctrines and remedies related to the failure to pay restitution when equity requires it) with Ghirardo v. Antonioli, 924 P.2d 996, 1003 (Cal. 1996) (explaining the incorporation of the common law concept of unjust enrichment into California's Civil Code in order to prevent a debtor from receiving a windfall when his mortgage was retired in error). We have previously noted that many federal courts have nonetheless found that unjust enrichment is not a stand-alone cause of action but rather just a restitution claim. Premier Payments Online, Inc. v. Payment Sys. Worldwide, 848 F. Supp. 2d 513, 527 (E.D. Pa. 2012).

To the extent that California courts do recognize unjust enrichment as an independent cause of action, its elements are (1) receipt of a benefit, and (2) unjust retention of the benefit at the expense of another. Baggett, 582 F. Supp. 2d at 1270. Plaintiffs argue that "SEPTA and those similarly situated Class Members who have purchased (and, in the future, purchase) Sovaldi and/or Harvoni conferred a benefit upon Gilead by purchasing these Hepatitis C drugs for themselves or their members." Amend. Compl. at ¶ 125. Plaintiffs allege that Gilead's retention of this benefit is unjust because "Gilead's price gouging was not done in good faith and, under the circumstances, was patently unconscionable." Id. at ¶ 127. See also Pl. Resp. at 47 (explaining by reference to the Amended Complaint how Gilead has "appreciated such benefits through the exorbitant profits it generated and retained from Plaintiffs and the Class").

Plaintiffs have failed to state a claim for unjust enrichment under California law. California law contemplates the use of this body of law to correct an unjust transfer of a benefit from one party to another when there has been a mistake or other circumstance rendering the retention of the benefit unjust. See, e.g., First Nationwide Sav. v. Perry, 11 Cal.App. 4th 1657,

1662-63 (Cal. Ct. App. 1992) (citing Restatement (First) of Restitution § 1 (1937) at length). Unjust enrichment, even if it is an independent cause of action under California law, arises from equitable principles and concerns about restitution. Plaintiffs allege no mistake or other circumstance requiring restitution. They merely allege that they wish they did not have to -- or will not in the future have to -- pay Gilead the prices it charges for Sovaldi and Harvoni. Plaintiffs' true complaint is that Gilead is making too much money and that it is unfair for Gilead to reap profits based on its high prices for widely needed drugs. See Amend. Compl. at ¶ 129 ("Gilead's pricing scheme has no end in sight and -- if left unchecked -- has the potential to literally bankrupt segments of the U.S. healthcare system, given the large number of Americans infected with Hepatitis C."). As explained in our discussion of preemption in Part IV.B.1, plaintiffs cannot use unjust enrichment as a vehicle to challenge Gilead's prices for its patented drugs.

Plaintiffs also fail to state a claim for unjust enrichment under either Pennsylvania or Arizona law. Under Pennsylvania law, unjust enrichment is an equitable doctrine providing a remedy when (1) one party confers a benefit on the recipient, (2) the recipient appreciates that benefit, and (3) the recipient accepts and retains the benefit under such circumstances that it would be inequitable or unjust for the recipient to retain the benefit without payment. Allegheny Gen. Hosp. v. Philip Morris, Inc., 228 F.3d 429, 447 (3d Cir. 2000) (summarizing 16 Summary of Pa. Jur. 2d Commercial Law § 2.2 (1994) (in turn citing cases)). To sustain a claim of unjust enrichment a plaintiff "must show that the party against whom recovery is sought either wrongfully secured or passively received a benefit that would be unconscionable for the party to retain without compensating the provider." Hershey Foods Corp. v. Ralph Chapek, Inc., 828 F.2d 989, 999 (3d Cir. 1987) (citing Torchia on Behalf of Torchia v. Torchia, 499 A.2d 581, 582-83

(Pa. Super. Ct. 1985)). There can be no recovery for unjust enrichment or under any other theory of quantum meruit if there is a written agreement or express contract. Hershey Foods Corp., 828 F.2d at 999; Amerisource Bergen Drug Corp. v. Allscripts Healthcare, LLC, 2011 WL 3241356, \*3 (E.D. Pa. July 29, 2011) (Jones II, J.) (explaining that permission to plead alternative theories of recovery under both breach of contract and unjust enrichment “turns on whether there is any question as to the validity of the contract”).

Jane Doe -- a Pennsylvania resident -- has conferred no benefit on Gilead, as she has not purchased the drugs from it. Amend. Compl. at ¶ 21. SEPTA has not alleged that it has conferred any benefit on Gilead beyond paying for Sovaldi and Harvoni pursuant to some written agreement or express contract to do so. Nor are there any allegations about the uncertainty of such a contract. See id. at ¶¶ 143-44 (alleging that Gilead has not carried out its contracts with third party payers in good faith). Protestations that Gilead’s prices are in bad faith -- or solely to inflate its bottom line and therefore unfair -- do not suffice to state a claim for unjust enrichment under Pennsylvania law.

Under Arizona law, unjust enrichment “occurs when one party has and retains money or benefits that in justice and equity belong to another.” Trustmark Ins. Co. v. Bank One, Ariz., N.A., 48 P.3d 485, 491 (Ariz. Ct. App. 2002). To establish a claim of unjust enrichment, a party must show (1) an enrichment, (2) an impoverishment, (3) a connection between the enrichment and the impoverishment, (4) the absence of justification for the enrichment and the impoverishment, and (5) the absence of a legal remedy. Id. John Doe -- an Arizona resident -- has conferred no benefit on Gilead, as he has not purchased its drugs. Amend. Compl. at ¶ 22. While plaintiffs maintain that Gilead “has no justification for its own enrichment,” id. at ¶ 127-28 & Pl. Resp. at 48, the type of justification plaintiffs desire is not the type of justification a

cause of action for unjust enrichment requires. Again, plaintiffs believe that Gilead's prices are too high and that their profit margin is somehow unreasonable or unfair, but that belief does not create a claim for unjust enrichment.

We will therefore dismiss Count I of the Amended Complaint for unjust enrichment.

**3. Breach Of The Implied Duty Of Good Faith And Fair Dealing**

Plaintiffs allege in Count III that Gilead has breached the duty of good faith and fair dealing implied in every contract. Amend. Compl. at ¶ 142. Plaintiffs allege that Gilead has not carried out its contracts in good faith because it “abused its discretion it may have possessed related to those agreements by charging grossly excessive prices for Sovaldi and Harvoni,” demanded excessive prices, and has leveraged “its market power and purported patent rights to successfully coerce” wholesalers into extracting “excessive purchase prices from third-party payers and patients alike.” *Id.* at ¶¶ 143-44. Plaintiffs fail to state under what state law they bring this claim, and on that basis alone Count III fails. In re Wellbutrin XL Antitrust Litig., 260 F.R.D. at 167.

Still, Gilead treated this claim as though plaintiffs brought it under California law. MTD at 20. Plaintiffs suggest that this claim is governed by California, Pennsylvania, and Arizona law. Pl. Resp. at 48 n.38. All three states imply a duty of good faith and fair dealing in every contract. Rawlings v. Apodaca, 726 P.2d 565, 569 (Ariz. 1986) (“The law implies a covenant of good faith and fair dealing in every contract.”); Guz v. Bechtel Nat’l, Inc., 8 P.3d 1089, 1110 (Cal. 2000) (“The covenant of good faith and fair dealing, implied by law in every contract, exists merely to prevent one contracting party from unfairly frustrating the other party’s right to receive the benefits of the agreement actually made.”) (emphasis omitted); Donahue v. Federal Express

Corp., 753 A.2d 238, 242 (Pa. Super. Ct. 2000) (“Every contract in Pennsylvania imposes on each party a duty of good faith and fair dealing in its performance and its enforcement.”).

Both California and Arizona law allow a plaintiff to recover for a breach of the duty of good faith and fair dealing even though there has been no breach of a specific contractual clause. Marsu, B.V. v. Walt Disney Co., 185 F.3d 932, 937-38 (9th Cir. 1999) (applying California law); Wells Fargo Bank v. Arizona Laborers, Teamsters, and Cement Masons Local No. 395 Pension Trust Fund, 38 P.3d 12, 29 (Ariz. 2002) (“a party may nevertheless breach its duty of good faith without actually breaching an express covenant in the contract”). But see McHale v. NuEnergy Group, 2002 WL 321797, \*8 (E.D. Pa. Feb. 27, 2002) (Giles, C.J.) (explaining the court’s finding “that Pennsylvania law would not recognize a claim for breach of covenant of good faith and fair dealing as an independent cause of action separate from the breach of contract claim”).<sup>7</sup>

Plaintiffs’ claim for a breach of the duty of good faith and fair dealing fails whether or not plaintiffs are required to show a separate breach of contract. Where there is a freestanding claim for the breach of these duties -- and therefore the defendant need not have breached a contractual provision to be held liable for failing to perform the duties undertaken in the contract

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<sup>7</sup> Williston on Contracts explains:

Some courts have held that it is not necessary for the defendant to have breached a specific provision of a contract in order to establish a breach of the implied covenant of good faith and fair dealing. . . While some courts allow a plaintiff to recover for breach of the duty of good faith and fair dealing even though there has been no breach of a specific contractual clause, provision or duty, perhaps the majority of courts declined to find a breach of the implied covenant of good faith and fair dealing absent breach of an express term of the contract. Under this view, there can be no independent cause of action brought for breach of the covenant of good faith and fair dealing, rather, the claim must be tied to an alleged breach of a specific contract term, often one that allows for discretion on the part of the party alleged to have violated the duty.

23 Williston on Contracts § 63:22 (4th ed. 2014).

in good faith -- it applies to situations when one of the parties to the contract has discretion as to how it performs its contractual obligations. It does not apply to situations where a party has merely elected to contract with other parties on different terms. Plaintiffs have not alleged that Gilead has discretion within any given contract with the plaintiffs or for which the plaintiffs are intended third party beneficiaries. Rather, they allege that Gilead has discretion with respect to the prices it sets among the different contractual relationships it enters into. See Amend. Compl. at ¶¶ 59-61 (claiming that Gilead’s exclusivity contracts “selectively lower[]” the prices for Sovaldi and Harvoni); id. at ¶ 41 (alleging pricing disparity between the international market and domestic market, as well as among federal agencies in the United States); Pl. Resp. at 50 (“Plaintiffs are not seeking to alter any of the language in the contracts between Gilead and its distributors. Rather, they are seeking to have Gilead carry out the terms of these contracts reasonably and in good faith. Because Gilead claims to have the sole discretion to set whatever price it wants [for its drugs]...the covenant of good faith and fair dealing requires that it exercise this discretion in good faith.”).

Plaintiffs plead no facts to suggest or raise the inference that Gilead has used pricing discretion within its contracts to provide Sovaldi and Harvoni, or that SEPTA or another member of the putative class has been on the receiving end of unfair or bad faith dealing by Gilead pursuant to any discretion Gilead may have in a contract with it or another party. As we explained in our discussion of preemption in Part IV.B.1, plaintiffs simply cannot invoke state law to challenge Gilead’s overall pricing scheme for its patented drugs.

We will therefore dismiss Count III of the Amended Complaint.



#### 4. California Business & Professions Code § 17200

In Counts IV and V, plaintiffs allege that Gilead's business practices constitute unfair competition and are unlawful on the basis of the federal and state laws described in Counts I, II, and III. Amend. Compl. at ¶¶ 149-50. Plaintiffs further allege that Gilead's conduct constitutes unfair business acts and practices because it "does not benefit consumers or competition." *Id.* at ¶¶ 156-57.

Section 17200 defines unfair competition in part as "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. Section 17200 "borrows rules set out in other laws and makes violations of those rules independently actionable." Graham v. Bank of America, N.A., 226 Cal.App. 4th 594, 610 (Cal. Ct. App. 2014) (internal quotations omitted). A violation of another law is a predicate for stating a cause of action under Section 17200's prohibition against unlawful business acts or practices. *Id.* Because plaintiffs have failed to show that any of the complained-of conduct violates any state or federal law, they lack the necessary predicate to state a cause of action under this portion of Section 17200. We will therefore dismiss Count IV of the Amended Complaint.

The standard for determining what business acts or practices are "unfair" under Section 17200 remains unsettled. *Id.* at 612; Yanting Zhang v. Superior Court, 304 P.3d 163, 174 n.9 (Cal. 2013) (collecting cases). Courts have suggested myriad standards for determining whether a practice is unfair.<sup>8</sup> Plaintiffs fail to state a claim under Section 17200 under any of those

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<sup>8</sup> See, e.g., Aleksick v. 7-Eleven, Inc., 205 Cal.App. 4th 1176, 1192 (Cal. Ct. App. 2012) (tethering the action's predicate public policy to a specific constitutional, statutory, or regulatory provision); Ticconi v. Blue Shield of Cal. Life & Health Ins. Co., 160 Cal.App. 4th 528, 539 (Cal. Ct. App. 2008) (balancing the utility of the conduct against the gravity of the harm to the alleged victim while also considering whether the practice offends an established public policy or is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers); Camacho v. Automobile Club of S. Cal., 142 Cal.App. 4th 1394, 1403 (Cal. Ct. App. 2006)

standards. Plaintiffs have not tethered public policy to any specific constitutional, statutory, or regulatory provision that survives a motion to dismiss. Plaintiffs propose several theories of advancing the public weal that they believe oblige Gilead to charge less for its drugs, but plaintiffs fail to tether those theories to any rule. To the extent that Section 17200, under any of the proposed standards, essentially balances competing public policies, Congress has already spoken definitively on that matter and, as discussed in Part IV.B.1, federal patent law preempts the use of state law to reassess or challenge the balance Congress has struck between patent rights and public access. We will therefore dismiss Count V of the Amended Complaint.

#### **5. Motion For Leave To File A Sur-Reply**

Plaintiffs filed a motion for leave to file a sur-reply, which Gilead opposed. We will grant plaintiffs' motion.

#### **6. Motion To Intervene**

Ronald A. Williams moved pro se under Fed. R. Civ. P. 24(a), or in the alternative, Fed. R. Civ. P. 24(b), to intervene in this case. See Motion to Intervene at 1. As we have dismissed the entire Amended Complaint, we will deny Williams's pro se motion to intervene as moot.

### **V. Conclusion**

Plaintiffs style their litigation as “a pointed challenge...to determine whether the law has any role in the heated public debate over a significant public policy issue” involving the affordability of Gilead's patented Hepatitis C treatments. Pl. Resp. at 1. Access to needed

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(considering whether the consumer injury is substantial, the injury is not outweighed by any countervailing benefits to consumers or competition, and the consumers themselves could not reasonably avoid that injury); Progressive West Ins. Co. v. Yolo Cnty. Super. Ct., 135 Cal.App. 4th 263, 285 (Cal. Ct. App. 2005) (examining the impact of the practice or act on the alleged victim and balancing it against the alleged wrongdoer's reasons, justifications, and motives).

pharmaceuticals is uneven, and there is no shortage of discontent with this status quo. But nothing in the Amended Complaint permits redress of plaintiffs' particular grievances in federal court. Our only task here is to determine whether plaintiffs' Amended Complaint contains sufficient factual matter, accepted as true, to state a facially plausible claim for relief under federal or state law. It does not. We will therefore grant Gilead's motion to dismiss.

An appropriate Order follows.

BY THE COURT:

/S/ STEWART DALZELL, J.