No.

In the Supreme Court of the United States

BRISTOL-MYERS SQUIBB CO., SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., FORMERLY KNOWN AS SANOFI-AVENTIS U.S. INC., AND SANOFI-SYNTHELABO LLC, PETITIONERS

v.

CLARE E. CONNORS, IN HER OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF THE STATE OF HAWAII

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, under *Sprint Communications, Inc.* v. *Jacobs*, 571 U.S. 69 (2013), a federal court must consider the specific characteristics of an underlying state-court civil proceeding to determine whether it is sufficiently "akin to a criminal prosecution" to warrant abstention under *Younger* v. *Harris*, 401 U.S. 37 (1971), as eight courts of appeals have held, or whether abstention is warranted whenever "the state proceeding falls within the general class" of state enforcement actions, App.7a, as the Ninth Circuit held in this case.

PARTIES TO THE PROCEEDINGS

Petitioners Bristol-Myers Squibb Company, sanofi-aventis U.S. LLC, Sanofi U.S. Services, Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo LLC, were plaintiffs in the U.S. District Court for the District of Hawaii and appellants in the Ninth Circuit.

Respondent Clare E. Connors was defendant in the U.S. District Court for the District of Hawaii and appellee in the Ninth Circuit.

RULE 29.6 STATEMENT

Petitioner Bristol-Myers Squibb Company has no parent company. No publicly held corporation owns 10% or more of its stock.

Petitioner sanofi-aventis U.S. LLC is a single-member limited liability company, whose sole member is petitioner Sanofi U.S. Services Inc. Sanofi, a French corporation that is publicly traded on the Paris exchange and NASDAQ, indirectly owns 100% of any class of the equity interests of petitioners Sanofi U.S. Services, Inc. and Sanofi-Synthelabo LLC.

RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *Bristol-Myers Squibb Co.* v. *Connors*, No. 20-15515 (9th Cir.), judgment entered on October 29, 2020;
- *Bristol-Myers Squibb Co.* v. *Connors*, No. 20-00010 (D. Haw.), judgment entered on March 16, 2020; and
- *State ex rel. Connors* v. *Bristol-Myers Squibb Co.*, No. 14-1-0708-03 DEO (Haw. 1st Cir. Ct.), judgment entered on February 15, 2021.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases—Continued Page(s)

Cases—Continued Page(s)

Statutes & Rules

Legislative Materials

Other Authorities

Other Authorities—Continued Page(s)

In the Supreme Court of the United States

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Bristol-Myers Squibb Co., sanofi-aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-9a) is reported at 979 F.3d 732. The opinion of the district court (App.11a-25a) is reported at 444 F. Supp. 3d 1231.

JURISDICTION

The court of appeals entered judgment on October 29, 2020. App.1a. The court denied a timely rehearing petition on December 8, 2020. App.10a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATEMENT

This case concerns the scope of abstention under *Younger* v. *Harris*, 401 U.S. 37 (1971), a fundamental and

recurring issue of federal court jurisdiction that has divided the courts of appeals.

In *Sprint Communications Inc.* v. *Jacobs*, 571 U.S. 69 (2013), this Court carved back years of doctrinal expansion. The Court rejected the formalistic approach to abstention that had developed in the lower courts in the decades since *Younger*, under which federal courts abstained simply upon identifying some plausibly important state interest in the state proceeding. *Id.* at 81-82. Instead, the Court made clear that, consistent with federal courts' "virtually unflagging obligation" to exercise the jurisdiction Congress has conferred, *Colo. River Water Conservation Dist.* v. *United States*, 424 U.S. 800, 817 (1976), *Younger* abstention is appropriate *only* for (1) ongoing state criminal prosecutions, (2) "certain 'civil enforcement proceedings'" that are "'akin to a criminal prosecution' in 'important respects,'" and (3) state "civil proceedings involving certain orders * * * uniquely in furtherance of the state courts' ability to perform their judicial functions." *Sprint*, 571 U.S. at 77-79. With respect to the second category of cases, the Court identified criteria to determine whether the proceeding is sufficiently "akin to criminal prosecutions" to warrant abstention.

Such actions, this Court explained, "are characteristically initiated to sanction the federal plaintiff, *i.e.*, the party challenging the state action, for some wrongful act. In cases of this genre, a state actor is routinely a party to the state proceeding and often initiates the action. Investigations are commonly involved, often culminating in the filing of a formal complaint or charges." *Id.* at 79-80 (citations omitted). The presence of these characteristics, which are commonly referred to as the "*Sprint* factors," signifies that a state-court civil proceeding furthers the "legitimate interests" of the State and represents the

exercise of a "state function[]" worthy of "proper respect." *Younger*, 401 U.S. at 44.

The courts of appeals are divided on the scope of the exception for "civil enforcement proceedings." Every other court of appeals to consider the *Sprint* factors has treated them as "essential characteristics" to support abstention. *E.g.*, *Minn. Living Assistance, Inc.* v. *Peterson*, 899 F.3d 548, 553 (8th Cir. 2018); accord *PDX N., Inc.* v. *Comm'r N.J. Dep't of Lab. & Workforce Dev.*, 978 F.3d 871, 885 (3d Cir. 2020). Thus, eight courts of appeals have adopted a detailed, case-specific inquiry of the sort *Sprint* itself employed to determine whether a particular enforcement action sufficiently resembles criminal prosecution to warrant abstention. In contrast, the Ninth Circuit below treated those factors as merely suggestive, rejecting the idea that *Sprint* "prescrib[ed] criteria that are * * * required" for abstention. App.6a. The Ninth Circuit instead reverted to a broad, categorical inquiry, saying that "[w]hat matters for *Younger* abstention is whether the state proceeding falls within the general class of quasi-criminal enforcement actions—not whether the proceeding satisfies specific factual criteria." App.7a. Far from this Court's "narrow" conception under which "[c]ircumstances fitting within the *Younger* doctrine * * * are 'exceptional,'" *Sprint*, 571 U.S. at 73, the Ninth Circuit's rule exempts broad swaths of garden-variety state consumer protection actions from federal jurisdiction, regardless of whether they have any of the characteristics of criminal prosecutions.

The Ninth Circuit's different rule was outcome-determinative here. In the underlying state proceeding, brought under Hawai`i's Unfair or Deceptive Acts or Practices statute ("UDAP"), private counsel suing under a contingency-fee arrangement on behalf of the State of Hawai`i sought nearly a billion dollars in civil penalties against the manufacturers of the antiplatelet drug Plavix

for failing to give a warning that conflicts with the scientific consensus. But the State's sovereign interest and involvement in the case were in name only. It is undisputed that Hawai`i's public health agencies never expressed any concern about Plavix, either before or after the suit was initiated. The State itself conducted no investigation into the drug or petitioners' labeling practices. The State's lawsuit did not even allege harm to any patient in Hawai`i resulting from petitioners' supposed misconduct. Unlike exercises of sovereign authority (such as criminal prosecutions), the case was not conceived, investigated, or litigated by disinterested public prosecutors "guided solely by their sense of public responsibility for the attainment of justice." *Young* v. *U.S. ex rel. Vuitton et Fils S.A.*, 481 U.S. 787, 814 (1987). Instead, private counsel with a financial interest in the matter solicited the State to bring litigation against petitioners on a no-cost, no-risk contingency-fee basis, and the State accepted the offer without any inquiry of its own. In short, nothing about the case has ever resembled a criminal prosecution or an exercise of state sovereign functions deserving of comity or deference. Compare Am. Bar Ass'n, *Standards on Prosecutorial Investigations*, Standard 2.17(a) (although prosecutor "may use information provided by non-governmental sources," "the prosecutor should make an independent evaluation of the information").

Had the Ninth Circuit conducted the fact-specific inquiry mandated by *Sprint* and followed by every other circuit, it would have been compelled to conclude that abstention was not warranted here. Instead, the Ninth Circuit deferred to the state proceeding, which recently ended with an $834 million judgment against petitioners—the largest in state history ($166 million of which represents private counsel's contingency fee, see App.49a). App.69a-126a. The state court copied the

State's proposed findings nearly verbatim, devoting just one paragraph of its 43-page final order to petitioners' substantial arguments that the First Amendment protected their speech about Plavix. App.107a-108a. The court based its record penalty in part on the fact that petitioners argued at trial that the medical consensus is that Plavix is safe and effective regardless of race and genotype—clearly punishing petitioners for their views on a scientific matter. See App.85-86a.

This question is exceptionally important because the Ninth Circuit's broad conception of *Younger* blocks parties with valid federal claims from a federal forum. And this case exemplifies the dangers of such an expansive *Younger* abstention doctrine. The underlying suit is one egregious example of the common and fast-growing practice of profit-seeking private contingency-fee counsel assuming the mantle of governmental authority by offering a state Attorney General a no-risk, no-cost chance at a multimillion dollar judgment. See, *e.g.*, Eric Lipton, *Lawyers Create Big Paydays by Coaxing Attorneys General to Sue*, N.Y. Times (Dec. 18, 2014), https://nyti.ms/3j1YqMh; Erin Mundahl, *Public Power, Private Gain: Private Attorneys Use AG's Office to Target Exxon for Big Payday*, Inside Sources (Mar. 20, 2019), https://bit.ly/3pkxUPw; Lynn Fitch, Att'y Gen., State of Miss., *Consumer Protection*, https://bit.ly/3qn2BoH (last visited Feb. 13, 2021) (see section "Outside Legal Counsel," listing more than 50 active consumer-protection matters litigated on Mississippi's behalf by contingency-fee counsel). While some of these suits may bear the hallmarks of traditional criminal prosecutions, others most certainly do not.

The Ninth Circuit's categorical rule allows *Younger* abstention—reserved for a narrow category of civil enforcement actions "'akin to a criminal prosecution' in 'important respects,'" *Sprint*, 571 U.S. at 79—to be

promiscuously granted to garden-variety civil suits that are masquerading as enforcement actions because States have chosen to "outsourc[e]" litigation "to private lawyers." Adam Liptak, *A Deal for the Public: If You Win, You Lose*, N.Y. Times (July 9, 2007), https://nyti.ms/2MD7fjX. Review is warranted to resolve the conflict on this important question and to correct the Ninth Circuit's manifest departure from this Court's precedent.

A. Consensus Develops That Plavix Is Safe And Effective Regardless Of Race And Genotype

In 1997, the U.S. Food and Drug Administration ("FDA") approved the antiplatelet drug Plavix (clopidogrel), finding it safe and effective in reducing the likelihood of a second heart attack or stroke. App.33a-34a.

In the late 2000s, scientists determined that one of the enzymes involved in the metabolism of Plavix, known as CYP2C19, played a greater role than previously thought. Research suggested that some people—primarily those of Asian or Pacific Islander descent—have a genetic variation that makes them "poor metabolizers" of drugs metabolized through CYP2C19. Some scientists theorized that patients with this variation could be less protected by Plavix and might have higher rates of heart attacks or strokes. App.37a.

The theory has not been shown to be true. Being a poor metabolizer of Plavix does not equate to worse real-world outcomes, *i.e.*, more heart attacks or strokes. The evidence regarding any correlation between the CYP2C19 variation and real-world clinical outcomes is equivocal at best and has not changed medical guidelines and practice. See App.29a.

In 2010, when research about the clinical effect of the CYP2C19 variation was still emerging, the FDA requested that petitioners add a boxed warning to the Plavix label. The warning stated that Plavix is principally

metabolized through CYP2C19, that Plavix has "diminished effectiveness" in CYP2C19 poor metabo-lizers, and that these patients have an increased risk of recurring heart attacks or strokes. App.39a. The label explained that genetic tests were available to identify CYP2C19 poor metabolizers and that doctors may consider alternative treatments for such individuals. The label did not, however, recommend that doctors order such genetic tests or proceed with alternative therapies. App.39a-40a.

This labeling revision was highly controversial in the medical community. Leading cardiologists and medical organizations criticized it as premature and unsupported by clinical data and experience. Cardiologists found no need to use genetic tests or alternative treatments. App.40a-41a. Prescribing guidelines issued by prominent medical organizations, including the American Heart Association and the American College of Cardiology, continued to recommend Plavix as a first-line therapy for patients without regard to race or ethnicity and without requiring routine genetic testing. App.29a.

For their part, State health officials took no action to notify Hawai`i doctors about diminished effectiveness of Plavix in CYP2C19 poor metabolizers. For example, although Hawai`i Medicaid routinely sends updates to advise doctors about medical concerns, it sent no updates about Plavix. The State can also impose restrictions on the use of certain drugs, but did not do so with respect to Plavix. App.45a-46a.

As the scientific understanding about CYP2C19 and Plavix metabolization continued to develop, additional studies cast doubt on the concerns raised by the statements in the boxed warning. App.41a-44a. Some studies, for example, showed that Asians have *better* results on Plavix (i.e., fewer heart attacks or strokes) compared to other ethnic groups, despite their higher prevalence of CYP2C19 poor metabolizers. App.41a-42a.

In 2015, in response to the UDAP lawsuit, several prominent Hawai`i cardiologists published an article recommending *against* genetic testing for patients using Plavix. App.43a.[1]

In September 2016, the FDA removed from the Plavix label the statement that CYP2C19 poor metabolizers have an increased risk of adverse clinical outcomes. App.43a The FDA's removal of this statement reflects the lack of clear evidence or consensus in the medical community to support it. See App.43a-45a.

Today, Plavix continues to be front-line therapy in various cardiac settings. It remains one of the most widely prescribed antiplatelets in the world, without regard to ethnicity or genetic status. App.33a. To this day, Hawai`i Medicaid reimburses Plavix prescriptions irrespective of the patient's race or genotype—and without requiring genetic testing. App.30a. And the World Health Organization lists clopidogrel on its Model List of Essential Medicines. See World Health Org., World Health Organization Model List of Essential Medicines 37 (2019), https://tinyurl.com/1ui3ekjc. At no time during the entire litigation did the State present evidence that a single doctor in Hawai`i did a single genetic test on a single patient. See generally Pl.'s Am. Proposed Findings of Fact, Conclusions of Law, and Order, *State ex rel. Connors* v. *Bristol-Myers Squibb Co.*, No. 14-1-0708-03 DEO (Haw. Cir. Ct. Dec. 22, 2020) [Dkt. No. 1355] (identifying no such evidence).

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[1] Adnan M. Bhopalwala et al., *Routine Screening for CYP2C19 Polymorphisms for Patients Being Treated with Clopidogrel Is Not Recommended*, 74 Haw. J. Med. Pub. & Health 16, 16 (2015), https://bit.ly/3rYwdZV.

B. Private Contingency-Fee Lawyers Persuade The State Of Hawai`i To Hire Them To Pursue Claims Under Hawai`i's UDAP Statute

1. Years after the boxed warning was added to the Plavix label, private plaintiffs' lawyers who had been involved in Plavix-related litigation elsewhere solicited Hawai`i's Attorney General to retain them on a contingency-fee basis to bring claims against petitioners under Hawai`i's UDAP statute. The plaintiffs' lawyers proposed bringing a suit based on the allegation that petitioners should have disclosed before the 2010 labeling revision that Plavix had diminished or no effect for patients with the CYP2C19 genetic variation, particularly those of Asian or Pacific Islander descent. App.48a.

Consistent with the scientific consensus that poor metabolizers—and Asian and Pacific Islander patients in particular—do not have worse clinical outcomes taking Plavix, the State had not seen fit to investigate any health or safety concerns relating to Plavix or the impact of Plavix on the Hawai`i population. App.48a, 57a-58a. Indeed, the State had received no patient, physician, or consumer complaints about Plavix at all. App.48a. Hawai`i Medicaid officials employed during and after the 2010 labeling revision recalled *no* concerns or actions about Plavix. App.57a-58a. At no time had State personnel suggested discontinuing or limiting reimbursement or coverage for Plavix, or excluding the drug from the State's formulary (a list of preferred medications that physicians may prescribe and pharmacists dispense without prior authorization). App.47a.

Nevertheless, without performing any investigation of its own or identifying any harms occurring within the State that health officials believed should be remedied, Hawai`i accepted the private lawyers' proposal and hired them to bring the suit. Under the contingency-fee agreement, the State would not be required to spend a

dime on the litigation, and would be exposed to no risk from any adverse outcome, but would still receive 80 percent of any recovery. App.49a. Private counsel would receive the other 20 percent. App.49a.

2. In March 2014, the private lawyers filed a UDAP suit in the name of the Attorney General in Hawai`i state court, seeking civil penalties, damages, disgorgement of profits, punitive damages, and injunctive relief. Private counsel alone signed the complaint; no attorney from the Attorney General's Office appeared on the signature block. App.49a, 63a. Indeed, throughout the litigation, the State appeared to give free rein to its private contingency-fee counsel, with private lawyers alone signing all significant pleadings or motions, arguing every motion, taking and defending depositions, and trying the case. See App.63a.

The lawsuit centered on two propositions: first, that people of Asian descent are genetically more likely to be poor metabolizers of Plavix, and second, that a large percentage of Hawai`i's population is of Asian descent. See App.49a-50a. Despite no evidence of adverse health outcomes in Hawai`i, the State pursued a statutory penalty of $500 to $10,000 for every unit of Plavix ever sold in Hawai`i, whether prescribed to a person with the genetic variation or not. App.51a; Haw. Rev. Stat. § 480-3.1.

The UDAP action culminated in a four-week bench trial in late 2020. On February 15, 2021, the state court issued findings of fact and conclusions of law, copying nearly verbatim findings drafted by the State's private counsel, and awarding the State the full amount requested by the State's private counsel: more than $834 million in civil penalties—the largest penalty imposed in state history. See App.69a-126a.

C. Proceedings Below

1. Late in 2019, through discovery in the underlying UDAP lawsuit, petitioners learned that Hawai`i health officials had never voiced any concerns about Plavix, and that the State itself had not conducted any investigation into Plavix before authorizing private contingency-fee lawyers to file the UDAP suit in its name. Shortly afterward, on January 7, 2020, petitioners filed a complaint in the U.S. District Court for the District of Hawai`i, alleging that the UDAP suit violates their First Amendment rights by seeking to impose massive penalties on them for not espousing Hawai`i's litigating position on a matter of scientific debate. Petitioners alleged that fact and expert discovery in the UDAP proceeding had shown that the suit serves no legitimate, health-related government interest. App.46a-47a. Petitioners sought preliminary and permanent injunctive relief against the state proceeding.

The State moved to dismiss, invoking Federal Rules of Civil Procedure 12(b)(6) and 12(b)(1). It did not challenge the factual allegations in petitioners' complaint but nevertheless argued that the UDAP suit was a quasi-criminal enforcement action warranting abstention under *Younger* v. *Harris*, 401 U.S. 37 (1971).

2. The district court granted the State's motion to dismiss. The court began by noting that, in *Sprint Communications Inc.* v. *Jacobs*, 571 U.S. 69 (2013), this Court had "summarized its precedent regarding the nature of quasi-criminal civil enforcement actions" that are sufficiently akin to criminal prosecutions to warrant *Younger* abstention. *Sprint*, the district court recognized, had held that "[s]uch enforcement actions are characteristically initiated to sanction the federal plaintiff, *i.e.*, the party challenging the state action, for some wrongful act," that "a state actor is routinely a party to the state proceeding and often initiates the action," and that "[i]n-

vestigations are commonly involved, often culminating in the filing of a formal complaint or charges." App.14a (quoting *Sprint*, 571 U.S. at 79-80).

The court, however, concluded the UDAP action was "quasi-criminal" because private counsel were suing on behalf of "the Attorney General seeking civil penalties, injunctive relief, and damages for unfair and deceptive acts in violation of Hawai`i consumer protection law." App.15a. The district court acknowledged that *only* "an investigation by private counsel preceded the filing of a formal complaint." App.18a. In other words, no state official—*i.e.*, no person pursuing solely the public interest rather than profit—had conducted any investigation before filing the complaint alleging wrongdoing. But the court stated that *Sprint* did not "set a certain standard of pre-filing investigation as the litmus test for abstention," and deemed sufficient private counsel's pre-suit investigation and the civil discovery conducted after the case was filed. App.17a-18a. The court did not question petitioners' uncontested allegations that Hawai`i's public health officials had raised no concerns whatsoever about the distribution of Plavix or any lack of warnings on its packaging.

3. The Ninth Circuit affirmed. App.1a-9a. Like the district court, the Ninth Circuit did not consider whether the UDAP action had any of the attributes of quasi-criminal enforcement actions that this Court described in *Sprint*, believing that such a "case-specific inquiry finds no support in precedent." App.6a.

Instead, relying on precedent predating *Sprint*, the Ninth Circuit asserted that "[w]hat matters for *Younger* abstention is whether the state proceeding falls within the general class of quasi-criminal enforcement actions—not whether the proceeding satisfies specific factual criteria." App.6a-7a (citing *Middlesex Cnty. Ethics Comm.* v. *Garden State Bar Ass'n*, 457 U.S. 423, 432 (1982), and *New*

Orleans Pub. Serv., Inc. v. *Council of New Orleans*, 491 U.S. 350 (1989)). Thus, "[l]ook[ing] to the general class of cases of which this state proceeding is a member," the court held that the fact that the case was "brought under a statute that punishes those who engage in deceptive acts in commerce" and sought civil penalties and punitive damages was on its own sufficient to justify abstention. App.8a. The Ninth Circuit did not even consider the fact that the State—and, in particular, state *health officials*—never expressed any concern about or took any health-related action concerning Plavix, either before or after bringing the UDAP suit. Nor did it matter that "private counsel conducted the bulk of the inves-tigation." App.6a. According to the Ninth Circuit, "to scrutinize the particular facts of a state civil enforcement action would offend the principles of comity" by pre-venting States from "perform[ing] their separate functions in their separate ways." App.8a (citation omitted).

The Ninth Circuit denied a timely petition for rehearing.

REASONS FOR GRANTING THE PETITION

The decision below creates a circuit conflict and disregards the teachings of this Court on the scope of *Younger* abstention in cases involving state civil enforcement proceedings. Until the decision below, every one of the eight courts of appeals to have considered the question had understood this Court's pathmarking decision in *Sprint Communications, Inc.* v. *Jacobs*, 571 U.S. 69 (2013), to require consideration of the features of the specific state civil proceeding at issue to determine whether it was sufficiently "akin to a criminal prosecution" to warrant abstention. The Ninth Circuit charted a different course. It broke with the case-specific inquiry embodied in *Sprint* and adopted by every other court of appeals to have passed on the question. Instead, the Ninth Circuit reverted to a broad, categorical inquiry

focusing on the statute under which the state proceeding was initiated, App.7a-8a, claiming that "principles of comity" preclude any case- or fact-specific analysis, App.7a. Disregarding this Court's "narrow" conception that limits *Younger* abstention to "exceptional circumstances," *Sprint*, 571 U.S. at 77-78 (citation omitted), the Ninth Circuit's rule transforms the doctrine into a sweeping exception that shields entire categories of garden-variety state consumer protection actions from federal jurisdiction.

I. The Decision Below Conflicts With *Sprint*

The Ninth Circuit's approach to determining whether a proceeding is a quasi-criminal enforcement action that warrants abstention is irreconcilable with this Court's past pronouncements. Certiorari is therefore warranted "[b]ecause the Ninth Circuit's holding is in direct conflict with [this Court's] precedents." *Lambert* v. *Wicklund*, 520 U.S. 292, 293 (1997) (per curiam).

In *Sprint*, this Court reaffirmed that the federal courts' "obligation to hear and decide a case" within their jurisdiction "is virtually unflagging." 571 U.S. at 77 (internal quotation marks omitted) (quoting *Colo. River*, 424 U.S. at 817). *Younger* abstention is a closely guarded exception to this rule. Accordingly, *Sprint* placed meaningful limitations on *Younger* abstention to cabin a doctrine that lower courts had applied too broadly. But the Ninth Circuit disregarded those limitations and instead reverted to the categorical approach that *Sprint* expressly repudiated.

1. In its seminal decision in *Younger* v. *Harris*, this Court held that federal courts generally should not interfere with ongoing state criminal prosecutions. 401 U.S. at 41. The Court soon extended *Younger* abstention to certain types of civil actions as well—specifically, civil proceedings "in aid of and closely related to criminal statutes," *Huffman* v. *Pursue, Ltd.*, 420 U.S. 592, 604

(1975), and those that lie "at the core of the administration of a State's judicial system," *Juidice* v. *Vail*, 430 U.S. 327, 335 (1977). Such proceedings, the Court explained, reflect a state's efforts to protect its core sovereign interests, *Huffman*, 420 U.S. at 604-606; *Juidice*, 430 U.S. at 336, and thus the "considerations of comity and federalism" underlying *Younger* favored abstention from these proceedings, too, *Huffman*, 420 U.S. at 606-607; see also *Juidice*, 430 U.S. at 338-339.

Subsequently, the Court in *Middlesex County Ethics Committee* v. *Garden State Bar Ass'n*, 457 U.S. 423 (1982), held that *Younger* abstention is appropriate when (1) there is an "ongoing state judicial proceeding" (2) that "implicate[s] important state interests" and (3) presents an "adequate opportunity * * * to raise constitutional challenges," *id.* at 432. Then, in *New Orleans Public Service, Inc.* v. *Council of New Orleans*, 491 U.S. 350 (1989), this Court reaffirmed that "only exceptional circumstances justify a federal court's refusal to decide a case in deference to the States [on *Younger* abstention grounds]," *id.* at 368. Such circumstances exist in (1) "state criminal prosecutions," (2) "civil enforcement proceedings," and (3) "civil proceedings involving certain orders that are uniquely in furtherance of the state courts' ability to perform their judicial functions." *Ibid.* Over the years, however, lower courts began to apply *Younger* to progressively broader classes of cases, transforming the doctrine from a narrow, comity-based exception into a wide-ranging rule of deference to ongoing state proceedings.[2]

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[2] See, *e.g.*, *Delta Dental Plan of Cal., Inc.* v. *Mendoza*, 139 F.3d 1289 (9th Cir. 1998) (requiring abstention in favor of administrative proceedings initiated by organization that had received a cease-and-desist order from the California Commissioner of Corporations); *Night Clubs, Inc.* v. *City of Fort Smith*, 163 F.3d 475 (8th Cir. 1998)

In *Sprint*, this Court sought to curb that doctrinal expansion. The case arose from a dispute between Sprint, a national telecommunications service provider, and Windstream, an Iowa communications company, about whether Sprint had to pay Windstream access fees for calls Sprint customers placed to Windstream's in-state customers. Sprint filed a complaint against Windstream before the Iowa Utilities Board; Sprint subsequently withdrew the complaint, but the Board, believing the legal question was likely to recur, decided to continue with the proceedings to resolve the issue. 571 U.S. at 73-74.

When the Board decided the question against Sprint, Sprint sought review of the Board's order in Iowa state court, and also filed a federal complaint seeking to enjoin its enforcement. *Id.* at 74. The district court dismissed the federal suit on *Younger* abstention grounds, and the Eighth Circuit affirmed, on the theory that *Middlesex* required abstention "whenever an 'ongoing state judicial proceeding * * * implicates important state interests, and * * * the state proceedings provide an adequate opportunity to raise [federal] challenges." *Id.* at 75 (alterations in original). Because Iowa had an "important state interest in regulating and enforcing its intrastate utility rates," the Eighth Circuit held that abstention was warranted. *Id.* at 76.

This Court disagreed. Emphasizing that "[c]ircumstances fitting within the *Younger* doctrine * * * are 'exceptional,'" the Court rejected the Eighth Circuit's expansive reading of *Middlesex*. *Id.* at 73. The Court explained that, "[d]ivorced from their quasi-criminal context, the three *Middlesex* conditions would extend

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(requiring abstention in favor of city planning commission's review of a business license application); *Kelm* v. *Hyatt*, 44 F.3d 415 (6th Cir. 1995) (abstaining in favor of divorce proceedings); *Brooks-McCollum* v. *Delaware*, 213 F. App'x 92 (3d Cir. 2007) (affirming abstention in favor of proceedings in Delaware Chancery Court).

Younger to virtually all parallel state and federal proceedings, at least where a party could identify a plausibly important state interest." *Id.* at 81. "[T]o guide other federal courts," *id.* at 82, the Court clarified that the *only* "civil enforcement proceedings" that come within *Younger*'s scope are those "'akin to a criminal prosecution' in 'important respects.'" *Id.* at 79 (citation omitted).

The Court identified criteria to help determine whether particular proceedings fit that description. Such enforcement actions, the Court explained, "are characteristically initiated to sanction the federal plaintiffs, *i.e.*, the party challenging the state action, for some wrongful act. In cases of this genre, a state actor is routinely a party to the state proceeding and often initiates the action. Investigations are commonly involved, often culminating in the filing of a formal complaint or charges." *Id.* at 79-80 (citations omitted). The presence of these factors signifies that a state-court civil proceeding furthers the State's "legitimate interests" and represents the exercise of a "state function[]" worthy of "proper respect." *Younger*, 401 U.S. at 44. They reflect that the *State itself* is treating the civil proceeding as akin to a criminal prosecution—as an exercise of the State's inherent sovereign power and authority. See *Puerto Rico* v. *Sanchez Valle*, 136 S. Ct. 1863, 1871 (2016) ("State prosecutions * * * have their most ancient roots in an 'inherent sovereignty' unconnected to, and indeed pre-existing, the U.S. Congress.").

The Court then examined the specific facts of the Board proceeding and concluded it did not warrant abstention. Although the Board had maintained the proceeding through to completion, "[a] private corporation, Sprint, initiated the action. No state authority conducted an investigation into Sprint's activities, and no state actor lodged a formal complaint against Sprint." 571 U.S. at 80. Accordingly, the case was not

"akin to a criminal prosecution," and there was no basis for the federal court to take the extraordinary step of abstaining from the exercise of federal jurisdiction.

2. The decision below renders *Sprint* a dead letter. It resurrects the broad application of *Middlesex* that this Court expressly rejected in *Sprint* itself.

The Ninth Circuit wrote that *Sprint* simply "described the characteristics of quasi-criminal enforcement actions in general terms by noting features that are typically present, not in specific terms by prescribing criteria that are always required." App.6a. Instead, citing *Middlesex*, the Ninth Circuit stated that "when evaluating whether the characteristics of actions entitled to *Younger* abstention are present, the Supreme Court has considered the nature of a State's interest in different classes of proceedings, not its interest in specific cases." App.6a-7a. The Ninth Circuit thus "[l]ook[ed] to the general class of cases of which this state proceeding is a member." App.8a. The court concluded that "[o]n its face, the action fits comfortably within the class of cases described in *Sprint*," merely because it had been brought under a consumer protection statute and sought civil penalties and punitive damages. App.8a.

But this Court in *Sprint* rejected such a categorical inquiry and made clear that the broad *Middlesex* factors on which the Ninth Circuit relied do not displace the need for a detailed assessment of whether the state case is akin to a criminal prosecution. *Sprint*, 571 U.S. at 81-82. The *Sprint* factors serve the critical purpose of identifying civil enforcement proceedings that not only advance state interests, but also embody the State's exercise of sovereign prerogatives in pursuing them. For this reason, *Sprint* specified that a court must consider the *Middlesex* factors only *after* assuring itself that the state proceeding falls into one of the three "exceptional" categories in which abstention is permitted. *Ibid.* The Ninth Circuit's

categorical approach improperly disregarded this Court's narrowing of *Middlesex* and rendered the *Sprint* inquiry superfluous.

3. Had the Ninth Circuit faithfully applied *Sprint*, it could not have deemed the UDAP action to be akin to a criminal prosecution, because the State failed to establish that it exhibited any of the features *Sprint* described.

First, the UDAP action was neither initiated nor prosecuted by a state actor. It is undisputed that private counsel conceived of the case, investigated and formulated the claims, and proposed to represent the State for a hefty contingency fee and at no risk to the State. App.45a-49a. Thereafter, private counsel alone litigated the case, arguing all motions and signing all filings. App.63a. No government attorney even signed the complaint. App.49a. That the State gave private contingency-fee counsel free rein to litigate the action distinguishes this proceeding from a criminal prosecution: In Hawai`i, as elsewhere, the State may use private contingency-fee counsel only in *civil*, not in criminal, proceedings. See Haw. Rev. Stat. § 28-8(b) (authorizing appointment of special deputies on a contingency fee in cases brought pursuant to Haw. Rev. Stat. § 661-10, which does not encompass criminal prosecutions); *Young*, 481 U.S. at 804, 814 (private attorneys hired to prosecute criminal contempt proceedings must be disinterested).

The Ninth Circuit "s[aw] no reason why" the State's decision to delegate its enforcement authority to private contingency-fee counsel should affect the analysis, reasoning that "even though the state proceeding is being litigated by private counsel, it is still an action brought by the State." App.5a. That misses the point. A State may use contingency-fee counsel to bring consumer protection actions in its name. But if the State does so—and particularly if it declines to exercise any meaningful oversight or control of the litigation—it is treating the matter as an

ordinary civil case, not as one "akin to a criminal prosecution in important respects." *Sprint*, 571 U.S. at 79 (quotation marks omitted). And the fact that the State has farmed the litigation out to private contingency-fee counsel, rather than had the work undertaken by a state employee (or at least a private lawyer whose incentives are not shaped by a contingency fee), is highly relevant to whether the matter represents the State's pursuit of *uniquely sovereign* interests deserving of comity. Those who wield sovereign power must "be guided solely by their sense of public responsibility for the attainment of justice," rather than an interest in pursuing profit. *Young*, 481 U.S. at 814.

Second, the State conducted no pre-suit investigation. There is no dispute that the *only* pre-suit investigation was undertaken by financially interested private counsel, without any request, involvement, or supervision by the State. See App.6a. That purported private investigation does not remotely resemble the inquiry that precedes a criminal prosecution. Prosecutors do not bring charges solely based on information gathered by private, *financially interested* persons and hope to unearth evidence of wrongdoing later through civil discovery; they must *first* independently evaluate the available evidence and find probable cause to believe that a crime has been committed. See Am. Bar Ass'n, *Standards on Prosecutorial Investigations*, Standard 2.17(a) (although prosecutor "may use information provided by non-governmental sources," "the prosecutor should make an independent evaluation of the information"); *id.* Standard 2.1(c)(iv) (prosecutors should consider "the motive, interest, bias or other improper factors that may influence those seeking to initiate or cause the initiation of a criminal investigation"). It is inconceivable that the State would initiate criminal proceedings before itself serving a subpoena on those suspected of wrongdoing, reviewing

their records, and interviewing witnesses. Nothing of the sort happened here, making the UDAP lawsuit akin not to a criminal prosecution, but to an ordinary civil tort case.

Finally, the UDAP suit does not seek to sanction wrongful conduct. To be sure, imposing hundreds of millions of dollars in penalties for not parroting Hawai`i's favored position on a disputed scientific issue—that the Plavix label should have warned earlier about genetic variability—would have a punitive *effect* on petitioners. But the question is whether the *purpose* of the proceeding is to address wrongdoing. Nothing suggests that Hawai`i's health authorities have ever perceived anything wrong with Plavix's label. There is no evidence the State received patient or physician complaints about Plavix or that state health officials took any health-related action concerning Plavix, before or after the UDAP suit. App.30a, 48a. Hawai`i *still* reimburses for Plavix prescriptions irrespective of race, ethnicity, or genotype, without any requirement for genetic testing. App.31a. Petitioners' complaint alleges, and no evidence refutes, that the UDAP action seeks to extract money from petitioners, not to punish them for any alleged wrongdoing identified by State officials. App.30a-31a.

In bypassing *Sprint*, the court below worried that "fact-intensive analysis" would intrude on a state's management of civil enforcement proceedings and "offend * * * principles of comity." App. 8a. That concern is unwarranted, as *Sprint* itself shows. The *Sprint* factors involve a straightforward inquiry. They do not require close analysis of "the thoroughness of the State's prefiling investigation," or intrusive second-guessing of "why a state attorney general chose to pursue a particular case." App.8a. At most, a state needs to provide a basic demonstration that its civil enforcement proceeding is a bona fide exercise of its sovereign law-enforcement prerogatives. There is no indication that the many other

courts of appeals that have examined the facts of individual cases as *Sprint* requires have become mired in complicated fact-finding exercises. See *infra* pp. 23-26. Those cases show that, where a State is treating a civil case "akin to a criminal prosecution," it has little difficulty establishing that.

Here, however, the State never even asserted (much less adduced proof) that it, rather than financially interested private lawyers acting before they were hired, undertook any investigation, or that this UDAP suit in fact aims to rectify what Hawai`i health officials deem to be misconduct or harms. That the State continues to reimburse for Plavix irrespective of race or genotype and without requiring genetic testing belies any claim that failure to warn about genetic variability warranted quasi-criminal prosecution. Petitioners are unaware of any case in which a court found a state civil enforcement proceeding was quasi-criminal, where the State itself otherwise acquiesced in the allegedly wrongful conduct. Where, as here, the State has never treated its outsourced UDAP action as akin to a criminal prosecution, there is no reason for a federal court to decline to hear petitioners' constitutional claims.

II. The Decision Below Creates A Clear Circuit Split

Before this case, every court of appeals to have considered whether to abstain in favor of ongoing civil enforcement proceedings post-*Sprint* had conducted the kind of case-specific factual analysis that *Sprint* itself undertook. The First, Second, Third, Sixth, Seventh, Eighth, Tenth and Eleventh Circuits uniformly consider the actual attributes of the underlying state proceeding—whether that very action was initiated to sanction the federal plaintiff, whether a state actor initiated it, and whether the state actor investigated before bringing the action. Only when all these factors are met have those courts been satisfied that the proceeding was in fact "akin

to a criminal prosecution" such that *Younger* abstention was warranted.

1. In *Sirva Relocation, LLC* v. *Richie*, 794 F.3d 185 (2015), the First Circuit closely analyzed the facts to conclude that a Massachusetts Commission Against Discrimination (MCAD) civil enforcement action regarding improper termination of disability benefits was "akin to a criminal prosecution." *Id.* at 195. While the court noted that "the MCAD proceeding is aimed at sanctioning the appellants for wrongful conduct," *id.* at 194, before concluding abstention was appropriate, the court first examined the facts of that case in detail to assure itself that "all the essential hallmarks of a civil enforcement action that is 'more akin to a criminal prosecution'" were present there. *Id.* at 195. The proceeding "satisfie[d] the *Sprint* Court's state-involvement and investigation criteria," *id.* at 193, because *in that case*, a complainant alleging discrim-ination "on the basis of disability" had "filed an MCAD complaint against the appellants; an MCAD investigator sought and obtained documents * * *; the Investigating Commissioner made a finding of probable cause; conciliation failed; and the Investigating Commissioner certified the matter for public hearing—an action which, under applicable regulations, was the functional equivalent of filing a formal complaint." *Id.* at 190, 193 (citation omitted).

The Second Circuit likewise considers the facts of the specific proceeding to determine whether abstention is appropriate. *Helms Realty Corp.* v. *City of New York*, 820 F. App'x 79 (2020), involved a prohibition on short-term housing rentals, which specified that it was to "be enforced by" the city government. See N.Y. Multiple Dwelling Law § 121(4). To determine whether abstention was justified, the Second Circuit went well beyond the general nature of the statute and instead discussed in detail how each *Sprint* factor applied to the facts of that

case. The court emphasized that the "enforcement action was initiated by the City—not a private actor—and it was predicated on a series of investigations undertaken by officers of" City departments. *Id.* at 81. The court recounted the dozens of inspections, summonses, and orders City officials had undertaken before filing the complaint. *Ibid.* "Taken together," the court concluded, "these facts make clear that the civil enforcement proceeding against Helms closely approximated a criminal proceeding: there was an investigation which led to a court action, all brought by the City for the express purpose of deterring and punishing a party for violating the law." *Ibid.*

The Third Circuit takes the same approach. In *PDX North, Inc.* v. *Commissioner New Jersey Department of Labor and Workforce Development*, 978 F.3d 871 (2020), the court stated that the applicability of *Younger* required "consider[ing] three factors described in *Sprint* to determine whether [plaintiffs] are subject to civil enforcement actions that are quasi-criminal in nature." *Id.* at 883 (footnote omitted). "[E]ach factor" supported the conclusion that specific civil proceedings before the New Jersey Office of Administrative Law concerning nonpayment of unemployment compensation taxes were "civil enforcement actions that are quasi-criminal in nature." *Ibid.* "The state administrative action was commenced by New Jersey in its sovereign capacity," and a state agency had "performed multiple audits of PDX and issued multiple formal assessments after the culmination of those audits." *Ibid.* In addition, the proceedings had been brought to sanction the "wrongful" acts of "misclassif[ying] * * * workers and fail[ing] to withhold unemployment compensation taxes." *Id.* at 883-884.

Numerous other courts of appeals have likewise given meticulous consideration to the individual facts of a case, rather than merely considering the *type* of case, to

determine if abstention is warranted. The Sixth Circuit abstained where "[a] state actor, the public University, [wa]s a party to the proceeding and initiated the action," and "the case * * * involved a filed complaint, an investigation" conducted by the state actor, "notice of the charge, and the opportunity to introduce witnesses and evidence." *Doe* v. *Univ. of Ky.*, 860 F.3d 365, 370 (2017). The Eighth Circuit, emphasizing that the *Sprint* factors are "essential characteristics," held *Younger* abstention warranted "[b]ecause all three [*Sprint* factors] are present here." *Minn. Living Assistance, Inc.*, 899 F.3d at 553. The case was akin to a criminal prosecution because the Minnesota Department of Labor and Industry was enforcing the Minnesota Fair Labor Standards Act: "the [Department] conducted the investigation, issued the compliance order, and brought the contested case proceeding against [the federal plaintiff] before the ALJ to enforce Minnesota law," resulting in "double damages" as a "sanction" for wrongful "failure to pay overtime wages." *Id.* at 552-553.

Similarly, the Tenth Circuit held that a state proceeding to revoke an insurance broker's license was "akin to a criminal prosecution" under *Sprint*, noting that the Wyoming Department of Insurance, "a state entity[,] initiated the proceedings to sanction [the plaintiff] for her misconduct," and "took evidence at a contested hearing and concluded there were grounds warranting revocation." *Hunter* v. *Hirsig*, 660 F. App'x 711, 717 (2016). The Eleventh Circuit likewise looked to the facts of a particular disciplinary proceeding by the Florida Judicial Qualifications Commission to determine that abstention was warranted, finding the proceeding "akin to a criminal prosecution because it sought to punish Watson for alleged unethical actions, and it was initiated and prosecuted by a state actor." *Watson* v. *Fla. Jud. Qualifications Comm'n*, 618 F. App'x 487, 490 (2015).

When analysis of the three *Sprint* factors shows the underlying case does not resemble a criminal prosecution, courts have refused to abstain. In *ACRA Turf Club, LLC* v. *Zanzuccki*, 748 F.3d 127 (2014), for example, the Third Circuit held *Younger* abstention was not warranted because the action "was not initiated by the State in its sovereign capacity, a point which is illuminated by the fact that no state actor conducted an investigation or filed any type of formal complaint or charges," *id.* at 138-139, nor was there any "indication that the policies implicated in the state proceeding could have been vindicated through enforcement of a parallel criminal statute," *id.* at 139; accord *Mulholland* v. *Marion Cnty. Election Bd.*, 746 F.3d 811, 816-817 (7th Cir. 2014) (declining to abstain after determining that "at least after *Sprint*," the election board's meeting "*in this case* is not the type of quasi-criminal proceeding that would warrant *Younger* abstention" (emphasis added)).

In short, each of the circuits that has considered whether particular state civil enforcement proceedings are "akin to a criminal prosecution" for purposes of *Younger* abstention has reviewed the actual facts and circumstances of those proceedings—just as this Court did in *Sprint*.

2. The Ninth Circuit's decision below clearly departs from the approach taken by the other circuits. "What matters for *Younger* abstention," the court stated, "is whether the state proceeding falls within the general class of quasi-criminal enforcement actions—not whether the proceeding satisfies specific factual criteria." App.7a.[3]

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[3] The Ninth Circuit stated that it "agree[d] with the First Circuit" in this regard, citing its statement that "courts ordinarily should look to the general class of proceedings in determining whether *Younger* abstention applies." App.7a (quoting *Sirva Relocation*, 794 F.3d at 195). But unlike the Ninth Circuit, the First Circuit actually

Therefore, rather than consider the genesis of the UDAP action and whether it had been preceded by any state investigation or complaints, the court "[l]ook[ed] to the general class of cases of which this state proceeding is a member." App.8a. The court noted that the action was "brought under a statute that punishes those who engage in deceptive acts in commerce, and the State seeks civil penalties and punitive damages to sanction the companies for their allegedly deceptive labeling practices." Thus, according to the Ninth Circuit, "[o]n its face," the UDAP action was a case in which *Younger* abstention was warranted. App.8a. Unlike its sister circuits, which consider the basic facts and characteristics of the underlying state proceeding, the Ninth Circuit refused to "scrutinize the particular facts of a state civil enforcement action," claiming that doing so would "offend the principles of comity at the heart of the *Younger* doctrine" and "would make the application of *Younger* turn on a complex, fact-intensive analysis." App.8a. That choice was outcome-determinative here: Had the Ninth Circuit conducted a case-specific analysis, it would have been compelled to conclude that abstention was not warranted.

In sum, the division of authority over the proper application of the analysis set forth in *Sprint* is stark. Eight circuits conduct a case-specific inquiry to determine whether the underlying action is in fact an exercise of the State's sovereign prerogative and deserving of comity. The Ninth Circuit, by contrast, conducts a categorical approach, asking only "whether the state proceeding falls within the general class of quasi-criminal enforcement

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considered the specific facts of the underlying proceeding to determine whether they satisfied *Sprint*. See *supra* pp. 22-23. The quoted statement addressed a different point, rejecting the appellants' argument that "garden-variety procedural defects" in the underlying proceeding made abstention inappropriate. *Sirva*, 794 F.3d at 195.

actions—not whether the proceeding satisfies specific factual criteria." App.7a. Only this Court can resolve the conflict.

III. The Question Is Exceptionally Important

The proper application of the *Sprint* factors, and thus the scope of *Younger* abstention, is an exceptionally important question. Whether and when federal courts may abstain from hearing challenges to ongoing civil enforcement proceedings in state courts implicates core questions of federalism and comity, as well as the ability—and right—of litigants to invoke the jurisdiction of federal courts to adjudicate federal rights. The importance of the issue is magnified by the steady rise in state and local governments' use of private contingency-fee counsel to bring civil enforcement proceedings against businesses. This case is an ideal vehicle for the Court to decide this question.

1. a. This Court has repeatedly reaffirmed that federal courts have a "virtually unflagging obligation" to decide cases brought before them. *Colo. River*, 424 U.S. 817. "Federal courts * * * have 'no more right to decline the exercise of jurisdiction which is given, than to usurp that which is not given.'" *Sprint*, 571 U.S. at 77 (quoting *Cohens* v. *Virginia*, 19 U.S. (6 Wheat.) 264, 404 (1821)). "The right of a party plaintiff to choose a Federal court where there is a choice cannot be properly denied." *England* v. *La. Bd. of Med. Examiners*, 375 U.S. 411, 415 (1964) (quoting *Willcox* v. *Consol. Gas Co.*, 212 U.S. 19, 40 (1909)).

Thus, although state courts also have the "solemn responsibility" to enforce the federal Constitution, "wherever the Federal courts sit, human rights under the Federal Constitution are always a proper subject for adjudication, and that we have not the right to decline the exercise of that jurisdiction simply because the rights asserted may be adjudicated in some other forum."

Zwickler v. *Koota*, 389 U.S. 241, 248 (1967) (citation omitted). In espousing a broad conception of *Younger* abstention, the Ninth Circuit indicated that it will refrain from exercising meaningful oversight of civil enforcement proceedings in state courts—even when the targets of such enforcement proceedings credibly allege that the proceedings infringe their federal constitutional rights and seek to vindicate those rights in a federal forum. Review is necessary to reaffirm the "primacy of the federal judiciary in deciding questions of federal law," *England*, 375 U.S. at 415-416 (footnote omitted), and the duty of federal courts to decide cases within their jurisdiction, *Sprint*, 571 U.S. at 77.

b. This case demonstrates the peril of an overly broad abstention doctrine. Petitioners argued that the UDAP suit burdened their First Amendment rights by threatening massive penalties for refusing to parrot the State's outside counsel's litigation-derived opinions about Plavix—effectively dictating the content of scientific speech. App.26a-28a, 30a-31a, 55a-60a. As this Court has previously recognized, "in the area of freedom of speech * * * courts must always remain sensitive to any infringement on genuinely serious * * * scientific expression." *Miller* v. *California*, 413 U.S. 15, 22-23 (1973). That is especially so "in the fields of medicine and public health, where information can save lives." *Sorrell* v. *IMS Health Inc.*, 564 U.S. 552, 566 (2011).

But the district court refused to hear the merits of petitioners' First Amendment claims, instead relegating them to state court. That state court denied them fair consideration. Over the course of the state proceeding, the judge decided 14 out of 14 motions against petitioners, and in every instance where it issued findings and conclusions, copied them virtually verbatim from the State's private counsel's proposals. In the final judgment —cut and pasted from the State's pleading to summarize

the court's conclusions after a four-week trial—the court dismissed petitioners' First Amendment claim out-of-hand in a single conclusory paragraph (drafted by the State's lawyers). App.107a-108a. The trial court failed to even cite, let alone analyze, this Court's recent decisions on compelled speech. *E.g.*, *NIFLA* v. *Becerra*, 138 S. Ct. 2361 (2018). And the court—again, copying verbatim language written by private counsel—explicitly penalized petitioners for taking a position *in the UDAP litigation* consistent with the consensus view of scientists that that its labeling of Plavix was appropriate. App.85a-86a. Absent this Court's review, the decision below will have deprived petitioners of the opportunity to bring their First Amendment claim in a federal forum.

2. This case is important for a second reason. The underlying UDAP suit is just one instance of the increasingly widespread practice of state attorneys general outsourcing public enforcement power to private counsel. See Martin H. Redish, *Private Contingent Fee Lawyers and Public Power: Constitutional and Political Implications*, 18 Sup. Ct. Econ. Rev. 77, 81-83 (2010); Douglas R. Richmond, *Turns of the Contingent Fee Key to the Courthouse Door*, 65 Buff. L. Rev. 915, 975-977 (2017).[4] In recent years, private plaintiffs' lawyers have convinced state attorneys general to permit them to litigate cases in the State's name for no up-front cost or commitment of resources, but the possibility of a hefty

[4] See also Richard O. Faulk & John S. Gray, *Alchemy in the Courtroom? The Transmutation of Public Nuisance Litigation*, 2007 Mich. St. L. Rev. 941, 968; Liptak, *supra* (stating that "[i]n courts around the nation * * * state attorneys general have been outsourcing government power to private lawyers," and that "[t]he use of contingent-fee contracts allows governments to avoid the appropriation process and create the illusion that these lawsuits are being pursued at no cost to the taxpayers." (quoting then-Alabama Attorney General William H. Pryor Jr.)).

payout if the litigation succeeds. See Lipton, *supra*. Because the State is "not on the hook for any downside," it would "practically be negligent to let a chance to sue pass by." Walter Olson, *Tort Travesty*, Wall St. J. (May 18, 2007), https://on.wsj.com/371nwpQ. In one study, 36 state attorneys general reported using contingency-fee counsel—a number that does not even include States that used contingency-fee counsel for the tobacco litigation of the 1990s. See Lise T. Spacapan et al., *A Threat to Impartiality: Contingency Fee Plaintiffs' Counsel and the Public Good?*, In-House Def. Q., Winter 2011, at 14.

To be sure, state attorneys general have the prerogative to use contingency-fee counsel to assist them in enforcing state law. Such arrangements have allowed state attorneys general to pursue suits on behalf of their citizens that would otherwise be impossible due to a lack of resources. But a State's use of contingency-fee counsel remains an important consideration in understanding whether a particular civil enforcement proceeding is akin to a criminal prosecution—*i.e.*, whether it represents the State's exercise of its sovereign authority to remedy some act of wrongdoing it has identified.

Often, as here, cases brought by contingency-fee counsel on behalf of State attorneys general "d[o] not originate with a government-identified need to protect consumers. Rather, private attorneys develop the theories of liability, approach state AGs, and then litigate the state's enforcement action in exchange for a contingency fee." Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws*, 65 U. Kan. L. Rev. 209, 217 (2016); see *Merck Sharp & Dohme Corp.* v. *Conway*, 947 F. Supp. 2d 733, 747 (E.D. Ky. 2013) (noting, in a case litigated by private contingency-fee counsel, the state attorney general's "disappointingly casual approach to the details of the [enforcement] proceeding" and a

"disconcerting" "uncertainty and unfamiliarity" with the basis for the State's requested recovery). The fact that private lawyers with a financial interest in litigation developed and initiated the case is an appropriate consideration in determining whether the suit implicates such particularly sovereign prerogatives that federal courts should take the "exceptional" step of declining to exercise jurisdiction. *Sprint*, 571 U.S. at 78; see also Silverman & Wilson, 65 U. Kan. L. Rev. at 223 (contingency fee may give private counsel incentives at odds with public interest); *Contingent Fees and Conflicts of Interest in State AG Enforcement of Federal Law: Hearing Before the Subcomm. on the Constitution of the H. Comm. on the Judiciary*, 112th Cong., 2d. Sess. 48 (2012) (same) (testimony of James R. Copland, Director and Senior Fellow, Center for Legal Policy, Manhattan Institute for Policy Research).

Where private actors can so readily assume "a mantle of legitimacy and state endorsement" for fundamentally private litigation, Olson, *supra*, it is critical that there be safeguards in place to prevent abuse and violations of constitutional rights. At least in cases like this one, where the State itself is not actually treating the case as a quasi-criminal action or seeking to vindicate sovereign interests, *Younger* abstention should not block the defendants from raising constitutional challenges to the conduct of the state proceeding in federal court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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FEBRUARY 2021

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 20-15515

BRISTOL-MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES INC., FKA SANOFI-AVENTIS US INC.; SANOFI-SYNTHELABO LLC,

PLAINTIFFS-APPELLANTS,

v.

CLARE E. CONNORS, IN HER OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF THE STATE OF HAWAII,

DEFENDANT-APPELLEE

Appeal from the United States District Court
for the District of Hawaii
Jill Otake, District Judge, Presiding

(No. 1:20-cv-00010-JAO-RT)

Argued and Submitted September 14, 2020
San Francisco, California

Filed October 29, 2020

Before: Paul J. Watford, Michelle T. Friedland, and Eric D. Miller, Circuit Judges.

Opinion by Judge Miller

[Summary section omitted]

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OPINION

MILLER, Circuit Judge:

After the State of Hawaii sued several pharmaceutical companies in state court for allegedly deceptive drug marketing, the companies turned to federal court, seeking an injunction against the state-court litigation. The federal district court dismissed the suit, concluding that *Younger v. Harris*, 401 U.S. 37 (1971), required it to abstain from exercising jurisdiction. We agree with the district court that the state-court litigation is a quasi-criminal enforcement proceeding and that *Younger* bars a federal court from interfering with such a proceeding. We therefore affirm.

This case involves Plavix, a medication introduced to the market in 1997 and used to help prevent heart attacks and strokes by inhibiting the formation of blood clots. In 2008, researchers reported that some people, particularly those of Asian or Pacific Islander descent, have a genetic variation in an enzyme involved in metabolizing Plavix, which may make the drug less effective. In 2014, the State of Hawaii filed suit in state court against the

pharmaceutical companies that produce Plavix—Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC. *See State ex rel. Louie v. Bristol-Myers Squibb Co.*, No. 14-1-0708-03 (Haw. 1st Cir. Ct. Mar. 19, 2014). The State alleged that the companies had known since 1998 that those with the genetic variation, a group that includes a significant portion of Hawaii's population, experienced worse clinical outcomes and that the companies had intentionally concealed that fact in violation of Hawaii's statute prohibiting unfair or deceptive acts or practices in commerce. *See* Haw. Rev. Stat. § 480-2. Two private law firms conducted the initial investigation of the companies and brought the state-court action on behalf of the State on a contingency-fee basis.

In January 2020, nearly six years after the state-court litigation began, the companies turned to federal court to seek an injunction against the state proceeding, which, they argued, violated their First Amendment rights. The State moved to dismiss under *Younger*, and the district court granted the motion. We review the district court's decision to abstain under *Younger* de novo. *Gilbertson v. Albright*, 381 F.3d 965, 982 n.19 (9th Cir. 2004) (en banc).

The Supreme Court has held that, with just a few exceptions, federal courts have a "virtually unflagging obligation . . . to exercise the jurisdiction given them." *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976). One such exception is the abstention doctrine recognized in *Younger*, in which the Supreme Court relied on "the basic doctrine of equity jurisprudence that courts of equity should not act . . . to restrain a criminal prosecution," reinforced by considerations of comity, to hold that federal courts generally must abstain from enjoining a pending state criminal proceeding. 401 U.S. at 43–44. In later cases, that "concern for

comity and federalism" led the Court to "expand the protection of *Younger* beyond state criminal prosecutions, to civil enforcement proceedings." *New Orleans Pub. Serv., Inc. v. Council of New Orleans* (*NOPSI*), 491 U.S. 350, 367–68 (1989); *see Huffman v. Pursue, Ltd.*, 420 U.S. 592, 604 (1975).

In *Sprint Communications, Inc. v. Jacobs*, 571 U.S. 69 (2013), the Court limited that expansion, holding that *Younger* abstention applies to only three categories of state proceedings: (1) "ongoing state criminal prosecutions"; (2) "certain 'civil enforcement proceedings'"; and (3) "'civil proceedings involving certain orders . . . uniquely in furtherance of the state courts' ability to perform their judicial functions.'" *Id.* at 78 (quoting NOPSI, 491 U.S. at 368). The Court described the type of civil enforcement proceedings to which *Younger* applies as those that are "'akin to a criminal prosecution' in 'important respects.'" *Id.* at 79 (quoting *Huffman*, 420 U.S. at 604). It described some of the characteristics of such proceedings as follows:

> Such enforcement actions are characteristically initiated to sanction the federal plaintiff, i.e., the party challenging the state action, for some wrongful act. In cases of this genre, a state actor is routinely a party to the state proceeding and often initiates the action. Investigations are commonly involved, often culminating in the filing of a formal complaint or charges.

Id. at 79–80 (citations omitted).

In this case, the district court determined that *Younger* abstention was appropriate because the state proceeding at issue is "a civil enforcement action brought by the Attorney General seeking civil penalties, injunctive relief, and damages for unfair and deceptive acts in violation of Hawai'i consumer protection law." The companies challenge that conclusion, arguing that none of the

characteristics of a civil enforcement action that the Court described in *Sprint* is present in this case.

First, the companies argue that the state-court litigation was not, in reality, brought by the State of Hawaii. In the companies' view, the State of Hawaii is not genuinely a party to the state-court litigation because the State's reliance on private counsel means that it is only a nominal plaintiff. But even though the state proceeding is being litigated by private counsel, it is still an action brought by the State— indeed, the first paragraph of the companies' federal complaint recognizes as much, alleging that "[t]he State of Hawai'i has sued the Companies."

An important principle of federalism is that it is up to "the people of the States to determine the qualifications of their government officials." *Gregory v. Ashcroft*, 501 U.S. 452, 463 (1991); *see Taylor v. Beckham*, 178 U.S. 548, 570– 71 (1900) (describing the authority of States "to prescribe the qualifications of their own officers" as "obviously essential to the independence of the States"). Conducting litigation on behalf of a State is a core sovereign function, and the people of each State, through their elected representatives, have the right to decide whether that function should be carried out by full-time government employees or, as here, by outside counsel retained for a particular case. Thus, we have held that the Due Process Clause does not require a State to use state employees, rather than outside counsel, to bring a civil enforcement action. *American Bankers Mgmt. Co. v. Heryford*, 885 F.3d 629, 633–37 (9th Cir. 2018).

We see no reason why the application of *Younger* should turn on the State's choice of lawyers. *Cf. Trump v. Vance*, 941 F.3d 631, 638 n.10 (2d Cir. 2019) (concluding, in a federal suit seeking an injunction against an ongoing investigation of the President in state court, that the *Younger* analysis—specifically, the importance of the federal interests at stake—was "unaltered by the fact that

the President is represented by private counsel"), *aff'd*, 140 S. Ct. 2412 (2020). Here, the state-court case against the companies is one that, under Hawaii law, only the Attorney General or another state official may bring; it is not available to a private party. Haw. Rev. Stat. § 480-3.1. The Attorney General of Hawaii made the decision to bring the action, and the people of Hawaii may hold her accountable for that decision. The action is therefore one "brought by the State in its sovereign capacity." *Trainor v. Hernandez*, 431 U.S. 434, 444 (1977). For purposes of *Younger*, it is an action in which a "state actor is . . . a party." *Sprint*, 571 U.S. at 79.

The companies next argue that we must employ a "rigorous inquiry" to determine "the true character of the underlying action" and whether it constitutes a civil enforcement action as described in *Sprint*. If we do, the companies assert, we will find that the state proceeding fails to qualify because private counsel conducted the bulk of the investigation and because the State's true motive in bringing the case is to make a profit, not to punish wrongdoing. That kind of case-specific inquiry finds no support in precedent.

In *Sprint*, the Supreme Court described the characteristics of quasi-criminal enforcement actions in general terms by noting features that are typically present, not in specific terms by prescribing criteria that are always required. Nothing in the Court's opinion suggests that the characteristics it identified should be treated as a checklist, every element of which must be satisfied based on the specific facts of each individual case. 571 U.S. at 79–80. Instead, the Court used terms such as "characteristically," "routinely," and "commonly" to describe the class of enforcement actions entitled to *Younger* abstention. *Id.* at 79.

And when evaluating whether the characteristics of actions entitled to *Younger* abstention are present, the

Supreme Court has considered the nature of a State's interest in different classes of proceedings, not its interest in specific cases. *See, e.g.*, *Middlesex Cnty. Ethics Comm. v. Garden State Bar Ass'n*, 457 U.S. 423, 432 (1982). In *NOPSI*, the Court explained that "when we inquire into the substantiality of the State's interest in its proceedings we do not look narrowly to its interest in the outcome of the particular case," but instead to "the importance of the generic proceedings to the State." 491 U.S. at 365 (emphasis omitted). So too here. What matters for *Younger* abstention is whether the state proceeding falls within the general class of quasi-criminal enforcement actions—not whether the proceeding satisfies specific factual criteria. For that reason, we agree with the First Circuit that "courts ordinarily should look to the general class of proceedings in determining whether *Younger* abstention applies." *Sirva Relocation, LLC v. Richie*, 794 F.3d 185, 195 (1st Cir. 2015).

The case on which the companies principally rely, *Cook v. Harding*, 879 F.3d 1035 (9th Cir. 2018), does not support the proposition that we must conduct a case-specific inquiry into the nature of the state proceeding. In *Cook*, we concluded that a civil action brought by a private party to enforce a surrogacy agreement is not a proceeding to which *Younger* applies. We explained that a private contract action does not fall within *Sprint*'s two categories of civil cases entitled to abstention: It is neither a civil enforcement proceeding nor a civil proceeding involving a State's interest in enforcing the orders of its courts. *Id.* at 1040–41. While we noted that *Sprint* limited the categories of cases to which *Younger* applies, we did not hold that the Court had required any kind of elevated scrutiny of cases that fell within these categories. *Id.* at 1039. Instead, we considered whether the general class of contract cases constituted civil enforcement proceedings, and we

concluded that they did not. *Id.* at 1040–41. That is consistent with the approach we take today.

Accepting the companies' invitation to scrutinize the particular facts of a state civil enforcement action would offend the principles of comity at the heart of the *Younger* doctrine. The "underlying reason for restraining courts of equity" is the "notion of 'comity,' that is, a proper respect for state functions . . . and a continuance of the belief that the National Government will fare best if the States and their institutions are left free to perform their separate functions in their separate ways." *Younger*, 401 U.S. at 44. A federal- court inquiry into why a state attorney general chose to pursue a particular case, or into the thoroughness of the State's pre-filing investigation, would be entirely at odds with *Younger*'s purpose of leaving state governments "free to perform their separate functions in their separate ways." *Id.* It also would make the application of *Younger* turn on a complex, fact-intensive analysis, in tension with the Supreme Court's admonition that jurisdiction should be governed by "straightforward rules under which [courts] can readily assure themselves of their power to hear a case." *Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010).

Looking to the general class of cases of which this state proceeding is a member, we conclude that *Younger* abstention is appropriate here. The State's action has been brought under a statute that punishes those who engage in deceptive acts in commerce, and the State seeks civil penalties and punitive damages to sanction the companies for their allegedly deceptive labeling practices. On its face, the action fits comfortably within the class of cases described in *Sprint*, and abstention under *Younger* is warranted. *See Williams v. Washington*, 554 F.2d 369, 370 (9th Cir. 1977).

Finally, asserting that the State is "using the threat of sky-high penalties" to force them to "take sides on

matters of scientific dispute," the companies argue that their First Amendment interests are at stake, and that we must therefore subject the state-court proceedings to more intense scrutiny than might otherwise be warranted. But *Younger* abstention routinely applies even when important rights are at stake— indeed, without some claim that a prosecution affects federally protected rights, there would be no basis for federal jurisdiction in the first place, and thus nothing from which to abstain. *See, e.g.*, *Younger*, 401 U.S. at 51; *Huffman*, 420 U.S. at 610; *Middlesex Cnty. Ethics Comm.*, 457 U.S. at 435–37. In *Younger* itself, for example, the plaintiffs argued that the state prosecution had a "chilling effect" on their exercise of First Amendment rights, but the Court declined to apply any heightened scrutiny on that basis. 401 U.S. at 51. Instead, it explained that "the existence of a 'chilling effect,' even in the area of First Amendment rights, has never been considered a sufficient basis, in and of itself, for prohibiting state action." *Id.*

The Supreme Court has stated that *Younger* does not apply in "extraordinary circumstances, where the danger of irreparable loss is both great and immediate." *Younger*, 401 U.S. at 45. That is a narrow exception, principally applying to "cases of proven harassment . . . by state officials in bad faith," and the companies have expressly disclaimed reliance on it. *Perez v. Ledesma*, 401 U.S. 82, 85 (1971); *Brown v. Ahern*, 676 F.3d 899, 901 (9th Cir. 2012). The companies' First Amendment concerns do not bring this case within the scope of that exception, so they have no bearing on the application of *Younger*.

AFFIRMED.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRISTOL-MYERS SQUIBB COMPANY;
ET AL.,
PLAINTIFFS-APPELLANTS,

v.

CLARE E. CONNORS, IN HER OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF THE STATE OF HAWAII,
DEFENDANT-APPELLEE.

No. 20-15515
D.C. No. 1:20-cv-00010-JAO-RT
District of Hawaii, Honolulu

ORDER

Before: WATFORD, FRIEDLAND, and MILLER, Circuit Judges.

The panel has voted to deny the petition for rehearing en banc.

The full court has been advised of appellants' petition for rehearing en banc and no judge of the court has requested a vote on the petition for rehearing en banc. Fed. R. App. P. 35. The petition for rehearing en banc, filed November 12, 2020, is DENIED.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF HAWAII

BRISTOL-MYERS SQUIBB COMPANY, ET AL.

PLAINTIFFS,

VS.

CLARE E. CONNORS,
IN HER OFFICIAL CAPACITY AS THE
ATTORNEY GENERAL OF THE STATE OF HAWAI'I,

DEFENDANT.

Civil No. 20-00010 JAO-RT

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

Plaintiffs Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services, Inc., and Sanofi-Synthelabo LLC ("Plaintiffs") filed a Complaint against Clare E. Connors in her official capacity as the Attorney General of the State of Hawai'i (the "State"). The State moved to dismiss the Complaint, arguing the Court must abstain under *Younger v. Harris*, 401 U.S. 37 (1971). For the reasons stated below, the motion [ECF No. 33] is GRANTED.

I. BACKGROUND

This is the second time Plaintiffs have asked a federal court to intervene in their dispute with the State of Hawai'i playing out in state court. The first time—back in early 2014—Plaintiffs removed the State's[1] lawsuit

[1] The state action was filed by and through the State's then-Attorney General, David Louie.

against them regarding their marketing of Plavix, an anti-platelet prescription drug approved by the Food and Drug Administration ("FDA") to reduce heart attacks, strokes, and vascular death. *See Hawaii, ex rel. Louie v. Bristol-Myers Squibb Co.*, Civ. No. 14-00180 HG-RLP, 2014 WL 3427387, at *2 (D. Haw. July 15, 2014) ("*Bristol-Myers I*").[2]

In *Bristol-Myers I*, the State alleged Plaintiffs engaged in false and deceptive acts in violation of Hawai'i law, for example: (a) misleadingly marketing Plavix as more effective and safer than competitor drugs; (b) marketing Plavix for uses that had not been shown to be safe or effective; (c) failing to disclose that Plavix had a diminished or no effect on 30% of the patient population while marketing higher doses of Plavix to these patients despite considerable health risks; and (d) marketing it as a replacement for aspirin, but ignoring or concealing data finding Plavix only as effective or less effective than aspirin, despite costing one hundred times more. See id. The State sought civil penalties, disgorgement of Plaintiffs' profits, punitive damages, and declaratory and injunctive relief. *See id.* at *2–3. The district court remanded *Bristol-Meyers I* to state court for lack of federal jurisdiction. *See id.* at *3–16.

Now, over five years later, *Bristol-Myers I* is set for trial in May 2020,[3] which prompted Plaintiffs to file this federal action. *See* ECF No. 1 ("Compl.") ¶ 17. Plaintiffs bring a single count against the State's current Attorney General under 42 U.S.C. § 1983 for violating their First Amendment rights. *See id.* ¶¶ 126–38. Plaintiffs' lengthy

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[2] *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (stating court may take judicial notice of matters of public record on motion to dismiss).

[3] Plaintiffs' Complaint indicates trial is scheduled for April 2020, *see* Compl. ¶ 17, but the State's Reply reports the trial date is now May 2020, *see* ECF No. 38 at 6.

Complaint details why the state action is meritless, contends that the State's position in that suit is unsupported by the facts or medical evidence and conflicts with the FDA's position on Plavix, and characterizes the state action as a ploy for private attorneys to profit rather than a suit motivated by any legitimate concern for the health and safety of the State's residents. *See generally* Compl.

In the state action, the State claims that any Plavix label that does not have a warning about the ineffectiveness of the drug among certain populations and the need for genetic testing to identify patients in that population is false or misleading. *See id.* ¶ 3. In this action, Plaintiffs claim that those warnings are unsupported by the evidence, controversial, and amount to improperly compelled speech. *See id.* ¶¶ 88–89, 126–38. Plaintiffs also claim that the prospect of a verdict against them in the state action—incurring large penalties for engaging in their own, truthful speech about Plavix without any proof of harm or malice—impermissibly chills their ability to engage in scientific debates about Plavix and other products, all in violation of their First Amendment rights. *See id.* Plaintiffs therefore ask this Court to declare that the state action violates their First Amendment rights and enjoin the State from proceeding with the state action or proceeding with the action using private counsel. *See id.* at 52–53. The State, in turn, asks the Court to abstain from exercising jurisdiction over this federal action under *Younger*, arguing that because Plaintiffs only seek declaratory and injunctive relief, the appropriate remedy is to dismiss the Complaint rather than stay the case. *See* ECF Nos. 33, 33-1. Plaintiffs oppose the State's motion to dismiss. *See* ECF No. 36.

II. DISCUSSION

"The doctrine of abstention involves a decision by a federal court to decline to exercise jurisdiction over the underlying claims for reasons of comity." *Washington v.*

Los Angeles Cty. Sheriff's Dep't, 833 F.3d 1048, 1058 (9th Cir. 2016) (citations omitted). In civil cases, *Younger* abstention is appropriate where a state court proceeding (1) is ongoing; (2) is a quasi-criminal enforcement action or involves a state's interest in enforcing the orders and judgments of its courts; (3) implicates important state interests; (4) provides an adequate opportunity to raise federal challenges; and (5) would be enjoined by the federal court action or where the federal proceeding would have the practical effect of doing so, and no exception to *Younger* applies. *See Rynearson v. Ferguson*, 903 F.3d 920, 924 (9th Cir. 2018). The parties dispute whether the State has met the second and third prongs, and whether an exception to *Younger* applies.

A. Quasi-Criminal Enforcement Action

The State contends the state action against Plaintiffs is a quasi-criminal enforcement proceeding. In *Sprint Communications, Inc. v. Jacobs*, the Supreme Court summarized its precedent regarding the nature of quasi-criminal civil enforcement actions:

> Such enforcement actions are characteristically initiated to sanction the federal plaintiff, i.e., the party challenging the state action, for some wrongful act. In cases of this genre, a state actor is routinely a party to the state proceeding and often initiates the action. Investigations are commonly involved, often culminating in the filing of a formal complaint or charges.

571 U.S. 69, 79–80 (2013) (citations omitted). The state action here—a civil enforcement action brought by the Attorney General seeking civil penalties, injunctive relief, and damages for unfair and deceptive acts in violation of Hawai'i consumer protection law—thus falls within this category of cases. *See, e.g.*, *Monster Beverage Corp. v. Herrera*, Case No. EDCV 13-00786-VAP (OPx), 2013 WL 12131740, at *4 (C.D. Cal. Dec. 16, 2013), *aff'd*, 650 F. App'x 344 (9th Cir. 2016) (holding *Younger* applied when

City Attorney filed complaint in state court challenging company's unfair, deceptive, and unlawful business practices and seeking an injunction, money damages, and civil penalties because the state suit was fundamentally a law enforcement action designed to protect the public rather than to benefit private parties); *TVI Inc. v. Ferguson*, CASE NO. C17-1845 RSM, 2018 WL 1610220, at *4 (W.D. Wash. Apr. 3, 2018) (concluding Attorney General's state action under Washington consumer protection statute for false and deceptive practices fell "squarely . . . under the category of 'state civil proceedings that are akin to criminal prosecutions,' . . . where *Younger* applie[s]" (citation omitted)); *State Farm Mut. Auto. Ins. Co. v. Metcalf*, 902 F. Supp. 1216, 1218 (D. Haw. 1995) ("Here, the State brought a civil action in order to enforce a state statute prohibiting unfair and deceptive advertising by insurance carriers. Such an action, allowing for fines and penalties for violations of the statute, is akin to a criminal prosecution."); *Backpage.com, LLC v. Hawley*, Case No. 4:17-CV-1951 PLC, 2017 WL 5726868, at *5–7 (E.D. Mo. Nov. 28, 2017) (holding *Younger* applied where Attorney General brought state action to enforce civil investigative demands issued to investigate violations of state consumer protection laws); *Cedar Rapids Cellular Tel., L.P. v. Miller*, 280 F.3d 874, 880–83 (8th Cir. 2002) (affirming *Younger* applied when Attorney General brought state action to enforce consumer protection statutes against corporation and entities related to that corporation filed suit in federal court arguing statutes could not apply to their business).

Plaintiffs nonetheless argue the state action is not a quasi-criminal enforcement action because it seeks to extract revenue rather than sanction them for wrongdoing. *See* ECF No. 36 at 22 (citing *Philip Morris, Inc. v. Blumenthal*, 123 F.3d 103, 106 (2d Cir. 1997)). Aside from *Philip Morris* being non-binding, Plaintiffs' reliance on it is misplaced. In that case, the state brought a subrogation

claim in state court against tobacco companies primarily to recover money it spent treating smoking-related illnesses that was monetary relief that would have been equally recoverable by private parties and had "little to do with eradicating unfair trade practices or anticompetitive business practices." 123 F.3d at 106–07 (citation omitted). Here, the State seeks to recover civil penalties that may *only* be collected in an action brought by the Attorney General or other state official on behalf of the State, s*ee, e.g.*, HRS § 480-3.1,[4] and there can be no dispute that the state action, including these penalties, seeks to eradicate what the State perceives to be the Plaintiffs' unfair and deceptive practices, *see, e.g.*, Compl. ¶ 17 (alleging state court action constitutes impermissible chilling because it seeks to eradicate certain types of conduct).[5] Indeed, Plaintiffs' Complaint repeatedly concedes the State is "seeking to punish them with massive civil penalties for failing to make [certain statements]." Compl. ¶ 1; *see also id.* ¶ 78.

Despite these and similar allegations, Plaintiffs also argue the state action is not a quasi-criminal enforcement proceeding because the State is merely a nominal plaintiff in a suit litigated by private counsel. Plaintiffs cite no authority to support their argument that this impacts the *Younger* analysis where, as here, it is undisputed the state

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[4] "Any person, firm, company, association, or corporation violating any of the provisions of section 480-2 shall be fined a sum of not less than $500 nor more than $10,000 for each violation, which sum shall be collected in a civil action *brought by the attorney general or the director of the office of consumer protection on behalf of the State.*" HRS § 480-3.1 (emphasis added); *see also* HRS § 480-15.1 (same regarding penalties for violating an injunction).

[5] As the State notes, the legislative history of these statutory penalties supports that they were intended to punish wrongdoers in order to deter and aid in more effective enforcement of the consumer protection law than mere injunctive relief could alone. *See* ECF No. 38 at 8–9; ECF Nos. 38-2, 38-3, 38-4.

action is brought by the Attorney General on behalf of the State in its sovereign capacity, and suing under certain Hawai'i statutes that authorize the Attorney General to bring such actions. *See, e.g.*, HRS §§ 480-3.1, 480-15, 661-22; *see also Bristol-Myers I*, 2014 WL 3427387, at *6, *9–10 (noting state court action was filed as a *parens patriae* action, which allows the State to bring an action to protect its quasi-sovereign interest in the health and well-being of its residents and concluding State was the "real party in interest" for jurisdictional purposes, based in part on the fact that the Attorney General or other state official were the only parties legally able to recover the relief sought). That the State is acting through private counsel in the state action thus does not alter the analysis under *Younger*. *See* HRS § 28-8(b) (authorizing Attorney General to appoint and retain private counsel to perform her duties and exercise her powers).

Nor is the Court persuaded by Plaintiffs' argument that *Younger* is inapplicable because there is insufficient evidence of an investigation preceding the filing of a formal complaint. Plaintiffs cite no authority that *Sprint* or Ninth Circuit cases interpreting it set a certain standard of pre-filing investigation as the litmus test for abstention under *Younger*. *See, e.g., Sprint*, 571 U.S. at 79–80 (noting *Younger* did not apply, not only because no state authority conducted an investigation into the federal plaintiff's activities, but also because no state actor lodged a formal complaint and because the state action was initiated by a private company rather than the state in its sovereign capacity); *cf. Cook v. Harding*, 879 F.3d 1035, 1040 (9th Cir. 2018) (summarizing *Moore v. Sims*, 442 U.S. 415 (1979), which Sprint cited to as an example of a quasi-criminal enforcement action, wherein "[p]rior to the parents' [federal] action, the state had initiated proceedings alleging child abuse, *leading to* an investigation and subsequent custody hearings" (emphasis added) (citation omitted)).

Regardless, as the State notes, an investigation by private counsel preceded the filing of a formal complaint, which has also been supplemented by six years of civil discovery. *See* ECF No. 38 at 11; *see also* ECF No. 6-11 (operative pleading in state court containing allegations that reflect investigation or inquiry into their factual bases); *cf.* Haw. R. Civ. P. 11(b) (filing a pleading constitutes certification that, to the best of the attorney's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, it is not presented for an improper purpose and all allegations and factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery). And in their Complaint, Plaintiffs allege the state action was the result of an investigation or inquiry by the Attorney General. *See* Compl. ¶ 66; *see also id.* ¶ 135 (alleging State did not conduct a "*serious* investigation" into Plavix (emphasis added)). Plaintiffs' argument that abstaining here would make a "mockery" of *Younger* is therefore unconvincing. *See* ECF No. 36 at 25.[6]

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[6] Plaintiffs take this "mockery" language from *New Orleans Public Service, Inc. v. Council of the City of New Orleans*, 491 U.S. 350, 368 (1989) ("*NOPSI*"), which noted that extending *Younger* to *any* state judicial proceeding *solely* because it is reviewing legislative or executive action would make a "mockery" of the rule that abstention applies in narrow circumstances. *See also Gilbertson v. Albright*, 381 F.3d 965, 974, 977 (9th Cir. 2004) (en banc) (describing *NOPSI* as "[m]aking clear that the mere existence of parallel proceedings is not sufficient but that the class of case matters" and noting that "a state proceeding which is nonjudicial or involves *the interpretation of completed legislative or executive action*" would not fit into that class of cases (emphasis added)). Plaintiffs have not characterized the state action here as judicial review or interpretation of a completed legislative or executive action. *See, e.g.*, *Nader v. Cronin*, Civil No. 04-00611 JMS/LEK, 2008 WL 336746, at *9 (D. Haw. Feb. 7, 2008), *aff'd*, 620 F.3d 1214 (9th Cir. 2010) (holding *Younger* inapplicable, noting there was *no* civil enforcement action brought by

The other cases Plaintiffs cite that concluded an action was not a quasi- criminal enforcement proceeding are similarly inapplicable here. *See Cook*, 879 F.3d at 1040 (holding *Younger* did not apply when state action involved contractual dispute between private parties); *Rynearson*, 903 F.3d at 925–26 (holding *Younger* did not apply to protection order proceeding under Washington law that was initiated by a private party, required no involvement from any state actor, and when the purpose was to protect the petitioner rather than punish the respondent); *ReadyLink Healthcare, Inc. v. State Comp. Ins. Fund*, 754 F.3d 754, 760 (9th Cir. 2014) (holding *Younger* did not apply when state action involved insurance dispute between private parties where one requested agency review and then judicial review). Plainly, the state action here is the type of proceeding to which *Younger* applies.

B. Implicates Important State Interests

Plaintiffs also contend *Younger* is inappropriate because the state action does not implicate important state interests. To the contrary, courts have repeatedly held that state actions to enforce consumer protection laws against unfair and deceptive business practices are sufficiently important for *Younger* purposes. *See, e.g., Commc'ns Telesystems Int'l v. Cal. Pub. Util. Comm'n*, 196 F.3d 1011, 1017 (9th Cir. 1999) (recognizing protection of consumers from unfair business practices as an important state interest in affirming abstention under *Younger*); *Williams v. Washington*, 554 F.2d 369, 370 (9th Cir. 1977) ("Because of Washington's governmental interest in enforcing its consumer protection act, federal abstention is required[.]"); *Cedar Rapids Cellular*, 280 F.3d

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the state, and characterizing the state court action as judicial review of completed executive action when plaintiffs brought parallel proceedings in state and federal court challenging the State's refusal to put them on an election ballot based on a determination they failed to obtain the requisite number of signatures).

at 879–80 (noting Iowa's interest in enforcing consumer protection statutes); *State Farm*, 902 F. Supp. at 1218 (noting Hawaii's strong interest in protecting consumers from unfair and deceptive trade practices by insurance carriers); *In re Standard & Poor's Rating Agency Litig.*, 23 F. Supp. 3d 378, 410 (S.D.N.Y. 2014) (collecting cases). This importance is underscored when health and safety are implicated. *See, e.g.*, *Meredith v. Oregon*, 321 F.3d 807, 818 (9th Cir. 2003) (noting that protecting residents' safety is an important state interest); *Fedex Ground Package Sys., Inc. v. Ingenito*, 86 F. Supp. 3d 1121, 1127 (E.D. Cal. 2015) (noting power to protect health and welfare of the public is primarily and historically a matter of local concern over which states have great latitude); *Monster Beverage*, 2013 WL 12131740, at *7 (noting state's interest in protecting the health and safety of its residents); *cf. Bristol-Myers I*, 2014 WL 3427387, at *9 ("The State has a specific, concrete interest in protecting its citizens and economy from false, unfair and deceptive practices related to prescription drugs." (citation omitted)).

Plaintiffs provide no support for their arguments that their affirmative defenses—under the safe harbor provision of HRS § 481A-5(a)(1) based on the FDA's approval of a certain label, or based on First Amendment concerns—somehow negate the State's interest for purposes of *Younger*. Indeed, the inquiry into the substantiality of the State's interest in its proceedings must not focus narrowly on its interest in the *outcome* of a particular case—prohibiting Plaintiffs from marketing Plavix with certain labels—but instead on the importance of the generic proceedings to the State, i.e., its interest in enforcing its consumer protection laws. *See NOPSI*, 491 U.S. at 365);[7]

[7] Indeed, in *NOPSI*, the Supreme Court held that "the mere assertion of a substantial constitutional challenge to state action will not alone compel the exercise of federal jurisdiction." 491 U.S. at 365

State Farm, 902 F. Supp. at 1218 (rejecting argument that *Younger* was inapplicable because state proceeding suppressed speech, which addressed the merits of the particular case, and focusing instead on State's general interest in protecting consumers from unfair and deceptive practices by insurance carriers);[8] *see also TVI*, 2018 WL 1610220, at *4 (rejecting argument that Attorney General's consumer protection action in state court did not implicate important state interests because it violated First Amendment rights, noting that such federal challenges could be raised in state court).[9] And, as discussed above,

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(citation omitted). The Court left open the possibility that *Younger* might *not* require abstention where the federal plaintiff makes a facially conclusive claim of federal *preemption*; however, a federal preemption claim is not facially conclusive if its determination requires further factual inquiry. *See id.* at 367. When faced with a similar argument that the FDA's interest in safety and labeling negated a state's interest, one district court concluded it need not engage in weighing federal versus state interests under this *Younger* prong unless a party raises a formal preemption challenge (which Plaintiffs have not done here). *See Monster Beverage*, 2013 WL 12131740, at *6 n.6 ("The Court is not persuaded that it needs to engage in a weighing of federal versus state interests, *aside from the preemption question*, in deciding whether an important state interest exists for the purposes of Younger abstention." (emphasis added)). Regardless, Plaintiffs' claim that they benefit from a safe harbor based on FDA approval requires further factual inquiry and legal analysis, and thus would not defeat *Younger* abstention even if considered.

[8] Plaintiffs argue *State Farm* is no longer relevant after *Sprint*. *See* ECF No. 36 at 28. But *State Farm* mirrors *NOPSI* with regard to the "important state interest" prong, and Plaintiffs agreed at the hearing that *NOPSI* articulates the relevant standard for that prong.

[9] *TVI also* rejected a federal plaintiff's similar attempt to avoid *Younger* by arguing the state court action *lacked merit*, noting that the federal plaintiff's claims "either act as a defense to the Attorney General's state claims, *i.e.* stating the [Attorney General] cannot seek the relief it is requesting, or serve to challenge the facts as

Plaintiffs' attempt to distinguish analogous cases based on more robust pre-filing investigations or investigations involving certain types of state actors lacks merit.

C. Exception to *Younger*

Finally, Plaintiffs argue that even if the *Younger* factors have been met, abstention is not appropriate because of the "extraordinary circumstances" exception to *Younger*.[10] Plaintiffs argue that their First Amendment claim constitutes an extraordinary circumstance because they face irreparable harm in the form of the state action chilling their speech. But the state court can resolve these First Amendment concerns and provide remedies as appropriate. *See Middlesex Cty. Ethics Comm. v. Garden State Bar Ass'n*, 457 U.S. 423, 431 (1982) ("Minimal respect for the state processes, of course, precludes any *presumption* that the state courts will not safeguard federal constitutional rights.").

Indeed, none of the binding First Amendment cases Plaintiffs cite pertain to abstention under *Younger*—where a party like Plaintiffs seeks the extraordinary remedy of a federal court enjoining a state proceeding (here, a state proceeding that has been ongoing for six years and is on the eve of trial). *See* ECF No. 36 at 29–32. Instead, Plaintiffs rely on cases addressing *Pullman*[11] abstention, under which a federal court refrains from addressing the constitutionality of a state statute because a state court ruling on a state law issue may moot or narrow the

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presented by the [Attorney General], *i.e.* the factual basis for its claims is unfounded" and that, either way, *Younger* applied because the court was "being asked to rule on facts and legal claims that would have a dispositive effect on the state court action." 2018 WL 1610220, at *4.

[10] Although Plaintiffs' brief makes a cursory reference to "bad faith," *see* ECF No. 36 at 30, Plaintiffs conceded at the hearing they do not argue the "bad faith" exception.

[11] *R.R. Comm'n of Tex. v. Pullman Co.*, 312 U.S. 496 (1941).

constitutional question. It is appropriate to abstain under *Pullman* only if: (1) the case touches on a sensitive area of social policy upon which the federal courts ought not enter unless no alternative to its adjudication is open, (2) constitutional adjudication plainly can be avoided if a definite ruling on the state issue would terminate the controversy, and (3) the proper resolution of the possible determinative issue of state law is uncertain. *See Porter v. Jones*, 319 F.3d 483, 492 (9th Cir. 2003). As the Ninth Circuit has explained, *Pullman* abstention is rarely appropriate in First Amendment cases because the first *Pullman* factor will almost never be present, as free speech guarantees are always an area of particular federal concern, and the delay in awaiting a state court ruling would chill those rights the plaintiff seeks to protect. *See id.*. The Court is not convinced that the same concerns exist here under *Younger*, where the state proceeding has been ongoing for years without a request for an injunction, and trial is imminent.

Nor is the Court persuaded by Plaintiffs' argument that an extraordinary circumstance exists here because proceeding with the state action might eliminate the opportunity to address their federal claim. Plaintiffs offer no argument—nor could they—that they are unable to raise their First Amendment challenge in the state court proceeding (and, as the State notes, Plaintiffs have raised this challenge in state court). *See* ECF No. 33-1 at 13–14. Nor have Plaintiffs articulated why full vindication of their rights necessarily requires intervention before trial—particularly when they waited six years to vindicate these rights. *See* ECF No. 36 at 33 (citing *Arevalo v. Hennessy*, 882 F.3d 763, 766 (9th Cir. 2018), which held *Younger* inapplicable because of a lack of interference with state proceedings, and alternatively applied the extraordinary circumstances exception to a pretrial detainee challenging his incarceration for six months without a constitutionally

adequate bond hearing); *cf. Moore*, 442 U.S. at 433 (noting that, although the "extraordinary circumstances" exception defies an easy definition, "such circumstances must be 'extraordinary' in the sense of creating an *extraordinarily pressing need for immediate federal equitable relief*" (emphasis added) (citation omitted)); *see also* Compl. ¶¶ 113, 116 (alleging harm every day the state court suit is pending and that the "chill is intensified" given Plaintiffs' liability will be decided by a lay jury or judge without expertise). The Court is thus unconvinced that extraordinary circumstances exist that take this action outside of *Younger*. *See Monster Beverage*, 2013 WL 12131740, at *9 (abstaining under *Younger* even though federal plaintiff alleged that City Attorney's investigation into and attempts to regulate it violated its First Amendment rights), *aff'd* 650 F. App'x at 346 (noting state court litigation provided federal plaintiff adequate opportunity to raise federal questions); *see also Corren v. Sorrell*, 151 F. Supp. 3d 479, 488 (D. Vt. 2015) (rejecting argument that First Amendment interests brought case within the "extraordinary circumstances" exception where these issues could be timely and adequately addressed in state court).

III. CONCLUSION

For the foregoing reasons, the Court concludes that abstaining under *Younger* is necessary. Plaintiffs do not respond to the State's argument that, because the federal action seeks only injunctive and declaratory relief, the appropriate remedy is dismissal rather than a stay. ECF No. 33-1 at 28 (citing *Gilbertson*, 381 F.3d 965). The Court therefore **DISMISSES** the Complaint without leave to amend. This dismissal is, however, without prejudice and nothing in this ruling shall prevent Plaintiffs from raising any constitutional challenge or claim in the ongoing state action.

IT IS SO ORDERED.

DATED: Honolulu, Hawai'i, March 16, 2020.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., and SANOFI-SYNTHELABO INC., Plaintiffs, vs. CLARE E. CONNORS, in her official capacity as the ATTORNEY GENERAL OF THE STATE OF Hawai`i, Defendant.	Civil Action No. **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Bristol-Myers Squibb Company ("BMS") and Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC (collectively "Sanofi" and, with BMS, the "Companies") allege as follows:

INTRODUCTION

1. The State of Hawai`i has sued the Companies, seeking to punish them with massive civil penalties for failing to make the controversial, untrue statements that

their life-saving cardiovascular drug, Plavix (clopidogrel), is less effective for Asian and Pacific Islander patients and that doctors should genetically test those patients before prescribing the drug. It is not just the Companies who believe these statements to be untrue; the scientific consensus strongly supports the Companies.

2. Hawai`i's effort to compel the Companies to parrot the State's contrary position violates the First Amendment. To justify an effort to compel protected speech, the State must satisfy heightened scrutiny by showing that the intrusion on free speech is narrowly tailored to serve a compelling state interest, or, at minimum, that it directly advances an important government interest and is no more extensive than necessary to do so. Here, what the Companies choose to say—or *not* to say—about their product is protected speech. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 576 (2011). The compelled speech at issue, moreover, is not "purely factual and uncontroversial." *NIFLA v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985)). See generally *NIFLA*, 138 S. Ct. 2361 (bolstering and clarifying protections against compelled speech). To the contrary, the State's lawsuit effectively compels the Companies to espouse scientific conclusions with which they steadfastly disagree. And in seeking to compel and punish this speech in an area of scientific controversy, the State discriminates based on the speaker (targeting only pharmaceutical companies) as well as the content of the speech and the viewpoint expressed (that Plavix is not safe and effective for patients of all races). *See, e.g.*, *Sorrell*, 564 U.S. at 562-66. Heightened scrutiny therefore applies, and the State cannot meet its burden under that standard.

3. Hawai`i's lawsuit to extract civil penalties from the Companies is plainly an effort to compel speech on issues of significant scientific controversy. Indeed, it goes

further and attempts to compel statements that the Companies believed are scientifically baseless. The thrust of Hawai`i's claim is that the Companies should have warned that Plavix is not effective or is less effective in patients with particular genetic traits (so-called "poor metabolizers"), that Asians are disproportionately poor metabolizers, and that genetic tests should be used to identify patients who have those traits. In 2010, the U.S. Food and Drug Administration ("FDA") required language describing the hypothesis to be added to the Plavix label. Yet in this case, the State claims that this hypothesis should have been added to the label more than a decade earlier, when there was absolutely no evidence linking poor metabolism to poor clinical outcomes. It asserts that every Plavix label without that warning from 1998 until 2010 was false or misleading, and therefore claims the Companies owe the State a civil penalty of $10,000 for every Plavix prescription made in the State of Hawai`i during that time under its Unfair or Deceptive Acts or Practices statute ("UDAP"). These civil penalties manifestly seek to coerce the Companies to parrot the State's view, and therefore constitute state action to compel speech.

4. The State's expert reports make clear that it also faults the Companies for not making statements far broader and more categorical than what is in the FDA's label—that the drug is nothing more than a placebo for poor metabolizers and that Asians should be genetically tested before being given Plavix.

5. The State has made inflammatory, racially-targeted claims regarding hazards to patients. The State says in its UDAP complaint that "Plavix has diminished or no effect on approximately 30% of the patient population," "that those patients for whom Plavix would not work could be identified through a simple genetic test," that "[f]or such patients, Plavix does not prevent heart attacks, strokes, or vascular death," and that it "presents a

considerable risk of gastrointestinal bleeding and other complications." Second Am. Compl. ¶ 2, *State ex. rel. Connors v. Bristol-Myers Squibb Co.*, No. 14-1-0708-03 DEO (Haw. Cir. Ct. Dec. 4, 2018). The Hawai`i Attorney General asserted at a press conference on the filing of the enforcement action that, "[f]or a very significant portion of our population, the drug had no effect," *State Sues Maker of Plavix for Misleading Marketing in Hawaii*, Hawaii News Now, https://www.hawaiinewsnow.com/story/25021441/hawaii-attorney-general-sues-drug-manufacturers/ (last updated July 9, 2014), and later told the press that Plavix was "essentially a placebo," Rafi Letzter, *White-Dominated Medical Studies Put U.S. Minorities at Risk*, Pop. Sci. (Sept. 17, 2014), https://www.popsci.com/article/science/white-dominated-medical-studies-put-us-minorities-risk. The State has accused the Companies of a "decades-long scheme to suppress" Plavix's supposed "dirty little secret: it had a diminished effect on Asians, including patients of East Asian and Pacific Island descent." Opposition to Defendant Sanofi's Motion To Dismiss for Lack of Personal Jurisdiction, State ex rel. Connors v. Bristol-Myers Squibb Co., No. 14-1-0708-03 DEO (Haw. 1st Cir. Ct. Apr. 25, 2019).

6. The State's expert witnesses have echoed these assertions in their reports, served on December 29, 2019. For example, Dr. Paul Gurbel claims that the Companies engaged in "active suppression and deliberate neglect of the data" regarding alleged genetic variability of response to Plavix, and that "the administration of a drug that was effectively a placebo caused an unnecessary financial cost to society." Expert Report of Paul Gurbel, MD (Dec. 29, 2019), *State ex rel. Connors v. Bristol-Myers Squibb Co.* No. 14-1-0708-03 DEO (Haw. Cir. Ct.), at p. 52 ("Gurbel Expert Report").

7. None of these statements by the State, its officials, or its experts is correct.

8. When FDA added the hypothesis to the label in 2010 and suggested that genetic testing be considered, it was controversial. Prominent members of the cardiology community criticized FDA's actions as premature. And today, the medical consensus, as reflected in all of the leading treatment guidelines issued by organizations such as the American College of Cardiology and the American Heart Association, continues to endorse Plavix as first-line therapy, has never recommended prescribing Plavix based on race or ethnicity, and continues to reject routine genetic testing.

9. In fact, a growing body of evidence shows that Plavix works as well if not better for patients of Asian descent than other antiplatelet medications. Plavix remains the prescription antiplatelet of choice in Asian countries. And in 2016, FDA removed the language from the label suggesting that poor metabolizers of Plavix have worse clinical outcomes.[1]

10. After the State filed its lawsuit in 2014, cardiologists at Hawai`i's largest hospital system were so concerned about the State's theory that they published an article rejecting the premise of the UDAP lawsuit and urging doctors to prescribe antiplatelets based on clinical efficacy and not genetics.

11. The warning that the State demands therefore is not "factual and uncontroversial" speech. That warning espouses, at the very best, a minority view in the scientific community even today. And it was entirely bereft of support in 1998, when the State asserts the Companies should have first made the warning. To compel the Companies to

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[1] *Compare* March 2010 Plavix label, at 1, 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020839s042lbl.pdf, *with* September 2016 Plavix label, at 1, 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020839s062s064lbl.pdf.

take a position in a scientific debate that they believe unsupported by the evidence, the State must (among other things) show an important government interest.

12. The State cannot meet that burden. Fact and expert discovery powerfully corroborates that Hawai`i's UDAP lawsuit serves *no* legitimate, health-related government interest. Despite the State's lawsuit, all of the State's Medicaid providers continue to reimburse for Plavix without regard to race or ethnicity and do not require genetic testing prior to prescribing the drug.

13. What is more, it appears that the State's responsible health officials never voiced any concern whatsoever about Plavix's effect in patients who have particular genetic traits or racial or ethnic backgrounds. When State Medicaid officials were deposed in August 2019, none recalled any concerns about Plavix. The former medical director of the State Medicaid program could remember no discussion of issues with Plavix. The current medical director of the State Medicaid program, who has held that position since 2011, likewise remembered no discussion of issues with Plavix, and could not identify any steps he took to advise doctors or patients about purported concerns regarding Plavix.

14. Similarly, the State's expert reports include no cardiologist from Hawai`i, no cardiologist from any Asian country, no evidence that any doctor in Hawai`i ever voiced concern about the genetic issue or changed their prescribing behavior in any way, and no evidence that anyone in Hawai`i was actually harmed.

15. Instead of supporting a genuine state interest, this suit appears to have been generated to achieve private financial gain. It was devised and marketed by private contingency-fee lawyers who are litigating it at no cost to the State. The State's main expert is participating as a qui tam relator in a suit regarding genetic variability of response to Plavix in New Jersey federal court—a

potentially lucrative engagement that expert has failed to disclose in the UDAP litigation. The UDAP complaint reflects no investigation by the State of Hawai`i but simply copies the substance of other complaints filed elsewhere.

16. In a traditional enforcement matter, when Hawai`i's Attorney General or one of her assistants sues on behalf of the State, they have a professional and ethical obligation as government employees to serve the public interest—not necessarily to win the case, but rather to pursue actions that are a sound use of public resources and to see that justice is done. In this case, the private lawyers hired by the State are not dedicated to the public interest. Instead, the higher the verdict, the more the lawyers make—creating an overpowering incentive to maximize the monetary award, without regard to the larger public interest, the medical consequences, or the constitutional values that constrain State action. The weakening of these restraints heightens the risk to First Amendment rights.

17. Hawai`i's lawsuit not only violates the Companies' First Amendment rights, but threatens to significantly chill their protected speech. Because the Companies did not adopt and propagate the State's controversial and unproven hypothesis, they face a looming trial in April 2020 at which the State will seek billions of dollars in penalties. The prospect of this massive liability for making truthful statements about their products and for failing to make untruthful statements has a chilling effect on the speech not only of the Companies, but of other pharmaceutical manufacturers as well. The chilling effect inflicted by the State's UDAP lawsuit is exacerbated by the inflammatory and divisive rhetoric used by the State's lawyers.

18. For companies under this type of assault, being right on the science does not alleviate the uncertainty of the process and the attendant chilling effect on speech.

See Gertz v. Robert Welch, Inc., 418 U.S. 323, 349 (1974) ("The largely uncontrolled discretion of juries to award damages where there is no loss unnecessarily compounds . . . [the risk of] inhibit[ing] the vigorous exercise of First Amendment freedoms.").

19. The State seeks to impose these massive liabilities without showing that anyone in Hawai`i was harmed, and the UDAP statute requires no such showing. The Supreme Court in *Gertz* held that the First Amendment does not permit such liability for protected speech absent a showing of injury, or malice, which the UDAP statute also does not require.

20. In sum, the State's lawsuit violates the First Amendment and must be stopped.

PARTIES

21. Plaintiff Bristol-Myers Squibb Company is a pharmaceutical company incorporated in Delaware and headquartered in New York. The State of Hawai`i, through contingency fee counsel, has brought a civil enforcement action under Hawai`i's UDAP statute against BMS.

22. Plaintiff Sanofi-Aventis U.S. LLC is a Delaware limited liability company headquartered in New Jersey. The State of Hawai`i, through contingency fee counsel, has brought a civil enforcement action under Hawai`i's UDAP statute against Sanofi-Aventis U.S. LLC.

23. Plaintiff Sanofi US Services Inc., formerly known as Sanofi-Aventis

U.S. Inc., is a Delaware corporation headquartered in New Jersey. The State of Hawai`i, through contingency fee counsel, has brought a civil enforcement action under Hawai`i's UDAP statute against Sanofi US Services Inc.

24. Plaintiff Sanofi-Synthelabo LLC is a Delaware limited liability company headquartered in New Jersey. The State of Hawai`i, through contingency fee counsel,

has brought a civil enforcement action under Hawai`i's UDAP statute against Sanofi-Synthelabo LLC.

25. Defendant Clare E. Connors is the Attorney General of the State of Hawai`i. She is sued in her official capacity.

JURISDICTION AND VENUE

26. This Court has jurisdiction over this action under 28 U.S.C. § 1331, which confers original jurisdiction on federal district courts over actions arising under the Constitution or laws of the United States. This case arises under the First Amendment of the Constitution, made applicable to the State by the Due Process Clause of the Fourteenth Amendment, and under 42 U.S.C. § 1983.

27. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to the claim occurred in this District. Specifically, the State is pursuing its UDAP action, which arises under Hawai`i state law, in Hawai`i state court.

FACTUAL BACKGROUND

A. Background on Plavix and Genetic Variability of Response

28. Cardiovascular disease is the leading cause of death in Hawai`i, causing almost 4,000 deaths per year in that State alone. The Companies developed Plavix— an antiplatelet therapy, *i.e.*, a blood thinner—as a revolutionary drug to treat cardiovascular disease.

29. Plavix has been successfully launched in the United States and more than 100 countries, including China, India, Indonesia, Japan, Malaysia, the Philippines, and Singapore. Today, Plavix is one of the most widely prescribed antiplatelets in the world, including Asia, and the medical community almost universally considers the drug safe and effective.

30. In 1997, FDA approved Plavix as safe and effective for use as a "monotherapy" (*i.e.*, without another

drug) to treat patients who suffered a recent heart attack or stroke or have been diagnosed peripheral arterial disease. Five years later, FDA approved Plavix for "dual antiplatelet therapy" with aspirin for the treatment of patients with particular types of acute coronary syndrome. FDA expanded this dual therapy approval in 2006.

31. Dual therapy of Plavix with aspirin has been the standard of care for many years, both in treating patients with acute coronary syndrome, as well as in conjunction with the placement of stents, *i.e.*, medical devices commonly implanted to keep patients' arteries open, but which can trigger blood clotting. For more than a decade, the principal medical organizations in cardiology have recommended Plavix in these and other clinical settings. They continue to recommend it today.

32. After Plavix's approval, the Companies continued to study the drug by funding studies conducted by independent investigators. Among those studies were ones focused on potential "variability of response" among patients using Plavix.

33. "Variability of response" is the difference "among individuals in their response to drugs. … [W]hen a group of patients receive the same drug dosage[,]some gain a therapeutic effect, others develop toxicity, and others derive no benefit at all."[2] Variability is common. "Most major drugs are effective in only 25 to 60 percent of patients."[3] Doctors are familiar with the phenomenon, and frequently switch patients from one drug to another until they find one that provides relief. Many things can cause

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[2] Michael D. Rawlins, *Variability in Response to Drugs*, 4 Brit. Med. J. 91, 91 (1974).

[3] Grant R. Wilkinson, *Drug Metabolism and Variability Among Patients in Drug Response*, 352 New Eng. J. Med. 2211, 2211 (2005).

variability of response, including environmental factors, genetics, and underlying medical conditions.[4]

34. Starting in 2001, there was a robust scientific debate regarding variability of response and the role of genetics in Plavix metabolism. The Companies supported more than 30 published studies as part of an integrated research plan on that topic. Numerous independent investigators not affiliated with the Companies also conducted research about variability of response to Plavix and published their findings. None of the early studies, however, concluded that people with certain genetic traits or ethnic backgrounds had worse health outcomes.

35. As the research on variability of response continued, the Companies kept FDA fully apprised of the findings, disclosing to the Agency approximately 200 published studies relating to the subject before the 2010 labeling revision.

36. Despite this intense study, before late 2008, not a single study had concluded that Asian or Pacific Islander patients, or patients with certain genetic traits, have worse health outcomes on Plavix than members of other racial groups.

37. In fact, much of the evidence suggested precisely the opposite:

a. In 1991, data in a Phase II study on Japanese patients suggested that Plavix worked *better* for the Japanese patients than other patients.[5]

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[4] Wilkinson, supra note 3, at 2211.

[5] FDA Investigational New Drug Application (IND) No. 34,663, Serial No. 161, PLAV_SAN_0168829, at PLAV_SAN_01648849 ("[I]t appeared that the Japanese are more sensitive to the platelet aggregation effect of clopidogrel . . . ."). Phase II studies are generally part of the drug approval process with the FDA and focus on effectiveness. *See* FDA Drug Approval Process 1,

b. In 2005, BMS and Sanofi sponsored the COMMIT trial in China, with more than *45,000* Chinese patients, the single largest clinical study conducted on Plavix.[6] That study found that adding Plavix to aspirin therapy significantly reduced the risk of heart attacks, strokes, and death in the population studied. These results led to a new FDA-approved indication to use the drug for the most serious types of heart attacks.

c. From the mid-1990s through mid-2000s, the Companies enrolled another 35,000 patients, without regard to race or ethnicity, in clinical trials showing the efficacy of Plavix.[7] Not a single trial signaled that

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https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf.

[6] COMMIT Collaborative Group, *Addition of Clopidogrel to Aspirin in 45,852 Patients with Acute Myocardial Infarction: Randomised Placebo-Controlled Trial, 366 Lancet 1607, 1607 (2005); see also Glenn N. Levine et al., World Heart Federation Expert Consensus Statement on Antiplatelet Therapy in East Asian Patients with ACS or Undergoing PCI*, 11 Nature Rev. Cardiology 597, 603 (2014) ("In the COMMIT trial, the benefit of clopidogrel added to aspirin was demonstrated for DAPT in Chinese patients with acute myocardial infarction, predominantly STEMI, not undergoing PCI. The primary composite end point of death, reinfarction, and stroke was significantly reduced by the addition of clopidogrel to aspirin therapy, without a significant increase in bleeding.").

[7] See CAPRIE Steering Committee, *A Randomized, Blinded, Trial of Clopidogrel Versus Aspirin in Patients at Risk of Ischaemic Events* (CAPRIE), 348 Lancet 1329, 1329 (1996) (19,185 patients); The Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators, *Effects of Clopidogrel in Addition to Aspirin in Patients with Acute Coronary Syndromes Without ST-Segment Elevation*, 345 New Eng. J. Med. 494, 494 (2001) (12,562 patients); Marc S. Sabatine et al., *Addition of Clopidogrel to Aspirin in Fibrinolytic Therapy for Myocardial Infarction with ST-*

Plavix was ineffective for Asians or Pacific Islanders.

38. In 2008—a decade after Plavix went on the market—Harvard professor Dr. Jessica Mega authored two studies assessing for the first time the clinical effect, if any, of a genetic variation in the CYP2C19 enzyme—the enzyme that converts Plavix to its active form. The variation exists in people of all races but is more prevalent in persons of Asian or Pacific Islander descent. In the first study, Dr. Mega found no significant difference in clinical outcomes based on genetic status. In the second study, published online in December 2008, involving a different patient set, Dr. Mega reported a potential link between a genetic variation in the CYP2C19 enzyme and real-world clinical outcomes for patients using Plavix. Dr. Mega noted, however, that the study could not "exclude meaningful effects of . . . other genetic variants" and therefore that "such variations also merit study."[8]

B. FDA Requires Revisions to Plavix Label Noting Genetic Variability of Response

39. Even though the science was nascent and the data were contradictory, FDA in March 2009 recommended certain changes to the existing Plavix label and required the Companies to conduct post-marketing clinical trials.

40. The Companies accepted several of the proposed labeling changes, but expressed concern with aspects of others. In particular, the Companies disagreed with changes that recommened genetic testing. The Companies explained that the variability of response and effect on clinical outcomes was only partially attributable to

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Segment Elevation, 352 New Eng. J. Med. 1179, 1179 (2005) (3,491 patients).

[8] Jessica L. Mega et al., *Cytochrome P-450 Polymorphisms and Response to Clopidogrel*, 360 New Eng. J. Med. 354, 361 (2009).

variations in the CYP2C19 enzyme, and that other factors, including other genetic variations, general health, comorbidities, and compliance with treatment, could also contribute. Further, the Companies considered a recommendation for genetic testing to be premature, as studies regarding the CYP2C19 variation and its importance were ongoing.

41. In May 2009, the Plavix label was revised to add the following language to the "precautions" section:

> Based on literature data, patients with genetically reduced CYP2C19 function have lower systemic exposure to the active metabolite of clopidogrel and diminished antiplatelet responses, and generally exhibit higher cardiovascular event rates following myocardial infarction than do patients with normal CYP2C19 function.[9]

42. The label further noted that "[p]harmacogenetic testing can identify genotypes associated with variability in CYP2C19 activity." But the label did not recommend testing patients for genetic traits or advise doctors to alter their treatment based on race or genetic status.

43. In November 2009, FDA approved a label that, among other changes, added the following language to the Warnings section:

> Reduced effectiveness due to impaired CYP2C19 function ("Avoid use of Plavix in patients with impaired CYP2C19 function due to known genetic variation or due to drugs that inhibit CYP2C19 activity.").[10]

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[9] May 2009 Plavix label, at 14, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020839s040lbl.pdf.

[10] November 2009 Plavix label, at 18, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020839s044lbl.pdf.

44. On November 20, 2009, FDA proposed a new label to the Companies that would move into a boxed warning information about genetic variability of response and worse clinical outcomes, and about the availability of genetic testing "as an aid in determining therapeutic strategy."

45. The Companies' response acknowledged FDA's position that CYP2C19 polymorphism is "an avoidable risk" but disagreed with the proposed warning. The Companies believed that the data did not show that the genetic variation had any clinical significance. They viewed a boxed warning as unwarranted, because, among other reasons, it would over-warn clinicians. As a result, some patients who needed the drug would not receive it.

46. Nevertheless, the Companies ultimately acceded to the Agency's position. FDA approved a label containing the following boxed warning:

> WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS . . . . Effectiveness of Plavix depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. (5.1). Poor metabolizers treated with Plavix at recommended doses exhibit higher cardiovascular event rates following acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function. (12.5) Tests are available to identify a patient's CYP2C19 genotype and can be used as an aid in determining therapeutic strategy. (12.5) Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers. (2.3, 5.1).[11]

47. However, given the still-limited data, FDA did not adopt the approach it has taken with other drugs: it

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[11] March 2010 Plavix label, at 1, 3, https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020839s042lbl.pdf.

did not instruct or recommend that doctors routinely conduct genetic tests before prescribing Plavix or that they limit its use among people of particular racial or ethnic groups.

C. Significant Scientific Debate Continues in the Wake of the FDA Label Changes

48. The 2009-2010 revisions to Plavix's label were highly controversial. Many leading cardiologists and organizations voiced concern that the newly evolving and mixed science on genetic variability of response did not support the new warnings.

49. For example, Dr. Harlan Krumholz—a world-renowned researcher and cardiologist at Yale School of Medicine—stated:

> Unfortunately the FDA has taken the step of warning people about a harm that has yet to be established. This warning could lead to non-compliance, unnecessary testing and increased cost without benefiting patients. The recommendation is based on platelet activation studies and not on clinical outcomes studies. To this point we do not know if a strategy of testing patients before prescribing will provide them a net benefit.[12]

50. Similarly, Dr. Steven E. Nissen, chairman of cardiovascular medicine at the Cleveland Clinic, published an editorial in the *Journal of American Medicine* calling the FDA warning "a case of 'irrational exuberance.'" Dr. Nissen observed:

> The consequences of the FDA's leap to judgment regarding CYP2C19 testing cannot be underestimated. Several companies subsequently received FDA

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[12] Larry Husten, *Plavix Label Gets Black Box Warning About Poor Metabolizers*, Cardio Brief (Mar. 12, 2010), http://www.cardiobrief.org/2010/03/12/plavix-label- gets-black-box-warning-about-poor-metabolizers/.

> approval to market products for testing either CYP2C19 reduced-function alleles or platelet reactivity. The societal cost of such testing procedures remains unknown, but according to the FDA, the 'per patient' charge for genetic testing ranges from $60 to $500.12. Because clopidogrel [Plavix] is one of the most widely used drugs in medicine, the potential cost to the health care system of universal genetic testing is substantial. Preventing inappropriate CYP2C19 testing could yield substantial savings for the health care system.[13]

51. The American College of Cardiology and American Heart Association—the nation's principal cardiology organizations—likewise concluded that the FDA-imposed warning prematurely informed about an unproven risk. The two organizations published a joint Clinical Alert, explaining that the "specific impact of the individual genetic polymorphisms on clinical outcome remains to be determined" and stressing that "[t]he evidence base is insufficient to recommend either routine genetic or platelet function testing."[14]

52. Additional studies cast further doubt on FDA's decision to add a black box warning on genetic variability of response to Plavix. Following the December 2008 Mega study, the Companies re-examined the data in their earlier trials by genotyping the thousands of patients in those studies based on blood samples retained from the trials. The results showed no association between genetic status

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[13] Steven E. Nissen, Editorial, *Pharmacogenomics and Clopidogrel: Irrational Exuberance?*, 306 J. Am. Med. Ass'n 2727, 2728 (2011).

[14] David R. Holmes Jr. et al., *ACCF/AHA Clopidogrel Clinical Alert: Approaches to the FDA "Boxed Warning": A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents and the American Heart Association*, 56 J. Am. C. Cardiology 321, 334 (2010).

and clinical effect.[15] Other independently researched studies published after the May 2009 labeling change made similar findings.[16] In fact, numerous clinical studies have now shown that Asian patients on Plavix have better clinical outcomes (i.e., reduced heart attacks or strokes) compared to other races.[17]

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[15] Deepak L. Bhatt, *The Relationship Between CYP2C19 Polymorphisms and Ischemic and Bleeding Outcomes in Stable Patients*: *The CHARISMA Genetics Study*, 33 Eur. Heart J. 2143, 2143 (2012) ("No relationship was seen between CYP2C19 status and ischemic outcomes in stable patents treated with clopidogrel."); Guillaume Paré et al., *Effects of CYP2C19 Genotype on Outcomes of Clopidogrel Treatment*, 363 New Eng. J. Med. 1704, 1714 (2010) (based on genotyping of 5,059 patients, "CYP2C19 loss-of-function variants do not modify the efficacy and safety of clopidogrel").

[16] See, e.g., Jacob A. Doll et al., *Impact of CYP2C19 Metabolizer Status on Patients with ACS Treated with Prasugrel Versus Clopidogrel*, 67 J. Am. C. Cardiology 936, 936 (2016) (finding that "CYP2C19 metabolizer status is not associated with the composite outcome of cardiovascular death, MI, or stroke" in ACS patients treated with Plavix, and noting that "[o]ur findings do not support routine CYP2C19 genetic testing in this population"); Robert S. Kumar et al., *Effect of Race and Ethnicity on Outcomes with Drug-Eluting and Bare Metal Stents: Results in 423,965 Patients in the Linked National Cardiovascular Data Registry and Centers for Medicare & Medicaid Services Payer Databases*, 127 Circulation 1395 (2013).

[17] Yong Huo, *2018 Update of Expert Consensus Statement on Antiplatelet Therapy in East Asian Patients with ACS or Undergoing PCI*, 64 Sci. Bull. 166, 167 (2019); Kumar et al., *supra* note 16; Kang et al., *Racial Differences in Ischemia/Bleeding Risk Trade-Off during Anti-Platelet Therapy: Individual Patient Level Landmark Meta-Analysis from Seven RCTs*, Thromb Haemost 2019; 119:149-62; *see also* Koon-Hou Mak et al., *Ethnic Variation in Adverse Cardiovascular Outcomes and Bleeding Complications in the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (CHARISMA) Study*, 157 Am. Heart J. 658, 658 (2009) ("[E]thnicity was not a significant, independent predictor of . . . cardiovascular event[s].").

53. Based on the findings in the more recent literature, even Dr. Mega herself has concluded, as part of a 2014 World Health Organization-affiliated panel, that the combination of Plavix plus aspirin remains a "reasonable first choice" for people of East Asian descent.[18]

54. And in 2015, cardiologists from Queen's Medical Center in Hawai`i published an article in the peer-reviewed *Hawai`i Journal of Medicine and Public Health* specifically addressing the State's claim in the UDAP suit. Notwithstanding the State's "assert[ion] that patients of Asian and Pacific Island ethnicity may be . . . less responsive to the actions of clopidogrel [Plavix],"[19] the article observed, their research did not find "any additional supporting evidence for tailored therapy based upon genetic testing." The authors expressly did "not recommend the routine testing for CYP polymorphisms as a basis for changing antiplatelet therapies."[20]

D. FDA Removes the Language Referring to Genetic Traits and Clinical Outcomes from the Plavix Label

55. In 2016 FDA took the rare step of removing the language referring to the link between genetic traits and clinical outcomes from the Plavix label.

56. Scientific discussion and debate about genetic variability in responsiveness to Plavix continues today, although the near unanimous view is that Plavix is effective in patients of all races and ethnicities and that routine genetic testing is not recommended.

a. The leading medical guidelines and consensus statements— including those authored by the

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[18] Levine et al., *supra* note 6, at 603.

[19] Adnan M. Bhopalwala et al., *Routine Screening for CYP2C19 Polymorphisms for Patients Being Treated with Clopidogrel Is Not Recommended*, 74 Haw. J. Med. & Pub. Health 16, 16, 19 (2015).

[20] *Id.* at 19.

Chinese Cardiology Society and the Japanese Society of Cardiology21—currently recommend Plavix to patients regardless of their race or genetic profile.22

b. Similarly, in its 2018 update, the World Heart Federation reaffirmed its prior recommendation that "[d]espite a lower platelet inhibitory response to clopidogrel, East Asian patients show a similar or even a lower rate of ischemic event occurrence" compared with Caucasian patients.23

c. From 2009 to the present, 46 medical consensus statements and guidelines have been issued in the United States, Europe, and Asia (China, Japan, Korea, and Taiwan) addressing the use of Plavix in various clinical settings. None of these 46 consensus statements and guidelines recommends the routine use of genetic testing to identify patients with low or no response to Plavix.

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[21] *See, e.g.*, Yukio Ozaki et al., *CVIT Expert Consensus Document on Primary Percutaneous Coronary Intervention (PCI) for Acute Myocardial Infarction (AMI) in 2018*, 33 Cardiovascular Intervention & Therapeutics 178, 182-83 (2018).

[22] *E.g.*, Holmes, Jr. et al., *supra* note 14; Glenn N. Levine, et al., *2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease*, 68 J. Am. C. Cardiology 1082 (2016); Ezra A. Amsterdam et al., *2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes*, 64 J. Am. C. Cardiology e139 (2014); Glenn N. Levine et al., *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions*, 58 J. Am. C. Cardiology e44 (2011).

[23] Huo, *supra* note 17, at 166.

d. The most recent consensus statement issued by the American College of Cardiology and American Heart Association in 2019 acknowledges that some studies reported an association between the CYP2C19 genetic defect and clinical outcomes in patients undergoing stent placements (as opposed to patients taking Plavix after a heart attack or stroke without stenting), and stated that testing may be an option in certain high-risk clinical situations (*e.g.*, complex, multi-vessel coronary disease).[24] But the authors again reaffirmed that routine genetic testing for Plavix patients is not recommended.[25] The authors also observed that despite a higher prevalence of CYP2C19 genetic defects, East Asians did not show an elevated risk for ischemic events.[26]

57. In other words, the most recent expert statement on genetic variability of response to Plavix confirms that the drug works as well, if not better, in Asian and Pacific Islander patients.

58. Plavix continues to be prescribed in East Asian countries.

E. The State Perceives No Public Health Risk Surrounding Plavix in Light of FDA's Revision to the Plavix Label

59. Although the State had means to address any concerns it had about the genetic variability of response

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[24] Dirk Sibbing et al., *Updated Expert Consensus Statement on Platelet Function and Genetic Testing for Guiding P2Y12 Receptor Inhibitor Treatment in Percutaneous Coronary Intervention*, 12 J. Am. C. Cardiology Cardiovascular Interventions 1521, 1532-34 (2019).

[25] *Id.* at 1534.

[26] *Id.* at 1527.

to Plavix, it neither did nor said anything suggesting the slightest unease regarding the supposed genetic variability of response to Plavix in light of FDA's revisions to the Plavix label.

a. The State's Medicaid program contractors include Plavix on their formularies and continue to cover the drug today without restrictions based on racial, ethnic, or genetic status.

b. The State has never sent any notification or warning to doctors about genetic variability of response issues related to Plavix, although it has sent "memoranda" on other occasions to provider health plans and prescribers with information about other drugs.

c. The State has never initiated any educational campaigns to urge doctors to alter prescribing practices, even though the State has initiated such campaigns on other occasions for other drugs.

d. Former Hawai`i Medicaid officials who worked at the agency during the 2009-2010 labeling revisions testified during recent depositions that they do not remember having any concerns about Plavix or informing physicians about any genetic issues relating to the drug.

e. State-affiliated hospitals have never imposed any requirement or conditions with respect to race or ethnicity on the prescription of Plavix.

60. In discovery, the Companies asked the State to identify any alerts, warnings, or advisories regarding Plavix that it sent providers and insurers. The State's only response was to refer to press conferences and news media related to the filing of the UDAP lawsuit.

61. Similarly, when asked to "describe all steps or actions taken by the State to protect or improve the health

of residents of Hawai`i from alleged Plavix-related harms," the State could point to nothing besides its "widespread publicity regarding the filing of the lawsuit . . . [which] helped inform physicians, patients, and the general public about the genetic issue and the availability of genetic testing."

62. The State also confirmed, in response to the Companies' request that it identify promotional materials on which State personnel relied in making decisions concerning coverage or reimbursement or Plavix, that the State "has not identified any responsive documents concerning decisions by State personnel."

63. The Companies also asked the State to "identify and describe every instance in which any Hawai`i Medicaid, MCO, Public Entity, or Third Party Contractor employee, agent, or consultant recommended, suggested, or otherwise expressed the view that [the State] should not continue to reimburse for the use of Plavix, should impose restrictions on its reimbursement, or should not include it on a PDL or formulary." The State confirmed that it is "not aware of any instance in which State personnel expressed such views."

64. The State's expert reports confirm the lack of any public health concern in Hawai`i regarding genetic variability of response to Plavix. The State's experts do not include any cardiologist from Hawai`i, nor from any Asian country. The reports are devoid of evidence that any doctor in Hawai`i ever expressed concern about genetic variability of response or changed their prescribing behavior in any way, or that anyone in Hawai`i actually suffered harm from Plavix.

F. Contingency-Fee Lawyers Persuade the State to Hire Them to Pursue Claims Under Hawai`i's Unfair or Deceptive Acts or Practices Statute

65. Five years after FDA's label revision, in or around 2014, private plaintiffs' lawyers approached the Attorney General of Hawai`i, proposing that the State retain them on a contingency fee basis to file an enforcement action against the Companies for alleged deceptive marketing.

66. The State had exhibited no independent interest in pursuing an enforcement action against the Companies for deceptive marketing. It conceded in discovery that the UDAP action was "a result of an investigation or inquiry by the Attorney General" only, and not by Hawai`i Medicaid or any other public entity. The Attorney General's Office reported no complaints.

67. The private firms' offer to bring and litigate an enforcement action for civil penalties on a contingency-fee basis presented no budgetary risk to the State, and offered a chance for a large payout if the private lawyers prevailed.

68. The State contracted with a Hawai`i law firm, Cronin Fried Sekiya Kekina & Fairbanks ("Cronin Fried"). Cronin Fried, in turn, partnered with Salim-Beasley LLC ("Salim-Beasley"), a plaintiffs' firm that—since its founding in 2012—has pursued numerous mass tort and consumer fraud suits against pharmaceutical companies.

69. Under the State's contract with Cronin Fried, that firm agrees to:

a. "[P]repare and fil[e] of all claims, pleadings, responses, motions, petitions, memoranda, briefs, notices and other documents,"

b. "[C]onduct negotiations and provide representations at all hearings, depositions, trials, appeals, and other appearances,"

c. "[C]ontrol and direct performance and details of the work and services required under this Agreement,"

d. "[A]dvance all costs and expenses and provide all necessary personnel in order to comply with any discovery request . . . [including] [w]orking directly with State personnel who may be tasked with responding to discovery requests," and otherwise

e. "[P]rovide all legal services that are reasonably necessary."

70. The contract further provides that Cronin Fried "shall receive a contingency fee of 20% from the net proceeds of any judgment or settlement," but shall recover "no compensation for any services rendered" if the State does not settle or is not awarded civil penalties.

71. Nothing in the contract suggests that Cronin Fried should consider or report to the Attorney General on the medical consequences, First Amendment implications, or even the *bona fides* of the claim.

72. On March 19, 2014, Salim-Beasley and Cronin Fried initiated a civil enforcement action on behalf of the State in the First Circuit Court of Hawai`i in 2014, seeking, among other things, civil penalties under the UDAP statute. No attorney employed by the State signed the pleading or appeared in the attorney signature block.

73. In a press conference on the lawsuit, the Attorney General claimed the Companies should have disclosed that "Plavix was not effective or had a diminished effect on people of East Asian descent or Pacific Islander descent, of which approximately 50% of the population in Hawai`i is of that extraction or descent." KITV, *Hawaii*

Files Suit Against Manufacturers of Plavix Heart Medication, YouTube (Mar. 19, 2014), https://www.youtube.com/watch?v=-90U08FU9aA (at 0:46-1:07).

74. In an interview on Hawai`i Public Radio that same day, the Attorney General again emphasized that Plavix "was particularly ineffective in Hawai`i" because the State "has a very large population of Pacific Islanders and East Asian people." Molly Simon, *Hawaii Attorney General Sues Makers of Plavix*, Hawaii Public Radio (March 19, 2014), http://hpr2.org/post/hawaii-attorney-general-sues- makers-plavix (at 0:40-1:03).

75. The thrust of the claims in the UDAP suit, as the State's expert reports confirm, is that "[s]ince at least 1998, [the Companies] have known that over 30% of patients had little or no response to Plavix," and that "[r]ather than publish this information, [the Companies] concealed it from treating physicians." Gurbel Expert Report ¶ 28; see also Second Am. Compl. ¶ 29, *State ex. rel. Connors v. Bristol- Myers Squibb Co.*, No. 14-1-0708-03 DEO (Haw. Cir. Ct. Dec. 4, 2018). In other words, the State claims that the Companies should have stated that Plavix worked less well in certain populations more than a decade before Dr. Mega's study first raised the possibility and long before FDA itself believed any such warning was warranted.

76. The State claims that the Companies engaged in "unfair or deceptive acts or practices in the conduct of any trade or commerce," Haw. Rev. Stat. § 480-2(a), by—among other things—"actively suppress[ing]" research about genetic variability of response to Plavix, Gurbel Expert Report ¶ 79, and "failing to timely and proactively comply with their obligation to update the Plavix label to provide prescribing physicians with 'adequate instructions for use,' and to alert the FDA and physicians to the fact that a significant portion of the population was

genetically predisposed to diminished or non-responsiveness to Plavix," *id.* at ¶ 123-27. *See also* Second Am. Compl. ¶¶ 94, 97, *State ex. rel. Connors v. Bristol-Myers Squibb Co.*, No. 14-1-0708-03 DEO (Haw. Cir. Ct. Dec. 4, 2018).

77. The State does not allege that a single person in Hawai`i was actually harmed by the Companies' purported deceptive statements or omissions regarding Plavix—indeed, on the State's theory, it does not need to allege any such harm.

78. The State seeks to punish the Companies through civil penalties of up to $10,000, per Company under the UDAP statute beginning in 1998 for each repeated violation of the UDAP, see Haw. Rev. Stat. § 480-3.1, and additional civil penalties of up to $10,000, per violation, per Company, for each repeated and willful violation of the UDAP statute directed toward or that targeted elders, *see id.* § 480-13.5. The State has provided expert witness testimony from Dr. Nicole Maestas purporting to quantify and support its claim for penalties. In her report, served on December 29, 2019, Dr. Maestas asserted that the total number of Plavix prescriptions and non-retail units sold in Hawai`i during the relevant period is 834,012. Expert Report of Nicole Maestas, PhD (Dec. 29, 2019), *State ex rel. Connors v. Bristol-Myers Squibb Co.* No. 14-1-0708-03 DEO (Haw. Cir. Ct.), ¶ 42. Dr. Maestas calculated penalties "ranging from a minimum of $417,006,000 to a maximum of $8,340,120,000." *Id.* ¶ 43.

79. The State also seeks disgorgement and punitive damages.

80. Salim-Beasley subsequently withdrew from the litigation, and a Texas law firm, Baron & Budd, P.C. took over the case.

81. Contrary to Hawai`i's procurement statute, the State has no formal contract with Baron & Budd.

Instead, Cronin Fried has apparently retained Baron & Budd as "outside assistance." The State's contract with Cronin Fried provides that "the Attorney General shall have final authority over all aspects of this Litigation" and "must approve in advance all aspects of this Litigation." The State has no such agreement with Baron & Budd. Any control or supervision of Baron & Budd by the Attorney General is, at best, indirect.

82. Moreover, Hawai`i relies on an expert who is also a relator in a qui tam suit regarding Plavix in New Jersey federal court involving allegations and claims similar to those in the Hawai`i UDAP suit. Gurbel Expert Report; *see United States ex rel. JKJ Partnership 2011, LLP v. Sanofi Aventis, U.S. LLC*, 315 F. Supp. 3d 817 (D.N.J. 2018). That case is now on appeal. Dr. Gurbel does not disclose in the UDAP litigation that he stands to gain tens of millions of dollars if courts accept his theory.

VIOLATIONS OF LAW

83. The Free Speech Clause of the First Amendment of the United States Constitution provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Fourteenth Amendment of the United States Constitution made this proscription applicable to the States and their political subdivisions. *E.g., NIFLA*, 138 S. Ct. at 2371.

84. In addition to providing protections against restrictions on speech, the First Amendment protects against the government's compelling individuals or entities to engage in speech. Compelled speech ordinarily is subject to strict scrutiny. *See, e.g.*, *id.* at 2371; *Wooley v. Maynard*, 430 U.S. 705, 715-17 (1977). As the Supreme Court held just last Term, "[f]orcing free and independent individuals to endorse ideas they find objectionable is always demeaning, and for this reason, one of our landmark free speech cases said that a law commanding 'involuntary affirmation' of objected-to beliefs would require 'even

more immediate and urgent grounds' than a law demanding silence." *Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, 138 S. Ct. 2448, 2464 (2018) (quoting *W. Va. Bd. of Ed. v. Barnette*, 319 U.S. 624, 633 (1943)).

85. Over the past several decades, the Supreme Court has expanded the First Amendment protections accorded to commercial speech. *See, e.g.*, *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1150-51 (2017) (holding that a law regarding merchants' communications of credit card surcharges to customers implicated constitutionally protected speech). Regulations of speech, including commercial speech, that are based on speaker, content, or viewpoint, are presumptively invalid, and are subject to "heightened judicial scrutiny." *Sorrell*, 564 U.S. at 565. Heightened scrutiny ranges from strict scrutiny—which requires that the regulation be narrowly tailored to serve a compelling state interest, *Reed v. Town of Gilbert, Ariz.*, 135 S. Ct. 2218, 2226 (2015)—to, at minimum, the less demanding, but still rigorous, standard of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980)—which requires that the regulation be no more extensive than necessary to directly advance a substantial government interest.

86. The Supreme Court's reinforcement of the protections for commercial speech reached new heights in 2018. In *NIFLA v. Becerra*, 138 S. Ct. 2361, itself a non-commercial case, the Court made clear that a regulation that compels, rather than restricts, commercial speech can survive First Amendment scrutiny only if it is "purely factual and uncontroversial," and even then, only if the regulation is not "unjustified or unduly burdensome." *See also, e.g.*, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Am. Beverage Assoc. v. City & County of S.F.*, 916 F.3d 749, 756-58 (9th Cir. 2019) (en banc) (granting preliminary injunction against required warning for sweetened beverages); *Nat'l Ass'n of Wheat Growers v.*

Zeise, 309 F. Supp. 3d 842, 850-54 (E.D. Cal. 2018) (granting preliminary injunction against state-required carcinogenicity warning for herbicide). The State bears the burden of establishing that its regulation of speech meets these standards. *Sorrell*, 564 U.S. at 571-72; *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993).

A. The State's UDAP Penalty Claims Violate the Companies' First Amendment Rights

87. The State's lawsuit to enforce a legal duty to provide an adequate warning constitutes state action that is subject to the First Amendment. Here, the State's UDAP enforcement action against the Companies for alleged failure to warn about genetic variability of response to Plavix violates the First Amendment for two reasons.

88. *First*, the State's UDAP suit attempts to compel the Companies to express specific views about Plavix on the package insert—views that the Companies (as well as almost all medical experts) believe are wrong, and that never had strong support, but rather were highly controversial and contested in the scientific literature. The burdens the lawsuit places on the Companies' speech fail any level of scrutiny.

89. *Second*, the State seeks to impose exorbitant penalties on the Companies' speech without a showing of harm or malice. Hawai`i's UDAP statute relieves the State of the need to show harm or malice in order to pursue a penalty action against the Companies. The Supreme Court has held that such a mismatch between the burdens imposed and the putative state interests violates the First Amendment.

1. The State's UDAP penalty claims cannot survive heightened scrutiny

90. The State's UDAP claims attempt to force the Companies to make specific, controversial statements about Plavix on the package insert.

91. The compelled speech in this case is noncommercial and thus subject to strict scrutiny. The package insert does not "propose a commercial transaction." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 760 (1976). The patient or consumer does not see the insert before receiving the product, if ever. *See, e.g.*, *Craft v. Peebles*, 893 P.2d 138, 155 (Haw. 1995) (learned intermediary doctrine "substitutes the [prescribing] physician for the consumer as the person to receive … warnings" (citations omitted)). Moreover, FDA regulations require that the labeling "be informative and accurate and neither promotional in tone nor false or misleading in any particular." 21 C.F.R. § 201.56(a)(2). These regulations preclude use of the package insert as a "commercial advertisement for the sale of goods and services," *U.S. Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 933 (3d Cir. 1990) (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983); *Central Hudson*, 447 U.S. at 561).

92. But even if information on a package insert were treated as commercial speech, the State's actions would still impermissibly intrude on the Companies' First Amendment rights.

93. The State's regulation of speech here discriminates on the basis of speaker, content, and viewpoint. It is speaker-based because it targets pharmaceutical companies. No one other than the Companies is required to make the challenged statements. The State's regulation of speech is content-based because it seeks to control the content of the Companies' speech about Plavix. And the State's regulation of speech is viewpoint-based because it seeks to require the Companies to adopt a viewpoint at odds with their position about Plavix. The regulation therefore must withstand heightened scrutiny.

94. The State cannot show that compelling speech through a UDAP lawsuit, piloted by private contingency-

fee plaintiffs' lawyers, is narrowly tailored to serve a compelling interest. Indeed, the State's regulation of speech through this UDAP enforcement action cannot even meet the *Central Hudson* test. The UDAP suit extends farther than necessary to directly advance a *substantial* government purpose—it does not advance even a *legitimate* government purpose. Nor can the State invoke the standard applicable to purely factual, noncontroversial and appropriate compelled commercial speech. The warnings the State seeks to mandate are not purely factual. They are controversial. And mandating that they be included on the Plavix label is both unjustified and an undue burden on the Companies' First Amendment rights.

a. The State's preferred warnings are neither factual nor uncontroversial

95. The State seeks to penalize the Companies for "failing to disclose, in Plavix's labeling and otherwise, that Plavix has diminished or no effect on a significant percentage of the patient population," as well as by marketing Plavix as "more effective and safer than other competitor drugs in Plavix's labeling and otherwise." In other words, the State's theory of liability is that the Companies should have voiced the State's preferred opinions about the genetic variability of response to Plavix from 1998 to the present.

96. The warning the State would mandate is not purely factual. It reflects opinions—indeed, wrong opinions. The overwhelming consensus of scientific experts, cardiology organizations and regulatory authorities is that no evidence supports a need for routine genetic testing, or a warning that East Asian or Pacific Islander patients have worse clinical outcomes while on Plavix.

97. Throughout the period covered by the State's UDAP action, the views the Companies expressed about Plavix in its labeling were truthful and consistent with the scientific evidence. The genetic variability of response to

Plavix was the subject of active scientific debate perhaps a decade ago, but the Companies' view that Plavix is safe and effective without regard to race or ethnicity has long reflected and continues to reflect the overwhelming medical consensus.

b. The State has no genuine interest in requiring the Companies to warn about genetic variability of response

98. The State may only regulate commercial speech that is not "purely factual and uncontroversial" if doing so would, at minimum, "directly advance a substantial government interest" and the measures are "no more extensive than necessary to serve that interest"—assuming that the even more rigorous standard of strict scrutiny does not apply.

99. Here, the State has no legitimate government interest in requiring the Companies to include information warning about the alleged genetic variability of response to Plavix.

100. Before private law firms approached the Attorney General proposing that the State hire them on a contingency fee basis to litigate a UDAP enforcement action seeking hundreds of millions of dollars in civil penalties, the State had exhibited no concern about the issue of variability of response to Plavix.

101. It appears that the State itself had never conducted any investigations or inquiries regarding Plavix, and never took steps to alert doctors about any concerns regarding genetic variability of response to Plavix. Even today, the State's Medicaid insurers continue to recommend and cover Plavix for patients of all races without genetic testing. In recent testimony in the UDAP enforcement action, State Medicaid officials reported that they recalled no concerns about the drug.

102. Even assuming the State did have a legitimate interest in public health and safety or consumer protection, the lawsuit, and the warnings the State seeks to impose, are more extensive and burdensome than necessary to serve that interest.

103. The State would apparently have the Companies say that Plavix has a diminished effect on approximately 30% of the patient population and that a simple genetic test would identify the patients for whom Plavix would not work. There is no scientific basis for such a statement—not now, and certainly not in 1998, when the State claims the Companies should have informed about this alleged risk. In fact, FDA in 2016 removed from the Plavix label the only language suggesting that those with a genetic variation had worse clinical outcomes than other patients—confirming that such warnings are unnecessary. Moreover, the way the State would coerce the Companies to make these statements is through a massive award of civil penalties that will chill speech not only about Plavix, but also about other drugs, and not only by BMS and Sanofi, but also by other pharmaceutical companies.

104. The State cannot avoid these constitutional limits on the compulsion of speech by claiming that the Companies' speech, absent the language the State seeks to mandate, is misleading. *Cf. Central Hudson*, 447 U.S. at 566. A claim of falsity does not automatically strip away First Amendment protections. "[E]rroneous statement is inevitable in free debate, and it must be protected if the freedoms of expression are to have the 'breathing space' that they 'need . . . to survive.'" *N.Y. Times v. Sullivan*, 376 U.S. 254, 271-72 (1964) (alteration in original) (quoting *NAACP v. Button*, 371 U.S. 415, 433 (1963)).

105. Indeed, the very process of determining whether a statement is false or misleading can have chilling effects. As the Supreme Court pointed out in *Gertz*, 418 U.S. at 340, "punishment of error runs the risk

of inducing a cautious and restrictive exercise of the constitutionally guaranteed freedoms of speech and press." *See also, e.g.*, *id.* at 341 (noting the "fear that the prospect of liability for injurious falsehood might dissuade a timorous press from the effective exercise of First Amendment freedoms"). Therefore, the Court has held, "First Amendment standards . . . must give the benefit of any doubt to protecting rather than stifling speech." *Citizens United v. FEC*, 130 S. Ct. 876, 891 (2010).

106. The Court has clarified that only "inherently misleading" speech—i.e., speech that "may [not] be presented in a way that is not deceptive"—falls outside the usual First Amendment protection. *In re R.M.J.*, 455 U.S. 191, 203 (1982); *see also Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). The Companies' position about Plavix is not "inherently misleading;" it reflects the expert medical consensus.

107. In any event, a contention that the Companies' statements were misleading would simply assume the validity of the State's UDAP claims. And the overwhelming scientific consensus—including dozens of peer-reviewed articles that support the Companies' position—makes plain that such an assumption would be plainly unwarranted.

2. The State's UDAP enforcement action impermissibly seeks penalties without a showing of harm

108. The State's enforcement action also violates the First Amendment because the Hawai`i UDAP statute permits the State to recover penalties without showing injury to any person or institution, or malice by the Companies. Unlike the consumer protection statutes of many states, Hawai`i's UDAP statute imposes a minimum $500 penalty per violation, leaving the court no discretion to forgo penalties even absent any injury. *Compare*, e.g., Haw. Rev. Stat. § 480-3.1, *with, e.g.*, W. Va. Code § 33-11-

6, *and* Cal. Bus. & Prof. Code § 17206(b). In other words, the UDAP civil penalty provisions relieve the State of the need to justify burdening speech through an enforcement action. The First Amendment does not permit such a mismatch between the burden on speech and any putative state interest in penalizing false or misleading statements.

109. Indeed, the Supreme Court in *Gertz*, 418 U.S. at 349, addressed a similar "oddity of tort law" that permitted damages for defamation "without evidence of actual loss." The Court held that the "strong and legitimate state interest" in compensating injured private parties "extends no further than compensation for actual injury." *Id.* at 348-49. Discretion "to award damages where there is no loss," the Court found, "unnecessarily compounds the potential of any system of liability for defamatory falsehood to inhibit the vigorous exercise of First Amendment freedoms." *Id.* at 349. Only where the defendant acted with actual malice could there be liability without injury. *Id.*

110. As the Court explained in *New York Times v. Sullivan*, 376 U.S. at 277- 78, absent such a limitation and "the need for any proof of actual pecuniary loss," the prospect of massive, disproportionate verdicts creates "an atmosphere in which the First Amendment freedoms cannot survive." The Court reaffirmed *Gertz* in *Dun & Bradstreet, Inc. v Greenmoss Builders, Inc.*, 472 U.S. 749, 763 (1985) (plurality opinion), barring presumed or punitive damages absent actual malice in defamation cases on matters of public concern.

111. Insofar as Hawai`i asserts some generalized interest in deterring false statements, it is no more substantial than the state's interest in *Gertz*, 418 U.S. at 341, in upholding "the individual's right to the protection of his own good name," which the Court revered as fundamental, "reflect[ing] no more than our basic concept of the

essential dignity and worth of every human being—a concept at the root of any decent system of ordered liberty."

112. Nor is there reason to believe that imposing penalties without injury or actual malice is necessary to further any such interest. It is no serious burden on the State to establish those elements as a predicate for a UDAP enforcement action. The UDAP enforcement provision and the State's deployment of it here therefore cannot stand.

B. The State's Pursuit of a UDAP Enforcement Action Chills Legitimate Scientific Debate

113. The First Amendment harms to the Companies are ongoing. Every day that the UDAP suit is pending, the threat of punishment for failing to make the State's preferred statements about Plavix intolerably threatens not only the scientific discussion that continues with respect to genetic variability of response to Plavix, but also debate about other drugs. That scientific debate is necessary to medical progress.

114. The Supreme Court has stated that, "in the area of freedom of speech[,]. . . courts must always remain sensitive to any infringement on genuinely serious. . . scientific expression." *Miller v. California*, 413 U.S. 15, 22-23 (1973); *see also, e.g.*, *Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) ("[T]he First Amendment protects scientific expression and debate just as it protects political and artistic expression."). The First Amendment serves a critical function "in the fields of medicine and public health, where information can save lives." *Sorrell*, 564 U.S. at 566.

115. By seeking enforcement against the Companies under the UDAP statute for the Companies' alleged failure to warn about the supposed genetic variability of response to Plavix, the State communicates that at its whim, pharmaceutical manufacturers must take public

positions and provide warnings that they believe are scientifically unjustified, or else face the prospect of hundreds of millions, if not billions, in penalties.

116. The chill is intensified given that the Companies' liability will depend on whether a lay jury or judge without expertise in the complex scientific issues at stake can be persuaded that the information the Companies did provide was not misleading—a situation that "is delicate and sensitive and has serious implications for the right to freedom of expression." *Nat'l Rev., Inc. v. Mann*, 140 S. Ct. 344, 346 (Alito, J., dissenting from the denial of certiorari). Whether "assertions about. . . scientific data can be shown to be factually false" is "highly technical" and "not an easy matter for lay jurors to assess." *Id.* And when allegedly false or misleading speech "concerns a political or social issues that arouses intense feelings, selecting an impartial jury presents special difficulties." *Id.* These factors make it all the more likely that the Companies will refrain from making statements about their products with which the State may disagree, for fear that an inexpert court or jury will later be the arbiter of the truth of those statements.

117. The chilling effects of this lawsuit range beyond the parties, to all pharmaceutical companies marketing products that are the subject of scientific—or even unscientific—controversy. Rather than risk incurring crippling liability, companies may refrain from participating in the scientific debate, or from engaging in truthful speech about their products where that speech does not accord with the State's views. The threat of massive liability similarly pressures companies to provide warnings beyond what is necessary or even prudent, in order to avoid assaults by private plaintiffs' lawyers who have appropriated the powers, as well as the credibility, of the State.

C. The State's Delegation of Its Enforcement Authority to Private Contingency Fee Counsel Heightens the Intrusion on the Companies' First Amendment Rights

118. The State's imposition on the Companies' First Amendment rights is even more problematic, and has even greater chilling effect, because the State has delegated its enforcement power to private outside counsel who are subject neither to the ordinary safeguards against private regulation of speech, nor to institutional constraints on government regulation of speech.

119. As far as can be discerned from the public, non-privileged aspects of the case, the State has left the direction of the litigation to its private contingency- fee counsel. No State attorney has entered any appearance as counsel of record, signed any significant pleadings or motions, argued at a hearing, or taken or defended a deposition.

120. Legal regimes that delegate to private parties the authority to bring enforcement actions against allegedly false or misleading speech lack the traditional "legal and practical checks that tend to keep the energies of public enforcement agencies focused upon more purely economic harm," and that protect against undue intrusion on First Amendment rights. *Nike, Inc. v. Kasky*, 539 U.S. 654, 679-80 (2003) (Breyer, J., dissenting from dismissal of writ of certiorari as improvidently granted); Brief for the United States as Amicus Curiae Supporting Petitioners at 9- 26, *Nike, Inc. v. Kasky*, 539 U.S. 654 (No. 02-575), 2003 WL 899100; *cf. Reno v. ACLU*, 521 U.S. 844, 880 (1997) (striking down a provision of the Communications Decency Act of 1996 because "[i]t would confer broad powers of censorship, in the form of a 'heckler's veto,' upon any opponent of indecent speech who might simply log on and inform the would-be discoursers that [a minor] child . . . would be present").

121. This is a case in point. By authorizing private contingency-fee counsel to pursue the UDAP claims, putatively on the State's behalf, the State enables those attorneys to circumvent the ordinary limits on private suits that regulate speech.

122. For example, private plaintiffs generally may not bring actions to punish or restrict speech absent some showing of actual injury or reliance. *See Gertz*, 418 U.S. at 348-49. But the UDAP statute allows the State to bring a civil enforcement action without alleging those elements, Haw. Rev. Stat. § 480-3.1, and the State's retention of private counsel permits those private attorneys to litigate UDAP claims unencumbered by the doctrinal limits that would ordinarily apply to them.

123. And while other legal and practical safeguards provide checks on the State's enforcement authority and generally prevent undue intrusion on First Amendment rights, those institutional checks do not constrain private counsel. For instance, State officials are elected or otherwise appointed to serve the public interest, and thus have an obligation to bring only actions that are a sound use of public resources and that promote the public interest. *See* Restatement (Third) of the Law Governing Lawyers § 97 & cmt. b; *State v. Lead Indus. Ass'n, Inc.*, 951 A.2d 428, 471-76 (R.I. 2008) (describing the distinct role of the Attorney General). But counsel for private parties are not elected or appointed to serve the public interest, are not subject to public oversight and supervision, are not stewards of limited public resources, and do not have to exercise prosecutorial discretion in their day-to-day practice. Private lawyers spend their careers seeking to win cases on behalf of clients whether or not the public interest or the interests of justice require it, see Model Rule of Professional Conduct 1.2, 1.3 & cmt. 1, and whether or not winning infringes on the defendants' constitutional rights. These lawyers routinely allow the adversarial system to

resolve issues that a government lawyer would not let get that far.

124. The incongruity between the obligations of government lawyers and private lawyers creates the possibility of abuse when private lawyers are retained to litigate on behalf of governmental clients and must suddenly assume a fundamentally different role.

125. When constitutional rights are at stake, it cannot be left to private lawyers to voluntarily abide by the unique obligations that apply to government lawyers—especially when those private lawyers are operating under a contingency-fee arrangement. The financial incentives intrinsic to such arrangements create an overwhelming incentive to pursue a judgment or settlement in the government's favor—even if that outcome would be at odds with the public interest or impinge on the constitutional rights of regulated parties. And here, where the State's baseless enforcement action against BMS and Sanofi for failing to make specific statements about Plavix itself constitutes and imposes continuing harm as a First Amendment violation, those incentives do not merely threaten fundamental constitutional rights—they impel contingency fee counsel to violate them.

COUNT I

(42 U.S.C. § 1983 - Violation of the First Amendment to the United States Constitution)

126. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

127. The Free Speech Clause of the First Amendment of the United States Constitution provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Fourteenth Amendment of the United States Constitution makes this proscription applicable to the States and their political subdivisions. *E.g.*, *NIFLA*, 138 S. Ct. at 2371.

128. In addition to protecting against restrictions on speech, the First Amendment strictly limits the government's ability to compel individuals or entities to speak when they do not wish to do so.

129. The State's action under the UDAP statute seeks, by means of massive punitive sanctions, to compel the Companies to provide specific warnings on the labeling for Plavix regarding genetic variability of response.

130. The State seeks to recover these civil penalties even though it has not alleged—and contends it need not allege—that anyone actually suffered injury from Plavix.

131. The warning that the State claims the Companies should have provided is neither factual nor uncontroversial, and is unduly burdensome and unjustified. Contrary to the State's proposed warning, there is no established link between genetic traits and clinical outcomes for patients using Plavix, and medical experts, professional associations, and regulatory agencies do not recommend routine genetic testing.

132. The warnings that the State claims the Companies should have provided would have been inaccurate.

133. At a minimum, the warnings that the State claims the Companies should have provided were the subject of active scientific debate during some of the period covered by this lawsuit, and conflicted with the overwhelming scientific consensus thereafter.

134. The State's attempt to compel speech about genetic variability of response to Plavix is speaker-based, content-based, and viewpoint-based.

135. Having conducted no serious investigation of Plavix, identified no medical concerns, and never contemplated this lawsuit before private lawyers presented it as a gift-wrapped package, the State lacked any legitimate sovereign interest in initiating a UDAP enforcement action against the Companies to compel them to warn on the

labeling of Plavix that the drug is less effective for patients with certain genetic traits. The State still lacks any legitimate sovereign interest in prosecuting the suit, particularly through private lawyers.

136. The State's UDAP action is not narrowly tailored to serve a compelling government interest.

137. The State's UDAP action does not directly advance a substantial government interest and burdens First Amendment rights more extensively than necessary to serve that interest.

138. The State's UDAP action, with the prospect of hundreds of millions or billions of dollars in liability for engaging in truthful speech, chills the Companies and other pharmaceutical manufacturers from engaging in scientific debates about Plavix as well as about other products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC demand judgment against the State as follows:

a. A declaration, pursuant to 28 U.S.C. § 2201, that the State's pursuit of a civil enforcement action against the Companies under Hawai`i's UDAP statute for alleged failure to warn about genetic variability of response to Plavix violates the First Amendment of the U.S. Constitution.

b. In the event the Court does not enter the declaration requested above, a declaration, pursuant to 28 U.S.C. § 2201, that the State's initiation and prosecution of a civil enforcement action against the Companies under Hawai`i's UDAP statute for alleged failure to warn about genetic variability of response to Plavix, using private

contingency fee counsel, violates the First Amendment of the U.S. Constitution.

c. Preliminary and permanent injunctive relief prohibiting the State from pursuing a civil enforcement action against the Companies under Hawai`i's UDAP statute for alleged failure to warn about genetic variability of response to Plavix.

d. In the event the Court does not grant the injunctive relief requested above, preliminary and permanent injunctive relief prohibiting the State from using private contingency fee counsel to litigate its UDAP enforcement action against the Companies statute for alleged failure to warn about genetic variability of response to Plavix.

e. All costs, attorneys' fees, and expenses that the Companies reasonably incur, *see* 42 U.S.C. § 1988.

f. Such other and further relief as this Court deems just and proper.

DATED: Honolulu, Hawai`i, January 7, 2020.

/S/ PAUL ALSTON
PAUL ALSTON
LOUISE K. Y. ING
ANAND AGNESHWAR
(*Pro Hac Vice pending*)
DANIEL PARISER
(*Pro Hac Vice pending*)
ROBERT N. WEINER
(*Pro Hac Vice pending*)
SALLY L. PEI
(*Pro Hac Vice pending*)

Attorneys for Plaintiffs

APPENDIX E

IN THE CIRCUIT COURT OF THE FIRST CIRCUIT
STATE OF HAWAI'I

STATE OF HAWAI'I, EX REL. CLARE E. CONNORS,
ATTORNEY GENERAL,
PLAINTIFF,

VS.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO, INC., SANOFI S.A., and DOE DEFENDANTS 2 TO 100,

DEFENDANTS.

Civil No. 14-1-0708-03 DEO
(Other Non-Vehicle Tort)

Trial Date: October 26 2020—November 20, 2020
Trial Judge: Honorable Dean E. Ochiai

FINDINGS OF FACT, CONCLUSIONS OF LAW, DECISION AND ORDER

This is a civil enforcement action brought on behalf of and in the name of the State of Hawai`i by its Attorney General ("**State**" or "**Plaintiff**"), against Defendants Bristol-Myers Squibb Company ("**BMS**") and Sanofi Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo Inc. (collectively "**Sanofi,**" and, together with BMS, "**Defendants**"), under Chapter 480, Hawai`i Revised Statutes

("**UDAP**"), Section 661-10, Hawai`i Revised Statutes, and other applicable Hawai`i law.[1]

The gravamen of the State's Second Amended Complaint is that Defendants marketed their prescription antiplatelet medication, Plavix (generic name clopidogrel), in an unfair or deceptive manner, in violation of Hawai`i Revised Statutes ("HRS") Section 480-2 ("HRS § 480-2" or "Section 480-2") and other applicable Hawai`i law, by failing to warn Plavix patient-consumers and their prescribing physicians that Plavix had diminished or no effect for many patients, particularly those of East Asian and/or Pacific Island ancestry due to the prevalence of genetic variants ("**polymorphisms**") in the enzymes produced in the livers of these patient populations. The State asserts that Defendants engaged in these alleged unfair or deceptive acts or practices from the time that Defendants first began selling Plavix in December 1998 (hereinafter "**launch**") until a "**boxed warning**," also known colloquially as a "**Black Box Warning**," was added to the Plavix label at the insistence of the U.S. Food and Drug Administration ("FDA") sometime in or after March 2010.

In its Second Amended Complaint the State prayed for declaratory and injunctive relief, civil penalties, disgorgement of profits, punitive damages, attorneys' fees, costs of suit, and such other and further relief as the Court deems just in the premises.

By agreement of the parties, this matter was tried before the Court without a jury over a period of four weeks, beginning on Monday, October 26, 2020 and ending on Friday, November 20, 2020. Due to the COVID-19

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[1] At one time, the Sanofi Defendants' French parent company, Sanofi S.A., was also a party to this action. However, it was dismissed as a party by agreement on February 14, 2020. [Dkt. No. 726]

pandemic the trial was conducted entirely via the Zoom videoconferencing platform.

As set forth in more detail below, the Court finds in favor of the State and against Defendants for the relief set forth herein.

Citations to specific evidence herein are merely illustrative and are not intended to reflect the entire body of evidence adduced at trial that supports the Court's findings and conclusions.

FINDINGS OF FACT

1. Plavix, whose generic name is clopidogrel bisulfate (hereinafter "Plavix" or "clopidogrel"), is an oral "antiplatelet" medication in tablet form. "Platelets" are cells that circulate in the bloodstream and bind together — "aggregate" — to form clots when a blood vessel is damaged. Antiplatelet medications are designed to inhibit the aggregation of platelets when the formation of clots is undesirable, for example when a patient has recently suffered a heart attack or stroke and is at risk of another adverse event if the formation of clots is not prevented.

2. Plavix, was developed, manufactured, and placed into the prescription drug marketplace by defendants BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC. formerly known as SANOFI-AVENTIS U.S. INC., and SANOFI-SYNTHELABO LLC (hereafter collective identified as "Defendants").

3. In the early 1990's new developments were taking place to treat cardiac events due to narrowing or "clogged" arteries. Balloon catheterization with the installation of an arterial stent was becoming a popular alternative to open heart bypass surgery. This new process was less invasive and produced the desired result without the need for major open-heart surgery.

4. One of the negative outcomes of heart stent insertions was that platelets reacted to the stents and formed clots thereby reducing or stopping the effectiveness of the stent.

5. The formation of clots in the blood vessel of a patient who has recently suffered a heart attack or stroke, or who suffers from other cardiovascular conditions such as peripheral artery disease ("PAD"), can have catastrophic, and often fatal, consequences. The purpose of antiplatelet medications like Plavix is to reduce the risk of such recurrent adverse events by inhibiting platelet aggregation.

6. Plavix is what is known as a "prodrug." Unlike most medications, which are active when ingested, a prodrug must be activated by the patient's body, usually by enzymes in the patient's liver ("hepatic enzymes"), but sometimes by enzymes elsewhere in the patient's body or other mechanisms of action.2 If, for any reason, the patient's body fails to bioactivate the prodrug, it is effectively a placebo and remains inert within the body until it is eliminated,3 in which case the patient receives none of the risk reduction or other benefit intended. If the patient's body only partially activates the prodrug, the patient may, to a greater or lesser degree, receive only partial benefit or risk reduction, which may be insufficient to prevent an adverse event.

7. Plavix is a prescription drug, and like all prescription drugs its marketing, sale and prescription are subject to regulation by the U.S. Food and Drug Administration

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[2] An enzyme is a substance, almost always a protein, which acts as a catalyst in living organisms, regulating the speed of biological reactions.

[3] When used herein, terms such as "bioactivate" and "bioactivation" mean the conversion of a prodrug to its active metabolite in order for the prodrug to produce its intended effect.

("FDA"). The FDA determines the approved uses ("indications") to which a prescription drug may be put, and under what circumstances it may be prescribed. The FDA also issues regulations that impose various obligations on a drug manufacturer regarding labeling of a drug, as well as obligations and limits regarding the manufacturer's marketing of the drug.

8. In order to obtain FDA approval of a new drug, a manufacturer or other "sponsor" must file a "New Drug Application" and subject the drug to a series of preclinical and clinical trials. Preclinical trials involve study of the drug *in vitro* or in animals. Clinical trials involve study of the drug in humans. Clinical trials ordinarily consist of three "phases": (a) Phase I, a study of the drug in a relatively small group of healthy volunteers or patients with the disease/condition over a period of several months in order to determine the appropriate dosage for the drug, how it should be given, and how it affects the body; (b) Phase II, a study of up to several hundred patients with the disease/condition over a period of several months to two years in order to evaluate the drug's efficacy and side effects; and (c) Phase III clinical studies are often referred to as "pivotal" clinical studies because they are the studies upon which the FDA bases its final determination of whether the drug is safe and effective for use in humans for the indication that will be on the drug's label. Phase III studies are large, usually thousands of patients, complex and expensive to perform.

9. The Phase III trial for Plavix (clopidogrel) involved a combined head-to-head comparison of Plavix to aspirin for the treatment of three different cardiovascular conditions, myocardial infarction (heart attack), ischemic stroke, and peripheral artery disease ("PAD"). The trial is known by the acronym "CAPRIE" (**C**lopidogrel versus **A**spirin in **P**atients at **R**isk of **I**schemic **E**vents).

10. In CAPRIE, Plavix was compared to aspirin because aspirin is also an antiplatelet medication. Aspirin has proven effective (versus placebo) in reducing cardiovascular events in patients with recent heart attack or stroke. In 1997 aspirin was considered the standard of care antiplatelet agent for prevention of arterial thromboses.

11. The results of the CAPRIE study showed only marginal overall benefit over aspirin across the three cardiovascular conditions studied. For patients who enrolled in the trial on the sole basis of a recent myocardial infarction, Plavix was numerically inferior to aspirin. The CAPRIE study showed a significant relative risk reduction for study participants with PAD (23.7%), but the risk reduction was less significant for study participants who had suffered a recent stroke (7.3%) and was actually less than aspirin for those who had recently suffered a heart attack (-4.0%). As a result, Plavix was not approved for the primary prevention of heart attack, stroke and/or PAD and was instead approved only for the secondary treatment of patients who had already suffered a heart attack or stroke or who had previously been diagnosed with PAD. This approval was issued on November 17, 1997.

12. When Defendants were seeking approval to conduct the CAPRIE clinical trial they made a commitment to the FDA to study the effects of race during the trial. Yet, when the study was conducted Defendants included only 5% non-Caucasians. Nevertheless, as relevant here, the trial did detect a **statistically significant** disparity in the number of adverse events suffered by non-white racial groups. ("There was a significant interaction between treatment and race (p=0.006), The event rate was higher for clopidogrel in Black patients, Oriental patients, and patients of "Other" race....")

13. This racial disparity in the response to Plavix was contained in Defendants' January 13, 1997 internal report

of the CAPRIE study (hereinafter "**CAPRIE Report**). However, the medical article about the results of that trial, which was published for the broader medical community, made no mention of this statistically significant racial disparity (hereinafter "**CAPRIE Article**"). As a result, outside scientific researchers were denied this important information, which likely impeded the evolution of the science in this area.

14. In February of 1997, the Defendants completed an internal report, "**MIH0012,**" which revealed that three Cytochrome P450 genes were principally involved in the metabolism of Plavix within the body, specifically the isoforms CYP2B6, CYP2C19 and CYP3A4, but others — CYP1A2, CYP2C9 and CYP2E1 — might possibly be involved.

15. In March of 1998, prior to Plavix's launch into the commercial market, Defendants completed a meta-analysis of internal data regarding Plavix. (hereinafter "**Meta-Analysis**"). The Meta-Analysis found that almost one-third of Plavix patients (32.2%) had less than 20% response to the drug and 3.4% did not respond to any pharmacological tests used (collectively hereinafter "poor responders").

16. The evidence indicated that this meta-analysis—and its findings that Plavix had a "poor responder" problem—was not shared with the FDA until 2005 (seven full years after the conclusions were known to the Defendants), in an appendix to a separate, subsequent meta-analysis. The State also asserted that, even when the information was eventually disclosed to the FDA, it was "buried" in a large volume of other documents in order to obscure the lengthy delay in its disclosure, as well as its findings.

17. In November of 1998, Defendants completed an internal report, "**MIV0265,**" which confirmed the results of "**MIH0012**" that CYP2C19 was one of the enzymes

principally involved in the metabolism of Plavix within the body.

18. Defendants launched the sale of Plavix to the public in December 1998.

19. Defendants assert that at the time of launch they did not know precisely how Plavix acted within the body to create its antiplatelet effect, *i.e.*, the inhibition of platelet aggregation. They argue that "science evolves," and therefore their failure to include information that they did not know cannot be unfair or deceptive. However, the State argues persuasively, and several of the Defendants' witnesses conceded that, "science only evolves if you do the research."

20. Further, the evidence presented at trial established that Defendants knew at least the following at the time of launch:

a) Plavix is a prodrug;

b) Plavix is bioactivated by enzymes in the patient's liver;

c) the enzymes necessary to activate a prodrug are often produced by a gene group known as Cytochrome P450 (each one of which is identified by an alphanumeric designation beginning with "CYP");

d) per Defendants' internal reports, CYP2C19 and CYP3A4 were two of the Cytochrome P450 genes principally involved in the metabolism of Plavix within the body.

e) CYP2C19 is and was known to be genetically polymorphic, i.e., had several different variant forms, some of which might

potentially be able to activate a prodrug and some of which might not; [4]

f) CYP3A4 is not polymorphic with respect to the activation of Plavix;

g) in other prodrugs known to be bioactivated by CYP2C19, the polymorphisms of CYP2C19 had been shown to be less effective or to have no effect in activating the prodrug;

h) more than four years before the launch of Plavix, CYP2C19 polymorphisms were shown to interfere with the metabolization of drugs, for example in an anticonvulsant named S-mephenytoin, which is a necessary step in the bioactivation of prodrugs metabolized by that gene;

i) the team of researchers who demonstrated the adverse effect of CYP2C19 polymorphisms on the bioactivation of S-mephenytoin (hereinafter "**de Morais Team**") developed a simple PCR-based laboratory test (which was later patented) to identify the CYP2C19 gene and its genetic polymorphisms;

j) in the published article regarding their study, the de Morais Team explained how to conduct their CYP2C19 PCR-based genetic test in a clinical setting, concluding that the PCR-based genetic test for the defective CYP2C19 allele: "will be useful in clinical studies investigating the importance of this

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[4] Where a gene has several different variations that are common enough not to be considered mutations, each of the variations is referred to as an "**allele**." Alleles that are unable to activate a prodrug are commonly referred to as "**loss-of-function**" alleles.

genetic defect in drug metabolism in humans." (Exhibit D1098);

k) the CYP2C19 polymorphisms that were shown to have impaired effect on the metabolization of S-mephenytoin (loss-of-function alleles) were known to be significantly more prevalent in East Asians than in other major races by as much as five-fold;

l) every individual has two CYP2C19 genes, one from each parent, both of which may be "normal" or one or both of which may be mutations (abnormalities) or alleles (normal genetic variations);

m) in two additional studies conducted by de Morais, CYP2C19 polymorphisms accounted for 100% of Japanese subjects who were "**poor metabolizers**," *i.e.*, who could not properly bioactivate the prodrug (S-mephenytoin) [P0264] and 100% of Chinese subjects [P0305];

n) there was a group of poor responders to Plavix; and

o) that Plavix patients who are poor metabolizers are likely at higher risk of a recurrent heart attack or stroke than those who are not poor metabolizers.

21. The lack of a uniform patient response to Plavix of the kind that was revealed by the Meta-Analysis has been referred to by a number of names, such as "Variability of Response" ("VOR"), Variability of Platelet Response ("VPR"), "Plavix resistance," "poor metabolism" and "poor response." Given the potential severity of the cardiovascular conditions Plavix was intended to guard against, the discovery that this drug was not working as intended for almost one-third of patients was a matter

that would be of great concern to patients and physicians and should have been of great concern to Defendants. Indeed, prior to launch, Defendants' MIH0012 emphasized that it was "important [to] identify[] potential interindividual differences in metabolism and/or clearance due to genetic polymorphism." Defendants further noted that "[t]he use of *in vitro* methods has been recommended to investigate these issues[.]" *Id.*

22. Despite this acknowledgement and Defendants' awareness that: (1) they did not know precisely how Plavix was bioactivated; (2) CYP2C19 played a role in the bioactivation of Plavix; (3) CYP2C19 was genetically polymorphic and its polymorphic nature prevented the activation of other prodrugs; (4) CYP3A4 did not have a known loss-of-function genetic polymorphism that impaired patients' metabolism and pharmacodynamic responses to drugs; (5) Defendants' own Meta-Analysis showed that as many as 32.2% percent of test subjects received less than 20% of Plavix's antiplatelet effect and 3.4% received no benefit at all; (6) the CAPRIE clinical trial had shown a statistically significant difference in the effectiveness of Plavix for Caucasians versus those of other races; and (7) the various de Morais studies prior to the Plavix launch indicated that CYP2C19 polymorphisms were found to be a 100% predictor of poor metabolizers (for S-mephenytoin), Defendants did not bring this information to the FDA's attention or actively conduct research in an effort to understand the problem and correct it, nor did Defendants try to warn the public or the FDA about these issues. Instead, Defendants, by their words and conduct over the ensuing years, evidenced a clear intent not to conduct or sponsor any research that might confirm the existence of and/or reason for "Plavix resistance" or "Variability of Response" to a patient's race or other identifiable genetic factors.

23. One of the State's medical and regulatory experts, Dr. Laura M. Plunkett presented unrebutted testimony that the Defendants were obligated to update their label to include a warning or precaution about the poor metabolizer issue based on the type of information brought to light by Defendants' 1998 Meta-Analysis, coupled with Defendants' knowledge that CYP2C19 was one of three principal enzymes for the metabolism of Plavix. She also testified that drug companies should be the primary entity investigating potential problems with their own drugs to ensure that their label contains all the warnings and information necessary. Her testimony is supported by the United States Supreme Court, which held:

> [I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. A drug manufacturer is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. Thus, ***when the risks of a particular drug become apparent, the manufacturer has a duty to provide a warning that adequately describe[s] that risk.***

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1677 (2019) (internal citations and quotations omitted) (emphasis added); Wyeth v. Levine, 555 U .S. 555, 571 (2009).

24. Instead of investigating the diminished response to Plavix observed in a significant percentage of the patient population, a limitation known to Defendants at the time of launch, Defendants instituted a policy of systematically opposing any research into Plavix resistance or related issues. Spanning the entire relevant time period, Defendants' internal records repeatedly demonstrated an intent to avoid pursuing the issue. In many instances, their internal statements reflecting an unwillingness to support Plavix-related research were tied to concerns

about the potential impact of adverse clinical trial results on sales of the drug.

25. The State's medical experts, Dr. Laura M. Plunkett and Dr. Paul A. Gurbel, testified at trial that at the time of launch, Defendants possessed the means to study the correlation between CYP2C19 polymorphisms and VOR, as well as the correlation between CYP2C19 polymorphisms and clinical outcomes (i.e. heart attacks, strokes, and cardiovascular death).

26. Defendants argued that they did not investigate the impact of CYP2C19 polymorphisms on Plavix Variability of Response because they believed at the time of launch and for many years afterward that the "primary metabolic pathway," i.e., the primary means by which a patient's body produced Plavix's active metabolite, was by way of hepatic enzymes produced by the CYP3A4 gene.

27. In evaluating why Defendants did not discover the cause of the poor response by non-Caucasians reflected in the CAPRIE study and the diminished response for 32% of subjects reflected in Defendants' Meta-Analysis, the Court finds much more persuasive the words and actions reflected in Defendants' corporate records, and testimony consistent with them, which evidence a clear intent by Defendants to avoid any studies that might unearth negative information about Plavix.

28. For example, in **May of 2000,** BMS's medical director proposed supporting a clinical trial to examine the role of race in patients' response to the drug and noted that "such a trial would be small, easy to do, and could be done well in time." (P0603). However, his counterparts at Sanofi quickly admonished him that such a trial "always run[s] the risk to show a difference . . . and then we are really in trouble." Sanofi further warned that such a study "could bear significant risk." *Id.* Shortly, thereafter, Defendants' joint Lifecycle Management Committee ("the LCM"), the internal body responsible for determining

which studies and what research to conduct/fund/support, determined "not to be proactive at present" on proposed trials regarding the role of race in Plavix resistance. (P0604). This statement of policy was particularly significant considering Defendants' earlier observation in the CAPRIE Report of "a statistically significant interaction between treatment and race."[5]

29. Betraying their own argument, Defendants, in an effort to combat a competitor drug, noted in an internal planning memo that "[a]dditional studies needed; can be small trials to help us to 'shape the debate." (P0430).

30. In **June 2001,** the LCM discussed a proposed study on aspirin resistance, but ultimately rejected it because "it could lead to a similar trial on [Plavix] resistance." (P0607). In **2002,** the LCM continued to reject any studies regarding aspirin because they "could lead to the same questions about [Plavix]," they "could open the door to `[Plavix] non-responders,' and because there was "no commercial interest" in such studies. (P0608; P0425).

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[5] At trial, Defendants introduced testimony of current and former executives that the LCM exercised decision-making authority only over "local" studies, which were characterized as small studies to be conducted within a particular country. Defendants asserted that larger, more significant studies were addressed at the "corporate" level. However, Defendants produced no persuasive corporate-level documents confirming the otherwise self-serving testimony of its executives that proposals for any large-scale, appropriately powered studies were being considered or approved for the purpose of determining the impact, if any, of a patient's race on their responsiveness to Plavix, and, if such an impact was found, whether genetic polymorphisms were the cause. Significantly, the State's medical/clinical research expert, Paul A. Gurbel, MD, explained persuasively that the larger studies that Defendants did conduct or sponsor were not designed to resolve the VOR issue, or the role of CYP2C19 in the bioactivation process, or the impact of race on variability of response.

31. Later that year, BMS's medical director acknowledged internally that "Sanofi has generally been 'down' on suggestions to study [aspirin] resistance because they are afraid that '[Plavix] resistance is right around the corner." (P0562). As one of his colleagues noted, "in my opinion, [Sanofi's]/our reluctance to go down the path toward documentation of [Plavix] resistance is understandable, but it will catch up with us and perhaps be an unpleasant and costly surprise when others document it without asking our permission to do so." *Id.* This statement was part of a pattern to conceal, and avoid documenting, facts available to the company but unknown to the public or the scientific community

32. In **2002,** a study conducted by researchers not affiliated with Defendants was published that reflected resistance to Plavix among 28% of the patient population.[6]

33. In **2003,** several important studies were published. One was conducted by the State's medical/clinical research expert, Dr. Paul A. Gurbel ("Dr. Gurbel"), which found that "[t]here was marked interindividual variability in drug response" in upwards of 31% of the patient population.[7] At the time, Dr. Gurbel was regarded by Defendants as "important and brilliant." For many years thereafter, Defendants considered him "the [world-wide] expert on VPR." (P0583).

34. Subsequent studies published that year confirmed Dr. Gurbel's findings. Nevertheless, Defendants'

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[6] Jaremo P, Lindahl TL, Fransson SG, Richter A. *Individual variations of platelet inhibition after loading doses of clopidogrel.* J Intern Med. 2002 Sep; 252(3):233-8.

[7] Gurbel PA, Bliden KP, Hiatt BL, O'Connor CM. *Clopidogrel for Coronary Stenting: Response Variability, Drug Resistance, and the Effect of Pretreatment Platelet Reactivity.* Circulation. 2003;107:2908-2913. This Court considers it significant that Defendants did not disclose their 1998 Meta-Analysis to the FDA until after this Gurbel study was published.

internal records noted that they "remain[ed] adverse to doing any further research on either aspirin—or [Plavix]—resistance because of the potential negative marketing implications." (P0569). This caused one of BMS's employees to observe that he "had difficulty mobilizing the LCM to address the importance of understanding Plavix resistance through our data and proactive research", and another to note that "[t]here doesn't appear to be a high sense of urgency around this on their [Sanofi's] side." *Id.*

35. In **2004,** Defendants continued rejecting clinical trials whenever "some negative conclusions could be drawn" (P0557), despite their own determination that "it is logical, although not definite, that this variability in response has clinical consequence." (P0507).

36. At a November **2005** meeting at the American Heart Association, Defendants' records indicate that one "Key Opinion Leader" stated that Plavix resistance "is a real phenomenon," however "BMS is putting out anything they can to say it doesn't exist."[8] (P0429).

37. In June of **2006,** a study conducted by researchers not affiliated with Defendants supported the hypothesis that there was an association between genetic polymorphisms in patient CYP2C19 liver enzymes and Plavix VOR. Though it was already established that these CYP2C19 polymorphisms were more prevalent among certain Asian populations, Defendants took no action to update Plavix's label to inform prescribing physicians and patients about Plavix resistance.

38. That same month, during a "Breakout Session" of an "Anti-Platelet Therapy Working Group," a group of

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[8] A "Key Opinion Leader" or "KOL" is an expert, typically a physician, with whom the drug companies work. KOLs are individuals that give advice to the company and who will speak on behalf of the company about a specific product.

Key Opinion Leaders told the Defendants that they had their "head in the sand about . . . clinical resistance." (P0082).

39. Throughout this period, Defendants repeatedly tried to position Plavix in the marketplace as superior to aspirin and other antiplatelet medications, particularly with respect to recent heart attacks. Likewise, at trial Defendants tried to argue that there were no available alternatives to Plavix for treatment of recent heart attacks. However, from even before the Plavix launch, and continuing through at least 2007, the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"), the division within the FDA responsible for evaluating the truthfulness of a drug manufacturer's marketing campaigns repeatedly advised Defendants that they could not state or imply that Plavix was superior to aspirin because the scientific research did not support such a claim. For this reason, the FDA repeatedly told Defendants that such claims were misleading — specifically using the term "misleading". This occurred with respect to both marketing materials that Defendants submitted to the FDA for prior approval and marketing materials the FDA learned were already in circulation through its routine surveillance program. Thus, the FDA repeatedly told Defendants, over at least the first nine years of Plavix's life cycle, that it was misleading to claim Plavix was superior to aspirin.

40. The Court notes this, not because the State is asserting any claims against Defendants for these kinds of promotional materials, but because the Court views them as a reflection of Defendants' unwavering refusal to accept the reality that Plavix, while potentially a very beneficial medication for many patients (which the State has never denied), was not a "silver bullet" or a "wonder drug" that would cure all ills for all patients. Rather, that it was a drug, like any other, that had its limitations. Those

limitations could potentially contribute to very significant harm, including death, to large groups of patients unable to bioactivate it, or only able to activate it partially. The Court makes a point of this because that seemingly blind refusal to accept the reality of Plavix's limitations has apparently continued to the present, including the course of this four-week trial.

41. Because Defendants' position is so at odds with the evidence against them —evidence that in many cases consists of their own internal corporate records — it could not help but affect this Court's view of Defendants' candor and credibility. The Court found that many times Defendants told only part of the story.

42. For example, Defendants presented expert testimony that according to the American Heart Association ("AHA") and the American College of Cardiology Foundation ("ACCF") Plavix is the "gold standard" for treatment of cardiovascular conditions, with a "Class 1" recommendation (the highest recommendation available) by the AHA/ACCF. But it was soon brought to light that Plavix has a Class 1 certification only for certain specific conditions and procedures, and only when it is prescribed with aspirin as part of a dual antiplatelet therapy program. One of Defendants' medical experts, Todd Seto, M.D., conceded this point when pressed.

43. In a similar vein, most of the clinical studies Defendants relied on to support their claim that Asian CYP2C19 poor metabolizers do no worse on Plavix than other patients involved dual antiplatelet therapy ("DAPT") in which patients were given not just Plavix but also aspirin. Dr. Seto conceded on cross-examination that he does not know, and does not have an opinion, whether the inhibition of platelet aggregation that a CYP2C19 poor metabolizer experiences while undergoing DAPT is due to the Plavix or to the aspirin. This concession entirely undermined the probative value of the DAPT-based

studies and Defendants' suggestion that these studies mean Plavix works just as well for CYP2C19 poor metabolizers.

44. Throughout **2007 and 2008,** further studies indicated that CYP2C19 polymorphisms were responsible for poor patient responsiveness to Plavix. Beginning in late 2008, and continuing throughout **2009,** additional studies established that CYP2C19-based poor responsiveness to Plavix led to an increased risk of cardiac events (i.e. "clinical outcomes") when compared to patients who were normal or intermediate responders.

45. Shortly before these studies regarding clinical outcomes emerged, clinical researchers determined that when Omeprazole (a proton-pump inhibitor) was given to a patient who was also taking Plavix, the Omeprazole interfered with the functioning of the CYP2C19 alleles and caused a corresponding reduction in Plavix's antiplatelet effect. This caused significant concern at the FDA, where key personnel pressed Defendants regarding the clinical implications of that study, the scientific history of VOR, and how the label should be updated to reflect this critical information.

46. While these discussions were underway, a study conducted by researchers not associated with Defendants was published in the New England Journal of Medicine which found that "[a]mong persons treated with clopidogrel, carriers of a reduced-function CYP2C19 allele had significantly lower levels of the active metabolite of clopidogrel, **diminished platelet inhibition,** and a higher rate of major adverse cardiovascular events, including stent thrombosis, than did noncarriers" (emphasis added) (hereinafter "**Mega Study**). The results of this study, in conjunction with the Omeprazole issue, prompted the FDA to insist on addition of language in the Plavix label explaining the CYP2C19 poor metabolizer phenomenon and noting the availability of genetic testing.

47. At trial, there was conflicting evidence regarding Defendants' response to the proposed label change. Defendants presented some evidence suggesting that Defendants worked collaboratively with the FDA to effect the label change. On the other hand, the State presented evidence suggesting that Defendants were more resistant to the label change, with Defendants arguing that the relationship between CYP2C19 polymorphisms and potential outcomes "is not yet fully understood." When the FDA continued to insist on the inclusion of VOR-related information in Plavix's label, Defendants sought help from their stable of "Key Opinion Leaders" ("KOLs") — doctors and scientists Defendants relied on to publicly speak favorably about Plavix — hoping to push back against the FDA's insistence. In an internal email following such an effort, one employee informed his colleagues that their KOLs would provide no such support, stating:

> I have to tell you that I have had in depth 1:1's with about 6 senior KOLs since I have been at [the American College of Cardiology] and the mood is very negative toward us (people like Dr Topol, Gurbel, Eikelboom, Fox are all saying that ***they have been telling us this for years and we chose to ignore them and bury our head in the sand and so they feel no sympathy toward our current situation!).*** Therefore, my concern is that we cannot look to KOL support should the FDA follow through.

(P0533) (Emphasis added)

48. In May 2009, the FDA required Defendants to add information to the Plavix label regarding CYP2C19 and poor metabolizers. The following information was also included regarding the many studies that established a link between CYP2C19 and clinical outcomes:

> To date, the impact of CYP2C19 genotype on the pharmacokinetics of clopidogrel's active metabolite has been evaluated in 227 subjects from 7 reported

studies. Reduced CYP2C19 metabolism in intermediate and poor metabolizers decreased the CMax and AUC of the active metabolite by 30-50% following 300 and 600mg loading doses and 75mg maintenance doses. Lower active metabolite exposure results in less platelet inhibition or higher residual platelet reactivity. To date, diminished antiplatelet responses to clopidogrel have been described for intermediate and poor metabolizers in 21 reported studies involving 4,520 subjects. The relative difference in antiplatelet response between genotype groups varies across studies depending on the method used to evaluate response, but is typically greater than 30%.

The association between CYP2C19 genotype and clopidogrel treatment outcome was evaluated in 2 post-hoc clinical trial analyses (substudies of CLARITY-TIMI 28 [N=465] and TRITON-TIMI 38 [n=1,477]) and 5 cohort studies (total n=6,489). In CLARITY-TIMI 28 and one of the cohort studies (n=765; Trenk), cardiovascular event rates did not differ significantly by genotype. In TRITON-TIMI 38 and 3 of the cohort studies (n=3,516; Collet, Sibbing, Giusti), patients with an impaired metabolizer status (intermediate and poor combined) had a higher rate of cardiovascular events (death, myocardial infarction, and stroke) or stent thrombosis compared to extensive metabolizers. In the fifth cohort study (n=2,208; Simon), the increased event rates were observed only in poor metabolizers.

Pharmacogenetic testing can identify genotypes associated with variability in CYP2C19 activity.

(P0410 at nn. 1-6 and accompanying text) (Footnotes omitted).

49. This information was included in the Pharmacogenetics section of the Plavix label. But very shortly thereafter, in March of 2010, the FDA took the additional

step of requiring Defendants to place this information in a "boxed warning," also known as a "black box warning," and to move information regarding this issue to the "Warnings and Precautions" section of the label.

50. A boxed warning is a section of the drug label reserved for serious warnings, particularly those that may lead to death or serious injury.

51. The 2010 boxed warning stated the following:

> **WARNING: DIMINISHED ANTIPLATELET EFFECT IN PATIENTS WITH TWO LOSS-OF-FUNCTION ALLELES OF THE CYP2C19 GENE**
>
> **The effectiveness of Plavix is dependent on its activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19 *[see Warnings and Precautions (5.1)]*. Plavix at recommended doses forms less of that metabolite and has a smaller effect on platelet function in patients who are CYP2C19 poor metabolizers. Poor metabolizers with acute coronary syndrome or undergoing percutaneous coronary intervention treated with Plavix at recommended doses exhibit higher cardiovascular event rates than do patients with normal CYP2C19 function. Tests are available to identify a patient's CYP2C19 genotype; these tests can be used as an aid in determining therapeutic strategy *[see Clinical Pharmacology (12.5)1* Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers. *[see Dosage and Administration (2.3).]***

(Emphasis in original)

52. In 2016, the boxed warning was modified to state the following:

WARNING: DIMINISHED ANTIPLATELET EFFECT IN PATIENTS WITH TWO LOSS-OF-FUNCTION ALLELES OF THE CYP2C19 GENE

The effectiveness of Plavix results from its antiplatelet activity, which is dependent on its conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19 *[see Warnings and Precautions (5.1), Clinical Pharmacology (12.3)1* Plavix at recommended doses forms less of the active metabolite and so has a reduced effect on platelet activity in patients who are homozygous for nonfunctional alleles of the CYP2C19 gene, (termed "CYP2C19 poor metabolizers"). Tests are available to identify patients who are CYP2C19 poor metabolizers *[see Clinical Pharmacology (12.5)1* . Consider use of another platelet P2Y12 inhibitor in patients identified as CYP2C19 poor metabolizers.

(Emphasis in original)

53. Defendants argued at trial that they could not have included the above information in the Plavix label prior to March of 2010 because they did not "know" of the information prior to late 2008/early 2009. However, the record establishes that at all times relevant hereto, Defendants knew, or should have known, all necessary and relevant information.

54. On July 21, 2020, the Court granted the State's motion for partial summary judgment that the information contained in the 2016 boxed warning was "material" within the meaning of Hawaii's UDAP statute.

55. Defendants argued at trial that the change in the 2016 boxed warning deleted any reference to a causal relationship between CYP2C19 poor metabolizer status and clinical outcomes. But since the boxed warning remains on the Plavix label, Defendants' argument is unpersuasive.

56. The "Medication Guide" portion of the Plavix label, distributed by Defendants themselves, which is directed to consumer-patients—and which patients are instructed to read before they "start taking Plavix and each time [they] get a refill"—stated in both 2016 and today that the information in the boxed warning is "the most important information [you] should know about Plavix."

57. At trial, the State presented the expert testimony of Paul A. Gurbel, MD, a renowned participant in the field of clinical research regarding prescription drugs, and in particular, Plavix.

58. Dr. Gurbel earned his medical degree at the University of Maryland School of Medicine and completed an internship and residency in internal medicine at Duke University Medical Center. He then completed a fellowship in pulmonary and critical care medicine at Johns Hopkins University, followed by fellowships in cardiovascular disease and interventional cardiology, as well as a chief residency in internal medicine at Duke. He is board certified in internal medicine, cardiovascular disease, and interventional cardiology by the American Board of Internal Medicine. In addition to prolific research, Dr. Gurbel remains a practicing clinical cardiologist, cardiac interventionalist, and leading expert on Plavix.

59. Dr. Gurbel serves on the editorial boards for several journals, including Journal of the American College of Cardiology, The American Heart Journal, Journal of the American College of Cardiology Heart Failure, Circulation, The Journal of the Royal Society of Medicine, among others. He is also a reviewer for the New England Journal of Medicine and has authored over 450 major articles in peer-reviewed journals.

60. Dr. Gurbel's research and concepts have been published in over 1,000 peer-reviewed documents. In 2012 alone, he authored 30 manuscripts in the peer-reviewed literature and, in fact, in that year three peer-reviewed

papers developed by Dr. Gurbel and his team were named "most Important Papers in Antiplatelet Therapy" by the prestigious medical journal *Circulation.*

61. Since shortly after Plavix was first introduced to the market, Dr. Gurbel's research has paved the way in understanding its effects. His laboratory pioneered the concept of antiplatelet response variability, a significant limitation of clopidogrel effectiveness. Dominique Roome, a senior medical employee at Sanofi who testified at trial and who was intimately involved with Plavix over the years, readily agreed that she has referred to Dr. Gurbel as an "important and brilliant" Key Opinion Leader, and the world-wide specialist in Variability of Response. Defendants' clinical research expert, Sonia de Morais, MD — the same de Morais who identified the CYP2C19 polymorphisms and their relationship to Variability of Response and race in the mid-1990s, and who developed and later patented the genetic test to identify the various CYP2C19 polymorphisms — likewise expressed deep respect for Dr. Gurbel.

62. At trial, Dr. Gurbel explained why he focused so much of his research on Plavix, stating, "[Y]ou have to remember that, that thrombosis in the coronary artery is what kills the patient, the No. 1 cause, that's why people die. They develop a clot ... they may not survive and have ventricular fibrillation and die. But the No. 1 event, the primary event that closes the artery is aggregation of platelets. So this drug particularly, what we're talking about today, has to be relied on to work all the time. It's not like a statin, it's not like a blood pressure pill, it not like an analgesic. This is the drug given to the patient to prevent the catastrophe. ... Doctors ... were relying on this workhorse drug to prevent the fatal event. So I felt that it was really important, particularly with this drug, to understand the limitations of the drug, and that everyone involved in the care of the patients, and the patients

themselves, being informed consumers and understanding whether to get a stent or whether they get bypass surgery to treat their problems, to know whether they can truly rely on this drug to work all the time." Transcript ("Tr."), 11/2/20 A.M., at 53:25-55:7.

63. Dr. Gurbel testified that he first expressed concern to Defendants about the lack of platelet inhibition in some patients in approximately 2001.

64. Responding to Defendants' assertion that they conducted many studies into Variability of Response, Dr. Gurbel testified: "They didn't. ... I would say broadly, you know, any meaningful research, no." Tr. 11/2/20 A.M., 93:8-17. "I would submit to you that I'm aware of all the meaningful research in this sphere that's ever been done, and there has been, as far as I know, being an expert in this area, publishing over 200 manuscripts on clopidogrel and its antiplatelet effect, that there has been no meaningful research that I know of by the defendants to address this issue of variability of response and its clinical importance." *Id.* at 78:4-11.

65. Responding to defense arguments that a study of 45,000 Chinese in a clinical trial known by the acronym "COMMIT" demonstrated that Plavix works just as well for East Asians as for other races, Dr. Gurbel testified: "What I'm trying to teach you about this, is that the COMMIT study had a relative risk reduction, you see, it's 9 percent, sir. The CURE study [made up primarily of Caucasian patients] had a relative risk reduction of 20 percent. That means that clopidogrel was half as effective clinically in the COMMIT study than in the CURE study. COMMIT had 100 percent Chinese. It was a hugely powered study, 45,000 patients it took to show that meager 9 percent risk reduction. That's the size of a study you need to have to show efficacy, as small as 9 percent. So, there is no question that the COMMIT study demonstrated totally clearly that there's less efficacy in Chinese from

clopidogrel, as compared to CURE, which is Caucasian. That is the clearest evidence of a reduction in treatment efficacy that can be shown up to 2020 between the races. Tr. 11/5/20 at 135:6-23.

66. Responding to Defendants' contention that they could not conduct studies that would establish a link between CYP2C19 poor metabolizers and Variability of Response because the technology was not available to identify the active metabolite, Dr. Gurbel testified:

> Q. And what technological limitations were there, if any, in 1997 or 1998 that would have prevented such a study from being undertaken?
>
> A. Well, the mutation in — in 2C19 that caused the dead gene was identified in landmark work by de Morais published in the Journal of Biological Chemistry [in the early and mid '90s], a very prestigious journal. And so there was an assay that she developed that could have been used.

Tr. 11/2/20 PM, at 66:18-25.

> A. ... You're asking me what could have been done. I mean, there was an assay that was available that was — her lab developed that was being used — they identified the cause of this ethnicity-based poor metabolizer — poor metabolism. Any you could — those patients could have been genotyped and given the drug and their antiplatelet effect could have been examined.
>
> Q. So were there in fact any sort of technological scientific limitations that would have prevented that kind of study from taking place in 1997?
>
> A. No. I mean, they had the — de Morais had the PCR, the assay. I don't — I don't see why it couldn't have been done. If there's an assay available and you know how to measure platelet function, you can do the study. I mean, that's what we did in our studies. We

> determined the genotype in patients undergoing stenting and we gave them clopidogrel. ... [T]hat's totally a doable study.

Id. at 67:1-18.

67. Dr. Gurbel also explained why he and his colleagues were only able to conduct smaller studies when Defendants refused to fund them or supply the drugs needed for larger studies: "We needed funding. So it's a simple matter of funding. ... [T]here's no lack of interest from these investigators around the world. But to put together a large-scale trial, such as a study in the tens of thousands, like has been done to get 15,000 to get the approval of clopidogrel in the CAPRIE trial, or 45,000 in a Chinese population with myocardial infarction, STEMI[.] . . [U]sually the funding comes from private industry, or it comes from a device manufacturer. The only caveat there is that private industry is not going to want to niche their drug. ... [T]hat cuts into market share, and total sale of the drug. ... So without big pharmaceutical interest to fund it, I don't see how these studies ever get done." Tr. 11/5/20 at 33:1-34:9.

68. The State also offered the testimony of pharmacology, toxicology and prescription drug regulation expert Laura M. Plunkett, DABT, at trial.

69. Dr. Plunkett is a pharmacologist, toxicologist, and a United States Food and Drug Administration ("FDA") regulatory specialist. She is board-certified as a Diplomate of the American Board of Toxicology and has authored or co-authored numerous scientific publications. She received her undergraduate degree from the University of Georgia and a Ph.D. in pharmacology in 1984 from the University of Georgia, College of Pharmacy. Her doctoral research was focused in the area of cardiovascular pharmacology, which is the study of mechanisms

underlying drugs used to treat diseases or conditions of the cardiovascular system

70. Dr. Plunkett has over thirty years of experience in the areas of pharmacology and toxicology and has worked in both government and academic research. She has taught pharmacology and toxicology at the undergraduate and post-graduate levels. As a pharmacologist, much of Dr. Plunkett's consulting work has related to understanding and explaining the mechanisms of action of drugs of all types, as well as the toxic effects of drugs. She has a specific expertise in cardiovascular pharmacology, which is the study of drugs used to treat cardiovascular diseases, including antithrombotic drugs. She also has an expertise in pharmacokinetics, which is a discipline within the general area of pharmacology that relates to the way drugs are absorbed, distributed, metabolized and excreted from the human body. Dr. Plunkett has designed clinical trials and analyzed pharmacokinetic data.

71. As a result of her training and work with various clients, Dr. Plunkett has knowledge, experience and expertise related to changes in the FDA regulations over the years from the initial passage of the Federal Food Drug and Cosmetic Act in 1938 up to the most current amendments to the FFDCA. She has published dozens of peer-reviewed articles. She has also authored a book chapter on FDA pharmacovigilance practices and served as a peer-reviewer for medical journals in her capacity as a pharmacologist and toxicologist. She has provided expert testimony and been qualified by both state and federal courts in the areas of pharmacology, pharmacokinetics, toxicology, risk assessment and FDA regulations.

72. Dr. Plunkett testified, among other things, that, in practice, under the criteria set forth in the applicable FDA regulations Defendants would have been obligated to update their label to include a warning or precaution about the poor metabolizer issue based on the type of

information brought to light by Defendants' 1997 Meta-Analysis, coupled with Defendants' knowledge that CYP2C19 was one of three principal enzymes for the metabolism of Plavix. Tr. 10/27/20 A.M. at 71:5-72:2.

73. Dr. Plunkett also testified that, in practice, under applicable FDA regulations Defendants were permitted to add or strengthen a warning or precaution about the poor metabolizer issue without first seeking approval from the FDA.

74. Addressing Defendants' contention that they had no duty to investigate the reasons for the diminished response to Plavix reflected in the Meta-Analysis and other available information, Dr. Plunkett testified that drug companies like Defendants "absolutely" have an obligation to investigate potential problems with their drugs, stating: "That's the basis for why pharmacovigilance and post-market surveillance or continual analysis of data goes on once the drug [is] approved. The paradigm for drug development and approval is that when you are developing a drug, it is understood that you're testing it in a — in a more selective population for the purposes of the clinical study that may or may not be relevant to the real-world experience of patients. So as a result they're — under Section 21 CFR 314, there are specific requirements for companies to perform this type of surveillance of their drugs and the literature, as I talked about earlier, in order to understand whether or not there are risks out there that are different either in terms of something you hadn't seen in your clinical development or you may be seeing it at a greater frequency than you had seen it in your initial clinical development. Or you may be seeing it like in this case where the benefit was shown in the clinical trial, but when it gets out in the real world, there are people that may not appear to be getting the benefit of the real drug. So those are the kinds of things that are a part of good

pharmacovigilance practice." Tr. 10/26/20 at 126:16-127:17.

75. Like Dr. Gurbel, Dr. Plunkett testified about the importance of drug companies to fund clinical trials, stating: "The reason is that the company who makes the drug is going to have the resources to provide the drug to the investigators and also the source of knowledge. It's the single best source of knowledge about the drug itself. As a result, it's difficult sometimes to get funding for large clinical studies that are — can be expensive from sources outside in private grants and things like that. So it is actually important that companies are willing to work with outside investigators to get studies done that involve their drugs." Tr. 10/27/20 P.M. at 92:9-20.

76. Regarding the Defendants' claim that they have conducted numerous studies relating to the poor metabolizer issue, Dr. Plunket testified: "I haven't seen a large clinical trial that has been done by the company or anyone else of the power to be able to answer definitively those questions, and specifically for the individuals that carry two loss-of-function alleles, we haven't completely defined that. No study has been done. But we do know there's an increased risk." Tr. 10/27/20 P.M. at 46:21-47:6.

77. Defendants' trial witness list identified an expert to respond to the opinions of Dr. Plunkett, but when it came time for her to be called to testify Defendants elected not to call her. Therefore, Dr. Plunkett's opinions were unrebutted at trial.

78. Having weighed the admissible evidence presented at trial, and having taken into account the credibility of the witnesses and other evidence presented, the Court finds that Defendants knew at the time of launch that there was a significant issue regarding diminished patient response to Plavix, particularly in those of non-Caucasian races; that for many years Defendants deliberately turned a blind eye toward the problem out of

concern that addressing it might adversely affect Plavix sales and Defendants' profits; that Defendants deliberately withheld vital information from the FDA and the greater medical community about the issue; that Defendants engaged in a pattern and practice of rejecting any proposed studies that might call attention to or generate interest in the issue of Plavix Variability of Response; that Defendants failed to conduct any studies that were designed and adequately powered to investigate Plavix Variability of Response and/or the impact of race and/or CYP2C19 polymorphisms on inhibition of platelet response in Plavix patients; that by engaging in the foregoing conduct Defendants intentionally set back the progress of research into the Plavix Variability of Response issue by many years; and that by doing so Defendants knowingly placed Plavix patients at grave risk of serious injury or death in order to substantially increase their profits.

79. For these reasons, the Court finds that the Defendants were engaged in unfair and deceptive practices in Hawai`i regarding Plavix since its launch in December 1998, and that such violations continued until the boxed warning was added to the Plavix label sometime in or after March 2010.

80. At trial, the State presented expert testimony from Nicole Maestas, Ph.D., regarding the number of retail prescriptions, refills and non-retail units sold in Hawai`i between December 1998 and March 12, 2010. Dr. Maestas is an associate professor of Health Care Policy at Harvard Medical School and a research associate at the National Bureau of Economic Research. She is an economist with broad training in the fields of health economics and health policy whose research concerns the economics of health care utilization, health insurance, and health outcomes. She has many years of experience analyzing health

care data of different types, including prescription drug claims, using a wide range of methodologies.

81. Dr. Maestas calculated the number of retail prescriptions, refills and non-retail units sold during the relevant time period to be 834,012.

82. The Court found Dr. Maestas's testimony to be both helpful and credible, and Defendants offered no expert testimony or even argument to dispute or otherwise counter her calculations. Therefore, the Court finds that 834,012 Plavix retail prescriptions, refills and non-retail units were sold in Hawai`i between December 1998 and March 12, 2010.

83. If any of the Findings of Fact set forth herein shall be deemed Conclusions of Law, they are hereby incorporated by reference in the Conclusions of Law set forth below.

CONCLUSIONS OF LAW

84. The Court has jurisdiction over the parties and the claims in this case.

85. The Attorney General is authorized to bring this action in the name of the State of Hawai`i under Hawai`i Revised Statutes ("HRS") Chapter 480 ("UDAP") and under HRS § 66110.

86. HRS § 661-10, grants the Attorney General broad authority to bring claims in the name of the State "[w]henever it is necessary or desirable ... in order to collect or recover any money or penalty ... or enforce any other right[.]" HRS § 480-3.1 grants the Attorney General the authority to bring a civil action for civil penalties against "[a]ny person, firm, company, association, or corporation violating any provisions of section 480-2[.]"

II. THE STATE'S UDAP CLAIMS

87. HRS § 480-2 declares unlawful any "unfair or deceptive acts or practices in the conduct of any trade or commerce[.]"

88. Hawaii's UDAP statute "outlaws unfair methods of competition and unfair or deceptive trade practices in **sweeping terms.**" *Han v. Yang,* 84 Hawai`i 162, 177, 931 P.2d 604, 619 (App. 1997) (Emphasis added). The statute "was constructed in broad language in order to constitute a flexible tool to stop fraudulent, unfair or deceptive practices for the protection of both consumers and honest businessmen [and businesswomen]." *Id.* To state a claim under UDAP, the State need only prove that Defendants engaged in "[u]nfair or deceptive acts or practices in the conduct of any trade or commerce." HRS § 480-2(a). "To violate HRS § 480-2, a practice need only be unfair or deceptive, not both." *Bald v. Wells Fargo Bank, NA.,* 688 Fed.Appx. 472, 475 (9th Cir. 2017).

A. Deceptive Acts or Practices of Defendants

89. A deceptive act or practice is defined as having "the capacity or tendency to mislead or deceive." *Courbat v. Dahana Ranch, Inc.,* 111 Hawai`i 254, 261, 141 P.3d at 434 (2006). To establish a deceptive act or practice under § 480-2, the State must show "(1) a representation, omission, or practice that (2) is likely to mislead consumers acting reasonably under the circumstances where (3) the representation, omission, or practice is material." *Courbat,* at 262, 141 P.3d at 435.

90. The test for deceptiveness is "an objective one, turning on whether the act or omission 'is likely to mislead consumers,' as to information 'important to consumers,' in making a decision regarding the product or service." *Id.* (internal citations omitted). The State must therefore prove by the "objective 'reasonable person' standard" that the representation or omission was deceptive. *Id.* at 263,

141 P.3d at 436. A UDAP violation need not involve a representation; it can involve other acts or practices. *Yokoyama v. Midland Nat. Life Ins. Co.*, 594 F.3d 1087, 1092 (9th Cir. 2010) (UDAP violation can involve "a representation, omission or practice").

91. The State "need not establish an intent to deceive on the part of the defendant, nor any actual deceit." *Courbat*, 111 Hawai`i at 262 fn.9, 141 P.3d at 435 (citations omitted). "Proof of actual deception is unnecessary" because the relevant inquiry is whether a representation, omission, or practice has "the capacity or tendency to mislead or deceive." *Tokuhisa v. Cutter Management Co.*, 122 Hawai`i 181, 195, 223 P.3d 246, 260 (App. 2009); *Hungate v. Law Office of David B. Rosen*, 139 Hawai`i 394, 411, 391 P.3d 1, 19 (2017); *State ex rel. Bronster v. U.S. Steel Corp.*, 82 Hawai`i 32, 51, 919 P.2d 294, 313 (1996).

92. As noted in Finding of Fact No. 54 above, the Court has already determined that the information in the 2016 boxed warning was material. Findings of Fact, Conclusions of Law, and Order Granting Plaintiff's Renewed Motion for Partial Summary Judgment Regarding the "Materiality" of Information Contained in the Plavix "Black Box Warning," filed July 21, 2020. [Dkt. No. 1023].

93. Here, the Court finds that the evidence presented shows that Defendants engaged in deceptive acts or practices when they failed to include information equivalent to that in the product label during the time period of December 1998 to March 12, 2010. The Court finds that the evidence before it overwhelmingly supports a conclusion that Defendants' acts and practices during the relevant period led to the omission of information crucial to physicians and patients.

94. The Court acknowledges that the Defendants could not have placed a "Black Box Warning" on the label without the FDA's prior approval. However, Defendants had the ability to update the label, specifically to add or

strengthen a warning, under the Changes Being Effected ("CBE") regulations of the FDCA. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A); *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668 (2019).

95. Further, the Court finds that Defendants had sufficient knowledge, after FDA approval but prior to launch, to change the Plavix drug label to warn patients and physicians about the lack of response exhibited by certain patients. The Court also finds that Defendants had sufficient knowledge, as well as the technical ability, to investigate the cause of variability of response which was known to Defendants before the drug launched in December of 1998.

96. Defendants argued repeatedly throughout trial that they did not know or could not have known the extent to which CYP2C19 played a role in the metabolism of Plavix or in variability of response to Plavix. Defendants also argued that they could not possibly have determined whether people with CYP2C19 polymorphisms experienced diminished effectiveness from the drug. The Court is not persuaded by the Defendants arguments. The facts presented show that Defendants had sufficient knowledge, technology, and ability to update the Plavix label from launch and continuing for many years. Yet, instead Defendants chose to establish a policy of inaction and denial.

97. The Court finds that the omission of this material information was likely to mislead consumers. The ability to give informed consent during medical treatment is a well-established tenet of our jurisprudence. As testified at trial by another of Defendants' medical experts, Dr. John Kao, doctors generally inform their patients about all risks and benefits of the drugs they prescribe so that the patient can make an informed decision concerning their course of treatment. Omitting information from a drug label about the efficacy and safety profile of a drug such as

Plavix, that is intended to lower the risk of a recurrent heart attack or stroke, certainly has the capacity and likelihood to mislead consumers. The evidence shows that Defendants deliberately hid material information from consumers that could have affected their choice of, or conduct regarding Plavix. Therefore, the Court finds that, based on the evidence presented at trial, all the elements for a claim of deceptive acts or practices have been met.

B. Unfair Acts or Practices of Defendants

98. Under UDAP, a practice "is unfair when it [1] offends established public policy and [2] when the practice is immoral, unethical, oppressive, unscrupulous or [3] substantially injurious to consumers." *Hungate, supra,* 139 Hawai`i at 411, 391 P.3 at 18, quoting *Hawai `i Community Federal Credit Union v. Keka (Keka),* 94 Hawai`i 213, 228, 11 P.3d. 1, 16 (2000). A UDAP plaintiff need not prove all of these elements. *Id.* Rather, "[a] practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three[.]" *Id.,* quoting *Kapunakea Partners v. Equilon Enters, LLC,* 679 F.Supp.2d 1203, 1210 (D. Haw. 2009).

99. The Court finds that the conduct of the Defendants in this case also constituted unfair acts or practices under § 480-2.

100. First, the Court finds that Defendants conduct in this case offends established public policy. In order to show that a practice is unfair because it offends established public policy, such policy must have been "established by statutes, the common law, or otherwise." *Hungate, supra,* 139 Hawai`i at 411, 391 P.3 at 18. In cases like this one, the Supreme Court of the United States has repeatedly acknowledged:

> [I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. A drug

> manufacturer is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. Thus, ***when the risks of a particular drug become apparent, the manufacturer has a duty to provide a warning that adequately describe[s] that risk.***

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1677 (2019) (internal citations and quotations omitted) (emphasis added); *Wyeth v. Levine, 555 U .S. 555,* 571 (2009).

101. The Court finds that Defendants' failure to update the Plavix drug warning after learning of the safety risks posed to poor metabolizers offends this well-established public policy. Defendants compounded their unfair conduct by suppressing research and continuously and repeatedly failing to further investigate the risks of reduced platelet inhibition in poor metabolizers because such studies regarding variability of response could have "negative marketing implications." These facts and others outlined above lead this Court to find Defendants' conduct offended the established public policy of Hawai`i.

102. Second, the Court also finds that Defendants conduct in this case was immoral, unethical, oppressive, or unscrupulous. The evidence showed that Defendants engaged in a pattern and practice of burying their heads in the sand regarding the weaknesses of Plavix. Regardless of the amount of evidence presented to Defendants (internally before launch of the drug, and later through repeated independent studies), they continued to deny the fact that there were Plavix poor metabolizers or that poor metabolizers received diminished or zero effect from taking Plavix. Such acts and practices were immoral, unethical and unscrupulous within the meaning of UDAP.

103. Finally, the Court also finds that Defendants' conduct was substantially injurious to consumers in several ways. First, Defendants deprived all patients of the

opportunity to consider whether to undergo genetic testing in order to determine the likelihood that they would be able to bioactivate Plavix's antiplatelet effect. Second, they deprived all patients with CYP2C19 loss-of-function alleles the opportunity to make informed decisions regarding the potential risk of taking Plavix against the potential risks associated with alternative treatment. Third, they deprived an indeterminate number of patients the drug's intended risk reduction the patients were relying on Plavix to provide. Fourth, Defendants deprived patients the ability to give informed consent to their treatment.

III. DEFENDANTS' AFFIRMATIVE DEFENSES

105. Defendants raised in their Pre-trial Statement several affirmative defenses. However, Defendants did not argue all these defenses during trial or closing arguments. It is not clear whether Defendants have since abandoned some of these defenses. Out of an abundance of caution, the Court will discuss the reasons why each of these defenses are unconvincing.

A. First Amendment Defense

105. Defendants have asserted that the State's prosecution of this action violates their First Amendment commercial free speech rights. Defendants' theory appears to be that the State is attempting to punish them for refusing to disseminate the State's preferred message on a matter of scientific debate. The Court finds no merit to this defense. It is well established that "[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-64 (1980) (internal citations omitted). For commercial speech to receive First Amendment protections, "it at least must concern lawful activity and not be misleading." *Id.* Here, the Court

has found that Defendants' omissions were deceptive and therefore the type of misleading statements not protected by the First Amendment.

B. Safe Harbor Defense

106. Defendants argued at trial that the statutory safe harbor provision codified in HRS § 481A-5(a)(1), bars the State's UDAP claim, which Defendants claim exempts "conduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency." *Id.* Defendants posit that because the FDA repeatedly approved the Plavix label and never initiated any enforcement action against the Defendants related to Plavix, that Defendants' conduct was therefore at all times in compliance with the FDA regulations. The Court disagrees.

107. Under the terms of the FDA regulations, drug manufacturers can and must make necessary changes to a drug's prescribing information without seeking prior FDA approval. The FDA's periodic approval of Plavix label changes over the years does not place the Defendants "in compliance" with federal label regulation standards. The Court finds that Defendants are not immune from liability under the state's UDAP laws because their specific applications to update the label were approved. On the contrary, the Court finds that Defendants' conduct—failing to discharge their ongoing, affirmative duty to adequately inform patients—places them well outside the protections of the UDAP's Safe Harbor provision and well outside the ambit of "compliance" with orders, rules, or statutes administered by a separate governmental entity.

108. Through the FDA regulations, the FDCA provides drug manufacturers a specific mechanism for unilaterally strengthening warning labels after initially approved by the FDA. As the Supreme Court explained in *Wyeth*, "Congress did not . . . require[] the FDA to preapprove all changes to drug labels . . . Instead, it adopted a

rule of construction to make it clear that manufacturers remain responsible for updating their labels." *Wyeth*, 555 U.S. at 567-68. That responsibility is made enforceable through state law claims. *Id.* at 578-79. Both Congress and the Supreme Court recognize that state consumer protection laws, such as Hawaii's UDAP statute, play an important role in enforcing a manufacturer's duty to update their label. *Id.* In particular, the Supreme Court concluded that Congress "determined that widely available state rights of action provided appropriate relief for injured consumers" in connection with failure to warn claims related to FDA approved drugs. *Id.* at 574. Further, failure to warn actions under state law "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA [has] long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth*, 555 U.S. at 579.

109. The Court finds that the Defendants' failure to update Plavix's label with material information was not conduct "authorized, permitted, or required by law." The responsibility for the adequacy of Plavix's drug label rested with Defendants, and Defendants were expressly empowered to fulfill that responsibility, but affirmatively chose not to out of fear that such disclosures would negatively impact their bottom line. As such, the Safe Harbor provision does not apply to Defendants' conduct in this case

C. Preemption Defense

110. In their trial brief, Defendants argued that the State's UDAP claim is preempted by federal law on prescription drug labeling and that the "relevant question is whether the FDA regulations allowed the [Defendants] to update the Plavix label before 2008 on its own, without first seeking the FDA's permission." To support this

defense, Defendants informed the Court that during trial it would hear from their regulatory expert, Dr. Dena Hixon, who would explain, Defendants could not have unilaterally updated the label before 2008. However, during their defense case Defendants informed the Court that they would not be calling Dr. Hixon to testify. As such, the only evidence in the record regarding Defendants' ability to update the product label is the unchallenged and credible testimony of Dr. Plunkett. The Court therefore finds Defendants' preemption argument unsupported and unpersuasive.

D. Duty to Test

111. Defendants repeatedly argued at trial that evidence concerning their willful suppression of research is irrelevant because Hawaii's UDAP statute does not impose on manufacturers any independent duty to conduct product testing or research. However, the State's allegations are not limited to the Defendants failure to conduct product testing or research. The State alleges Defendants ignored and concealed critical risk information concerning their drug, and then deliberately rejected and suppressed any further research into those risks, and in so doing, severely retarded the growth of pertinent scientific literature in the area of Plavix resistance and its causes, and the Court has so found. This conduct is part-and-parcel with Defendants' deceptive acts and practices, as it directly prevented correction of their material omissions.

112. Further, federal regulations require a drug's manufacturer to include in the labeling of its products complete and accurate information about health risks, adequate instructions regarding the use of the drug product, and adequate warnings to ensure that patient health is protected. *See, e.g.,* 21 CFR § 201.57; 21 CFR § 314.70; 21 CFR § 314.80. As such, manufacturers have the responsibility for ensuring that the labeling *continues* to reflect current knowledge concerning risks posed by the drug.

113. By failing to fulfill their duty to ensure Plavix's label reflected the current knowledge concerning risks posed by the drug, by deliberately shirking their obligation to conduct responsible postmarketing surveillance, by suppressing the efforts of concerned third parties to conduct postmarketing investigational studies, and by basing these critical decisions on sales and marketing concerns, Defendants engaged in unfair and deceptive practices that culminated in the material omissions at issue here.

IV. PENALTIES

114. Based on the foregoing and the evidence presented at trial, the Court concludes that the imposition of civil penalties under HRS § 480-3.1 is warranted. The parties disagree on the way in which penalties should be calculated.

A. Penalties under § 480-3.1 are not Restricted to a "Per Day" Calculation as Posited by Defendants

115. Primarily, Defendants have argued before trial and during closing arguments that the calculation of penalties under HRS § 480-3.1 requires the court to calculate violations on a "per day" basis. The Court rejects Defendants' reading of the statute.

116. The relevant statutory provision, HRS § 480-3.1, states the following: Any person, firm, company, association, or corporation violating any of the provisions of section 480-2 shall be fined a sum of not less than $500 nor more than $10,000 for each violation, which sum shall be collected in a civil action brought by the attorney general or the director of the office of consumer protection on behalf of the State. The penalties provided in this section are cumulative to the remedies or penalties available under all other laws of this State. Each day that a violation of section 480-2 occurs shall be a separate violation.

117. In construing a statute, the Court's "foremost obligation is to ascertain and give effect to the intention of the legislature, which is to be obtained primarily from the language contained in the statute itself. And [the court] must read statutory language in the context of the entire statute and construe it in a manner consistent with its purpose." *Beneficial Hawaii, Inc. v. Kida*, 96 Hawai`i 289, 307, 30 P.3d 895, 913 (2001). "[W]here the terms of a statute are plain, unambiguous and explicit, [the Court is] not at liberty to look beyond that language for a different meaning." *State v. Haugen*, 104 Hawai`i 71, 76, 85 P.3d 178, 183 (2004). But where the language of a statute appears on the surface to be plain, obvious, and unambiguous, the court may look beyond that language "for the purpose of ascertaining its underlying legislative intent . . . if a literal construction would produce an absurd and unjust result." *Id.* at 77, 184 (internal citations and quotations omitted).

118. The UDAP statute "is remedial in nature and must be liberally construed in order to accomplish the purpose for which it was enacted." *Keka, supra*, 94 Hawai`i at 229, 11 P.3d at 17 ("Remedial statutes are liberally construed to suppress the perceived evil and advance the enacted remedy.") Therefore, this consumer protection statute "must be interpreted broadly in order to effectuate its remedial purposes." *Kida, supra*, 96 Hawai`i at 307, 30 P.3d at 913.

119. Applying a "per day" method of calculating penalties, as Defendants suggest, regardless of the circumstances of the deceptive or unfair act or practice is inconsistent with the plain language of the statute and would severely reduce its remedial power. Such a reading would also lead to absurd results and is inconsistent with similar cases under the Federal Trade Commission Act, 15 U.S.C. §§ 41-58 ("FTC Act").

120. First, the plain language of the statute shows the intent of the legislature to create a mechanism by which the State may hold those accountable who engage in deceptive or unfair practices. The first sentence of HRS § 480-3.1 states in unambiguous terms that a penalty "shall" be imposed "for each violation." (Emphasis added). This statutory language expresses a clear legislative intent that wrongdoers will be held accountable for each violation they commit. Therefore the Court must first determine what constitutes a violation in order to assess a penalty. Defendants' interpretation—which would allow a wrongdoer to cap its liability to a maximum daily penalty of $10,000 no matter how many times it deliberately violated the statute in a single day—would only incentivize large and powerful corporations to violate Hawaii's consumer protection laws with impunity. A single daily penalty could easily just be absorbed as "the cost of doing business," or a "rounding error," and, even then, only *if* the perpetrators were caught and prosecuted.

121. The second sentence of HRS § 480-3.1 is consistent with the first in that it likewise expresses an intent to hold wrongdoers fully accountable for their actions by providing that the aforementioned civil penalties are cumulative of all other "remedies or penalties available under all other laws of this State." This provision does not suggest a legislative intent to let violators off lightly or limit the penalties available under this section, but rather to impose upon them the full weight of all applicable laws violated by the wrongful conduct.

122. The final sentence of HRS § 480-3.1 must be construed in a manner consistent with these first two sentences. First, the sentence reads: "Each day that a violation of section 480-2 occurs shall be a separate violation." By its own terms, this sentence does not define a violation but instead it modifies or multiplies the application of a violation if it is a continuing violation.

123. For example, there are some circumstances in which a single act can constitute a violation over a period of days without the violator having acted more than once, such as the posting of a deceptive billboard by the side of a highway. The offender would install the billboard only once, but the billboard would continue to have its deceptive impact every day until it was removed. Similarly, a court might issue an order for the offender to remove the billboard, but the offender might ignore the court's order. Although ignoring the order would be a single act, that single violation could continue for several days, until the offender eventually complied. In both examples, the third sentence of HRS § 480-3.1 would provide an appropriate remedy. It would not limit the violator's exposure to a single penalty but would instead impose a penalty on the violator for each day that the violation continued. The plain reading of the entire statute shows that this "each day" language was intended to act as multiplier not a limiter in the calculation of penalties.

124. Second, Defendants' reading of the statute so that penalties are restricted to a maximum of one "per day" would lead to absurd and unjust results. For example, suppose that 30,000 mail advertisements were distributed in a single day, which contained material determined to constitute unfair or deceptive acts or practices by the sender. Under Defendants' reading of the statute, these 30,000 advertisements sent to 30,000 separate consumers would constitute only one violation—because they were committed in a single day—with a ***maximum*** penalty of no more than $10,000, i.e., 33 cents per advertisement and deceived consumer. However, if 30 of these same unfair and deceptive advertisements were mailed—one *per day for thirty days* (1 month)—under Defendants' theory, that would constitute thirty separate violations with a ***minimum*** penalty of $15,000.

125. In the first example, the sender could make unfair and deceptive representations 30,000 times to 30,000 separate consumers, but if the representations were made in the same day, the sender would face a maximum penalty of $10,000, or 33 cents per advertisement. In the second example, the sender could make only 30 unfair and deceptive representations, but if the representations were made over the course of one month, one per day, the sender will face a maximum penalty of $300,000 — a thirty-fold increase over the other sender's maximum penalty — merely because the representations were made on separate days. Under Defendants' theory, the first sender would be subject to a maximum civil penalty that is 1130th the maximum civil penalty the second sender is subject to, despite having misled 29,970 more consumers than the second sender. Such an absurd result would not serve the purpose of the UDAP statute "to suppress the perceived evil and advance the enacted remedy." *Keka, supra,* 94 Hawai`i at 229, 11 P.3d at 17.

126. Third, courts in Hawai`i have routinely recognized that the purpose of statutes such as UDAP is to be a tool that can be used to combat deceptive and unfair practices in whatever iteration they exist. HRS § 480-2 was "constructed in broad language in order to constitute a flexible tool to stop and prevent fraudulent, unfair or deceptive business practices for the protection of both consumers and honest businesspersons." *Keka, supra,* 94 Hawai`i at 228, 11 P.3d at 16. UDAP cannot both be construed as a broad and flexible remedial statute for the purpose of protecting consumers while also construed to severely limit penalties so that any enforcement of the statute by the Attorney General would equate to a slap on the wrist for large corporations.

127. The plain language of the § 480-3.1 and the purpose of the UDAP statute show that the determination of what constitutes a "violation" of § 480-2 depends on the

facts and circumstances of the case and the deceptive or unfair conduct at issue. Should a violation occur in a manner that a single violation extends over a period of multiple days, then the "each day" language may act as a multiplier to penalize the wrongdoer for the extended nature of the conduct. However, the determination of what counts as a violation still relies heavily on the circumstances of each case.

128. The Court's reading of the statute is further supported by targeted consumer protection statutes enacted by the Hawai`i Legislature — *i.e.,* laws *in pan materia,* HRS § 1-16 —that calculate violations based on the number of deceptive acts or practices of the violator. For instance, in HRS § 245-59, enacted in 2005, the Legislature declared that certain acts related to the sale of cigarettes constitute "unfair and deceptive practices" under § 480-2 and "shall be subject to civil penalty as provided in section 480-3.1." Section 245-59 then continues on, saying, ***Mach package of cigarettes sold*** in violation of this part shall constitute a separate violation." *Id.* (Emphasis added.)

129. Similarly, in HRS § 127A-30, enacted in 2014, the Legislature prohibits price increases during a state of emergency, and in those circumstances allows civil penalties under §480-3.1 because price gouging constitutes an unfair and deceptive practice. The statute further provides that ***[e]ach item sold*** at a price that is prohibited by this section shall constitute a separate violation." HRS §127-30(e) (Emphasis added). These statutes clearly evidence a legislative intent in the consumer protection arena to define the number of violations based on the circumstances of the deceptive acts or practices at issue. Defendants argue that the above-cited statutes undercut the Court's reasoning because HRS § 480-3.1 does not have the equivalent of "each item" language in it, as the other statutes do. But this Court is not persuaded that Defendants' view is the correct one.

130. The above-cited statutes are each very narrowly tailored to address a single, discrete issue, such as price gouging or the sale of cigarettes. Therefore, specific "each item" or "each package" language could be added to those statutes with little difficulty. In contrast, UDAP is an extremely broad statute applicable to a virtually unlimited number of widely differing circumstances affecting consumers. Adding language that would properly fit all of those potentially innumerable circumstances would be impractical, highly problematic, and likely impossible. *See e.g., F.T.C. v. Sperry & Hutchinson Co.,* 405 U.S. 233, 240 (1972) ("It is impossible to frame definitions which embrace all unfair practices. There is no limit to human inventiveness in this field. Even if all known unfair practices were specifically defined and prohibited, it would be at once necessary to begin over again."). Therefore, the absence of such precise language in HRS § 480-3.1 is neither surprising nor indicative of any legislative intent to restrict the definition of a violation to specific verbiage applicable in all cases.

131. The Court's interpretation of the calculation of penalties under HRS § 480-3.1 is also consistent with federal case authority construing UDAP's federal counterpart, the Federal Trade Commission Act, 15 U.S.C. §§ 41-58 ("FTC Act").

132. In determining what constitutes a UDAP violation, HRS § 480-2(b) provides that "courts and the office of consumer protection shall give due consideration to the rules, regulations, and decisions of the Federal Trade Commission and the federal courts interpreting section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended." Federal case law calculating penalties under the FTC Act shows that the definition of a violation is defined based on unfair or deceptive conduct in each case. *United States v. Reader's Digest Ass 'n, Inc. (Reader's Digest),* 662 F.2d 955, 965-66

(3d Cir. 1981) (holding that "*each letter* included as part of a mass mailing constitutes a separate violation") (emphasis added); *United States v. J. B. Williams Co.,* 498 F.2d 414, 435 (2d Cir. 1974) (holding that "*each separate broadcast* of [a] commercial was a separate violation" rather than each day the commercial aired) (emphasis added); *United States v. Floersheim,* No. CV 74-484-RF, 1980 WL 1852, at *9 (C.D. Cal. May 1, 1980) (holding that "*[e]ach individual form* [containing the misrepresentations] constitutes a separate violation") (emphasis added); *accord State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.,* 414 S.C. 33, 84-85 (2015) (upholding that "distribution of *each sample box* containing the deceptive labeling, *each [Dear Doctor Letter]* , and *each follow-up sales call* to the DDL by a Janssen representative constituted a separate . . . violation") (emphasis added).

133. Further, under the FTC Act, the "each day" calculation is reserved for circumstances in which there is a "continuing failure to comply with a rule or with [§ 45(a)(1).]" 15 U.S.C. § 45(m)(1)(C). It is therefore appropriate to construe the "each day" provision in HRS § 480-3.1 as a clarifying sentence that compounds the penalty on a daily basis for a single violation that continues to have an impact over a number of days, rather than as a limiting factor on the calculation of civil penalties.

134. As such, the Court rejects Defendants' reading of § 480-3.1 as requiring the Court to calculate penalties in terms of one violation per day. Instead, the Court will analyze the facts and circumstances of this case and determine the appropriate definition and number of violations based on the evidence presented at trial.

B. Factors to Consider in Penalties Calculations

135. Courts exercising discretion in determining the measure of penalties to be assessed under the FTC Act or similar state consumer protections statutes utilize the

factors articulated in *United States v. Reader's Digest Ass'n (Reader's Digest),* 662 F.2d 955, 967 (3rd Cir. 1981):

(1) The good faith or bad faith of the Defendant;

(2) The injury to the public;

(3) The desire to eliminate the benefits derived by a violation;

(4) The necessity of vindicating the authority of the agency involved; and

(5) The Defendant's ability to pay.

See State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 414 S.C. 33, 84-85, 777 S.E.2d 176, 203 (2015); *U.S. v. Natl. Fin. Services, Inc.,* 98 F.3d 131, 140 (4th Cir. 1996); *U.S. v. Gurley,* 235 F. Supp. 2d 797, 806 (W.D. Tenn. 2002), *aff* 384 F.3d 316 (6th Cir. 2004); *U.S. Dept. of J. v. Daniel Chapter One,* 89 F. Supp. 3d 132, 148 (D.D.C. 2015). Here, the Court considers each of these factors in turn in determining the civil penalties to impose on Defendants.

i. Good or Bad Faith of Defendants

136. The Court finds that the Defendants acted in bad faith during the relevant period of 1998 to March 2010. As discussed above, the law allowed Defendants to unilaterally strengthen the warning section of the drug label as soon as there was reasonable evidence of a safety issue with their drug. Nothing in those regulations required a showing of any sort of association of "clinical outcomes" before making such updates, as Defendants argued. Defendants had knowledge of the involvement of CYP2C19 in the metabolism of Plavix, and the ability of its polymorphisms to prevent activation of other prodrugs, as well as Plavix's own issues with variability of response as early as 1998, before the drug was ever sold on the market. Yet Defendants ignored these glaring warning signs and did nothing to warn patients or physicians, nor did Defendants investigate the reasons for this

resistance. Further, Defendants systematically, through policies and guidelines, suppressed studies of Plavix resistance and avoided documenting variability of response due to perceived threats to sales and potential negative marketing implications.

137. Even after Key Opinion Leaders began discovering the issue of variability of response, Defendants continued their obfuscation campaign and refused to fund or run the type of clinical studies that could have answered the questions about variability of response that Key Opinion Leaders and other researchers continued to ask. Once the medical community—without the aid of Defendants—performed research showing the links between the 2C19 loss-of-function alleles and lack of platelet response, Defendants did not update their label or run a large-scale trial investigating this genetic link. Instead, Defendants buried their heads in the sand and continuously maintained that the 2C19 polymorphism was not linked to "clinical outcomes" as a self-serving excuse to avoid addressing the problem.

138. From 1998 to March 2010, Defendants had the ability and knowledge necessary to update the Plavix drug label. Yet, they chose not to because it would affect their bottom line. Defendants repeatedly chose to act in their own financial best interest rather than fulfilling their obligations with respect to patient safety. Therefore, the Court finds Defendants' bad faith to be considerable during the period of December 1998 to March 12, 2010.

ii. Injury to the Public

139. The Court finds the issues in this case to be of critical importance to the public. Requiring drug manufacturers to fully disclose all material information available to them concerning the safety of their drugs in a fair and non-deceptive manner is of paramount importance to the health and safety of those using the drugs. This is especially true where, as here, the drug at issue is a

potentially lifesaving course of therapy, and where a patient's failure to fully bioactivate the drug leaves them more vulnerable to heart attacks, strokes, and cardiovascular death. Doctors and patients can only make fully informed decisions regarding treatment when a complete, honest, and fair disclosure of material information is made by the drug manufacturer. As drug manufacturers are the ones with the best and most complete information surrounding their drug, the public must be able to rely on these companies to disclose important information, such as lack of efficacy based on genetic factors. Injury to the public obviously occurs when consumers are denied material information that is necessary for them to make informed decisions concerning their course of treatment and when the risk of a recurrent heart attack or stroke is not lowered as represented by the drug manufacturer. As such, the public interest affected by Defendants' actions in this case is substantial.

iii. Desire to Eliminate the Benefits Derived from a Violation

140. The benefits derived by Defendants' material omissions were substantial. After its launch in 1998, Plavix became a "blockbuster drug" and prescribing Plavix in addition to aspirin became the standard of care for treatment of many cardiovascular related conditions. We cannot turn back the clock to see what would have happened had the label included adequate warnings from the beginning. Nonetheless, it is clear from the revenue generated by Defendants, discussed below, that Defendants were able to reap huge financial benefit from the success of Plavix, including from the consumers within the State of Hawai`i, while using unfair and deceptive practices to do so. Moreover, the evidence at trial clearly established that Defendants themselves feared the loss of Plavix sales and questions from health authorities should the limitations of their drug be documented. The civil

penalty calculations therefore must also account for the need to eliminate the benefits derived by Defendants from their use of unfair and deceptive business practices.

iv. Necessity of Vindicating the Authority of the Agency Involved

141. The UDAP statute was enacted by the legislature to act as a consumer protection measure and under § 480-3.1 the State, through its Attorney General, was given power to enforce those protective measures for the people of Hawai`i. When corporations or other business entities come into this State and conduct their business in an unfair and deceptive manner, it is incumbent upon the Attorney General as the chief law enforcement officer of the State to act in protection of the public's interest. Remedial statutes, such as UDAP, are to be construed "to suppress the perceived evil and advance the enacted remedy." *Keka, supra,* 94 Hawai`i at 229, 11 P.3d at 17.

142. The Court finds that the State has a particularly strong interest in ensuring that drug companies operate legally in Hawai`i and are not making false statements about pharmaceutical drugs to the public, especially when it comes to potentially life-saving drugs like Plavix. The State's interest is heightened where, as here, the omission of warning information raises a serious risk of harm to all consumers, but especially to high risk patients of East Asian and Pacific Island descent, who represent a significant portion of Hawaii's population.

143. As such, the penalties imposed in this case will take into account the interests of the State in preventing similar acts and practices in the future.

v. Defendants' Ability to Pay

144. Here, it is important to consider what penalties are necessary for Defendants to fully appreciate the wrongfulness of their conduct and to deter them from taking similar actions in the future. To achieve that goal, the

penalty must take into consideration the financial ability of the wrongdoer to pay. As the primary purpose of statutes such as UDAP are to protect consumers and deter future unfair or deceptive conduct by Defendants and others, the penalty must be of an amount that is appropriate for each particular defendant involved. If a penalty is more than a defendant can pay, then justice would not be served. Similarly, if a penalty is so small that it can be written off as a mere cost of doing business, then consumers would not be adequately protected. The legislature has already determined what constitutes the fair range of penalties per violation under § 480-3.1: between $500 and $10,000. Therefore, the Court must determine an amount within that range.

145. Defendants in this case are large multinational corporations with very substantial resources. As shown by Defendants' financial filings with the SEC for years 1998 through 2012, Defendant BMS reported net sales of Plavix totaling $50.3 billion. In the financial filings with the SEC for years 2002 through 2012, Defendant Sanofi reported net sales from Plavix totaling €22.1 billion.[9] Therefore, Defendants have the ability to pay an award appropriate to the egregiousness of their misconduct toward Hawai`i consumers.

C. What Constitutes a Violation

146. As discussed above, the Court finds that Defendants' unfair and deceptive conduct in this case was far reaching and persistent. Based upon the evidence presented at trial and the above Findings of Fact, the Court finds that a violation of UDAP occurred with the distribution of each copy of the Plavix label (package insert), by

[9] These sales figures do not include numerous other drugs, from which each Defendant has also generated billions of dollars in sales, according to the SEC filings in evidence.

way of retail prescriptions filled (including refills) and non-retail units sold, in the State of Hawai`i.

147. Tallying the number of violations in terms of the retail prescriptions filled and non-retail units sold is appropriate given the circumstances of the unfair and deceptive acts in this case. The warnings, risks, and benefits listed in a drug's label are a cornerstone to the patient's ability to make an informed decision regarding that drug. The "Medication Guide" portion of Defendants' own label instructs patients to read the label before they "start taking Plavix and each time [they] get a refill." The label also notes that the information in the boxed warning is "the most important information [you] should know about Plavix[.]" This Medication Guide is required by law to be included with the drug label in every unit (retail and non-retail) of Plavix. As such, the Court finds that each retail prescription filled and refilled, and non-retail units sold in the State of Hawai`i constitute a separate and distinct violation of UDAP.

148. The Court finds Defendants' arguments about reducing the number of violations unconvincing, as well as unsupported by the law or evidence presented in this case.

D. Number of Violations and Penalty Amount

149. Given the evidence presented at trial, the above Findings of Fact, and the above Conclusions of Law, this Court finds that each retail prescription filled and refilled, and each non-retail unit sold in the state of Hawai`i by Defendants, between December 1998 and March 12, 2010 to be a separate UDAP violation. Defendants argued briefly in closing arguments that the time period for calculations should be limited to the date of publication of either (1) the research paper published by Jessica Mega in November 2008 (which Defendants contend first showed the prevalence of CYP2C19 in Plavix metabolism), or (2) the paper published by Jean Sebastian Hulot in 2006 (which was an independent research study showing the

link between CYP2C19 poor metabolizers and poor responders). The Court is not persuaded by these arguments. As discussed above, the overwhelming weight of the evidence is that Defendants' unfair and deceptive business practices extended back to the launch of Plavix in December 1998. As such, the Court finds that the number of violations of UDAP resulting from the Defendants' joint misconduct is **834,012,** as calculated by the State's expert Dr. Nicole Maestas, which went unchallenged.

150. The Court further finds the appropriate penalty to be $1,000 per violation, for a total of **$834,012,000.00** in civil penalties.

151. Under Hawai`i law, the Court acknowledges that the penalties under HRS § 4803.1 may not be assessed jointly and severally against distinct legal entities except where several entities are subject to a single control, such as in the corporate parent-subsidiary relationship. *State by Doi v. Shasteen,* 9 Haw. App. 106, 113, 826 P.2d 879, 883 (1992). While Sanofi and Bristol-Myers Squibb acted jointly in their venture of selling Plavix between December 1998 and March 12, 2010, the Court finds that they are legally separate entities. On the other hand, the Court finds that defendants Sanofi-Aventis U.S. LLC, Sanofi US Services, Inc., and Sanofi-Synetholabo LLC are all entities under a single control and thus shall be considered one legal entity for purposes of penalty assessment. Therefore, the Court will assess one set of penalties against Bristol-Myers Squibb and one set of penalties jointly and severally against the Sanofi defendants.

152. At no point has any party in this trial argued or presented evidence that either Bristol Meyers Squibb or Sanofi were more or less culpable than the other in engaging in the unfair and deceptive business practices at issue. As such, the Court finds that Bristol-Myers Squibb and the Sanofi defendants are both equally responsible for each violation of UDAP in this case and, therefore,

assesses civil penalties in the amount of **$417,006,000** against Defendant Bristol-Myers Squibb Company and civil penalties in the amount of **$417,006,000** jointly and severally against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc.

153. The Court considers the foregoing award of civil penalties to be an adequate remedy for Defendants' wrongful conduct. Therefore, the Court finds it unnecessary to determine whether the circumstances of this case might otherwise warrant either an award of punitive damages or the remedy of disgorgement.

154. If any of the Conclusions of Law set forth herein shall be deemed instead to be Findings of Fact, they are hereby incorporated by reference in the Findings of Fact set forth herein above.

DECISION AND ORDER

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that judgment shall be entered in favor of Plaintiff State of Hawai`i and against Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc. in the amount of $834,012,000.00, to be assessed against each of the Defendants in the manner described above.

This document shall be filed in the State of Hawaii Judiciary electronic portal and distributed to counsel for the parties via email.

DATED: Honolulu, Hawai`i, February 15, 2021.

/s/ Dean E. Ochiai [seal]

JUDGE OF THE ABOVE-ENTITLED COURT