CAAP-24-0000531

IN THE INTERMEDIATE COURT OF APPEALS

STATE OF HAWAI‘I

STATE OF HAWAI‘I, EX REL. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff-Appellee, vs. 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, Defendant-Appellants, and SANOFI S.A., Defendant-Appellee.	ORIGINAL PROCEEDING Civil No. 1CC141000708 (JHA) APPEAL FROM THE: JUNE 10, 2024 FINAL JUDGMENT; JULY 31, 2024 ORDER DENYING DEFS.’ RULE 52 AND 59 MOTION TO AMEND THE JUDGMENT; FEBRUARY 25, 2021 FINAL JUDGMENT; MARCH 10, 2021 AMENDED JUDGMENT; INTERLOCUTORY ORDERS; AND POST-JUDGMENT ORDERS FIRST CIRCUIT COURT Hon. Edwin C. Nacino Hon. Dean E. Ochiai Hon. James H. Ashford

MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE* OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

EXHIBIT 1

CERTIFICATE OF SERVICE

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MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE* OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

Pursuant to Hawai'i Rules of Appellate Procedure ("**HRAP**") Rules 27 and 28(g), Amicus Curiae The Chamber of Commerce of the United States of America (the "Chamber") respectfully moves for an order permitting it to participate as a friend of the Court in the above-captioned case by filing the Amicus Brief attached as Exhibit 1. Rule 28(g) provides that "[a]n amicus curiae brief may be filed only by leave of the appellate court." Leave is "frequently" granted where the "legal issues . . . have potential ramifications beyond the parties directly involved." *NGV Gaming, Ltd. v. Upstream Point Molate, LLC,* 355 F. Supp. 2d 1061, 1067 (N.D. Cal. 2005).

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the Nation's business community.

The Chamber and its members have a strong interest in ensuring a fair and predictable legal environment across the United States. Unfortunately, and with increasing frequency, states and localities are seeking excessive fines from businesses and individuals based on novel legal theories. Such excessive fines needlessly drive up costs for businesses, increase prices for consumer goods and services, and hamper

economic growth. The Chamber thus has a particular interest in ensuring that the Fourteenth Amendment's requirements of clear notice and proportionality are enforced. That interest applies keenly here, where the unprecedented statutory fine imposed against the defendants bears no relationship to any harm from their conduct, profit made from that conduct, or any other consideration that could rationally justify a punishment of nearly one billion dollars.

Because of the importance of these issues, the Chamber respectfully requests that the Court grant its motion for leave to file the Amicus Brief in this matter attached as Exhibit 1.

DATED: Honolulu, Hawai'i, November 27, 2024.

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A Limited Liability Law Partnership

/s/ Calvert G. Chipchase
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INTERESTS OF AMICUS CURIAE

The Chamber of Commerce of the United States of America ("**Chamber**") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the Nation's business community.

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INTRODUCTION AND SUMMARY OF ARGUMENT

The court below imposed fines of nearly a billion dollars on the defendant manufacturers of the antiplatelet drug Plavix. That fine is at least *seven times* the defendants' gross sales of Plavix in Hawai‘i during the relevant period, is not tied in any way to harms anyone suffered, and came with no notice to defendants that selling Plavix in Hawai‘i could result in such a massive fine. The Chamber respectfully submits that this extraordinary unanticipated application of Hawai‘i Revised Statutes § 480-2 concerning unfair or deceptive acts or practices (the "**UDAP**") violates the Due Process and Excessive Fines Clauses of the United States and

Hawai‘i Constitutions, both of which are fundamental to the rule of law and the functioning of our Nation's economy.

The State should never punish anyone without first making it clear what is prohibited or required and what the consequence for non-compliance will be. Due process requires prior notice so that parties can conform their conduct to the law. Clear prior notice is particularly critical for business interests that need to plan, invest, and market based on an accurate understanding of their duties, costs, and risks.

Likewise, consequences for violating the law should be proportional to the offense. A fine must be measured in relation to the harm actually caused or improper profits earned by the defendant. Punishment that is neither foreseeable nor proportional not only violates the U.S. Constitution's protection against excessive fines, it renders the legal environment uncertain and unsteady, which discourages businesses from investing and hiring, introducing new products or services, and entering markets where they may be subject to arbitrary state action.

Unprecedented fines like the one ordered below undermine the stability and predictability necessary to Hawai‘i's functioning market economy. Such instability discourages out-of-state businesses like drug manufacturers from selling products or investing in Hawai‘i. As a result, the citizens of Hawai‘i will suffer higher prices, fewer choices, poorer health, and reduced employment. This Court should ensure that Hawai‘i's UDAP statute is not misused in such an unconstitutional and self-destructive manner.

ARGUMENT[1]

I. Due Process requires states to provide businesses clear notice of what the law requires or prohibits.

A. Notice is a basic component of due process, and is critical for business planning and investment in highly regulated areas of the economy.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). "This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment." *Id.*; *see also Sessions v. Dimaya*, 584 U.S. 148, 177 (2018) (Gorsuch, J., concurring in part and concurring in the judgment) ("Perhaps the most basic of due process's customary protections is the demand of fair notice."). "Statutes must be defined 'with sufficient definiteness that ordinary people can understand what conduct is prohibited.'" *Hamilton ex rel. Lethem v. Lethem*, 126 Hawai'i 294, 303, 270 P.3d 1024, 1033 (2012) (citation omitted). For as long as this country has had a constitution, it has been well understood that "[i]t will be of little avail to the people that the laws are made by men of their own choice if the laws be . . . so incoherent that they cannot be understood." *The Federalist* No. 62, at 381 (James Madison) (Clinton Rossiter ed., 1961). Indeed, as James Madison recognized, "how can that be a rule, which is little known, and less fixed?" *Id.*

Notice requires that "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed." *Bittner v. United States*, 598 U.S. 85, 102 (2023) (opinion of Gorsuch, J., joined by Jackson, J.) (quoting *McBoyle v. United States*, 283 U.S. 25, 27 (1931)). These "elementary notions of fairness" require "notice not only of the conduct that will subject [someone] to punishment, but also of the severity of the penalty that a State may impose." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 417

[1] Hawai'i Rule of Appellate Procedure 28(g) states in part, "All *amicus curiae* briefs shall comply with the applicable provisions of subsection (b) of this Rule." This brief only seeks to present argument on the issues before the Court.

(2003) (quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996)) (brackets omitted).

Clear, prior notice is not only required by the Due Process Clause, "[p]redictability of law enforcement is critical . . . to the functional operation of a marketplace." U.S. Chamber Inst. for Legal Reform, *French Fries to Fossil Fuels. The Misplaced Reliance on UDAPs to Pursue Policy Agendas* 33 (Aug. 2023), http://bit.ly/4h8VElX ("***Misplaced Reliance on UDAPs***"). A business cannot do what the law requires, or refrain from doing what the law prohibits, unless the law clearly specifies the prohibited or required acts.

This is particularly true in heavily regulated areas, like pharmaceuticals, where businesses have a primary regulator like the Food and Drug Administration ("**FDA**") but are also regularly subject to other regulations or laws in each of the various jurisdictions where they operate or their products are sold. Where federal and local law are both clear, conflicts between them can be resolved in advance through established principles of supremacy, pre-emption, and federalism. But if a local law does not provide fair notice of what it requires, a business can find itself—as the defendants here do—in full compliance with its primary regulator's commands yet still facing unforeseen liability. Without proper notice of what is required or prohibited, businesses cannot forecast the cost of future commercial actions and make reliable decisions about which markets to enter, how much to invest in particular ventures, how many employees to hire on what terms, or myriad other choices necessary to run a profitable enterprise.

B. The circuit court's extreme, unanticipated application of Hawai'i's unfair or deceptive act or practice law denies notice in violation of the U.S. and Hawai'i Constitutions.

The circuit court's judgment in this case is such an extreme, unanticipated application of Hawai'i's UDAP statute in that it denies due process of law by taking property without sufficient advanced notice.

First, while the statute is "a flexible tool to stop and prevent fraudulent, unfair or deceptive business practices," *State ex rel. Shikada v. Bristol-Myers Squibb Co.*, 152

Hawai‘i 418, 446, 526 P.3d 395, 423 (2023) (citation omitted), flexible tools are susceptible to unforeseeable applications. Where a state UDAP statute is applied in a novel context, it has a high risk of failing to provide the clear, prior notice of what is unlawful that due process requires. Deceptiveness is a concept well-rooted in the common law to the extent that the traditional elements of fraud are enforced. But those traditional requirements did not apply here. *See Courbat v. Dahana Ranch, Inc.*, 111 Hawai‘i 254, 262, 141 P.3d 427, 435 (2006). And as for "unfair" practices, whether past practices were fair is largely in the eye of the beholder, particularly in a novel context. The circuit court concluded that it was an "unfair" act or practice for defendants to market Plavix without further research. But it is the federal government that regulates which drugs are approved for medical use and what research trials are required before such approval. *See* 21 U.S.C. § 355; 21 C.F.R. § 312.1 *et seq*. No Hawai‘i law or regulation gave defendants notice prior to the 1998-2010 period at issue here that the State required them to conduct more (or different) research before selling Plavix or after the drug entered the market. In such circumstances, businesses like defendants "may not be able to understand fully how to modify their activities in order to come into compliance." *Misplaced Reliance on UDAPs* at 35. Instead, the courts like the one below "decide, retroactively, what conduct is lawful and what conduct is unlawful." *Id.* at 33.

The extreme judgment here reflects the due process risks inherent in state UDAP laws. The combination of looser standards under these laws and the outsourcing of enforcement to private attorneys paid on a contingency basis has resulted in "an explosion in consumer protection litigation that serves no social function and for which consumers pay indirectly through higher prices and reduced innovation." James Cooper & Joanna Shepherd, *State Unfair and Deceptive Trade Practices Laws: An Economic and Empirical Analysis*, 81 Antitrust L.J. 947, 947-48, 957-59 (2017) (*Economic and Empirical Analysis*); *see also* Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 U. Kan. L. Rev. 209, 217-56 (2016) ("***Emerging***

Concerns") (analyzing "four problems in State AG enforcement" of UDAP laws (capitalization altered)); *Misplaced Reliance on UDAPs* at 2-3, 20.

Second, these problems with notice are aggravated by the fact that although at the relevant time Hawai'i imposed a four-year statute of limitations on private claims under its UDAP statute, HRS § 480-24, an enforcement action by the State is not subject to *any* statute of limitations. *State ex rel. Shikada*, 152 Hawai'i at 437, 526 P.3d at 414. This action was filed in 2014, *sixteen years* after Plavix was federally approved and began being used in Hawai'i. There is nothing in the circuit court's findings that suggests anyone from the State raised any concerns to defendants while their challenged conduct was occurring. Yet now, several decades later, they face a retroactive fine of nearly a billion dollars.

Third, nothing in the law gives notice that the statutory fine of $500 to $10,000 would be applied by a court separately to each prescription, refill, and non-retail unit of a federally approved drug. The circuit court cited four cases in support of its calculations: *United States v. Reader's Digest Ass'n*, 662 F.2d 955 (3d Cir. 1981); *United States v. J.B. Williams Co.*, 498 F.2d 414 (2d Cir. 1974); *United States v. Floersheim*, No. CV 74-484, 1980 WL 1852 (C.D. Cal. May 1, 1980); and *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 07-CP-42-1438, 2011 WL 2185861 (S.C. Ct. Com. Pl. June 3, 2011). But those cases do not support the fine imposed here.

The two published appellate decisions and *Floersheim* all involve violation of a Federal Trade Commission ("**FTC**") cease-and-desist order. *Reader's Dig.*, 662 F.2d at 958-59; *J.B. Williams Co.*, 498 F.2d at 418; *Floersheim*, 1980 WL 1852, at *1. Where the defendant has been specifically instructed to cease a practice, there is clearly prior notice as required by due process. Penalties imposed for conduct *after* being ordered to cease and desist are fundamentally different than the wholly retrospective analysis applied in this case. Federal law *only* allows civil penalties for violations of an FTC order or acts the defendant *knows* violate the law. 15 U.S.C. § 45(*l*), (m). "The public policy underlying this [FTC] process recognizes that 'unfair' and 'deceptive' are vague terms and that it is improper to punish a business without

first giving it notice that its conduct violates the law." *Emerging Concerns* at 243. Unlike the federal statutory scheme, Hawai'i's UDAP has no such safeguards. U.S. Chamber Inst. for Legal Reform, *Unfair Practices or Unfair Enforcement? Examining the Use of Unfair and Deceptive Acts and Practices (UDAP) Laws by State Attorneys General* 24-25 (Oct. 2016) ("***Unfair Practices or Unfair Enforcement?***"), https://bit.ly/4eMs7gd (discussing how state UDAP laws lack the safeguards of FTC enforcement).

The fourth case cited is the circuit court order from the South Carolina Risperdal litigation. That litigation illustrates the same problem as this case, while also demonstrating the arbitrariness of the "per unit" penalty. South Carolina retroactively claimed that a pharmaceutical company engaged "in unfair methods of competition by willfully failing to disclose known risks and side effects associated with Risperdal," a new type of antipsychotic medication. *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharms., Inc.*, 777 S.E.2d 176, 182 (S.C. 2015). The two cases are thus at least facially similar, although the two medications and relevant facts are quite different. The South Carolina circuit court decision cited by the court below awarded civil penalties of $327 million, but those were reduced by the South Carolina Supreme Court to $124 million, the bulk of which ($101.5 million) did *not* arise from the product labeling, but instead from letters to doctors that the court found deceptive and inconsistent with FDA guidance (as the FDA itself also found). *Id.* at 183, 187. The product labeling fine was reduced to $100 per box—one-tenth of the fine imposed here. *Id.* at 204.

Nor does the counting of each prescription, refill, or non-retail unit map onto the "deceptive" conduct the circuit court found in this case. The labeling content decisions that the circuit court found deceptive were made at the corporate level, not anew each and every time someone filled or refilled a prescription in Hawai'i. Indeed, applying the same statute, the circuit court here imposed a fine of $82,000,000 for "unfair" practices based on a $1,000 per-day calculation for each group of defendants. It is difficult to understand how any company could be considered to be on notice that decades after the fact it might be subject to either an $82 million or $*834 million* fine

depending on whether a particular attorney for the State characterizes the defendant's conduct as "deceptive" or "unfair," much less subject to both fines. Such unpredictable fines "raise serious constitutional concerns" "due to the lack of notice as to the illegality of conduct . . . [and] the unpredictability of the potential penalty." *Emerging Concerns* at 243.

Ultimately, a meaningful notice requirement asks whether an ordinary person in defendants' shoes would have understood in 1998 that selling Plavix—with the federally approved label, and after all research required by the FDA—was prohibited in Hawai‘i and could result in nearly a billion dollars in civil fines from a Hawai‘i court. *See Hamilton*, 126 Hawai‘i at 303, 304, 270 P.3d at 1033, 1034. It is hard to conceive of any universe in which that would be possible, which makes clear that the penalty assessed below violates constitutional due process.

II. Excessive civil penalties violate the Excessive Fines Clause, create undue barriers for Hawai‘i businesses, and discourage national businesses from investing in Hawai‘i or providing goods and services to consumers in Hawai‘i.

A. Penalties must be proportional to the harm done or profit earned and must not be destructive.

Both the United States Constitution and the Constitution of the State of Hawai‘i prohibit the government from imposing excessive fines. U.S. Const. amend. VIII; Haw. Const. art. I, § 12. "Protection against excessive punitive economic sanctions is . . . both 'fundamental to our scheme of ordered liberty' and 'deeply rooted in this Nation's history and tradition.'" *Timbs v. Indiana*, 586 U.S. 146, 154 (2019) (Eighth Amendment prohibition on excessive fines is incorporated into the Fourteenth Amendment) (citation omitted). The prohibition traces back to the Magna Carta and "has been a constant shield throughout Anglo-American history." *Id.* at 151, 153. Excessive fines present a particular threat to liberty because "fines may be employed 'in a measure out of accord with the penal goals of retribution and deterrence,' for 'fines are a source of revenue,' while other forms of punishment 'cost a State money.'" *Id.* at 154 (citation omitted). The Excessive Fines Clause applies to "the government's power to extract payments . . . as punishment for some offense." *United States v.*

Bajakajian, 524 U.S. 321, 327-28 (1998) (citation omitted). It applies to civil penalties as well as in criminal cases. *Pimentel v. City of Los Angeles*, 974 F.3d 917, 921-22 (9th Cir. 2020).

"The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. "To determine whether a fine is grossly disproportional to the underlying offense, four factors are considered: (1) the nature and extent of the underlying offense; (2) whether the underlying offense related to other illegal activities; (3) whether other penalties may be imposed for the offense; and (4) the extent of the harm caused by the offense." *Pimentel*, 974 F.3d at 921. Those factors are also relevant to the court's selection of an appropriate fine in the first instance. *See Reader's Dig.*, 662 F.2d at 967 (considering the defendant's intent, injury to the public, the benefits derived from a violation, the authority of the licensing agency, and the defendant's ability to pay). "In calculating a civil penalty, 'the financial benefit that accrued to the respondent and/or the loss suffered by customers as a result of the wrongdoing are especially pertinent factors.'" *R&W Tech. Servs. Ltd. v. CFTC*, 205 F.3d 165, 178 (5th Cir. 2000) (citation omitted). "[C]ases analyzing punitive damages under the Due Process Clause are instructive in analyzing punitive sanctions under the Excessive Fines Clause." *Grant ex rel. United States v. Zorn*, 107 F.4th 782, 798, 799-800 (8th Cir. 2024).

B. Aggregation of statutory claims converts every business practice into a bet-the-company risk.

Concerns about excessive statutory fines are greatly heightened where the number of violations is calculated in a way that converts one course of conduct (often based on a single decision) into hundreds of thousands of "violations." A statute that sets a penalty range of $500 to $10,000 "per violation" gives no notice that, because a product is popular or widely used, the actual range of penalties is in the hundreds of millions or billions of dollars. "The arbitrariness of the amount of the civil penalty is compounded by how courts calculate the number of violations. Attorneys General

often seek 'per violation' civil penalties based on every prescription filled, letter sent, product sold, or advertisement published or aired for the longest period allowed under the statute of limitations. As a result, businesses are exposed to extraordinary penalties for a single action even when the conduct did not mislead anyone or cause an economic loss." *Emerging Concerns* at 242.

Such awards are "untethered to the statute's purpose." *Wakefield v. ViSalus, Inc.*, 51 F.4th 1109, 1122-23 (9th Cir. 2022). In *Wakefield*, the Ninth Circuit remanded a $925 million statutory fine for a weight-loss company's 1.85 million unwanted "robocalls" because the district court had not considered whether, in the aggregate, the nearly billion-dollar fine was unconstitutional. *Id.* at 1124-25 (noting that "in the mass communications class action context, vast cumulative damages can be easily incurred, because modern technology permits hundreds of thousands of automated calls and triggers minimum statutory damages with the push of a button"); *see Stillmock v. Weis Mkts., Inc.*, 385 F. App'x 267, 276 (4th Cir. 2010) (Wilkinson, J., concurring) ("The exponential expansion of statutory damages through the aggressive use of the class action device is a real jobs killer that Congress has not sanctioned."); *Parker v. Time Warner Ent. Co.*, 331 F.3d 13, 27 (2d Cir. 2003) (Newman, J., concurring) ("I do not believe that in specifying a $1,000 minimum payment for Cable Act violations, Congress intended to expose a cable television provider to liability for billions of dollars.").

Companies should not be subject to crippling and potentially bankrupting fines simply because a statutory penalty that is facially reasonable when applied once is multiplied hundreds of thousands (or even millions) of times based solely on the number of customers, communications, or units of product affected by a single business decision. That is particularly true where the penalty requires no showing of actual harm to anyone or, if harm is required, the penalty is not calculated based on that harm. *Stillmock*, 385 F. App'x at 281 (Wilkinson, J., concurring) (explaining that class-wide statutory penalties on a company for technical violations in which no consumer was actually harmed risks the annihilation of entire companies); *compare In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 458-59 (E.D.N.Y. 2009)

("[P]roper assessment of the claimed penalties would require individualized consideration of the circumstances of each prescription alleged to be in violation of the statute.").

The circuit court made no effort to ensure that its fines were proportional to either the amount of harm it found was caused or the amount of profit made from the challenged practice. The court did not even calculate the amount of harm or profit, much less compare those figures to the amount of aggregate fines imposed. Nor did the court account for the fact that the majority of patients using Plavix were *not* genetically poor metabolizers of the drug and were helped by the medication, or that not all poor metabolizers were actually injured. The fines thus fail the most fundamental test of the Excessive Fines Clause: "The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 324.

Instead, the court's fines appear to be based solely on defendants' wealth. The court noted how much the defendants had collected on a gross basis selling Plavix *everywhere* (not just in Hawai'i), and also quite irrelevantly noted that defendants made "billions of dollars" selling "numerous other drugs." R2039 at 59-60 & n.22 [COL ¶ 41]. Nationwide (or global) sales revenue is not a measure of profit from purportedly improper practices in Hawai'i, a State whose residents are 0.4% of the U.S. national population. Indeed, the trial record showed that defendants' total Plavix sales in Hawai'i during the relevant period were only $126 million—one-seventh of the fines imposed.

It is one thing to *reduce* a fine because of a defendant's inability to pay. A fine "should not deprive a wrongdoer of his livelihood." *Bajakajian*, 524 U.S. at 335. But it is quite improper to fine a company *more* simply because its other, lawful activities have generated substantial wealth. Basing a fine on the resources of the fined company violates another fundamental principle that all persons are equal before the law. "The guarantee of equal protection of the laws under Hawai'i and United States Constitutions requires that persons similarly situated with respect to the legitimate purpose of the law receive like treatment." *State v. Miller*, 84 Hawai'i 269, 276, 933

P.2d 606, 613 (1997). "Normally the legal system bases civil damages and penalties on harm done, not on the depth of the wrongdoer's pocket." *United States v. Dish Network L.L.C.*, 954 F.3d 970, 980 (7th Cir. 2020). The "best way" to "ensure that the penalty was within a constitutionally allowable range" "is to start from harm rather than wealth." *Id.* The ability to pay may provide a reason to *reduce* a fine, but a defendant's wealth cannot justify a different calculation in the first instance. "The wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award." *Campbell*, 538 U.S. at 427. Nor should the fact that a product is popular or widely used convert a relatively manageable civil fine into a massive unforeseen liability simply through multiplication.

And, of course, business entities are frequently subject to multiple potential fines by different government actors for the same conduct. *See Emerging Concerns* at 248 (discussing the "[p]ile on [e]ffect"); *Unfair Practices or Unfair Enforcement?* at 29-30 (same). Plavix was sold nationwide (and indeed worldwide). A court "may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." *Campbell*, 538 U.S. at 422. If this judgment is affirmed, then many other jurisdictions may try to follow suit, particularly if—like Hawai'i in this case—they recognize no statute of limitations. UDAP litigation by the states also does not prevent litigation by individual consumers—if any—who can show that they were actually harmed. Excessive awards in one jurisdiction thus create a substantial risk of overlapping pile-on litigation that can rapidly destroy even the largest companies.

C. Allowing unpredictable, excessive, crippling awards injures Hawai'i business and consumers.

The type of unpredictable massive fine imposed here harms business and consumers both in numerous ways. First, when a business suffers a large, unexpected cost, the business inevitably passes that cost along to consumers. Excessive fines "will more likely than not hurt consumers by requiring an excessive increase in prices as well as an excessive diversion of resources to prevention activities." Michael K. Block, *Optimal Penalties, Criminal Law and the Control of Corporate Behavio*r, 71 B.U. L.

Rev. 395, 402 (1991). "Low quality consumer protection claims—facilitated by loose substantive standards and motivated by the promise of attorneys' fees and generous remedies—increase litigation costs for businesses that are ultimately passed on to consumers in the form of higher prices, lower product quality, and reduced innovation." *Economic and Empirical Analysis* at 973-74. "[A] 2011 study finds evidence that state consumer protection statutes inflict substantial economic harm on consumers through increased prices, especially when the laws assign broad liability with indulgent damages provisions." *Id.* at 974.

Large fines—and particularly those like this one that are not proportional to any actual harm or improper profit in this State—thus at best represent a way of indirectly taxing future consumers. Moreover, "excessive fines may lead to insolvency . . . , which in certain markets may significantly weaken competition and ultimately hurt consumers in that market." John Terzaken & Pieter Huizing, *How Much Is Too Much? A Call for Global Principles to Guide the Punishment of International Cartels*, Antitrust, Spring 2013, at 53, 56 (*How Much Is Too Much?*).

Second, because this statutory fine can be imposed with no statute of limitations and no requirement of a clear prior warning as is required under the federal FTC law that originally inspired state UDAP statutes, companies are discouraged to develop and market new products that may end up triggering crippling fines years or even decades later. Why risk developing and promoting a new medication if—despite FDA approval—decades later a crippling judgment can be imposed even in the absence of quantifiable harm to anyone? When corporations face the prospect of excessive and unpredictable financial penalties, products are "withheld from market by lawsuit-leery companies," L. Stuart Ditzen, *Are Punitive Damage Awards Too Punishing?*, Phila. Inquirer, Oct. 29, 1989, at D.1, thereby depriving businesses of profitable opportunities and consumers of the products that they might want (or, with products like life-saving medicine, need) to purchase. Indeed, the same market forces lead risk-avoidant businesses to provide *less* information to consumers, not more. "[F]irms often refrain from informative advertising out of fear of consumer protection liability. Ironically, firms have a disincentive to provide any information at all when they fear

the information could be claimed to be deceptive. When this happens, consumers suffer again by either making less-informed purchases or by incurring costs to seek out relevant product information that is no longer supplied to them." *Economic and Empirical Analysis* at 974-75 (footnote omitted).

This is not just a problem for large, distant manufacturers. Local retailers risk being caught up in an allegation years later that a product they sold had risks that were not sufficiently described (or maybe, as alleged here, not sufficiently discovered). Similarly, the risk of unknown future liability poses a barrier to entry for new participants in the market who wish to compete with established companies. These problems are more severe for local companies that are plainly subject to the jurisdiction of Hawai'i's courts than mainland or foreign corporations which may not be. And the resulting lack of competition necessarily harms consumers by depriving them of product choices and lower prices.

Third, the uncertain nature of litigation, particularly in cases like this where the defendant is not alleged to have violated a clear statutory obligation or cease-and-desist order, increases transaction costs, hinders entrepreneurial investment, and deters consumer purchases. "Businessmen [and women] . . . require the decisions of the courts on commercial issues to be predictable so that they know where they stand." M.A. Clarke et al., *Commercial Law: Text, Cases, and Materials* 10 (5th ed. 2017). This is particularly true here, where the product at issue was sold nationwide—after being federally approved—spanning numerous jurisdictions that may each have their own view of what is or is not deceptive or fair. Applying general state UDAP laws to nationally regulated conduct destroys the "predictability and fairness for businesses that rely on government decision making" that uniform regulation provides. *Emerging Concerns* at 224.

As the risk of excessive fines grows, businesses may need or choose to avoid transactions in jurisdictions where businesses are treated unfairly. "With such unpredictability inevitably comes a chilling effect, as businesses respond to unknown liability with retreat." *Misplaced Reliance on UDAPs* at 33. Thus, "[o]ne consequence of unpredictable enforcement and litigation, given the resulting disengagement by

businesses from commerce in certain jurisdictions, is less consumer access to products and services in those jurisdictions." *Id.* These inefficiencies, caused by legal uncertainty and a patchwork of inconsistent legal regimes, injure both businesses and consumers. *Emerging Concerns* at 224-40.

These problems are of particular interest to this State. Among the United States, Hawai'i is uniquely dependent on trade, importing over eighty percent of food and other goods consumed in the State. With a population of 1.44 million, Hawai'i represents an important market, but also one which mainland or foreign manufacturers might choose to forego if the price of doing business includes unforeseeable catastrophic fines that bear no relationship to the businesses' economic activity in this State. That result would not only hurt Hawai'i's consumers, but would also injure local businesses that need to obtain either finished goods or materials from manufacturers or wholesalers outside of the State. Just as large environmental disasters have caused a homeowners' insurance crisis in this State as insurers to withdraw from the market,[2] large, unprecedented fines like this one may cause mainland or foreign companies to move their business elsewhere, leaving Hawai'i's residents and businesses worse off.

It is no answer to these problems to assert that only unfair or deceptive practices are prohibited because—unlike the FTC regime where compliance starts with a clear cease-and-desist notice—compliance under the Hawai'i UDAP statute is entirely ex post facto. "Over-punishment can [ ] lead to over-deterrence, where businesses become too cautious and refrain from undertaking competitive activity because of fear that the activity may be deemed" a violation of law. *How Much Is Too Much?* at 56.

The reality is that this type of unforeseeable and excessive fine serves no one. It severely punishes offenders without regard for the actual harm or profit from their

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[2] *See* Janis Magin Meierdiercks, *Insurance Crisis Worsens in Hawai'i's "Condoland"*, Haw. Bus. Mag. (June 21, 2024), https://www.hawaiibusiness.com/hawaii-condo-insurance-market-challenges-crisis; Press Release, State of Hawai'i Dep't of Com. & Consumer Affs., Universal Property & Casualty to Exit Hawaii Insurance Market (July 27, 2023), https://cca.hawaii.gov/blog/release-universal-property-casualty-to-exit-hawaii-insurance-market.

alleged misconduct. It discourages business by creating an environment of uncertainty and unmeasurable risk. It injures consumers through higher prices and fewer choices. And it hurts the overall community by making it economically unattractive to manufacturers and suppliers who can look elsewhere for customers and business partners.

CONCLUSION

Civil penalties have a proper role. Predictable and proportionate consequences for violating clearly established rules help maintain a fair marketplace for everyone. But massive, unexpected awards based on novel theories do not, particularly where their calculation bears no relationship to either the profit made from alleged misconduct or the resulting harm. It is not consistent with due process or the prohibition on excessive fines to fine defendants more than seven times their total gross revenue from sales in Hawai‘i of what is overall a highly beneficial and successful drug that has helped save the lives of millions of people, including thousands of Hawai‘i residents. Fines like the one imposed here are unconstitutionally excessive, and affirming this judgment would send a strong but dangerous signal that businesses are more a source of windfall revenue than partners in the Hawai‘i economy.

DATED: Honolulu, Hawai‘i, November 27, 2024.

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CAAP-24-0000531

IN THE INTERMEDIATE COURT OF APPEALS

STATE OF HAWAIʻI

STATE OF HAWAIʻI, EX REL. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff-Appellee, vs. 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, Defendant-Appellants, and SANOFI S.A., Defendant-Appellee.	ORIGINAL PROCEEDING Civil No. 1CC141000708 (JHA) APPEAL FROM THE: JUNE 10, 2024 FINAL JUDGMENT; JULY 31, 2024 ORDER DENYING DEFS.' RULE 52 AND 59 MOTION TO AMEND THE JUDGMENT; FEBRUARY 25, 2021 FINAL JUDGMENT; MARCH 10, 2021 AMENDED JUDGMENT; INTERLOCUTORY ORDERS; AND POST-JUDGMENT ORDERS FIRST CIRCUIT COURT Hon. Edwin C. Nacino Hon. Dean E. Ochiai Hon. James H. Ashford

CERTIFICATE OF SERVICE

I hereby certify that on this date a true and correct copy of the foregoing document was served upon the following parties by the method listed below:

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Case ID: CAAP-24-0000531

Title: State of Hawaii, Ex Rel. Anne E. Lopez, Attorney General, Plaintiff-Appellee, vs. Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc. (formerly known as Sanofi-Aventis U.S. Inc.), Sanofi-Synthelabo LLC, Sanofi S.A., Defendants-Appellants, and Doe Defendants 2 to 100, Defendants.

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