IN THE SUPREME COURT OF THE STATE OF HAWAIʻI

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STATE OF HAWAIʻI, EX REL. HOLLY T. SHIKADA, 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,
Defendants-Appellants,

and

SANOFI S.A., Defendant-Appellant.

SCAP-21-0000363

CERTIORARI TO THE INTERMEDIATE COURT OF APPEALS
(CAAP-21-0000363; CASE NO. 1CC141000708)

MARCH 30, 2023

RECKTENWALD, C.J., NAKAYAMA, McKENNA, WILSON, AND EDDINS, JJ.

DISSENTING OPINION BY WILSON, J.

I. INTRODUCTION

The Majority's holding strips protection from a global set of consumers who unwittingly took Plavix without understanding that it imposed risk of heart attack, stroke and death. These consumers did not understand Plavix imposed grave risk because they were deceived, in violation of Hawaiʻi's Unfair or Deceptive Acts or Practices law ("UDAP"), by pharmaceutical companies Bristol-Myers Squibb ("BMS") and Sanofi (together, the "Defendants"). BMS and Sanofi deceived consumers for approximately eleven years by failing to warn that they may respond poorly to Plavix—the antiplatelet drug consumers were trusting to save their life. The Defendants earned approximately $74 billion selling Plavix from the drug's launch in December of 1998 through 2012. Yet the record reflects that BMS and Sanofi knew in March of 1998, prior to Plavix's launch in December of 1998, that almost one-third of Plavix patients (32.2%) received less than 20% of Plavix's antiplatelet effect, making them a "poor responder." BMS and Sanofi omitted this "poor responder" information from the Plavix label. This omission constituted a failure to warn, and exposed Plavix poor responders to what was quantified in 2008 to be "a 50 percent greater risk of having a heart attack, a stroke or death." This deception by omission perpetrated by BMS and Sanofi lasted approximately eleven years, until the Food and Drug

Administration ("FDA") compelled the Defendants to update the Plavix label with a warning to consumers about the increased risks of death and serious injury to Plavix poor responders.

Antiplatelet drugs are used to treat medical patients already at increased risk of heart attack, stroke and death. This acutely vulnerable set of consumers were victimized by BMS and Sanofi's omission of the poor responder issue, and the systematic suppression of information and research into the variability of response to Plavix. This egregious conduct deprived consumers of Plavix's promised antiplatelet effect, and prevented them from undergoing genetic testing to determine whether they were poor responders who should seek alternative drugs or treatment.

At issue in this case is the viability of the legal framework protecting consumers whose lives depend on pharmaceutical companies not deceiving them about the safety and efficacy of the drugs they sell. The Circuit Court of the First Circuit ("circuit court") was correct to grant summary judgment on materiality as a matter of law. The judgment and penalties should be affirmed.

II. BACKGROUND

BMS and Sanofi brought Plavix to market in December of 1998 knowing that almost one-third of patients who take Plavix would be poor responders, and would not receive the drug's

promised antiplatelet effect. This "poor responder" problem was discovered by the Defendants' internal 1998 meta-analysis study. The Defendants also knew at Plavix launch that (1) the CYP2C19 enzyme played a principal role in Plavix metabolization; (2) the CYP2C19 enzyme was a 100% predictor of poor responders for the drug S-mephenytoin; and (3) genetic tests were available to determine one's CYP2C19 status.

The variability in response to Plavix dramatically increased the risk of heart attack, stroke, and death for poor responders, and would ultimately become the single most important data point the FDA compelled BMS and Sanofi to warn consumers about. But because BMS and Sanofi omitted poor responder information from its labeling, failed to disclose it to the FDA, and suppressed research into why Plavix had a variability of response, the warning about poor responders didn't reach Plavix's label until 2009, approximately eleven years after the launch of Plavix.

The poor responder issue began its journey to disclosure when the Defendants submitted the 1998 meta-analysis study demonstrating the poor responder problem to the FDA in 2005—a full seven years after the poor responder problem was known to the Defendants. When the Defendants did submit the 1998 meta-analysis to the FDA in 2005, it was submitted as an appendix to a separate, subsequent study, and not as a stand-

alone disclosure of the 1998 meta-analysis itself. There is nothing in the record to support the inference that the FDA became aware of the poor responder issue as a result of the 2005 submission of the 1998 meta-analysis study.

In 2006, independent researcher Dr. Jean-Sebastien Hulot published a study supporting the hypothesis that CYP2C19 was linked to reduced clopidogrel responsiveness (Plavix's chemical name is "clopidogrel"). In October 2008, a study concluded that when the drug Omeprazole, a drug known to impede CYP2C19's function, was given to patients who were taking Plavix, the Omeprazole caused a corresponding reduction in Plavix's antiplatelet effect, making those patients more likely to have diagnostic codes for heart attack and stroke than Plavix patients not taking Omeprazole.

This study caused significant concern at the FDA, and a December 5, 2008 meeting was called between the FDA, BMS and Sanofi. The FDA pressed BMS and Sanofi for information regarding (1) the implications of CYP2C19 impact on Plavix effectiveness, and (2) how the Plavix label should be updated accordingly.

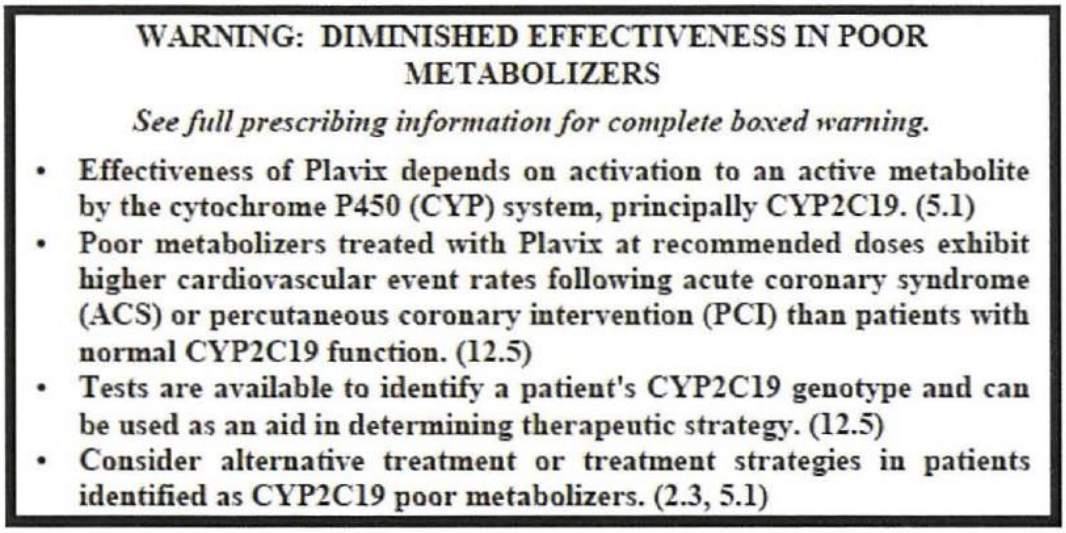
Just two weeks later, and before any changes were made to the Plavix label, Dr. Jessica Mega published her study on December 22, 2008 (the "Mega study") which showed that carriers of a reduced-function CYP2C19 allele (poor responders) "had a

three-fold greater risk of clotting their stent, and a 50 percent greater risk of having a heart attack, a stroke or death."

Several months later, the FDA amended Plavix's label to include the poor responder issue and warn consumers about the increased risk of heart attack, death and stroke ("higher cardiovascular event rates") for poor responders ("patients with genetically reduced CYP2C19 function"): "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[.]"

In May of 2010 the FDA compelled BMS and Sanofi to place the CYP2C19 poor responder information in a boxed warning. The FDA boxed warning is the most serious warning a drug label can reflect, and is particularly reserved for warnings that may lead to death or serious injury. The Plavix boxed warning prominently alerts the consumer of "diminished effectiveness" for "poor metabolizers" (poor responders) who take Plavix

because they "exhibit higher cardiovascular event rates" (heart attack, stroke or death)[1] than non-poor responders:



WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS

See full prescribing information for complete boxed warning.

- **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)**

For approximately eleven years, BMS and Sanofi omitted the poor responder problem from the Plavix label, exposing Plavix patients who were poor responders to a fifty-percent greater risk of heart attack, stroke and death, along with a three-fold risk of clotting their stent. Only when the Defendants' hand was forced by independent research verifying Plavix's CYP2C19 poor responder issue, followed by the FDA's regulatory authority compelling the Defendants to revise their label, did the Plavix poor responder warning finally reach consumers.

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[1] Sanofi defines cardiovascular events as death, myocardial infarction, and stroke. The Merriam-Webster Online Dictionary defines myocardial infarction as "heart attack." Myocardial infarction, Merriam-Webster,https://www.merriam-webster.com/dictionary/myocardial%20infarction (last visited March 1, 2023).

In March of 2014, the State filed a complaint alleging that BMS and Sanofi violated UDAP. The State's complaint alleged that between 1998 and 2010 BMS and Sanofi had violated UDAP by: (1) failing to disclose that Plavix has diminished or no effect in poor responders; and (2) suppressing research and inquiry into Plavix for financial reasons. The State claimed the Defendants' behavior was both deceptive and unfair.

The circuit court ruled for the State on both points. Following a bench trial that lasted more than a month, the court held that BMS and Sanofi had violated UDAP by engaging in deceptive and unfair acts and practices. The circuit court found that BMS and Sanofi misled Hawaiʻi consumers by failing to warn them that Plavix was less effective for poor responders. The circuit court determined that this omission injured consumers by denying them Plavix's full promised antiplatelet effect. The circuit court further determined that the omission prevented consumers from undergoing genetic testing to determine whether they were poor responders, and seeking alternative treatments accordingly. In addition, the circuit court concluded that the Defendants failed to sufficiently research the variability of response in Plavix, and actively suppressed research that might confirm a link between ethnicity or genotype and Plavix responsiveness. The circuit court imposed an $834 million penalty for these violations of UDAP.

The Majority now vacates the penalty and remands for retrial on the deceptive acts claim. The Majority holds that the trial court erred in granting the State's motion for partial summary judgment on the deceptive act claim with respect to whether the poor responder information was material to consumers. The Majority leaves the unfair acts or practices claim under UDAP intact.

III. DISCUSSION

A. The circuit court did not err in granting summary judgment. Omitted information about poor responders was material as a matter of law.

After conducting a bench trial, the circuit court concluded BMS and Sanofi violated UDAP by engaging in both deceptive and unfair acts and practices. Prior to trial, the circuit court granted summary judgment with respect to the materiality component of the State's deceptive acts claim. The Majority contends that the circuit court erred in granting summary judgment on the issue of materiality, and that such error infected the remainder of the trial, the deceptive acts holding, and the penalty. The Majority's position is without merit.

The centerpiece of the State's deceptive acts claim is that BMS and Sanofi misled Hawaiʻi consumers by failing to warn them that Plavix was less effective for poor responders, and that poor responders using Plavix faced increased risks of death

and serious injury. The State alleged that the omission from Plavix's label about poor responders from 1998 until 2009 injured consumers by denying them the drug's full promised antiplatelet effect, hindering their ability to give informed consent, and preventing them from taking an alternative drug, or undergoing genetic testing to determine whether they were poor responders. UDAP provides that "unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful." Hawaiʻi Revised Statutes ("HRS") § 480-2(a) (2008). An unlawful deceptive act is defined as: "(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 v. Dahana Ranch, Inc., 111 Hawaiʻi 254, 262, 141 P.3d 427, 435 (2006) (cleaned up). The State argued that the deceptive act's third prong – materiality – was already established as a matter of law, because the omitted information with respect to Plavix poor responders was ultimately published in Plavix's federally mandated black box warning. Specifically, the State argued there was "no doubt that the information contained in Plavix's federally mandated black box warning is material as a matter of law." On these grounds, the State asked the court to resolve materiality at summary judgment in order to "eliminate any unnecessary time at trial." Materiality is an essential element

of a UDAP deceptive acts violation. Id. In order to prevail on its deceptive acts claim, the State must establish that the poor responder information was material to consumers, and that BMS and Sanofi likely misled consumers by omitting it from the Plavix label.

The test for UDAP materiality is objective, "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." Courbat, 111 Hawaiʻi at 262, 141 P.3d at 435. (cleaned up) (emphases added). It considers the viewpoint of the "reasonable consumer, not the particular consumer." See Yokoyama v. Midland Nat'l Life Ins. Co., 594 F.3d 1087, 1092 (9th Cir. 2010). Although the objective materiality test "is ordinarily for the trier of fact," where "evidence is so clear that no reasonable person would determine the issue in any way but one[,]" summary judgment is appropriate. Courbat, 111 Hawaiʻi at 263, 141 P.3d at 436 (cleaned up). In addition, materiality is in fact presumed for "claims that significantly involve health, safety, or other areas with which the reasonable consumer would be concerned, including a claim that concerns the purpose, safety, efficacy, . . . performance, . . . or a finding by another agency regarding the product." Novartis Corp. v. FTC, 223 F.3d 783, 786 (D.C. Cir. 2000) (cleaned up). In 2010 the FDA mandated the poor

responder issue to be placed in an FDA boxed warning. An FDA boxed warning (colloquially known as a "black box warning") is the strongest warning that the FDA requires, and is solely reserved for risks of death or serious injury. Since 2010, consumers have been warned that their life might be at risk if they consume Plavix and prove to be a poor responder. Consumers who took Plavix between 1998 and 2009 were deprived of this life-protecting information, and likely misled by this omission in their decision to take Plavix.

1. The FDA boxed warning is material as a matter of law.

It is unequivocal: information contained within an FDA boxed warning is of the highest legal magnitude, specifically designated under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., to protect consumers from death and life-altering injury with the force of law. A boxed warning is the strongest warning that the FDA requires, and it is reserved for risks of death or serious injury.

Here, the FDA placed the poor responder issue in a boxed warning to warn consumers about the potentially fatal consequences of taking Plavix as a poor responder. Because the FDA designated the poor responder issue to be the most important information under law that a consumer must know when considering

Plavix, it is axiomatic that such information is material. Information is material to consumers when it is "important to consumers" and therefore "likely to affect their choice of, or conduct regarding, a product." Courbat, 111 Hawaiʻi at 262, 141 P.3d at 435 (citations omitted) (emphasis added). The poor responder information is "important to consumers" as a matter of law because of the FDA boxed warning designation bestowed upon it for posing a potentially fatal threat to consumers. Id. Because BMS and Sanofi omitted the poor responder information for eleven years from the Plavix label, consumers were misled with respect to their choice of Plavix, because they did not have the material information that Plavix may pose a fatal threat to them. The State is correct that there is "no doubt that the information contained in Plavix's federally mandated black box warning is material as a matter of law." The FDCA's statutory and regulatory framework set forth below outlines the FDA's legal authority, and further illustrates why the FDA boxed warning makes the poor responder issue material as a matter of law.

The FDCA is a consumer protection statute enacted in 1938 by the United States Congress. The FDCA's primary purpose is to "safeguard" and "protect" the consumer from being exposed to "dangerous products" affecting public health and safety.

United States v. Sullivan, 332 U.S. 689, 696 (1948). The FDA, established under the FDCA, is the primary agency that administers and enforces the FDCA. 21 U.S.C. § 393(a).[2] The central mission of the FDA is to "promote" and "protect the public health" with respect to product safety, and specifically to "ensure[] that . . . drugs are safe and effective[.]" 21 U.S.C. § 393(b)(1)-(2).

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[2] 21 U.S.C. § 393 [Food and Drug Administration] states in part:

(a) In general. There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) Mission. The Administration shall —

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that —

(A) foods are safe, wholesome, sanitary, and properly labeled;
(B) human and veterinary drugs are safe and effective;
(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
(D) cosmetics are safe and properly labeled; and
(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

To carry out its mission, the FDA is statutorily empowered to enforce the FDCA's mandates through administrative actions. Specifically, the FDA has the statutory authority to prohibit certain products from being sold in interstate commerce unless those products have been evaluated and approved by the FDA. See, e.g, 21 U.S.C. § 355(a)-(b) (prohibiting market entry for any new drug unless FDA-approved). With respect to the instant case, the FDA has the statutory authority to prohibit any new drug from entering into interstate commerce unless the FDA has approved it through its extensive new drug application process. Id. Put simply, the FDA has the force of law with respect to pre-market approval of a drug, and determining whether a drug comes to market. That force of law includes authority to ensure a drug is accurately and effectively labeled so that consumers are aware of the drug's safety and efficacy. See, e.g., 21 C.F.R. § 201.56(a)(1) (labeling must contain "essential scientific information needed for the safe and effective use of the drug[.]") (emphasis added). As such, the FDA has a statutory mandate to ensure drugs are safe and effective and accurately labeled, and no drug enters the streams of commerce without the FDA's approval and oversight.

Importantly, the FDA's statutory mandate does not end with pre-market approval: the FDA is endowed with substantial post-market surveillance authority, including overseeing the

continued safety of an approved drug and the continued adequacy of its label. See, e.g., 21 C.F.R. § 314.70(c)(6)(iii)(A) (requiring drug manufacturers to notify the FDA about changing a label in order to "reflect newly acquired information . . . [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c)[.]") (emphasis added).

A boxed warning is the strongest warning that the FDA requires, and is reserved for risks of death or serious injury. Boxed warnings reveal "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury" and "ordinarily must be based on clinical data." 21 C.F.R. § 201.57(c)(1) (emphasis added). The boxed warning isn't just the strongest warning the FDA has in its arsenal to regulate the safety of drugs; a "black box warning is the strongest type of warning allowed in drug labeling, and to ensure their significance is undiluted, use of a black box warning is permitted only where specifically required by the FDA." Amos v. Biogen Idec Inc., 249 F.Supp.3d 690, 694 (W.D.N.Y. 2017) (emphasis added).

On these grounds, information contained in an FDA boxed warning is designated by law to be the most essential information a consumer needs to know with respect to the safety

and efficacy of a drug. As such, information in an FDA boxed warning is material as a matter of law. Here, the FDA mandated the poor responder information to be placed in a boxed warning to alert consumers about Plavix's diminished effectiveness in poor responders, and the consequent risks of death and life-altering injury (in the form of higher cardiovascular event rates) for poor responders:

WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS

See full prescribing information for complete boxed warning.

- **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)**

The title of the boxed warning, in bold black capitalized letters, prominently warns the consumer of "diminished effectiveness[.]" The bullet-points in the boxed warning clarify that: (1) poor metabolizers (poor responders) taking Plavix exhibit higher cardiovascular events rates (heart attack, stroke or death) than non-poor responders; (2) "tests are available" for a consumer to determine if they are a poor responder, which will aid in determining an appropriate therapeutic strategy; and (3) poor metabolizers are directly

instructed to "consider alternative treatment or treatment strategies[.]"

The provision of the information in the FDA boxed warning that Plavix poor responders face higher risk of cardiovascular events is material for consumers who are specifically seeking to reduce their risks of cardiovascular events. This information informs the consumer that Plavix may not deliver the antiplatelet effect they seek, and that they should seek testing and/or alternative treatments. The consumers in this case are categorically vulnerable medical patients with cardiac issues, already at increased risk of death, heart attack and stroke, who are seeking to reduce their risks of cardiovascular events by taking an antiplatelet drug that is specifically designed to do just that. It is axiomatic that information relating to the possibility that Plavix would in fact exacerbate the very risks of heart attack, stroke and death the patient seeks to treat would be information profoundly important to the consumer. The Defendants themselves now acknowledge and explicitly state in the Plavix medication guide that the poor responder information is the most important information a consumer needs to know when considering Plavix.

The Plavix medication guide, authored by BMS and Sanofi and included within the Plavix label, directs patients to "[r]ead this Medication Guide before you start taking Plavix and

each time you get a refill." That medication guide states that "the most important information [consumers] should know about Plavix" includes "Plavix may not work as well in people who [] have certain genetic factors that affect how the body breaks down Plavix" and that a physician "may do genetic tests to make sure Plavix is right for you." Thus, BMS and Sanofi themselves agree with the FDA that information about poor responders is "the most important information [a consumer] should know about Plavix" and therefore essential to consumers' choice about whether to take Plavix. Pursuant to the FDCA's statutory and regulatory framework, the FDA's boxed warning, and even the Defendants' Plavix medication guide, there is no information about Plavix that is more important for consumers than the poor responder information. Because the poor responder information warns consumers that (1) they may face fatal consequences if they respond poorly to Plavix, and (2) they can get tested to see if they should seek alternative treatment, there is no question this information is important to consumers themselves. As such, the poor responder information is "information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product." Courbat, 111 Hawaiʻi at 262, 141 P.3d at 435 (cleaned up). There is no genuine dispute of material fact: the poor responder information is material as a matter of law. The Defendants' conduct to suppress and omit

the poor responder information prior to its inclusion on the Plavix label further proves its materiality.

2. BMS and Sanofi demonstrated materiality through their efforts to conceal the poor responder issue.

The record reflects that BMS and Sanofi suppressed research and inquiry into Plavix for financial reasons. For reasons set forth below, this conduct further demonstrates the materiality of the omitted poor responder issue with respect to the State's deceptive acts claim.

The Majority concedes that BMS and Sanofi's suppression of research and inquiry into Plavix for financial reasons constituted an unfair act or practice in violation of UDAP. Specifically, the Majority upholds the circuit court's findings of fact that: (1) BMS and Sanofi "suppress[ed] research and continuously and repeatedly fail[ed] to further investigate the risks of reduced platelet inhibition in poor metabolizers[;]" (2) BMS and Sanofi "knew - from the moment Plavix launched - about the diminished effects of Plavix in non-White populations;" (3) BMS and Sanofi did not volunteer this information to the FDA; and (4) that the reason BMS and Sanofi did so was to avoid "negative marketing implications" for Plavix. As such, the Majority finds sufficient support in the record to conclude that BMS and Sanofi (1) knew about poor responder outcomes; (2) suppressed research into the poor

responder issue; and (3) failed to disclose this knowledge to the FDA. It is undisputed that the Defendants engaged in this conduct for financial reasons, and to avoid negative marketing implications for Plavix. The Majority relies on these findings of fact in holding that BMS and Sanofi committed unfair acts or practices in violation of UDAP with respect to Plavix by suppressing information and research. BMS and Sanofi have thus been determined by the Majority to have suppressed information and research concerning reduced efficacy and increased risks of death and serious injury for poor responders, all for "financial reasons."

BMS and Sanofi's conduct of suppressing research and inquiry into the Plavix poor responder issue demonstrates the materiality of the poor responder issue, because the Defendants believed their conduct would influence consumer choice of Plavix. See, e.g., Kraft v. FTC, 970 F.2d 311, 323 (7th Cir. 1992) (finding the defendant's conduct was evidence of materiality, where it was determined that the defendant thought its conduct induced consumers to purchase the product). Here, the record demonstrates that it was known to the Defendants that the poor responder information would be relied upon by consumers in a way that would affect their purchasing decisions. On June 11, 2003 (seven years before the FDA mandated the 2010 Plavix boxed warning) Juergen Froehlich, a former BMS Vice President

involved in the BMS/Sanofi Plavix Lifecycle Management Committee ("LCM"), wrote in an email that "Sanofi had an in-house meeting on aspirin resistance in January and presented their data at the January LCM meeting. However, Sanofi remains adverse to doing any further work on either aspirin or clopidogrel resistance because of the potential negative marketing implications." In addition, LCM meeting minutes from June 2003 further noted an increase in publications concerning "[v]ariability of response with clopidogrel[,]"which was determined to be a "[p]otential threa[t] for future sales."

These facts demonstrate that the Defendants viewed suppression of the poor responder information as material to an informed consumer choice. BMS and Sanofi's conduct in suppressing research and inquiry into the poor responder issue was believed to eliminate "potential threat[s] for future sales." By "eliminating potential threats for future sales[,]" BMS and Sanofi were inducing consumers to continue purchasing Plavix, unimpeded by a warning that they may not receive the life-saving antiplatelet effect Plavix promised. Therefore, BMS and Sanofi's conduct in suppressing research and inquiry into the poor responder issue further demonstrates the materiality of the omitted poor responder issue with respect to the State's deceptive acts claim.

3. BMS and Sanofi failed to present any evidence to overcome the presumption of materiality with respect to the poor responder information.

Because the poor responder information in the Plavix boxed warning "significantly involves health, safety . . . [and] efficacy" the information is in fact "presumed material[]" with respect to the State's deceptive acts claim. Novartis Corp. v. FTC, 223 F.3d 783, 786 (D.C. Cir. 2000) (finding that materiality is presumed for "claims that significantly involve health, safety, or other areas with which the reasonable consumer would be concerned, including a claim that concerns the purpose, safety, efficacy, . . . performance, . . . or a finding by another agency regarding the product."). Here, the poor responder information warns consumers of diminished efficacy, and increased risk of death and serious injury for patients who respond poorly to Plavix. The State's claim is that BMS and Sanofi omitted the Plavix poor responder information for approximately eleven years, which exposed almost one-third of all Plavix users to increased risk of death, stroke and heart attack. As such, this claim "significantly involves health, safety…[and] efficacy" of the highest order. Id. This claim also involves "a finding by [an] agency"—the FDA—that the product poses a risk of death and serious injury that warrants a boxed warning, which is the most serious warning label a drug can be given under law. Id. The poor responder information is

thus presumed material for the State's deceptive acts claim pursuant to Novartis Corp. v. FTC, 223 F.3d 783, 786 (D.C. Cir. 2000). Because BMS and Sanofi failed to present any evidence that created a genuine dispute of material fact with regard to whether the poor responder information was material to consumers, the Defendants failed to overcome the presumption of materiality in the instant case.

Contrary to the conclusion of the Majority that the omitted poor responder information may not have been of consequence to the consumer, the FDA, BMS and Sanofi all agree that the poor responder issue is information of the highest order that a consumer needs to know about Plavix when determining whether Plavix is "right for [them]." BMS and Sanofi's omission of this information in their labeling prior to 2009 is thus an omission of "information that is important to consumers" which is therefore "likely to affect their choice of, or conduct regarding, a product." Courbat, 111 Hawai'i at 262, 141 P.3d at 435 (emphasis added).

The Majority, however, opines that such a conclusion amounts to mere "intuition" that just because the FDA, BMS and Sanofi have determined this information to be life-and-death material to a reasonable consumer, it therefore is material to a reasonable consumer. The Majority states that "materiality is about what consumers do, not what the FDA thinks" and cites

Courbat for the proposition that "the standard is whether the information is material to a *reasonable consumer*, not the defendants." See Courbat, 111 Hawai'i at 262, 141 P.3d at 435. To be clear: the record reflects that almost one-third of all Plavix patients were poor responders, and therefore subject to "a 50 percent greater risk of having a heart attack, a stroke or death." The Defendants' eleven-year omission of the poor responder information from its label therefore exposed nearly one third of all Plavix patients to a secret, life-threatening risk: they faced a 50 percent greater chance of having a heart attack, stroke or death because they would not receive the antiplatelet effect Plavix promised. It is indisputable that the potentially fatal consequences of the poor responder issue would be material to a reasonable Plavix consumer, and that its "omission is likely to mislead consumers as to information important to consumers in making a decision regarding" Plavix. Courbat, 111 Hawai'i at 262, 141 P.3d at 435 (cleaned up) (emphases added). Yet the Majority argues that this potentially fatal information is so inconsequential that it could be ignored by a reasonable consumer, and that the Defendants should have been able to present evidence to that effect. The Majority's position strains credulity.

The Majority cites no evidence in the record with respect to "what consumers do" with the poor responder

information. Instead, the Majority points out that BMS and Sanofi sought to avoid summary judgment on the basis of evidence comprised of (1) the post-disclosure prescribing decisions of a few doctors in Hawaiʻi, along with (2) an article from the State's public health journal purportedly encouraging doctors to ignore the Plavix boxed warning, and (3) insurance reimbursement practices and trends with respect to Plavix. In this respect, the Majority concludes that BMS and Sanofi should have had the opportunity to present evidence that some "cardiologists in Hawaiʻi continued to prescribe Plavix to patients of all ethnicities even after the introduction of the black box warning" and that such evidence "bore on whether a 'reasonable' patient would choose to purchase the drug."

Evidence about a doctor choosing to prescribe Plavix after the introduction of the black box warning does not implicate the materiality of the poor responder information to the consumer. The Majority states that "[o]bjectively reasonable patients may rely on their doctors to help them make sense of drug labels." First, this statement proves an important point: a doctor cannot help a reasonable patient make sense of a drug label that omits a life-threatening warning such as the Plavix poor responder issue. It is simply self-evident that the doctor cannot advise a patient on what they themselves do not know. Second, the Majority still concedes that "patients

and doctors cannot be conflated." The Majority is correct—doctors and consumers cannot be conflated. UDAP provides legal protections to consumers. The UDAP materiality standard for assessing deceptive acts is whether the information is material to a reasonable consumer, not the reasonable consumer's doctor. See Courbat, 111 Hawaiʻi at 262, 141 P.3d at 435. Even taken in the light most favorable to BMS and Sanofi, none of the evidence cited by the Majority overcomes the presumption of materiality with respect to the poor responder information in the FDA's boxed warning. BMS and Sanofi failed to overcome the presumption of materiality, and evidence concerning doctor prescription habits is irrelevant to the materiality standard concerning the reasonable consumer. The test for materiality is objective, "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." Courbat, 111 Hawaiʻi at 262, 141 P.3d at 435 (emphases added). Failing to inform a reasonable consumer about the potentially fatal consequences of Plavix's poor responder issue would objectively be likely to mislead the consumer about information important to them in deciding to take Plavix, or seek an alternative treatment. Because the "evidence" of poor responder materiality "is so clear that no reasonable person would determine the issue

in any way but one," the circuit court did not err in granting summary judgment. Courbat, 111 Hawai'i at 263, 141 P.3d at 436.

The Majority holds that there is a genuine issue of material fact about whether BMS and Sanofi deceived reasonable consumers already at increased risk of heart attack, stroke or death by failing to include information in their label about the fact that consumers who take Plavix may experience greater risk of heart attack, stroke and death because the drug won't work as well—or at all—for them. The Majority finds the suppression of this information "immoral, unethical, oppressive, unscrupulous" and yet not sufficient to even "likely" influence a reasonable consumer's choice of Plavix. This position is untenable. A global set of consumers rely on the legal framework comprised of the FDCA, the FDA, and UDAP to protect them from being exposed to dangerous products and deceived by the companies that sell them. The Majority's holding removes those protections and fails to hold BMS and Sanofi accountable for their deceptive acts and practices.

IV. CONCLUSION

The Majority's decision rejects the legal authority and life-saving import of the FDA boxed warning. Pharmaceutical companies cannot omit information from their drug labels concerning the most serious risks known to them concerning possible death and life-altering injury for consumers. The

comprehensive legal framework comprised of the FDCA, the FDA and UDAP is specifically designed to protect consumer health and safety in the pharmaceutical arena. This legal framework exposed calculated suppression of unequivocally life-threatening information, and compels holding that the Plavix poor responder issue is material as a matter of law. Summary judgment in this case was proper. Because summary judgment was proper, I would affirm the entirety of the circuit court's Findings of Fact, Conclusions of Law, Decision and Order. Respectfully, I dissent.

/s/ Michael D. Wilson