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IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

PDX, INC. & NATIONAL HEALTH INFORMATION NETWORK, INC,

Defendants and Appellants,

vs.

KATHLEEN HARDIN & DANE HARDIN,

Plaintiffs and Respondents.

REAL PARTIES IN INTEREST KATHLEEN HARDIN'S AND DANE HARDIN'S ANSWER TO DEFENDANTS/APPELLANTS PDX, INC. & NATIONAL HEALTH INFORMATION NETWORK, INC.'S PETITION FOR REVIEW

1st Civ. No. A137035
(Alameda Superior Court. No. RG11-600291)

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INTRODUCTION: WHY REVIEW SHOULD BE DENIED

Petitioners PDX, Inc. and National Health Information Network, Inc. (collectively "PDX") ignore the record and the Court of Appeal's statement of the issues and facts in contending that the decision burdens First Amendment speech. That is not the case. The Court of Appeal decision does not allow for liability for truthful statements in public records. This case involves PDX's conduct, the intentional modification of its software so that Safeway could distribute patient drug education monographs that excluded warnings, conduct that PDX knew would pose a risk of harm to consumers.

Nonetheless, PDX seeks review contending that the Court of Appeal decision is unprecedented and inconsistent with First Amendment principles. PDX's First Amendment arguments are premised on the factual

misstatement that the monograph was a truthful statement based on public records. There is no dispute that the monograph given to Mrs. Hardin omitted FDA-mandated black box warnings about life threatening risks of taking Lamotrigine.

In its decision under the anti-SLAPP statute, the Court of Appeal did not decide whether PDX's conduct was in furtherance of the exercise of the constitutional right of petition or free speech.

The Court of Appeal's decision rests on the second prong of the anti-SLAPP statute, whether plaintiffs showed a probability of prevailing on the merits. PDX never attempted to defend the reasonableness of its conduct in the court below. Its primary argument in the Court of Appeal was that it owed no duty to Mrs. Hardin as a matter of law. In rejecting these contentions, the Court of Appeal applied the law of negligence in line with established precedent. The Court of Appeal conducted an independent review of the record to determine under the anti-SLAPP statute that the evidence presented was sufficient to support a favorable judgment. As such, Plaintiffs' negligence and products liability claims withstood PDX's anti-SLAPP motion.

PDX further contends that the Court of Appeal erred when it found PDX assumed a duty of care and contends that the opinion is, therefore, in conflict with *Rivera v. First Databank, Inc.* (2010) 187 Cal.App.4th 709, on which PDX relied for the contention that it owed no duty to Mrs. Hardin as a matter of law. PDX's assertions fail on several grounds. First, PDX essentially seeks review for determinations as to controlling factual issues that may not be decided at the pleading stage. As noted by the Court of

Appeal, factual issues such as those raised by PDX go to whether PDX acted with due care, and are not relevant to finding whether PDX assumed a duty under California law. Second, PDX ignores the distinctions made by the Court of Appeal between this case and *Rivera*, distinctions that were based on evidence in this case. The Court of Appeal explained that, unlike in *Rivera*, there was in this case an FDA-required black box warning that applied to all consumers, and it was omitted. PDX knew – and even told Safeway – that warnings were required to avoid injury to consumers. Nonetheless, PDX entered into a contract with Safeway in 2006 to modify its software so that abbreviated monographs without important warnings would be given to Safeway customers. Review of these controlling factual determinations at this stage would be premature. An anti-SLAPP motion is decided at the pleading stage prior to discovery, not after full discovery, as with a motion for summary judgment.

PDX petitions for review on the additional grounds that it is insulated from liability pursuant to Section 230 of the Communications Decency Act. This argument does not warrant review because the Court of Appeal found, based on relevant law and the evidence in this case, that Section 230 does not immunize PDX. The Court of Appeal correctly found, based on the evidence, that Plaintiffs' claims do not arise from PDX's role as a distributer of information that was furnished by another content provider.

Finally, there is no concern that courts in the future would interpret this decision as allowing liability for truthful statements about public records because the Court of Appeal's decision hinges on the

evidence in this case and makes narrow findings. Review would be unnecessary and premature.

STATEMENT OF THE CASE[1]

A. PDX provided software that assembles and prints patient education monographs.

PDX is "'an independent provider of software that distributes drug information to pharmacy customers'" including patient drug education monographs ("monographs"). (Op. at 2.) The monographs are authored by third parties, in this case Wolters Kluwer Health, Inc. ("WKH"), an independent publisher of patient education drug monographs and are summaries of information from package inserts and medication guides "written in lay language for consumers" to supplement oral counseling received when a prescription is filled. (Op. at 2 & 3 [referencing generally *Rivera v. First Databank, Inc.* (2010) 187 Cal.App.4th 709, 713 (*Rivera*)].) Based on the record, the Court of Appeal found that there was no factual dispute as to the nature of PDX's activity. (Op. at 2.)

PDX has a licensing agreement with WKH to obtain and provide the information in monographs through its software, enabling pharmacies to print and distribute monographs when a prescription is filled. (Op. at 3.) According to PDX, the purpose of the monograph is to provide patients useful, accurate and comprehensive information about their prescription

[1] Real parties in interest agree with the facts stated in the Court of Appeal's opinion. We summarize those facts and supplement with additional facts from the record.

drug, including warnings of known health risks associated with the drug. (3 C.T. 719 [Loy Decl. ¶ 9].)

PDX had a license agreement with Safeway, Inc. ("Safeway") to provide its software for use by Safeway in its pharmacies. (3 C.T. 717; Op. at 2-3.) Under this agreement, Safeway paid PDX in excess of $1 million every year in license and maintenance fees for 605 Safeway pharmacies in the U.S. and Canada. (3 C.T. 725-737.) Using the PDX software, Safeway *automatically* prints monographs, which are attached to a label with the patient's personal information. (3 C.T. 688 [Safeway Person Most Knowledgeable Depo. ("PMK Depo") 26:13-23][emphasis added].) Safeway considers the monograph to be part of the label. (3 C.T. 686 [PMK Depo. 20:11-21].)

B. The Industry staved off mandatory FDA regulation of patient drug information by adopting an industry "Action Plan."

In 1996, Congress enacted Public Law 104-180, which was an industry-supported alternative to the FDA's proposed regulations that would have required a regulatory approval process for drug information sheets or monographs. (3 C.T. 776; Op. at 2.)

P.L. 104-180 required that "health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, [and] patient drug information database companies" develop a plan:

> to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in

> an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product. (3 C.T. 770. 110 Stat. 1593 [Aug. 6. 1996].)

Under P.L. 104-180, the FDA could not enact mandatory regulations of consumer drug information if the industry came up with its own "Action Plan" to address the problem of inadequate drug information to consumers. (3 C.T. 776.)

In 1996, drug product information producers (including WKH), pharmacists, physicians, pharmaceutical companies, industry associations and consumer advocates collaborated on a "private sector initiative aimed at preventing further FDA regulation" by ensuring that the companies met the goals of P.L. 104-180. (3 C.T. 741, 813-819; SAA 055.) The industry committee issued its "Action Plan for the Provision of Useful Prescription Medicine Information" ("Action Plan" or "Keystone Criteria") in December 1996. (3 CT 767-822.) The Secretary of Health and Human Services approved the Action Plan in January 1997. (3 C.T. 762; Op. at 2.)

"The goals [of the Keystone Criteria] were to improve the quality of information, and ***thereby reduce injury***." (3 C.T. 719 [Loy Decl. ¶ 9][emphasis added].) "'The purpose of this Action Plan is to improve the quality and availability of useful information that is voluntarily provided to consumers with their prescription medicines. The rationale for the Plan is that providing consumers with useful information about their prescription medicines can reduce the risk of preventable, medication-induced injury and improve health outcomes.'" (Op. at 2 [quoting the Action Plan].) The Action Plan defined useful information as "'that which is sufficiently comprehensive and communicated such that consumers can make informed

decisions about how to receive the most benefit from medicines and protect themselves from harm. Both the substance and presentation of the information are important.'" (*Id.*)

Prior to 2005, PDX software permitted retailers, including Safeway, to print abbreviated (five-section) or complete (eight-section) versions of the drug monograph for a given drug. (Op. at 3.) The five-section monographs excluded three sections: "Before Using This Medicine", "Overdose" and "Additional Information." (3 C.T. 718 [Loy Decl. ¶ 7]; Op. at 3.) The excluded section "Before Using This Medicine" contained warnings as to known serious risks from the prescription drug. (*Id.*)

In 2005, PDX revised its software program to prevent retailers, including Safeway, from printing abbreviated drug monographs. (3 C.T. 719 [Loy Decl. ¶ 12]; Op. at 3.) Benjamin Loy, Senior Vice President of Industry Relations for PDX, Inc. and National Health Information Network, Inc. stated that "'[t]his software revision was made in response to both regulatory guidelines for the provision of patient education information and an internal recommendation by Jim Boyd, R.Ph., then Sr. Vice President [of] Network Services NHIN.'" (Op. at 4-5 [quoting the trial court's ruling].)

C. PDX intentionally modified its software to permit Safeway to provide abbreviated monographs.

In 2006, after PDX made printing all eight-sections mandatory, "'a Safeway representative contacted PDX because it wanted to use the five section monograph, rather than the eight section monograph with the warnings at issue here.'" (*Id.*) Thus, in 2006, PDX and Safeway entered

into a written agreement in which PDX agreed to provide "'[p]rogramming to allow the system to provide the five section monograph . . .'" *after* PDX "obtained a release of liability and indemnity from Safeway." (Op. at 3 & 5 [emphasis added].)

In the 2006 agreement with Safeway, PDX acknowledged "that providing the full eight-section version would better enable patients to 'use the medication properly and appropriately, receive the maximum benefit, and ***avoid harm.***'" (Op. at 11[quoting the 2006 agreement with Safeway] [emphasis added].)

D. Kathleen Hardin was given a five-section monograph that omitted necessary warnings.

Plaintiff Kathleen Hardin suffered complete blindness, as well as permanent, severe and painful scarring as a result of Stevens-Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis ("TEN") caused by taking Lamotrigine, the generic form of Lamictal.[2] (Op. at 1.) Plaintiff later learned that Lamotrigine carries a significant risk of SJS and TEN. (Op. at 1.)

Since 1994, the FDA has required "boxed warnings" about the possibility of "life threatening rashes" caused by Lamictal. (1 C.T. 40 [Loy Decl. ¶ 11].) Also called "black box warnings," this is the strongest warning that the FDA requires and signifies that medical studies indicate

[2] Lamotrigine is the generic form of Lamictal. The names are used interchangeably throughout this answer.

that the drug carries a significant risk of serious or even life-threatening adverse effects. (21 C.F.R. § 201.57 (c)(1).)

Mrs. Hardin filled her prescription for Lamictal at a Safeway pharmacy. (Op. at 3.) The abbreviated monograph was the only product information she received with her prescription and was the only information she read and considered in deciding to take Lamictal. (Op. at 3.) The monograph was attached to a label with her personal information. (3 C.T. 664, 667.)

The abbreviated monograph provided to Mrs. Hardin excluded the "Black Box" warnings that were contained in the section "Before Using This Medicine," which was one of the sections omitted from the five-section Lamotrigine monograph that WKH provided to PDX. The omitted warning stated:

> WARNING: SERIOUS AND SOMETIMES FATAL RASHES HAVE OCCURRED RARELY WITH THE USE OF THIS MEDICINE.... Contact your doctor immediately if you develop rash symptoms, including red, swollen, blistered, or peeling skin. Treatment with this medicine should be stopped unless it is clearly determined that the medicine did not cause the rash. Even if the medicine is stopped, a rash caused by this medicine may still become life threatening or cause serious side effects (such as permanent scarring.) (Op. at 3-4.)

If Mrs. Hardin had been given the warning of serious and sometimes fatal rashes, she would have read it and would not have taken the medication. (Op. at 4.)

E. The trial court denied PDX's anti-SLAPP motion to strike.

Kathleen Hardin and her husband sued her physician, the generic drug company that manufactured and distributed Lamotrigine, Safeway, Inc., WKH and Doe Defendants. (Op. at 1-2.) WKH filed a motion to strike Mrs. Hardin's claims under Code of Civil Procedure section 425.16 (the "anti-SLAPP" statute). (Op. at 4.) WKH asserted that Plaintiffs' negligence and products liability claims against it arose from WKH's "protected speech concerning a public issue or an issue of public interest." (Op. at 1 & 4.) Attached to WKH's motion was a complete eight-section Lamotrigine monograph that included the section titled "Before Using This Medicine." (3 C.T. 674-678.) The trial court granted WKH's motion to strike and ruled that "WKH's production of drug monographs was protected speech under section 425.16, subdivision (e)(4)." As to the second prong, the trial court ruled that Plaintiffs "had no probability of prevailing on her claims because, following the rationale of *Rivera, supra*, 187 Cal.App.4th 709, she could not establish that WKH owed her any duty." (Op. at 4.)

Plaintiffs amended their complaint to allege causes of action for negligence and products liability against PDX. (Op. at 4.) PDX filed an anti-SLAPP motion to strike and argued that the claims against it were identical to those brought against WKH and should be dismissed for the same reasons. (Op. at 4.) "The trial court disagreed" and found that the "activity underlying PDX's alleged liability was the reprogramming of its software to permit Safeway to give customers an abbreviated, five-section monograph that omitted warnings about SJS instead of the full eight-section

version that included those warnings." (Op. at 4.) The trial court concluded: "'Plaintiffs have asserted acts by PDX that go beyond mere distribution of the WKH's monographs'" and "that PDX's reprogramming activities were not acts in furtherance of the defendant's right of petition or free speech within the meaning of section 425.16 and denied PDX's motion to strike." (Op. at 4 & 5.) PDX appealed the trial court's ruling.

F. The Court of Appeal affirmed the trial court's ruling denying PDX's Anti-Slapp Motion to Strike.

The Court of Appeal in a unanimous decision affirmed the trial court's ruling, finding that the trial court had not erred in denying PDX's anti-SLAPP motion to strike "because the plaintiff demonstrated a probability she may prevail on her claim." (Op. at 1.)

The Court of Appeal noted that the trial court had denied the anti-SLAPP motion on the first prong, ruling that "PDX's role in the production and dissemination of the short-form monograph Hardin received was not 'conduct in furtherance of the exercise of the constitutional right of petition or the constitutional right of free speech . . .'" (Op. at 7.) The Court of Appeal determined that it "need not answer this interesting question, for, *assuming arguendo* that Hardin's claims against PDX arose from protected first amendment activity, *if credited at trial her evidence would be sufficient to support a favorable judgment.*" (Op. at 7 [emphasis added].) Thus, the Court of Appeal reviewed the "trial court's determinations as to *whether the plaintiff has shown a probability of prevailing independently.*" (Op. at 6-7 [citing *ComputerXpress, Inc. v. Jackson* (2001) 93 Cal. App. 4th 993, 999] [emphasis added].)

As noted by the Court of Appeal, in order to prevail on an anti-SLAPP motion, a plaintiff need only provide "'evidence establishing a prima facie case which, if believed by the trier of fact, will result in a judgment for the plaintiff'" and that the Court "'accept as true the evidence favorable to the plaintiff [citation] and evaluate the defendant's evidence only to determine if it has defeated that submitted by the plaintiff as a matter of law.'" (Op. at 7 [quoting *Nygard, Inc. v. Uusi-Kertyla* (2008) 159 Cal.App.4th 1027, 1036].) The Court of Appeal further noted that the "burden placed on the plaintiff must be compatible with the early stage at which the motion is brought and heard [citation] and the limited opportunity to conduct discovery." (*Id.* [quoting *Wilcox v. Superior Court* (1994) 27 Cal.App.4th 809, 823].) "[O]nly a minimal showing of merit is required." (*Id.* [quoting *Yu v. Signet Bank/Virginia* (2002) 103 Cal.App.4th 298, 318].)

The Court of Appeal held that the record in this case "sufficiently makes out a claim that PDX assumed a duty of care by undertaking to render services to Safeway 'of a kind [it] should have recognized as necessary for the protection of third persons . . ." (Op. at 11.)

The Court of Appeal in so finding determined that *Rivera* did not control for several reasons. (Op. at 8.) First, the "evidentiary shortcomings presented in *Rivera* are not present here." (Op. at 8-9.) In *Rivera*, plaintiff provided no evidence to support the allegation that the monograph excluded a black box warning, or that the black box warning would have applied to the plaintiff in that case. In this case, the evidence shows that a black box warning existed, that it was intentionally excluded from the monograph

Plaintiff received and that it would have applied to *all* consumers of the drug. (*Id.*)

Second, *Rivera* did not consider, as alleged in this case, the negligent undertaking doctrine. The Court of Appeal cited section 324A of the Restatement (Second) of Torts, which provides, in part: "'One who undertakes . . . to render services to another for which he should recognize as necessary for the protection of a third person of his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform] his undertaking . . .'" (Op. at 9.) The Court set forth the requirements under section 324A and cases applying section 324A, including *Artiglio v. Corning, Inc.* (1998) 18 Cal.4th 604. (Op. at 10.) The Court then held that "PDX knew that enabling Safeway to print the abbreviated monograph could place patients at risk . . ." (Op. at 10.) The evidence in support of this included, among other things, the 2006 agreement between Safeway and PDX that specifically noted that the complete eight-section monograph would "better enable patients to 'use the medication properly and appropriately, receive the maximum benefit, and avoid harm.'" (Op. at 11.) Based on this record, the Court of Appeal found that PDX had assumed a duty of care. (Op. at 11.)

Third, the Court of Appeal rejected the contention that PDX had no duty on the grounds that the monograph indicated "it did not cover all possible adverse effects and advised patients to read the medication guide . . ." (Op. at 11.) This disclaimer was irrelevant to the scope of PDX's duty. (*Id.*) Instead, the Court of Appeal noted:

> The cited provisos and their foreseeable effect on consumers are relevant to whether PDX acted with due care when it enabled Safeway to omit warnings from WKH monographs, but it is the nature of PDX's undertaking, not the care with which it was carried out, that determines whether it assumed a duty under section 324A in the first place.

(Op. at 11.)

The Court of Appeal similarly rejected each of PDX's remaining arguments. The court rebutted the contention that section 230 of the federal Communications Decency Act (47 U.S.C. § 230)("CDA) "immunizes [PDX] from liability for providing electronic access" to monographs. The Court of Appeal clarified that the claims do not arise from PDX's role as a service provider enabling Safeway to access software. (Op. at 12.) Instead, "Hardin sued PDX because it *intentionally modified its software* to allow Safeway to distribute abbreviated drug monographs that automatically omitted warnings of serious risks" and, as such, the Court of Appeal affirmed that "'this is not a case in which a defendant merely distributed information from a third party author or publisher.'" (Op. at 12 [emphasis added].)

The Court of Appeal further addressed PDX's claims that the First Amendment and Civil Code section 47(d) "immunize it from liability for distributing what it describes as 'truthful summaries of the FDA's Package Insert and Medication Guide.'" (Op. at 13.) The Court of Appeal stated that "[i]t has not been established at this juncture that WKH's monographs are 'truthful summaries' of official FDA proceedings" or that "they qualify as 'public journals'", or "that they 'do nothing to dilute' the warnings in FDA-approved medication guides . . . and are not otherwise

misleading." (Op. at 13.) There is no evidence that monographs are not misleading. PDX's evidence did not defeat evidence "submitted by Hardin as a matter of law." (Op. at 13.)

PDX petitioned the Court of Appeal for rehearing on the grounds that the Court of Appeal's opinion "did not resolve Plaintiffs' products liability claim" and "misstated and/or omitted a number of material facts", including, according to PDX, the fact that the Action Plan provides guidelines and does not carry the force of the law. (Pet. Reh., filed 7/7/14, 1.) PDX presented arguments similar to the arguments presented in its petition for review. The petition for rehearing was denied. The Court of Appeal held that "Hardin's theory is that PDX's software program, not the information it produces, is the defective product. PDX has not argued, let alone shown, that Hardin cannot prevail under that theory. Maybe so, but at this early juncture we cannot so conclude." (Order, 7/21/14.) The Court of Appeal reaffirmed that "'[t]he causes of action need only be shown to have 'minimal merit.'" (Order, 7/21/14.)

LEGAL DISCUSSION

I. REVIEW IS NOT NECESSARY BECAUSE THE PETITION FAILS TO PRESENT A FIRST AMENDMENT ISSUE BASED ON THE RECORD IN THIS CASE.

PDX's First Amendment arguments are premised on the claim – repeated throughout the petition – that the monograph was a "truthful statement . . . based on public records." (Pet. at 18.) That is a material factual misstatement. As stated in the Court of Appeal, there is no dispute that the monograph omitted the black box warning, the most important of

all the warnings, as to "serious and sometimes fatal rashes." (Op. at 12.) The logic of PDX's arguments would permit an immunity for misrepresentations.

Even further, in so arguing, PDX sets forth factual contentions, based on the language of the monograph, and asks that this Court review this case and the language of the monograph to make a determination as to controlling facts as a matter of law. (Op. at 19.) Such review is unnecessary and premature. The Court of Appeal stated that PDX's evidence has not defeated that submitted by Plaintiffs as a matter of law. (Op. at 13.) Factual issues must be developed in the trial court beyond the pleading stage.

As to PDX's new argument that the First Amendment requires "knowing falsity" for liability, PDX did not make that argument in the Court of Appeal. (Pet. at 24.) The Supreme Court does not ordinarily "consider an issue that the petition failed to timely raise in the court of appeal." (Cal. Rules of Court, rule 8.5000(c)(1).) In any event, the record here was sufficient to establish knowing falsity because PDX "intentionally modified its software to allow Safeway to distribute abbreviated drug monographs" that excluded warnings that it knew were important to avoid harm to consumers. (Op. at 11 & 12.)

While PDX's petition attempts to reframe the Court of Appeal's decision as premising liability on truthful statements, as the trial court observed, PDX's conduct went "'beyond mere distribution of the WKH's monographs'" and "that PDX's reprogramming activities were not acts in furtherance of the defendant's right of petition or free speech within the

meaning of section 425.16 . . ." (Op. at 4 & 5.) The Court of Appeal did not decide this issue. The Court of Appeal's decision rests on the second prong of the anti-SLAPP statute and was an independent basis for affirming the trial court ruling. To the extent that PDX may be asking this Court to decide whether its conduct was somehow protected activity for the purposes of the first prong of the anti-SLAPP statute, that issue is moot.

The Court of Appeal explicitly stated that it reviewed the "probability of prevailing independently" and decided that it did not have to answer the question raised by the first prong as the trial court did before it, because it stated that, even "assuming arguendo that Hardin's claims against PDX arose from protected first amendment activity, *if credited at trial her evidence would be sufficient to support a favorable judgment.*" (Op. at 7 [emphasis added].) While PDX now argues that this case presents the First Amendment issue of liability for "truthful statements" – without ever mentioning the anti-SLAPP statute – PDX ignores the evidence in the case to the contrary and that the case arises out of its conduct.

II. REVIEW SHOULD NOT BE GRANTED BECAUSE THE FACTUAL RECORD IS INCOMPLETE AND THERE IS NO CONFLICT OF LAW TO RESOLVE.

The Court of Appeal affirmed the denial of PDX's anti-SLAPP motion, which means the case returns to the trial court for discovery and trial. Review of controlling factual issues at this time would be premature. The Court of Appeal noted that "'the burden placed on the plaintiff must be compatible with the early stage at which the motion is brought and heard [citation] and the limited opportunity to conduct discovery.'" (Op. at 7

[quoting *Wilcox v. Superior Court* (1994) 27 Cal.App.4th 809, 823, disapproved on other ground in *Equilon, supra,* 29 Cal.4th at p. 68, fn. 5].) Controlling factual issues must be developed at the trial court. Plaintiffs met their burden at this stage. The standard required in evaluating the causes of action, as well as the evidence in support thereof in the context of the two-step process delineated in the anti-SLAPP statute is clearly set forth in the Court of Appeal's decision. (Op. at 7.)

Nonetheless, PDX is requesting that determinations be made as to controlling facts at the pleading stage and prior to discovery. As to the existence of a duty PDX owed to Plaintiff, PDX again bases its argument on the same misstatement – that the monograph PDX produced is "truthful consumer product information." (Pet. at 26.) The Court of Appeal addressed this point as stated hereinabove. PDX argues that there could be no liability under a negligent undertaking theory because Mrs. Hardin's injuries were not foreseeable. (Pet. at 36.) This argument flies in the face of the evidence and the law as articulated by the Court of Appeal, including the contract that PDX and Safeway entered into (contained in the record), in which PDX expressly acknowledged that the complete monograph (which included the black box warning) were necessary to comply with industry standards and to "avoid harm" to consumers. (3 C.T. 762.)

PDX contends that certain facts, including that Safeway decided to give a five-section monograph, that the FDA required a medication guide, that PDX relied on others to provide warnings (for which there is no evidence), and that the monograph referred to a medication guide (an argument the Court of Appeal explicitly addressed in its opinion), warrant

review by the Supreme Court as to PDX's liability under a theory of negligent undertaking. (Pet. at 7; Op. at 8.) However, PDX's arguments do not make review necessary because the arguments are factual arguments that go to whether or not PDX acted with due care or caused the injuries, and do not show that the Court of Appeal's finding of whether it assumed a duty under section 324A, was erroneous under the applicable law. (Op. at 11.) PDX seeks review to have its defenses prematurely evaluated and to thereby make an anti-SLAPP motion, a motion at the pleadings stage which precludes discovery, into a motion for summary judgment.

The Court of Appeal further properly addressed arguments of this nature when it noted that it "disagreed with PDX's view that, as a matter of law, this language had any bearing upon the scope of [PDX's] duty." (Op. at 11.) Instead, the Court of Appeal determined that "the cited provisos and their foreseeable effect on consumers are relevant to whether PDX acted with due care when it enabled Safeway to omit warnings from WKH monographs, *but it is the nature of PDX's undertaking, not the care with which it was carried out, that determines whether it assumed a duty under section 324A in the first place*." (Op. at 11 [emphasis added].)

PDX further asserts that under *Rivera*, it had no duty. *Rivera* is not persuasive authority in that it does not cite authority for, nor stand for the proposition that, the producer of consumer drug information owes no duty to consumers. Based on the Court of Appeal's decision, there is no conflict of law as PDX suggests. (Pet. at 8.) As the Court of Appeal explained, *Rivera* is not controlling because "[u]nlike *Rivera*, here there was evidence that the black-box warning had been deleted from the monograph Hardin

received with her prescription" and that it "would have applied to *all* potential consumers of Lamotrigine." (Op. at 8-9.)

Finally, PDX's petition regarding the products liability theory is also premature for the same reasons as stated above. Again, the Court of Appeal in its opinion affirmed the denial of an anti-SLAPP motion to strike, which means the case returns to the trial court for discovery and trial. As the Court of Appeal stated, "at this early juncture we cannot …conclude" that PDX has shown that it must prevail on the products liability claim as a matter of law. (Op. at 20.)

III. REVIEW IS NOT NECESSARY BECAUSE THE COURT OF APPEAL CORRECTLY APPLIED SECTION 230 OF THE COMMUNICATIONS DECENCY ACT TO THE INSTANT CASE.

PDX argues that it is insulated from liability under Section 230 of the Communications Decency Act ("CDA"). The Court of Appeal decision correctly stated that the claims in this case do not arise from PDX's role as a software provider enabling Safeway to access the monograph. (Op. at 12.) The claims were brought because PDX "intentionally modified its software to allow Safeway to distribute abbreviated drug monographs . . ." which is conduct that is not immunized by the CDA. (*Id.*)

PDX inaptly analogizes its role to that of an internet website that publishes content provided by others. But as the Court of Appeal explained, PDX's conduct in contracting with Safeway to distribute monographs that omitted important drug warnings takes this case out of the purview of Section 230. "'One need look no further than the face of the statute to see

why. The CDA only immunizes 'information provided by *another* information content provider.' (47 U.S.C. § 230 (c)(1).)" (Op. at 12.)

In addition to the reasons stated in the Court of Appeal decision, Section 230 does not apply because Mrs. Hardin was not involved in any way with obtaining information online. (Op. at 12.) As the Court of Appeal noted, and as continues to be true, none of the cases upon which PDX relied or that PDX cited applied the CDA to a case such as the present one. (Op. at 12.)

This is a case in which a recipient had no interaction with or knowledge of any "interactive computer service." If PDX's view were adopted, the seller of a physical product that used an "interactive computer service" to create the paper label could avoid the traditional seller's product liability for failure to warn, or a publisher could download defamatory information for a website, print it in a newspaper and deliver it to newsstands – all without a traditional publisher's liability for defamatory content. No case supports such an interpretation. In the information age, almost all commerce can be traced back to one or more transactions over the Internet. For that reason, to stretch the CDA to immunize PDX's conduct in this case would lead to unintended and virtually limitless immunity from tort liability.

CONCLUSION

PDX has provided no grounds for review by this court of the decision affirming the denial of PDX's anti-SLAPP motion to strike. Review would be unwarranted and premature. Review at this time would require this Court to make determinations of controlling factual issues at

the pleading stage. Moreover, PDX mischaracterizes the record and makes factual misstatements in seeking protection under the First Amendment. The decision of the Court of Appeal does not, as PDX suggests, burden First Amendment rights or permit liability for truthful summaries of public records. There is no First Amendment immunity for harm caused by omitting necessary drug warnings.

Dated: August 18, 2014

Respectfully submitted,

NEWDORF LEGAL
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By: _____
KATE HERSH-BOYLE

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CERTIFICATE OF WORD COUNT

Pursuant to California Rules of Court, Rule 8.204(c)(1), I certify based on the "Word Count" feature in my Microsoft Word 2011 software, this brief contains 5,473 words including footnotes.

Dated: August 18, 2014

KATE HERSH-BOYLE

PROOF OF SERVICE

I, **LAUREN L. DIAZ**, declare as follows:

I am a citizen of the United States, over the age of eighteen years and not a party to the within entitled action. I am employed at Newdorf Legal, 220 Montgomery Street, Suite 1850, San Francisco, California 94104.

On August 18, 2014, I served the attached:

REAL PARTIES IN INTEREST KATHLEEN HARDIN'S AND DANE HARDIN'S ANSWER TO DEFENDANTS/APPELLANTS PDX, INC. & NATIONAL HEALTH INFORMATION NETWORK, INC.'S PETITION FOR REVIEW

on the interested parties in said action, by placing a true copy thereof in sealed envelope(s) addressed as follows:

SEE ATTACHED SERVICE LIST

and served the named document in the manner indicated below:

☒ **BY MAIL**: I caused true and correct copies of the above documents, by following ordinary business practices, to be placed and sealed in envelope(s) First Class postage prepaid and addressed to the addressee(s), for collection and mailing with the United States Postal Service, and in the ordinary course of business, correspondence placed for collection on a particular day is deposited with the United States Postal Service that same day.

☐ **BY PERSONAL SERVICE:** I caused true and correct copies of the above documents to be placed and sealed in envelope(s) addressed to the addressee(s) and I caused such envelope(s) to be delivered by hand on the office(s) of the addressee(s).

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed August 18, 2014 at San Francisco, California.

LAUREN L. DIAZ

SERVICE LIST

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