No. 24-6659

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEDA HEALTH CORPORATION, a Delaware Corporation,

Plaintiff-Appellant,

v.

JAY ROBERT INSLEE, in his official capacity as Governor of Washington, and ROBERT W. FERGUSON, in his official capacity as Attorney General of Washington,

Defendants-Appellees.

On Appeal from the U.S. District Court for the Western District of Washington
No. 2:24-cv-00871-DGE
The Honorable David G. Estudillo

DEFENDANTS-APPELLEES' ANSWERING BRIEF

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I. INTRODUCTION

Prosecutors, law enforcement officers, sexual assault nurses, forensic professionals, and survivor advocates overwhelmingly agree that self-collection sexual assault kits are unlikely to be treated as competent and admissible evidence in criminal prosecutions, prejudice the prosecutions of sexual offenders, divert survivors from timely medical treatment, and mislead survivors, exposing them to further trauma. To protect against such harms, Washington's Legislature enacted House Bill 1564, which makes the sale, offer for sale, and distribution of sexual assault kits intended for self-collection a per se violation of the state's Consumer Protection Act. Leda Health Corporation, a for-profit seller of self-collection kits, asks the courts for sweeping relief to enjoin enforcement of the law and declare it invalid. The district court correctly dismissed Leda's free speech and bill of attainder claims and denied Leda's preliminary injunction motion. This Court should affirm for several reasons.

First, Leda's free speech claims fail because HB 1564 does not regulate speech. By prohibiting a person from selling, offering for sale, or otherwise making available over-the-counter self-collection sexual assault kits, HB 1564 regulates conduct. Courts routinely agree that laws like this one, banning the sale of harmful products based on the intended use—from tobacco to

unapproved medications—do not limit speech. Leda's First Amendment challenge fundamentally mischaracterizes HB 1564 as banning speech or marketing about over-the-counter sexual assault kits. It does not.

Even if HB 1564 did implicate some speech, it would at most restrict commercial speech, thus triggering *Central Hudson*'s lesser form of scrutiny. HB 1564 passes *Central Hudson*'s four-prong test at the decisive threshold step, because it (at most) regulates speech proposing illegal conduct and inherently misleading speech. HB 1564 also satisfies *Central Hudson*'s remaining prongs, because it directly advances the government's substantial interest in protecting sexual assault survivors from self-administered kits that can imperil successful prosecutions of sexual assault and discourage survivors from obtaining timely medical treatment.

Second, HB 1564 is not an unconstitutional bill of attainder. The law does not single out Leda for punishment; it extends beyond Leda, applies to prospective conduct, and furthers the non-punitive purposes of protecting survivors of sexual assault and promoting successful criminal investigations and prosecutions of sexual offenses.

Finally, Leda fails to make the clear showing on the four *Winter* factors and thus is not entitled to the extraordinary and drastic remedy of a preliminary injunction.

II. STATUTORY AUTHORITIES

Statutory authorities appear in the Addendum to this brief.

III. ISSUES PRESENTED

1. Did the district court correctly decide Leda's free speech claims fail as a matter of law because HB 1564 targets non-expressive conduct?

2. If HB 1564 alternatively affects speech, does the law target commercial speech and satisfy *Central Hudson*?

3. Did the district court correctly decide Leda's bill of attainder claim fails as a matter of law because HB 1564 does not single out Leda for punishment based on past, irrevocable acts?

4. Did the district court properly deny Leda's motion for preliminary injunction because Leda did not establish a likelihood of success on the merits of its claims and irreparable harm?

IV. STATEMENT OF THE CASE

A. Properly Administered Exams Support Survivors of Sexual Assault and Ensure the Preservation of Evidence

At least one out of every six American women and one out of every thirty-three American men will survive an attempted or completed rape.[1] Properly treating and gathering competent evidence from this vulnerable group without inflicting further trauma requires specialized training.[2] SER-116-118. Sexual Assault Nurse Examiners (SANEs) are trained to provide trauma-informed, patient-centered forensic medical exams.[3] House Hr'g, *supra* note 2, at 1:42:48-1:43:08; Senate Hr'g, *supra* note 2, at 50:00-50:45; *see also* SER-116-117; SER-27. SANE examinations improve survivors' treatment for

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[1] RAINN, *Scope of the Problem: Statistics*, https://rainn.org/statistics/scope-problem (last visited Dec. 18, 2024).

[2] Hr'g Before H. Comm. on Cmty. Safety, Just., & Reentry (Wash. Feb. 7, 2023), at 1:42:48-1:43:08, *video recording by* TVW, https://tvw.org/video/house-community-safety-justice-reentry-2023021199/?eventID=2023021199 (House Hr'g); and Hr'g Before S. Comm. on L. & Just. (Wash. Mar. 8, 2023), at 50:00-50:45, *video recording by* TVW, https://tvw.org/video/senate-law-justice-2023031248/?eventID=2023031248 (Senate Hr'g). Summaries of public testimony are also provided in bill reports at SER-255-264.

[3] SANEs are available 24/7 at seven King County hospitals and SANEs provide consultations to critical access and very rural hospitals through a tele-SANE program. SER-119; *see also* Christen Bourgeois, *24/7 Forensic, Trauma-informed Medical Care will soon be available at a sixth Seattle area hospital*, Harborview Injury Prevention & Research Center (Apr. 7, 2023), https://hiprc.org/blog/sane-program/.

injuries and sexually transmitted diseases, increase reporting to law enforcement, and improve engagement with follow-up treatment and community support services. *See* House Hr'g, *supra* note 2, at 1:28:20-1:29:10, 1:41:31-1:41:46, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33; SER-118. SANE-administered exams are free in Washington and protected by the Health Insurance Portability and Accountability Act (HIPAA). Wash. Rev. Code § 70.125.110; House Hr'g, *supra* note 2, at 1:24:44-1:25:35, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33; *see also* SER-117-118, SER-120, SER-123.

SANEs place the highest priority in an exam on the well-being of the patient. House Hr'g, *supra* note 2, at 1:42:48-1:43:08; *see also* SER-117-118. Subject to patient consent, the examination will generally also include collection of bodily fluids, hair samples, and clothing. House Hr'g, *supra* note 2, at 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 26:46-26:56; *see also* SER-119-120. The exam typically includes preparing a body "map" and injury log; locating, documenting, and photographing the patient's injuries; and documenting the patient's statements and demeanor. *See* House Hr'g, *supra* note 2, at 1:43:40-1:43:50; *see also* SER-119.

SANEs are trained to ensure proper collection of evidence, packaging, and chain of custody so that the evidence will be admissible at trial. House Hr'g, *supra* note 2, at 1:40:55-1:41:30, 1:43:50-1:44:05; SER-119, SER-124; SER-47; SER-52-53. SANEs also receive training for testifying in court.[4] *See* SER-122; SER-47; SER-53.

In addition to the forensic exam, SANEs administer prophylactic treatment for sexually transmitted infections, including HIV. House Hr'g, *supra* note 2, at 1:41:31-1:41:46, 1:43:09-1:43:32; *see also* SER-120-121. Survivors are also offered pregnancy prevention treatment in appropriate cases and information about necessary follow-up care. House Hr'g, *supra* note 2, at 1:43:09-1:43:32; *see also* SER-120-121. SANE nurses are trained to provide compassionate and comprehensive care that specifically meets the needs of the vulnerable population of sexual violence survivors whom they treat. House Hr'g, *supra* note 2, at 1:42:48-1:43:39; *see also* SER-117-118.

SANEs typically work with social workers, community sexual assault advocacy organizations, and other crisis services to provide emotional and community support to patients. House Hr'g, *supra* note 2, at 1:23:30-1:24:45,

[4] Brian Bonlender, *Sexual Assault Nurse Examiners*, Wash. Dep't of Commerce: Report to the Legislature (Dec. 2016), https://www.commerce.wa.gov/wp-content/uploads/2017/03/Commerce-SANE-2016-Final.pdf.

1:41:30-1:41:47, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33; *see also* SER-121-122; SER-27. SANEs routinely assess for risk of suicide, help survivors develop a safety plan to mitigate the risk of future violence, and use validated screening questions to identify possible human trafficking victims. *See* House Hr'g, *supra* note 2, at 1:41:31-1:41:46, 1:43:09-1:43:32; *see also* SER-118-119, SER-121; SER-27. SANEs provide adult patients with the option of reporting an assault to law enforcement officials, but do not require them to engage with law enforcement. House Hr'g, *supra* note 2, at 1:28:20-1:29:10, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33; SER-121; SER-33.

If the assault is reported, the results of any DNA collected by the SANE can be uploaded to the Combined DNA Index System (CODIS), a program that links local, state, and national databases of DNA profiles from convicted offenders, unsolved crime scene evidence, and missing persons. House Hr'g, *supra* note 2, at 1:26:24-1:27:15, 1:35:14-1:35:26, 1:39:09-1:39:33; Senate Hr'g, *supra* note 2, at 32:55-34:12, 50:45-51:01; *see also* SER-59; SER-54-55. CODIS is a critical tool for identifying repeat offenders across jurisdictions. SER-62; SER-110-111; SER-54-55; SER-48. Washington recently eliminated a backlog of over 10,000 untested sexual assault kits, in the process matching

over 2,300 DNA samples on CODIS from prior perpetrators or specific cases previously added to CODIS.[5] SER-109-110. To date, these hits have helped solve at least twenty-one cold sexual assault cases, a number likely to grow over time. SER-109-110.

B. Washington's Attorney General Issued a Letter to Leda Demanding it Cease and Desist Selling and Marketing Its "Early Evidence Kits"

Leda sells and distributes what it calls "Early Evidence Kits" (EEKs), sexual assault kits where users self-collect DNA. *See* ER-145; ER-87; ER-89. The EEK is an evolution of a product Leda—then doing business as MeToo Kits Company—previously marketed as "MeToo Kits." These self-collection kits sparked concerns that any forensic evidence collected would not be admissible in court and do not address the health needs of survivors. States across the country issued cease-and-desist letters to, or consumer warnings about, MeToo Kits in 2019. *See* ER-35-70 (letters and consumer warnings from state attorneys general of New York, Oklahoma, Connecticut, Michigan, North Carolina, Hawai'i, and Florida).

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[5] Wash. State Off. of the Att'y Gen., *All backlogged sexual assault kits cleared from shelves and sent for testing* (Oct. 26, 2023), https://www.atg.wa.gov/news/news-releases/all-backlogged-sexual-assault-kits-cleared-shelves-and-sent-testing; Wash. State Off. of the Att'y Gen., *Sexual Assault Kit Initiative*, https://wasaki.atg.wa.gov/ (last visited Dec. 19, 2024).

In October 2022, upon discovering Leda's efforts to market and distribute the latest version of its EEKs to college students at the University of Washington, the Consumer Protection Division of the Washington State Attorney General's Office (AGO) issued a cease-and-desist letter. The letter directed Leda to "immediately cease and desist from advertising, marketing, and sales to Washington consumers related to its 'Early Evidence Kits' on the basis that Leda's business practices related to these kits violate the Washington Consumer Protection Act, ch. 19.86 RCW ('CPA')." ER-101. The cease-and-desist letter outlined "the unfair and deceptive nature of Leda's 'Early Evidence Kits' and related advertising and marketing schemes, the bulk of which have the capacity to deceive Washington consumers in violation of the CPA." ER-101. The cease-and-desist letter highlighted several significant concerns with the EEKs, including that EEKs "face numerous barriers to admission as evidence" in court. ER-101.

Leda ultimately complied with the cease-and-desist letter and, among other things, removed all EEKs from Washington. ER-148; ER-89.[6]

[6] In 2024, Pennsylvania issued a cease-and-desist letter to Leda related to their sale of EEKs and has since filed a consumer protection action against Leda. *AG Henry Sends Cease-And-Desist Letter, Files Suit Against Leda Health Regarding Misleading Marketing of 'Early Evidence Kits' for Sexual Assault Victims*, Penn. Att'y Gen. (June 18, 2024), https://www.attorneygeneral

C. The Legislature Adopted HB 1564 to Prevent Future Exploitation of Sexual Assault Survivors

At the request of advocacy groups and consumers, in early 2023, the Legislature considered House Bill 1564, 68th Leg., Reg. Sess. (Wash. 2023), prohibiting the sale and distribution of over-the-counter sexual assault kits. The Legislature held multiple days of public hearings, during which it received extensive testimony from law enforcement, prosecutors, survivor advocates, hospital representatives, university students, nurses' associations, and women's groups, detailing how at-home "evidence" kits prejudice the prosecution of sexual assault crimes, subject survivors to further trauma in the courtroom, discourage survivors from seeking essential healthcare, and deceive and exploit this vulnerable population. House Hr'g, *supra* note 2, at 1:18:40-2:12:14, Senate Hr'g, *supra* note 2, at 22:58-1:01:30.

As law enforcement and prosecutors testified, sexual assault cases are already difficult to prosecute, and self-collection sexual assault kits make admitting key evidence even harder. Prosecutors are rarely, if ever, able to admit such kits into evidence or establish appropriate chain of custody needed to admit any testing results on samples. Senate Hr'g, *supra* note 2, at 52:50-

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.gov/taking-action/ag-henry-sends-cease-and-desist-letter-files-suit-against-leda-health-regarding-misleading-marketing-of-early-evidence-kits-for-sexual-assault-victims/.

53:40; House Hr'g, *supra* note 2, at 1:41:17-1:41:30, 1:45:01-1:45:47. Samples collected and preserved by SANEs and law enforcement officers, and the test results from such samples, are regularly admitted into evidence in Washington courts. House Hr'g, *supra* note 2, at 1:41:17-1:41:30; Senate Hr'g, *supra* note 2, at 27:36-27:56, 28:39-29:19, 54:14-54:56. With over-the-counter kits, neither the witness who self-collects nor the individual who processes the results can establish an unbroken chain of custody to confirm that test results are authentic and reliable. Senate Hr'g, *supra* note 2, at 34:54-36:40, 52:50-53:40; House Hr'g, *supra* note 2, at 1:41:17-1:41:30, 1:45:01-1:45:47. Without testimony from the person who conducted the test to establish the authenticity and reliability of test results, and who can be subject to cross-examination, courts will not admit test results into evidence. *Id.* In contrast, witnesses testified that a self-collection kit sample test result has never been successfully admitted into evidence in Washington, whether in a criminal prosecution or civil suit. Likewise, while several Leda executives testified at public hearings, none were able to identify any instance where an over-the-counter kit had been successfully admitted as evidence in a Washington case. House Hr'g, *supra* note 2, at 1:46:28-1:50:25, 1:53:23-1:57:05.

Even if prosecutors could overcome these barriers, survivors who rely on an at-home kit over a SANE-administered exam—believing them to be equivalent—would face additional trial burdens. House Hr'g, *supra* note 2, at 1:41:31-1:41:46, 1:42:48-1:43:39, 1:44:13-1:44:31. For example, self-collection requires survivors to testify in detail about their own post-assault evidence collection and the chain of custody, storage, and possible cross-contamination of the evidence, in addition to recounting information about the assault itself. Senate Hr'g, *supra* note 2, at 52:50-53:40; House Hr'g, *supra* note 2, at 1:41:52-1:42:18, 1:45:01-1:45:47. This opens the survivor to multiple additional lines of cross-examination and risks further trauma. *Id.* In contrast, one of a SANE's most important trial roles is to corroborate a victim's injuries, demeanor, and statements, which testimony can generally be admitted as evidence as statements supporting a medical diagnosis. House Hr'g, *supra* note 2, at 1:23:30-1:24:45, 1:43:40-1:43:50, 1:45:20-1:45:33.

Medical professionals also testified to the Legislature that self-collection kits discourage survivors from seeking essential treatment for injuries, prophylactic treatment for sexually transmitted infections, or pregnancy prevention treatment. *Id.* at 1:41:31-1:41:46, 1:43:09-1:43:32. Where an individual has experienced strangulation, this missed treatment opportunity can

be deadly. Survivors who do not obtain a SANE exam lose other essential support services, including an opportunity to connect with a rape crisis counselor and information about follow-up care. *Id.* at 1:23:30-1:24:45, 1:41:30-1:41:47, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33. And because self-collection kits are not medical treatment, the information collected from such a kit is not subject to HIPAA protections. House Hr'g, *supra* note 2, at 1:24:47-1:25:35.

Numerous witnesses also testified about the likelihood that self-collection kits will deceive and retraumatize sexual violence survivors. Such kits push a false narrative that SANE-administered exams are traumatizing and costly and require reporting to law enforcement. *Id.* at 1:42:55-1:43:08, 1:44:13-1:44:31. Law enforcement representatives also testified that self-collection kits raise larger public safety concerns and may shield repeat offenders, because any test results cannot be entered into the national DNA database, CODIS. *Id.* at 1:26:24-1:27:14, 1:35:14-1:35:26, 1:39:09-1:39:33. Because many offenders are repeat or serial predators, this may subject even more individuals to sexual violence. *Id.* at 1:39:09-1:39:33; Senate Hr'g, *supra* note 2, at 32:55-34:12. Witnesses also testified that SANE-administered exams are completely free in Washington, whereas companies that sell

over-the-counter sexual assault kits often charge money to purchase their kits. Senate Hr'g, *supra* note 2, at 26:56-27:36, 54:57-55:33; House Hr'g, *supra* note 2, at 1:24:47-1:25:35, 1:43:09-1:43:32; *see also* SER-117-118, SER-120, SER-123.

During the hearings, legislators questioned the need for the bill given the AGO's existing cease-and-desist order to Leda. Supporters informed legislators that additional companies were considering over-the-counter sexual assault kits. House Hr'g, *supra* note 2, at 2:05:50-2:06:44. For example, a second company, the Preserve Group, had previously offered at-home sexual assault kits that were subject to cease-and-desists by New York and Oklahoma.[7]

The Legislature overwhelmingly passed HB 1564 with wide bipartisan support. The law (codified at Wash. Rev. Code § 5.70.070) went into effect on July 23, 2023.[8] The Legislature found that "[t]horough and professional investigations, including preservation of forensic evidence, are imperative and a fundamental component" of supporting survivors by "building victim-

[7] Victoria Knight, *At-Home Rape Kits Now Off The Market*, KFF Health News (Sept. 16, 2019), https://kffhealthnews.org/news/at-home-rape-kits-now-off-the-market/; *see also* ER-40-42; ER-47-48.

[8] Washington is not alone in legislating in this area. In 2020, New Hampshire enacted N.H. Rev. Stat. Ann. § 359-R:1, which prohibits the sale or offer for sale of over-the-counter rape test kits. And in 2024, Maryland enacted a similar law. Md. Code Ann. Com. Law § 14-4601.

centered, trauma-informed systems that promote successful investigations and prosecutions of sexual offenses." 2023 Wash. Sess. Laws, ch. 296, § 1. The Legislature explained the harms of over-the-counter sexual assault test kits, including prejudicing the successful investigations and prosecutions of offenders, and that the sale of over-the-counter sexual assault kits "may prevent survivors from receiving accurate information about their options and reporting processes; from obtaining access to appropriate and timely medical treatment and follow up; and from connecting to their community and other vital resources." *Id.*

HB 1564 prohibits a person, as defined, from selling, offering for sale, or otherwise making available a sexual assault kit:[9]

> (a) That is marketed or otherwise presented as over-the-counter, at-home, or self-collected or in any manner that indicates that the sexual assault kit may be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider; or
>
> (b) If the person intends, knows, or reasonably should know that the sexual assault kit will be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider.

[9] "'Sexual assault kit' means a product with which evidence of sexual assault is collected." Wash. Rev. Code. § 5.70.070(1)(d). HB 1564 does not prohibit the sale of all "sexual assault kits," only those which the seller presents as over-the-counter, at-home, or self-collected, or intends to be used as such. *Id.* at (2)(a)-(b).

Wash. Rev. Code § 5.70.070(2). The acts prohibited by the statute are "an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying" the Consumer Protection Act (CPA). Wash. Rev. Code § 5.70.070(3).

In addition to passing HB 1564, the State has also significantly reformed the process for testing SANE administered sexual assault kits over the last decade. It passed new laws requiring kits to be tested within set timeframes and allowing survivors to track the progress of such testing online. Wash. Rev. Code §§ 5.70.040, 43.43.545; *see also* SER-112-113; SER-31-32. The State has dedicated significant resources to eliminating its backlog on testing sexual assault kits and expanding training and capacity of SANE nurses. Wash. Rev. Code §§ 70.125.110(1)(a), 7.68.170; *see also* SER-109-110, SER-113. The State has no backlog problem on testing of sexual assault kits and examinations by SANE nurses are free and available statewide.[10] *Id.*

D. The District Court Dismisses Leda's Complaint and Denies Its Motion for a Preliminary Injunction

Eleven months after HB 1564 took effect, Leda filed its complaint and motion for preliminary injunction. ER-143-170; ER-113-142. The district court

[10] Wash. State Dep't of Lab. & Indus., *Sexual Assault Victims*, https://www.lni.wa.gov/claims/crime-victim-claims/sexual-assault-victims#information-for-victims (last visited Dec. 18, 2024).

dismissed Leda's complaint and denied its request for preliminary injunction. ER-3-34. It held that Leda's facial and as-applied First Amendment claims failed as a matter of law because HB 1564 regulates "transactional conduct," not speech. ER-11, ER-23. But to the extent HB 1564 implicates speech, the court found it implicates commercial speech and passes intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 564 (1980), because it regulates speech proposing illegal conduct excluded from First Amendment protections. ER-16, ER-33-34.

The district court also rejected Leda's remaining overbreadth, vagueness, and bill of attainder claims.[11] In rejecting Leda's bill of attainder claim, the district court held HB 1564 "does not set forth a rule based on irreversible past conduct like the commission of a felony, rather, it attaches only if a person engages in generally prohibited activities" and does not, in any event, inflict legislative punishment, but instead furthers nonpunitive legislative purposes. ER-28-29.

The district court also denied Leda's preliminary injunction motion, finding Leda could not demonstrate likelihood of success on the merits of any of its claims and failed to establish a likelihood of irreparable harm. ER-32.

[11] Leda does not appeal the district court's rejection of its overbreadth and vagueness claims.

V. SUMMARY OF ARGUMENT

This Court should affirm the district court's judgment.

Leda has no cognizable free speech claim because HB 1564 is an economic regulation of commerce and conduct—not a restriction on speech. Prohibiting the sale of harmful products based on the intended use—determined by how the seller presents the product—does not limit speech or expressive conduct. The law prohibits the sale and distribution of sexual assault kits that sellers intend for at-home use. It does not restrict companies like Leda from telling sexual assault survivors they can self-collect DNA.

Even if this Court were to conclude HB 1564 regulates speech rather than conduct (which it does not), the law would at most restrict *commercial* speech, thus triggering *Central Hudson* scrutiny. HB 1564 passes the *Central Hudson* test at the first step, because it concerns speech about an illegal product and is inherently misleading. HB 1564 also satisfies *Central Hudson*'s remaining prongs, because it directly advances the government's substantial interest in protecting survivors from self-administered kits that can imperil successful investigations and prosecutions of sexual assault and discourage survivors from obtaining timely medical treatment.

Second, HB 1564 is not a bill of attainder. The law does not relegate Leda to a class of one based on its conduct before the law was enacted and advances the non-punitive purpose of protecting survivors of sexual assault and ensuring they can bring their assailants to justice through successful investigations and prosecutions.

Finally, Leda is not entitled to extraordinary preliminary relief. It meets none of the *Winter* factors. Leda cannot show a likelihood of success on the merits of its claims and fails to even argue on appeal that it's irreparably harmed or that the equities and public interest tip in its favor.

VI. STANDARD OF REVIEW

The Court reviews de novo the district court's judgment granting a Rule 12(b)(6) motion for failure to state a claim upon which relief can be granted and "may affirm the dismissal 'based on any ground supported by the record.'" *Kwan v. SanMedica Int'l*, 854 F.3d 1088, 1093 (9th Cir. 2017) (citation omitted).

The Court reviews the denial of a preliminary injunction for abuse of discretion and reviews the district court's underlying legal conclusions de novo. *CDK Glob. LLC v. Brnovich*, 16 F.4th 1266, 1274 (9th Cir. 2021).

VII. ARGUMENT

A. The Eleventh Amendment Bars Leda's Claims Against the Governor

The Eleventh Amendment "generally prohibit[s] federal courts from hearing suits brought by private citizens against state governments without the state's consent." *Sofamor Danek Grp., Inc. v. Brown*, 124 F.3d 1179, 1183 (9th Cir. 1997). The narrow exception articulated in *Ex parte Young*, 209 U.S. 123, 157 (1908), permits suits for prospective injunctive relief only against state officials with a proven connection to enforcing the challenged law.

The *Ex parte Young* exception does not apply to the Governor here because he does not have a "fairly direct" connection to enforcement of HB 1564. *L.A. Cnty. Bar Ass'n v. Eu*, 979 F.2d 697, 704 (9th Cir. 1992). Because the Governor does not "direct, in a binding fashion, the prosecutorial activities of the officers who actually enforce the law" or bring his own enforcement, "he may not be a proper defendant." *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 919 (9th Cir. 2004).

Leda's complaint named the Governor, but its only allegation against him is that he has a duty to ensure Washington laws are faithfully executed. ER-145. But in this Circuit, the "generalized duty to enforce state law" is an insufficient nexus for enforcement and "will not subject an official to suit." *Eu*,

979 F.2d at 704; *see also Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 943 (9th Cir. 2013) (governor immune from claims for injunctive relief because "his only connection to [the statute] [wa]s his general duty to enforce California law[]"); *Nat'l Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 847 (9th Cir. 2002) (no requisite enforcement connection between the governor and new state law banning certain kinds of animal traps). Here, the Governor does not directly enforce HB 1564. Washington law confers authority to enforce the CPA on the Attorney General's Office. *See* Wash. Rev. Code § 19.86.080. The *Ex parte Young* exception does not apply to the Governor.

Before the district court, Leda argued the Governor waived his sovereign immunity defense. Leda is wrong. The Governor properly preserved this defense in opposing Leda's preliminary injunction motion and moving to dismiss Leda's complaint—the first opportunities to address the issue in substantive briefs. *See* SER-288; SER-18-19. Because the Governor raised this defense at the first opportunities, this is nothing like the waiver cases Leda relied on below. *See, e.g.*, *Hill v. Blind Indus. & Servs. of Maryland*, 179 F.3d 754, 759 (9th Cir.), *amended on denial of reh'g*, 201 F.3d 1186 (9th Cir. 1999) (waived defense by first raising defense on opening day of trial); *In re*

Bliemeister, 296 F.3d 858, 862 (9th Cir. 2002) (waived by raising defense after filing answer, summary judgment motion, and attending hearing).

The Governor has not waived sovereign immunity and is immune.

B. Leda's Free Speech Claims Fail as a Matter of Law

1. HB 1564 regulates non-expressive conduct, not speech

The First Amendment prohibits the government from "abridging the freedom of speech." U.S. Const. amend. I. Here, Leda "bears the burden 'to demonstrate that the First Amendment even applies.'" *B&L Prods., Inc. v. Newsom*, 104 F.4th 108, 112 (9th Cir 2024.), *pet. for certiorari docketed*, (U.S. Dec. 3, 2024). And because it mounts a facial challenge to HB 1564, it "must establish that no set of circumstances exists under which the [statute] would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Leda does not have cognizable First Amendment claims because HB 1564 regulates non-expressive conduct—the conduct of selling, offering for sale, or making available self-collection sexual assault kits—which does not implicate the First Amendment. As the Supreme Court has made clear, "restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). It is well established that "the First Amendment does not

prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech." *Id.*

HB 1564 regulates non-expressive conduct. As the district court correctly explained, the law's "operative verbs—'sell,' 'offer for sale,' and 'make available'—contemplate transactional conduct, i.e. the transfer of a sexual assault kit from one person to another, and not speech or expression." ER-11. HB 1564 prohibits this conduct based on the intended use of the product—sexual assault kits used over-the-counter or at-home for self-collection—and speech may be used to infer that intended use. Wash. Rev. Code § 5.70.070(2)(a) (looking to whether the sexual assault kit is "marketed or otherwise presented as over-the-counter . . . ."); *id.* § 5.70.070(2)(b) (looking to whether a person "intends, knows, or reasonably should know" the kit will be used by someone other than law enforcement or a health care provider). The statute uses the terms "marketed" and "presented" to modify "sexual assault kit" to identify the illegal product by its intended use. In other words, the intent to sell sexual assault kits to be used "over-the-counter," "at-home," or "self-collected," is what renders the sale and distribution of the product unlawful. Wash. Rev. Code § 5.70.070(2)(a).

a. Relying on how a seller markets a product to determine the intended use of that product does not violate the First Amendment

Leda is wrong that First Amendment protections apply whenever a law references speech to determine the legality of conduct. *See* Opening Br. 26-29. Reliance on speech, such as how a seller markets or labels its product, to determine whether the conduct of selling that product is unlawful "does not run afoul of the First Amendment." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 282 (D.C. Cir. 2019); *see also Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (explaining the First Amendment allows "the evidentiary use of speech to establish the elements of a crime or to prove motive or intent[ ]").

Many cases support this point. For example, in *Whitaker v. Thompson*, the D.C. Circuit held that the Food and Drug Administration could rely on the marketer's speech, in the form of labeling, to infer the marketer's intent and determine whether the proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug. 353 F.3d 947, 948 (D.C. Cir. 2004). In that case, because marketing indicated an intent to treat a disease, the court (including Chief Justice Roberts then serving on the D.C. Circuit), held that the FDA could prohibit the sale of saw palmetto extract sold under a specific label

without drug approval, though the extract could be legally sold in other contexts. *Id.* at 953.

So, compare the two hypothetical advertisements created by Leda's counsel against *Whitaker*. An advertisement's statement that a sexual assault kit is "[f]or use by police officers and nurses," Opening Br. 21, can be used to infer the seller intends use of the product by police officers and nurses—which HB 1564 does not regulate. And an advertisement's statement that a sexual assault kit has "[e]asy-to-follow instructions for comfortable use at home[ ]," Opening Br. 22, can be used to infer the seller intends the consumer to self-collect at home—which HB 1564 does regulate. *See id.* at 22. In the same way, the plaintiff in *Whitaker* could lawfully sell saw palmetto extract if its labeling did not characterize it as preventing disease but could not sell the same product without FDA approval otherwise. *See* 353 F.3d at 948-49. In neither case does the law regulate speech. And it is constitutionally permissible to "use . . . speech to infer intent, which in turn renders an otherwise permissible act unlawful[.]" *Id.* at 953.

Nicopure Labs likewise makes clear that speech may be used to determine a product's lawfulness. There, an e-cigarette manufacturer challenged, *inter alia*, the "premarket review pathway" provisions of the

Tobacco Control Act on First Amendment grounds. The premarket review pathway classified products for regulation based on "how the manufacturer describe[d] the product's characteristics and intended use." *Nicopure Labs*, 944 F.3d at 282-83. The e-cigarette manufacturer argued that this use of its claims—"such as a claim that the product is 'safer than cigarettes'"—to assign the product to a review pathway impermissibly burdened speech. *Id.* The D.C. Circuit disagreed. The court held that the FDA did not "burden the seller's speech" by relying "on [the] seller's claims about a product as evidence of that product's intended use." *Id.* The D.C. Circuit explained, "[j]ust as the government may consider speech that markets a copper bracelet as an arthritis cure or a beach ball as a lifesaving flotation device in order to subject the item to appropriate regulation, so, too, the FDA may rely on e-cigarette labeling and other marketing claims in order to subject e-cigarettes to appropriate regulation." *Id.* at 283. Likewise, the State may rely on how a sexual assault kit is presented or marketed to subject it to appropriate regulation.

This proposition applies outside of the FDA context too. For example, the First Circuit upheld a local ordinance that restricted flavored tobacco products against a First Amendment challenge. *See Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013). There, a

"Flavor Ordinance" established that it would be "unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer," *id.* at 74, and provided that a "statement or claim made or disseminated by the manufacturer of a tobacco product . . . that such tobacco product has or produces a characterizing flavor shall constitute presumptive evidence that the tobacco product is a flavored tobacco product." *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, C.A. No. 12-96-ML, 2012 WL 6128707, at *19 (D.R.I. Dec. 10, 2012), *aff'd*, 731 F.3d 71. Like Leda, the plaintiffs there argued that the Flavor Ordinance " 'presumptively bans products based on what Plaintiffs *say* about them' " in violation of their First Amendment rights. *Id.* at *7 (citation omitted). The district court rejected this argument, holding "[t]he inclusion of a 'public claim or statement made by the manufacturer' to determine whether the described product falls under the definition of a 'flavored tobacco product' . . . does not amount to a prohibition against speech[,]" it "merely serve[d] to explain which tobacco products fall under the prohibition." *Id.* at *8. Likewise, here, HB 1564 explains which sexual assault kits "fall under the prohibition": those that are "marketed or otherwise presented as over-the-counter, at-home, or self-collected or in any manner that indicates that the sexual assault kit may be used for the collection of evidence

of sexual assault other than by law enforcement or a health care provider" or where a "the person intends, knows, or reasonably should know that the sexual assault kit will be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider." Wash. Rev. Code § 5.70.070(2). Like the Flavor Ordinance, HB 1564 is "an economic regulation of the sale of a particular product" and not a regulation of speech. *Nat'l Ass'n of Tobacco Outlets*, 2012 WL 6128707, at *7.

HB 1564 does not prohibit a company from telling survivors of sexual assault they can self-collect DNA. Nor does HB 1564 regulate commercial speech by, for example, prohibiting plaintiffs from advertising accurate information about lawfully sold products. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 489 (1996) (prohibition on advertising prices of legal alcoholic beverages violates the First Amendment); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 750 (1976) (same for prohibition on pharmacists advertising truthful information about legally prescribed prescription drugs). HB 1564 only regulates what people and businesses "must *do*[,] . . . not what they may or may not *say*." *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 60 (2006).

The sale and distribution of over-the-counter sexual assault kits is prohibited based on the intended use of the products, which may be based on marketing or any number of ways a state can establish the intended use of a product. *Cf. Whitaker*, 353 F.3d at 953; *Wisconsin*, 508 U.S. at 489; *Fla. Businessmen for Free Enter. v. City of Hollywood*, 673 F.2d 1213, 1219 (11th Cir. 1982) (upholding prohibition on use, possession, and advertisements of drug paraphernalia where a person knows or reasonably should know the object will be used with drugs).

b. Prohibiting offers to sell an illegal product does not infringe on the Free Speech Clause

Prohibiting an "offer for sale" of an unlawful over-the-counter sexual assault kit likewise does not implicate the First Amendment. "Offers to engage in illegal transactions are categorically excluded from First Amendment protection." *United States v. Williams*, 553 U.S. 285, 297 (2008); *see also Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 496 (1982) (ordinance banning sale of drug paraphernalia without a license didn't violate First Amendment rights because the ordinance's scope reached only "speech proposing an illegal transaction, which a government may regulate or ban entirely[ ]"); *Levi Strauss & Co. v. Shilon*, 121 F.3d 1309, 1312 (9th Cir. 1997)

("For commercial speech to come within the protection of the First Amendment, it must concern lawful activity.").

This Court's decision in *Nordyke v. Santa Clara County*, 110 F.3d 707 (9th Cir. 1997), illustrates this point. There, the Court explained that "proposals to engage in commercial transactions are not accorded First Amendment protection" where the underlying transaction is illegal. *Id.* at 710. In *Nordyke*, because neither state nor federal law proscribed the sale of firearms at a gun show, prohibiting an offer of "lawful activity" implicated *Central Hudson*'s commercial speech test. *Id.* at 711. But here, selling over-the-counter sexual assault kits is illegal under state law. Thus, proscribing the offer to sell over-the-counter sexual assault kits does not implicate the First Amendment. *Id.* at 710.

HB 1564's prohibition on the sale, offer for sale, and distribution of over-the-counter sexual assault kits is a restriction on commerce and conduct—not a restriction on speech implicating the First Amendment. *See also B&L Prods.*, 104 F.4th at 114-15 (statutes prohibiting contracting for sale of firearms or ammunition on state property did not implicate First Amendment); *Eastchester Tobacco & Vape Inc. v. Town of Eastchester*, 618 F. Supp. 3d 155, 161-62 (S.D.N.Y. 2022) (dismissing First Amendment challenge to ordinance

banning "[t]he sale, offer for sale, or distribution of Electronic Nicotine Delivery Products[ ]" (brackets in original)).

c. Selling self-collection sexual assault kits is not inherently expressive

HB 1564 targets non-expressive conduct. The First Amendment applies only when "conduct with a 'significant expressive element' drew the legal remedy or the [statute] has the inevitable effect of 'singling out those engaged in expressive activity.'" *Int'l Franchise Ass'n, Inc. v. City of Seattle*, 803 F.3d 389, 408 (9th Cir. 2015) (quoting *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 706-07 (1986)). Here, the legal remedy under HB 1564 is not drawn by speech. Leda can tell survivors they can self-collect DNA. It can speak about its "Early Evidence Kits" and write op-eds about self-collection sexual assault kits. It can write or say any of the information that is contained on the packaging of its EEKs. It is only if Leda sells their at-home sexual assault kits, or otherwise makes them available to individuals, that draws HB 1564's legal remedy. *Id*. Moreover, HB 1564 applies to all sellers who want to sell or distribute over-the-counter sexual assault kits "for purely financial reasons or other

purposes"—they do not single out people who wish to engage in expressive activity. *B&L Prods.*, 104 F.4th at 115.[12]

International Franchise Ass'n v. City of Seattle is instructive. There, an ordinance set two schedules for minimum wage increases, one putting franchisees with franchisors on an accelerated schedule. *Int'l Franchise Ass'n*, 803 F.3d at 397. This Court rejected the challengers' theory that a business agreement between a franchisor and a franchisee is expressive, acknowledging that the ordinance "is not wholly unrelated to a communicative component, but that in itself does not trigger First Amendment scrutiny." *Id.* at 408. This Court held that the ordinance was an economic regulation that did not target expressive conduct because it "applies to businesses that have adopted a particular business model, not to any message the businesses express." *Id.* at 409.

Here too. HB 1564 applies to people who sell or distribute a particular type of product—self-collection sexual assault kits—not to any particularized message conveyed. *Compare Hurley v. Irish-Am. Gay, Lesbian & Bisexual*

[12] Leda also asserts the law restricts "the general public's right to hear truthful speech about a product that is legal for them to buy and use." Opening Br. 17. Setting aside that Leda hasn't otherwise argued it has standing to assert the First Amendment rights of third-party consumers, nothing about the law stops Leda from telling survivors they may self-collect DNA.

Grp. of Boston, 515 U.S. 557, 569-70 (1995) (discussing instances in which the Supreme Court has found conduct to be inherently communicative); *with Rumsfeld*, 547 U.S. at 66 (statute denying federal funding to educational institutions restricting military recruiting did not regulate "inherently expressive" conduct because expressive nature of act of preventing military recruitment necessitated explanatory speech); *HomeAway.com, Inc. v. City of Santa Monica*, 918 F.3d 676, 680, 685 (9th Cir. 2019) (ordinance regulating forms of short-term rentals was "plainly a housing and rental regulation" that "regulate[d] nonexpressive conduct—namely, booking transactions").

Likewise, in *B&L Productions*, this Court looked at a California statute that banned contracting for, authorizing, or allowing the sale of firearms or ammunition on fairgrounds property. 104 F.4th at 111. The plaintiff contended that the statute specifically "jeopardized the pro-gun speech that occurs at gun shows," including information sharing and educational activities. *Id.* at 114. The Court explained that "celebration of America's gun culture . . . can still take place on state property, as long as that celebration does not involve contracts for the sale of guns." *Id.* at 114-15 (cleaned up). Thus, because "'the only inevitable effect, and the stated purpose' of [the] statute [wa]s to regulate nonexpressive conduct," this Court concluded that its inquiry was essentially

complete. *Id.* at 116 (quoting *HomeAway.com*, 918 F.3d at 685). Here, the only inevitable effect and the stated purpose of HB 1564 is to regulate non-expressive conduct—the sale of self-collection sexual assault kits. As the district court rightfully observed: Leda, and others, can assert the message that survivors can self-collect DNA following a sexual assault, so long as that message does not involve the sale of self-collection sexual assault kits. ER-19-20.

Were it otherwise, First Amendment protections would extend to every commercial transaction on the ground that the transaction communicates information about a product or service. But courts have long rejected the "view that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea." *United States v. O'Brien*, 391 U.S. 367, 376 (1968); *see also Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 570 (1991). This Court should too.

2. To the extent HB 1564 implicates commercial speech, it satisfies *Central Hudson* scrutiny

To the extent HB 1564 regulates speech at all, the district court correctly concluded in the alternative that the statute regulates commercial speech and readily satisfies the *Central Hudson* test. *Central Hudson*, 447 U.S. at 564. Leda ignores the characteristics of commercial speech under *Bolger v. Youngs*

Drug Products Corp., 463 U.S. 60, 66 (1983), and instead urges application of strict scrutiny on grounds that courts have expressly and repeatedly rejected. Leda's challenge fails at every step.

a. If HB 1564 implicates speech, it regulates commercial speech

The district court correctly concluded that HB 1564, at most, regulates commercial speech. "[T]he core notion of commercial speech [is] 'speech which does "no more than propose a commercial transaction."'" *Bolger*, 463 U.S. at 66 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 762). Because such speech "is 'linked inextricably' with the commercial arrangement that it proposes," the State's interest in regulating the transaction gives it "a concomitant interest in the expression itself." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). As "the offspring of economic self-interest," commercial speech is considered a "hardy breed of expression that is not 'particularly susceptible to being crushed by overbroad regulation.'" *Central Hudson*, 447 U.S. at 564 n.6. As such, restrictions on commercial speech are subject only to an "intermediate standard of review[.]" *Id.*

Speech is properly characterized as commercial when (1) the speech is admittedly advertising, (2) it references a specific product, and (3) the speaker has an economic motive for the speech. *Bolger*, 463 U.S. at 66-67; *Am. Acad.*

of Pain Mgmt. v. Joseph, 353 F.3d 1099, 1106 (9th Cir. 2004). In addition to information related to "proposing a particular transaction," commercial speech "can include material representations about the efficacy, safety, and quality of the advertiser's product, and other information asserted for the purpose of persuading the public to purchase the product." *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1143 (D.C. Cir. 2009) (citing *Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio*, 471 U.S. 626, 637 & n.7 (1985) (information and legal advice about a defective product and the possibility of suing were commercial)); *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 38, 43 (D.C. Cir. 1985) (claims that cigarettes contained one milligram of tar and were "99% tar free" were commercial); *Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 159, 163 (7th Cir.1977) (holding egg trade association's advertisements about the relationship between eggs and heart disease were commercial speech).

Here, the speech implicated by HB 1564 bears the key hallmarks of commercial speech under *Bolger*, the "combination" of which provide "strong support" for the district court's conclusion HB 1564 implicates only commercial speech. *Bolger*, 463 U.S. at 67 & n.14 (each characteristic need not "necessarily be present in order for speech to be commercial[]" but the

presence of all three provide "strong support" for classification as commercial speech). As the district court detailed, HB 1564 "prohibits 'offering' sexual assault kits 'for sale'—" speech that "does no more than propose a commercial transaction" ER 14-15 (citing *Bolger*, 463 U.S. at 66). This is quintessential commercial speech. HB 1564 implicates only marketing (at most) and references a specific product, meeting the first and second *Bolger* factors. And Leda has an economic motive for offering EEKs. As the district court found, "[e]ven a hypothetical 'offer for sale' at no cost (free distribution of EEKs) would still explicitly 'reference the product' itself and be directed at the 'provision of services'—services that are typically provided so that the company can turn a profit." ER-14-15 (citing *Am. Acad. of Pain Mgmt.*, 353 F.3d at 1106; *First Resort, Inc. v. Herrera*, 860 F.3d 1263 (9th Cir. 2017)). The district court thus properly found that any speech implicated by HB 1564 is "'linked inextricably' with the commercial arrangement that it proposes." ER-15 (citing *Edenfield*, 507 U.S. at 767 (quoting *Friedman v. Rogers*, 440 U.S. 1, 10, n.9 (1979))).

Leda sidesteps the *Bolger* factors, and instead baldly asserts that an implied message in offering EEKs—that sexual assault evidence can be collected "at-home"—constitutes core political speech, triggering strict

scrutiny. Opening Br. 40. But *Bolger* rejected this same argument, holding "advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech." 463 U.S. at 68 (quoting *Central Hudson*, 447 U.S. at 563, n.5). As *Bolger* explained, "[a] company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection when such statements are made in the context of commercial transactions." *Id*. at 68. *Bolger* thus held that mailings of contraceptive advertisements constituted commercial speech even though the mailings included discussions of "important public issues such as venereal disease and family planning." *Id.*

Here, as in *Bolger*, Leda has the "full panoply" of First Amendment protections available to it if it wants to publish an op-ed about collecting DNA at home following a sexual assault or criticize HB 1564 or the State in myriad other ways. But when it offers EEKs for its economic benefit, the reference to sexual assault does not render its speech any less commercial in nature.

Leda also argues that strict scrutiny applies to any content-based regulation of commercial speech. But this argument conflicts with established Supreme Court and Ninth Circuit precedent. In *Central Hudson*, the Court

specifically acknowledged that "[t]wo features of commercial speech *permit* regulation of its content." 447 U.S. at 564 n.6 (emphasis added). First, "commercial speakers have extensive knowledge of both the market and their products. Thus, they are well situated to evaluate the accuracy of their messages and the lawfulness of the underlying activity." *Id.* Secondly, the economic motive for commercial speech renders it less vulnerable to chilling effects. *Id.*; *see also Bolger*, 463 U.S. at 68 (recognizing that "regulation of commercial speech based on content is less problematic" than content-based regulation of non-commercial speech because of "the greater potential for deception or confusion in the context of certain advertising messages[.]").

Although Leda cites *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, and *Reed v. Town of Gilbert*, 576 U.S. 155 (2015) to argue for strict scrutiny of content-based regulations, this Court has repeatedly rejected the argument that *Sorrell* or *Reed* altered the *Central Hudson* framework governing commercial speech. *See Retail Digit. Network, LLC v. Prieto*, 861 F.3d 839, 841 (9th Cir. 2017) (en banc) (rejecting argument that *Sorrell* "fundamentally altered the *Central Hudson* test by adopting a more demanding standard for assessing restrictions on commercial speech[ ]" and reaffirming the *Central Hudson* test applies to content-based restrictions on commercial speech); *Nationwide Biweekly*

Admin., Inc. v. Owen, 873 F.3d 716, 732 (9th Cir. 2017) (rejecting argument that *Reed* "undermines both *Central Hudson* intermediate scrutiny," or stands for proposition "that all content-based restrictions (or compelled disclosures) of commercial speech are now subject to strict scrutiny[]"); *IMDb.com Inc. v. Becerra*, 962 F.3d 1111, 1121 (9th Cir. 2020) (affirming "reduced level of scrutiny to content-based regulation of commercial speech" under *Central Hudson*).

Leda's reliance on *Barr v. American Ass'n of Political Consultants, Inc.*, 591 U.S. 610 (2020), and *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 632 (1980), is similarly unavailing. The statute challenged in *Barr* prohibited all manner of robocalls, including "political speech, charitable fundraising, [and] issue advocacy," not just commercial advertising. 591 U.S. at 621. There, the Supreme Court struck down an amendment to a federal law which generally prohibits robocalls, to allow robocalls made to collect debts owed to the federal government. *Id.* at 613-14. The Court concluded that the amendment unconstitutionally favored debt-collection speech over other speech (like political speech) and severed the exception. *Id.* at 614. And *Schaumburg* analyzed *charitable solicitations*—speech that "is *not* primarily concerned with providing information about the

characteristics and costs of goods and services," and thus not generally analyzed under the rubric of commercial speech. 44 U.S. at 632. These cases have no application here.

As HB 1564, at most, implicates speech that does no more than propose a commercial transaction, the district court properly categorized such speech as commercial speech subject to intermediate scrutiny under *Central Hudson*.

b. HB 1564 readily satisfies *Central Hudson*'s threshold prong

The district court also correctly determined that Leda's challenge to HB 1564 fails at the threshold prong of *Central Hudson*'s test. That prong asks (1) whether the regulated commercial speech concerns unlawful activity or is inherently misleading. Because the First Amendment's concern for commercial speech is based on the "informational function of advertising," there can be no "constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." *Central Hudson*, 447 U.S. at 563-64 (citing *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 783 (1978)). As such, if speech proposes illegal activity or is misleading, First Amendment protections do not apply and the court's inquiry ends. *Id*. at 563-64 ("[t]he government may ban forms of communication more likely to deceive the public than to inform it" or "commercial speech related to illegal

activity"). Only if the regulated speech concerns lawful activity and is not misleading will courts examine the remaining three *Central Hudson* factors: (2) whether the asserted governmental interest is substantial, (3) the regulation directly advances the governmental interest, and (4) the regulation is more extensive than necessary to serve the government's stated interest. *Id.* at 564-66.

Here, Leda's challenge to HB 1564 falters out of the gate because its speech concerns both unlawful activity and is inherently misleading. First, the statute only prohibits offers to engage in illegal conduct, which are "categorically excluded from First Amendment protection." ER-16 (quoting *Williams*, 553 U.S. at 297; *Levi Strauss & Co.*, 121 F.3d at 1312); *see also Pittsburgh Press Co. v. Pittsburgh Comm'n on Hum. Rels.*, 413 U.S. 376, 388 (1973) (no First Amendment right to publish a discriminatory employment advertisement). Specifically, the district court determined that HB 1564 forbids the sale or distribution of sexual assault kits for use in the self-collection of evidence and that any "offer for sale" of an EEK thus constitutes an offer to engage in an illegal transaction. ER-16.

Leda's only argument in response is that the State does not prohibit possession or use of sexual assault kits and that no illegal conduct is therefore

implicated. Opening Br. 44. But this is a strawman. HB 1564 explicitly prohibits the sale and distribution of sexual assault kits for use in the self-collection of evidence. Leda does not dispute this: it simply ignores the statute's actual prohibitions. And contrary to Leda's suggestion (*id.*), the State may bar all "[o]ffers to engage in illegal transactions[,]" not just when *possession* of an item is illegal. *Williams*, 553 U.S. at 297. An offer to sell or distribute EEKs is plainly an "offer to engage in [an] illegal transaction[]" under HB 1564 and thus falls outside of First Amendment protections. *Id.* This determination ends the court's First Amendment inquiry.

Second, to the extent HB 1564 implicates speech at all, it also implicates inherently misleading speech that is not entitled to First Amendment protection and "may be prohibited entirely." *In re R.M.J.*, 455 U.S. 191, 203 (1982); *see also Edenfield*, 507 U.S. at 768 ("the State may ban commercial expression that is fraudulent or deceptive without further justification"); *Bolger*, 463 U.S. at 69 ("[t]he State may deal effectively with false, deceptive, or misleading sales techniques"); *Central Hudson*, 447 U.S. at 563-64 (recognizing government's right to ban speech that is "more likely to deceive the public than to inform it"). As the Supreme Court has noted, "[M]uch commercial speech is not provably false or even wholly false, but only deceptive or misleading. We

foresee no obstacle to a State's dealing effectively with this problem. The First Amendment, as we construe it today, does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely." *Va. State Bd. of Pharmacy*, 425 U.S. at 771-72.

Whether speech is inherently misleading is a question of law that courts review *de novo*. *See Peel v. Att'y Reg. & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 108 (1990) (plurality opinion) ("Whether the inherent character of a statement places it beyond the protection of the First Amendment is a question of law over which Members of this Court should exercise *de novo* review."); *Am. Acad. of Pain Mgmt.*, 353 F.3d at 1107 (determining that speech was inherently misleading as a matter of law); *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1056 (8th Cir. 2014) (determination that speech is inherently misleading is question of law). In determining whether speech is inherently misleading, the court considers such factors as the "possibilities for deception," whether "experience has proved that in fact such advertising is subject to abuse," and the "ability of the intended audience to evaluate the claims made." *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 731 (9th Cir. 1994) (citations omitted). Courts have long recognized that commercial speech about legal issues pose greater risks of deception given the

general public's lack of sophistication and awareness of such matters. *See In re R.M.J.*, 455 U.S. at 200 ("'[B]ecause the public lacks sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in legal advertising.'" (citation omitted)).

Here, an offer to sell an over-the-counter sexual assault kit is inherently misleading because it deceptively conveys to sexual assault survivors that the kit's test results constitute "evidence," and is thereby admissible in a court of law to prove the sexual assault. *See Evidence*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/evidence (last visited Dec. 19, 2024) ("something that furnishes proof . . . *specifically*: something legally submitted to a tribunal to ascertain the truth of a matter"). But the results of an over-the-counter sexual assault kit has never been admitted into evidence in *any* case, by *any* court. Leda cites a single case—*State v. Keen*, 14 Wash. App. 2d 1068 (Wash. Ct. App. Oct. 27, 2020) (unpublished)—to suggest otherwise (Opening Br. 8 n.6), but that case had nothing to do with the admissibility of self-collected, self-authenticated DNA. The DNA at issue in that case was collected and tested by law enforcement. *Id.*

Leda also ignores extensive testimony considered by the Legislature about the significant obstacles preventing over-the-counter sexual assault kits from ever being admitted into evidence in sexual assault prosecutions. Numerous members of the criminal justice community testified to the Legislature that over-the-counter sexual assault kits harm successful prosecution of sexual assault crimes because prosecutors cannot admit testing from self-collection kits into evidence. Senate Hr'g, *supra* note 2, at 52:50-53:40; House Hr'g, *supra* note 2, at 1:41:17-1:41:30, 1:45:01-1:45:47. While testing conducted and preserved by SANEs and law enforcement officers is regularly admitted into evidence, testing from self-collection kits has never been successfully admitted into evidence in Washington. House Hr'g, *supra* note 2, at 1:41:17-1:41:30; Senate Hr'g, *supra* note 2, at 27:36-27:56, 28:39-29:19, 54:14-54:56. The key problem with over-the-counter kits is that neither the witness who self-collects, nor the individual who processes the results can establish an unbroken chain of custody as required to establish that test results are authentic and reliable. Senate Hr'g, *supra* note 2, at 34:54-36:40, 52:50-53:40; House Hr'g, *supra* note 2, at 1:41:17-1:41:30, 1:45:01-1:45:47. Absent such foundational testimony, numerous experts testified to the Legislature that test results from such kits will not be admitted by courts.

Leda does not even attempt to explain how these barriers could be overcome. Although Leda would obviously charge sexual assault survivors to test any bodily fluids or DNA collected with an EEK, Leda does not suggest that the individuals performing the DNA tests would be available or obligated to testify in court to establish essential foundation for admitting such test results. But even if they were made available (presumably at great cost to the survivor), the testers still could not establish the full chain of custody of such testing materials required to admit the test results. *Id.* And Leda ignores the additional trauma survivors would be forced to bear in testifying about their self-collection. The State does not violate the First Amendment by prohibiting Leda from exploiting vulnerable and traumatized survivors with a deceptive product that would compromise rather than facilitate successful sexual assault prosecutions.

Leda argues that its disclaimer that it does not "guarantee" admissibility of EEK test results inoculates this deception. But Leda cannot sell a block of wood as a computer simply by disclaiming that it does not "guarantee" accurate computing. *FTC v. Cyberspace.Com LLC*, 453 F.3d 1196, 1200 (9th Cir. 2006) ("[a] solicitation may be likely to mislead by virtue of the net impression it creates even though the solicitation also contains truthful

disclosures[ ]"). Offering EEKs for self-collecting "evidence" of sexual assault is inherently misleading and can be prohibited by the State.

c. HB 1564 readily satisfies *Central Hudson*'s remaining three prongs

Moreover, even if this Court were to find that HB 1564 implicates only potentially misleading rather than inherently misleading speech, Leda's challenge to HB 1564 would still fail because Leda does not even attempt to argue *Central Hudson*'s remaining three prongs. *Am. Acad. of Pain Mgmt.*, 353 F.3d at 1108 (upholding state prohibition on potentially misleading speech that meets *Central Hudson* factors). HB 1564 meets *Central Hudson*'s second prong: that the State has a substantial interest in protecting sexual assault survivors

from deceptive products and avoiding prejudice to sexual assault prosecutions. *Id.* at 1108-09 ("[t]here is no question that California has a substantial interest in protecting consumers from misleading advertising from medical professionals."); *Edenfield*, 507 U.S. at 769 (the state has a substantial interest "in ensuring the accuracy of commercial information in the marketplace"); *cf. United States v. Morrison*, 529 U.S. 598, 618 (2000) ("[W]e can think of no better example of the police power, . . . than the suppression of violent crime and vindication of its victims."); *In re Grand Jury Empaneling of Special*

Grand Jury, 171 F.3d 826 (3d Cir. 1999) (compelling interest in securing needed evidence); *Heffner v. Murphy*, 745 F.3d 56, 92 (3d Cir. 2014) (state's "articulated interest in consumer protection is undoubtedly substantial[ ]").

Nor does Leda directly address *Central Hudson*'s third prong: that HB 1564 directly advances the governmental interest. Prohibiting the sale and distribution of over-the-counter sexual assault kits eliminates the grave risk that survivors will be misled into using kits that are later declared inadmissible in cases trying to bring their assailants to justice. *Cf. Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) ("common sense" that "restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait[ ]"). It also prevents diversion of sexual assault survivors from seeking exams by trained and certified SANEs, thus improving their access to care and providing greater assurances that the exam and the forensic evidence collected can be successfully used in the criminal justice process. *See* House Hr'g, *supra* note 2, at 1:23:30-1:24:45, 1:41:30-1:41:47, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33.

Under *Central Hudson*'s final prong, HB 1564 is not "'more extensive than reasonably necessary'" in light of the State's interests. *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (quoting *In re R.M.J.*, 455 U.S.

at 207). Commercial speech restrictions need not be the "least restrictive means" to achieve the desired end. *Id.* Instead, the State need only achieve a "reasonable" fit between means and ends, with a scope that is "'in proportion to the interest served,'" and courts are "loath to second-guess" legislative judgment in this area. *Id.* at 478, 480 (citation omitted). HB 1564 does not ban protected speech, but instead, prohibits the sale and distribution of over-the-counter sexual assault kits by making those acts per se violations of the Washington Consumer Protection Act. *See* Wash. Rev. Code § 5.70.070; *see also* House Hr'g, *supra* note 2, at 1:29:11-1:31:45 (sponsor testimony reflecting similar application of consumer protection statutes by other state attorneys general). This is a reasonable fit between means and end.

Finally, this Court should reject Leda's argument that HB 1564 discriminates based on viewpoint for these same reasons. In *Herrera*, this Court rejected a similar attack on a regulation "aimed at protecting women from the false or misleading" commercial speech about abortion care. 860 F.3d at 1277-78. It should reach the same conclusion here. HB 1564 is unquestionably aimed at protecting survivors of sexual assault from a deceptive product sold as collecting "evidence," when the test results will likely not be admissible in court, will prejudice sexual assault prosecutions, will cost sexual

assault victims money when reliable testing and evidentiary collection is available for free, and will expose sexual assault survivors to further trauma and suffering. HB 1564 does not target "based on" Leda's supposed "at-home" viewpoint. It instead regulates "because of" the threat to sexual assault survivors posed by Leda's inherently misleading and exploitive product. *Id.*

3. HB 1564 satisfies any level of scrutiny

Even if this Court were to conclude HB 1564 regulates speech rather than conduct (which it does not) and regulates protected non-commercial speech rather than unprotected speech or commercial speech (which it also does not), HB 1564 would pass strict scrutiny. To satisfy strict scrutiny, the State must prove a statute is "narrowly tailored to serve compelling state interests." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 395 (1992). Strict scrutiny dictates a content-based restriction "be narrowly tailored, not that it be 'perfectly tailored,'" and that courts should "decline to wade into th[e] swamp" of calibrating an individual restriction's exact tailoring, particularly when the State's compelling interest is intangible. *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 454 (2015).

The State's interest in promoting thorough and professional investigations and prosecutions of sexual offenses and protecting sexual

violence survivors from exploitation by companies selling unfair and deceptive products, is doubtlessly compelling. To determine whether a statute is narrowly tailored, a court asks "if less restrictive alternatives would be at least as effective in achieving the legitimate purpose that the statute was enacted to serve." *In re Nat'l Sec. Letter*, 33 F.4th 1058, 1070 (9th Cir. 2022) (citation omitted). Here, HB 1564 is the least restrictive alternative to serve the State's interest in protecting sexual violence survivors. Leda suggests this is not the case and claims that the State could restrict "advertising with misleading promises of admissibility" or amending the rules of evidence to "prohibit" the admission of over-the-counter kits as less restrictive options. Opening Br. 43. Yet restrictions on advertisements do not solve the central concerns about the manner of collection and transfer of forensic evidence and the chain-of-custody. And regulating admissibility would draw serious separation of powers concerns. *See State v. Gresham*, 269 P.3d 207, 217 (Wash. 2012).

Prohibiting the sale of over-the-counter sexual assault kits furthers the State's compelling interest in protecting survivors. *E.g.*, *Williams-Yulee*, 575 U.S. at 454 (holding law banning personal solicitations by judicial candidates narrowly tailored to advance state's compelling interest in promoting public confidence in the judiciary).

Leda's First Amendment challenge to HB 1564 should be rejected.

C. Leda's Bill of Attainder Claim Fails as a Matter of Law

The Constitution states that "No State shall . . . pass any Bill of Attainder." U.S. Const. art. I, § 10. Historically, a bill of attainder was a parliamentary act sentencing an individual to death or banishment. *United States v. Brown*, 381 U.S. 437, 441-42 (1965). The Bill of Attainder Clause was adopted as a separation-of-powers mechanism to prevent a particular vehicle for abuse of power: "trial by legislature." *Id.* To violate the Bill of Attainder Clause, a statute must (1) specify the affected persons, and (2) inflict punishment (3) without a judicial trial. *SeaRiver Mar. Fin. Holdings, Inc. v. Mineta*, 309 F.3d 662, 668 (9th Cir. 2002).[13] And even if a law singles out an individual, if it "furthers a nonpunitive legislative purpose, it is not a bill of attainder." *Id.* at 674. Courts presume that statutes are constitutional, and "[o]nly the clearest proof suffices to establish the unconstitutionality of a statute as a bill of attainder." *Id.* at 669.

Here, the district court correctly dismissed Leda's Bill of Attainder claim because HB 1564 neither singles out nor inflicts punishment on Leda.

[13] This Court has not determined whether the Bill of Attainder Clause extends to corporations but has assumed without deciding that the clause protects them. *Fowler Packing Co., Inc. v. Lanier*, 844 F.3d 809, 817 (9th Cir. 2016). Appellees likewise assume the Clause applies to corporations.

1. HB 1564 does not apply exclusively to Leda

HB 1564 does not single out Leda within the meaning of the Bill of Attainder Clause. Several guideposts lead to this conclusion. *See SeaRiver*, 309 F.3d at 669-71 (discussing guideposts to determine whether legislation singles out a person or class).

First, HB 1564 does not explicitly name Leda and instead "describes the affected population in terms of general applicability." *Id.* at 669 (statutory provision did not name the plaintiff). Here, the statute proscribes any "person" from selling or distributing over-the-counter sexual assault kits. Wash. Rev. Code § 5.70.070(2).

Second, Leda is not singled out because HB 1564 does not define the targeted class in terms of their *past conduct*. *See SeaRiver*, 309 F.3d at 670. Instead, the law turns on *future* business decisions to sell or distribute over-the-counter sexual assault kits after the effective date of the law. *See, e.g.*, *Hettinga v. United States*, 677 F.3d 471, 477 (D.C. Cir. 2012) (rejecting argument that law affecting only plaintiffs' businesses applied with specificity because it was based on future volumes and markets); *Franceschi v. Yee*, 887 F.3d 927, 942 (9th Cir. 2018) (state law publicly listing top 500 delinquent taxpayers was not

specific because the list could change over time and effect "is not limited to any particular group in existence at the time of the statute's enactment[]").

The challenged legislation in *SeaRiver* is a sharp study in contrast. There, after Exxon Valdez spilled nearly 11 million gallons of oil into Prince William Sound on March 23, 1989, Congress enacted a law excluding any vessel that spilled more than one million gallons of oil after March 22, 1989, from the Sound. *SeaRiver*, 309 F.3d at 666. But here, the "prospective and generalized effect" of HB 1564 "tempers the concerns of 'tyranny' by the 'multitude' that motivated the inclusion of the Bill of Attainder Clause." *Id.* at 670-71 (quoting *Brown*, 381 U.S. at 443).

Leda misleadingly cites *United States v. Brown*, to argue that a statute can be forward looking and still constitute a bill of attainder. Opening Br. 49-50. In *Brown*, the Supreme Court considered a law that "disqualifie[d] from the holding of union office not only present members of the Communist Party, but also anyone who ha[d] within the past five years been a member of the Party." 381 U.S. at 458. Although the government argued that a person could avoid the law by resigning their membership in the Community Party, the Court determined that the law violated the Bill of Attainder Clause because it inflicted a legislative deprivation for past conduct without a trial. *Id.* Here,

HB 1564 does not name Leda specifically: nor can Leda show that the law singles out Leda by describing it "in terms of conduct which, because it is past conduct, operates only as a designation of particular persons." *Communist Party of U.S. v. Subversive Activities Control Bd.*, 367 U.S. 1, 86 (1961).

Third, HB 1564 does not define the class affected by the law based on "irreversible acts committed by them." *SeaRiver*, 309 F.3d at 671 (quoting *Selective Serv. Sys. v. Minn. Pub. Int. Rsch. Grp.*, 468 U.S. 841, 848 (1984)). A person can avoid enforcement by "correcting . . . past conduct, thereby exiting the targeted class"—by not selling or distributing over-the-counter sexual assault kits. *Id.*

Finally, Leda's identity was not "easily ascertainable" when the legislation was passed. Although Leda and its EEKs were raised as examples of a business selling self-collection sexual assault kits during hearings on HB 1564, Leda is not the only company that has ever sold or considered selling such kits. *Supra* p. 14. And the legislative history and text of the statute show the purpose of the law is to protect sexual assault survivors from the evidentiary challenges these kits present—regardless of the kit's maker. At bottom, even if HB 1564 began with specific concerns about the EEKs Leda distributed within Washington, "[i]t is utterly commonplace for legislation to

be incited by concern over one person or organization . . . . Not the motive or stimulus, but the generality and consequences, of an enactment determine whether it is really legislation or really something else." *L C & S, Inc. v. Warren Cnty. Area Plan Comm'n*, 244 F.3d 601, 604 (7th Cir. 2001). Crediting Leda's contention that it was "the clear target" of the law, Opening Br. 47, would mean legislative acts born out of concerns of one or a few entities—like the Sherman Act in response to the Standard Oil Trust or the Sarbanes-Oxley Act following the Enron scandal—are unconstitutional bills of attainder. That is not the law.

In sum, HB 1564 turns on prospective acts following the effective date of the law and applies to all persons, not just Leda. All the relevant guideposts point against Leda, who additionally has not adduced the "clearest proof" that the statutory scheme constitutes a bill of attainder.

2. HB 1564 does not inflict punishment

Leda's bill of attainder claim additionally fails because nothing about the law "'legislatively determines guilt and inflicts punishment'" upon Leda "'without provision of the protections of a judicial trial.'" *Selective Serv. Sys.*, 468 U.S. at 846-47 (quoting *Nixon v. Adm'r of Gen. Servs.*, 433 U.S. 425, 468 (1977)); *see Nixon*, 433 U.S. at 472 (specificity as to create a "legitimate class

of one" is insufficient; the act must also inflict punishment without a trial to constitute a bill of attainder). Three inquiries guide this result. *SeaRiver*, 309 F.3d at 673.

First, HB 1564 includes none of the historical means of punishment that characterize an unconstitutional bill of attainder. HB 1564 does not sentence a named individual to death, imprisonment, or banishment, or prevent designated people or groups from pursuing a particular vocation. *See id.* Contrary to Leda's assertion below, the law does not "ban[] Leda Health from conducting business in the State of Washington." ER-161. Setting aside that "banishment" refers to individuals, *SeaRiver*, 309 F.3d at 673, Leda's arguments about interference with the products it sells is not a punishment under the historical description. *See Olson v. California*, 62 F.4th 1206, 1222 (9th Cir.), *reh'g en banc, opinion vacated*, 88 F.4th 781 (9th Cir. 2023), *aff'd on reh'g en banc*, 104 F.4th 66 (9th Cir. 2024) (reinstating bill of attainder holding). Moreover, Leda offers many products, including testing for sexually transmitted infections, toxicology screenings, educational workshops, and emergency contraceptives. House Hr'g, *supra* note 2, at 1:48:01-1:48:14, 2:01:26-2:02:07 (Leda officer testifying Leda could provide other services if HB 1564 passed).

HB 1564 does not prevent Leda from offering these services to Washingtonians.

Leda mistakenly contends that the Legislature's passage of HB 1564 is the punishment, following the Attorney General's cease-and-desist letter. Opening Br. 47, 50. But the Legislature acted to make prospective conduct a per se violation of the Consumer Protection Act, given additional companies who sought to sell or could sell over-the-counter sexual assault kits. The Legislature did not "determine[]" guilt where the challenged law proscribes conduct after the law's effective date and is subject to penalties through enforcement actions. *Communist Party*, 367 U.S. at 86 (laws that apply "not to specified organizations but to described activities in which an organization may or may not engage[]" are not bills of attainder). Nothing about HB 1564 itself inflicts legislative punishment without a trial for past, irrevocable acts by Leda.

Second, HB 1564 is not "'punishment'" but "'the legitimate regulation of conduct.'" *SeaRiver*, 309 F.3d. at 674. HB 1564 indisputably furthers nonpunitive purposes. The Legislature specified its aim of supporting "survivors of sexual offenses through building victim-centered, trauma-informed systems that promote successful investigations and prosecutions of sexual offenses[]" and its view that "[t]horough and professional

investigations, including preservation of forensic evidence, are imperative and a fundamental component in achieving these outcomes." 2023 Wash. Sess. Laws, ch. 296, § 1.

Third, HB 1564's legislative record is "probative of nonpunitive intentions" and does not show that the Legislature "found it 'expedient openly to assume the mantle of judge—or, worse still, lynch mob.'" *SeaRiver*, 309 F.3d

at 676 (citation omitted). Again, Leda points to the Legislature's decision to make the sale and distribution of over-the-counter sexual assault kits a per se violation of the CPA after the Attorney General issued a cease-and-desist letter. Opening Br. 47, 50. But it's not unusual for the Legislature to make certain statutory violations per se violations of the CPA. Many statutes are structured this way. *See* 6A *Washington Practice: Washington Pattern Jury Instructions: Civil* 310.03L (7th ed.) (WPI) (citing many statutes). The legislative record reflects the aim of protecting sexual assault survivors against future over-the-counter sexual assault "evidence kits" as expressed by prosecutors, law enforcement, health practitioners, advocates, and students. *See supra* pp. 10-14. And as one supporter testified, HB 1564 was needed because other companies

had created or were working to create similar products. House Hr'g *supra* note 2, at 2:05:50-2:06:44.

Leda's reliance on *United States v. Lovett*, 328 U.S. 303 (1946), illuminates why HB 1564 is not a bill of attainder. In *Lovett*, Congress had passed an appropriation bill cutting off the salaries of three named individuals who were suspected by investigators of subversive activities and of association with "communist front organizations." *Id.* at 308-11. The prohibition by Congressional act of federal employment by three named individuals with the concomitant stigma upon their reputations fell precisely within the bill of attainder prohibition. *Id*. at 315. But again, HB 1564 neither limits its application to Leda nor prevents it from conforming its conduct to follow the law prospectively.

Unable to identify any part of the text of HB 1564 that punishes Leda without a trial, Leda instead repeatedly reads its own name into quotes of legislators and supporters of the bill to argue its points. *See* Opening Br. 51-52 (using brackets to reference Leda and Leda Health). But heard in context, testimony from legislators and supporters of the bill do not refer to Leda by name, instead expressing appropriate umbrage for companies and people who seek to profit off sexual assault survivors. For example, Leda complains that a

legislator called Leda's actions "unconscionable." Opening Br. 52. But here, the legislator referred to other state attorneys general who had issued cease-and-desists against companies selling over-the-counter sexual assault kits, and quoted North Carolina's Attorney General Office as saying it was "unconscionable . . . that this company is suggesting that victims pay for sexual assault rape kits that won't bring a rapist to justice . . . ." House Hr'g *supra* note 2, at 1:29:10-1:30:33. Leda likewise asserts that legislators stated they wanted to make sure "[Leda Health] leave[s] Washington State." Opening Br. 52. But in full, the sponsor of the bill testified to the Senate Law & Justice Committee:

> People are profiting, I would argue, off of trauma . . . . We've spent our careers fighting to be the voice of survivors, to bring things out of the darkness, to shine a light and make sure that those who are being harmed are no further harmed and given the voice that was taken away from them. So unfortunately, we're here today to make sure that they leave Washington State. They don't sell a product that targets and profits off of our most vulnerable on the worst day of their life.

Senate Hr'g *supra* note 2, at 27:56-28:38.

Leda repeatedly reads itself into quotes to suggest specific, targeted punishment that cannot be supported by the statute's plain text, the operation of its provisions, and the evinced intent of the Legislature.

* * *

Leda's disagreement with being subject to HB 1564, as with any business who sells an over-the-counter sexual assault kit, does not transform into a constitutional violation. *See Nixon*, 433 U.S. at 670. The bill of attainder claim fails as a matter of law.

D. The District Court Properly Denied Leda's Motion for Preliminary Injunction Because Leda Established None of the *Winter* Factors

1. Leda has failed to show a likelihood of success on the merits

Leda argues that the Court should reverse the district court's denial of a preliminary injunction and remand with a mandate to enter a preliminary injunction. Opening Br. 18-19. But Leda cannot make a "clear showing" that it: (1) is likely to succeed on the merits; (2) would suffer irreparable harm; (3) the balance of equities tips in its favor; and (4) a preliminary injunction is in the public interest. Fed. R. Civ. P. 65(b)(1); *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

The district court's dismissal of Leda's complaint for failure to state a claim necessarily meant Leda could not show a likelihood of success on the merits. As such, the court is not required to consider the remaining preliminary injunction factors. *See CDK Glob.*, 16 F.4th at 1274; *Pimentel v. Dreyfus*, 670 F.3d 1096, 1111 (9th Cir. 2012) (per curiam).

2. Leda has not demonstrated irreparable harm

Leda cannot additionally show irreparable harm for several reasons. First, Leda's decision not to seek relief until nearly a year after HB 1564 took effect undermines any claim of irreparable harm. *Oakland Trib., Inc. v. Chron. Pub. Co., Inc.*, 762 F.2d 1374, 1377 (9th Cir. 1985) ("Plaintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm."); *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016) (delay of "even only a few months . . . militates against a finding of irreparable harm"). Leda was well aware of the existence of HB 1564 going back to February 2023, having testified against it before the Legislature.

Second, Leda fails to argue, let alone demonstrate, irreparable injury. Below, Leda's only argument for demonstrating the likelihood of irreparable harm was that it was likely to succeed on the merits, ER-138, and on appeal, Leda makes no argument about irreparable injury at all, Opening Br. *See Paramount Land Co. LP v. Cal. Pistachio Comm'n*, 491 F.3d 1003, 1012 (9th Cir. 2007) ("[S]imply raising a serious [First Amendment] claim is not enough to tip the hardship scales.").

Even in the First Amendment context, the Supreme Court has stated that "[a]s a matter of equitable discretion, a preliminary injunction does not follow as a matter of course from a plaintiff's showing of a likelihood of success on the merits." *Benisek v. Lamone*, 585 U.S. 155, 158, 160-61 (2018) (per curiam) (affirming denial of a preliminary injunction based on equities and public interest even assuming likelihood of success on First Amendment challenge).

While this Circuit has recognized that the loss of First Amendment freedoms can constitute irreparable harm, it has also held that, "even where a plaintiff has demonstrated a likelihood of success on the merits of a First Amendment claim," the plaintiff "'must also demonstrate that he is likely to suffer irreparable injury in the absence of a preliminary injunction, and that the balance of equities and the public interest tip in his favor.'" *Doe v. Harris*, 772 F.3d 563, 582-83 (9th Cir. 2014) (citation omitted). Courts should "not simply assume that these elements 'collapse into the merits of the First Amendment claim.'" *Id.*

Further, regardless of the merits of its First Amendment claim, Leda cannot show that HB 1564 chilled Leda in any way. To the contrary, Leda removed its product from the market long before the Legislature passed HB 1564. The AGO issued its cease-and-desist letter in October 2022—before

HB 1564 was even under consideration by the Legislature. *Supra* pp. 8-9; *see also* ER-148; ER-89. The cease-and-desist letter directed Leda to "immediately cease and desist from advertising, marketing, and sales to Washington consumers related to its 'Early Evidence Kits' on the basis that Leda's business practices related to these kits violate the [CPA.]" ER-100 (emphasis omitted). Leda acknowledges that it removed all EEKs from the Washington market "[i]n response to the AGO's cease and desist demand[.]" ER-148; *see also* ER-89. It also alleges that it was not until "three months later"—after it had already pulled its product from the Washington market—that the Legislature introduced HB 1564. ER-148.

Leda does not challenge Washington's Consumer Protection Act. Thus, even if HB 1564 were hypothetically enjoined here, Leda would still be subject to enforcement under the CPA and would not be free to re-introduce its over-the-counter sexual assault kits in the State without facing a threat of enforcement under the general statute. HB 1564 did not chill any alleged speech by Leda, and Leda cannot show irreparable harm warranting entry of a preliminary injunction.

3. The equities and public interest tip sharply against an injunction

The final two *Winter* factors—the balance of the equities and the public interest—also weigh heavily against Leda. Where the government is a party, these factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

Leda makes no argument about the equities and public interest. *See generally* Opening Br. Nonetheless, the equities and public interest tip sharply in the State's favor because the State's "inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State." *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018).

Beyond this interest, the public has a significant interest in preventing unfair and deceptive exploitation of sexual violence survivors from products marketed as collecting "evidence," but that have never been successfully admitted as evidence in a criminal trial in Washington. House Hr'g, *supra* note 2 at, 1:46:28-1:50:25, 1:53:23-1:57:05; *see also* SER-55; SER-50; SER-23. It also has an interest in promoting thorough and professional investigations and prosecutions of sexual offenses. 2023 Wash. Sess. Laws, ch. 296, § 1. HB 1564 prevents diversion of survivors from SANEs, who can properly preserve forensic evidence and provide medical treatment and

accurate information about options, reporting processes, and community resources. House Hr'g, *supra* note 2, at 1:28:20-1:29:10, 1:41:31-1:41:46, 1:43:09-1:43:32; Senate Hr'g, *supra* note 2, at 54:57-55:33; *see also* SER-118, SER-121, SER-123-124; SER-42; SER-27. The sale and distribution of over-the-counter sexual assault kits hinders the State's interest in these outcomes.

Leda's interest in profiting from its self-collection kits does not outweigh the public's interest in protecting survivors of sexual violence. The balance of harms and the public interest weigh decidedly against a preliminary injunction.

VIII. CONCLUSION

This Court should affirm the district court's dismissal of Leda's Complaint and denial of Leda's motion for preliminary injunction.

RESPECTFULLY SUBMITTED this 20th day of December, 2024.

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ADDENDUM

Wash. Sess. Laws 2023, ch. 296, § 1

It is the intent of the legislature to support survivors of sexual offenses through building victim-centered, trauma-informed systems that promote successful investigations and prosecutions of sexual offenses. Thorough and professional investigations, including preservation of forensic evidence, are imperative and a fundamental component in achieving these outcomes. At-home sexual assault test kits create false expectations and harm the potential for successful investigations and prosecutions. The sale of over-the-counter sexual assault kits may prevent survivors from receiving accurate information about their options and reporting processes; from obtaining access to appropriate and timely medical treatment and follow up; and from connecting to their community and other vital resources.

Wash. Sess. Laws 2023, ch. 296, § 2 (*codified at* Wash. Rev. Code § 5.70.070)

(1) For purposes of this section:

(a) "Health care facility" means a hospital, clinic, nursing home, laboratory, office, or similar place situated in Washington state where a health care provider provides health care to patients.

(b) "Health care provider" means a person licensed, certified, or otherwise authorized or permitted by law, in Washington state, to provide health care in the ordinary course of business or practice of a profession, and includes a health care facility.

(c) "Person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, or any other legal or commercial entity. The term does not include a government or governmental subdivision, agency, or instrumentality.

(d) "Sexual assault kit" means a product with which evidence of sexual assault is collected.

(2) A person may not sell, offer for sale, or otherwise make available a sexual assault kit:

(a) That is marketed or otherwise presented as over-the-counter, at-home, or self-collected or in any manner that indicates that the sexual assault

kit may be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider; or

(b) If the person intends, knows, or reasonably should know that the sexual assault kit will be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider.

(3) The legislature finds that the practices covered by this section are matters vitally affecting the public interest for the purpose of applying the consumer protection act, chapter 19.86 RCW. A violation of this section is not reasonable in relation to the development and preservation of business and is an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying the consumer protection act, chapter 19.86 RCW.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

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9th Cir. Case Number(s) 24-6659

I am the attorney or self-represented party.

This brief contains 14,000 **words,** including _____ words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

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