24-2481
IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATIONAL INSTITUTE OF FAMILY AND LIFE ADVOCATES, GIANNA'S HOUSE, INC., CHOOSE LIFE OF JAMESTOWN, INC. d/b/a Options Care Center,

Plaintiffs-Appellees,

v.

LETITIA JAMES,

Defendant-Appellant.

On Appeal from the United States District Court
for the Western District of New York

BRIEF OF AMICI CURIAE SUMMIT LIFE CENTER, INC, and THE EVERGREEN ASSOCIATION, INC, D/B/A EXPECTANT MOTHER CARE and EMC FRONTLINE PREGNANCY CENTERS, SUPPORTING APPELLEES

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INTEREST OF AMICI

Amici curiae Summit Life Center, Inc. and The Evergreen Association, Inc. d/b/a Expectant Mother Care and EMC Frontline Pregnancy are nonprofit prolife organizations that advocate the doctor-prescribed medical procedure commonly known as "abortion pill reversal" (APR). APR involves physician-directed administration of supplemental progesterone to counteract the effects of mifepristone, the first pill in the two-pill sequence of chemical abortion, for women who elect to save their unborn children in the exercise of their reproductive rights. Supplemental progesterone has been administered millions of times to help problem pregnancies, including pregnancies rendered problematic by the ingestion of progesterone by women who quickly regret having taken the pill.

These two amici are plaintiffs in a separate action consolidated below with the action by Plaintiff-Appellees NATIONAL INSTITUTE OF FAMILY and LIFE ADVOCATES, GIANNA'S HOUSE, INC., CHOOSE LIFE OF JAMESTOWN, INC. d/b/a Options Care Center (collectively referred to as "NIFLA"). These amici sought the same relief as NIFLA. With the consent of Defendant-Appellant Attorney General Letitia

James ("James"), these amici obtained an injunction replicating that already obtained by NIFLA ("the NIFLA Injunction"), barring James from pursuing any enforcement action based on alleged "consumer fraud" in amici's own advocacy of doctor-administered APR. While James elected not to appeal that parallel injunction in order to preclude a separate appeal by these amici, amici's interest will obviously be directly affected by the outcome of this appeal, as the NIFLA Injunction and amici's parallel injunction rest upon essentially the same determinations by the district court respecting First Amendment liberty. *See* Verified Complaint by amici and parallel injunction. *See* District Court Dkt. 49 (parallel injunction in consolidated case No. 1:24-cv-00514-JLS) and Dkt. 1 (amici's Verified Complaint in 1:24-cv-00741-JLS deemed filed in consolidated case).

AUTHORITY TO FILE

All parties to this case have consented to this filing by prior written notice.

INTRODUCTION[1]

APR has been administered safely and effectively to countless women *on the advice of their physicians*. The women who opt for APR do so in the well-founded hope, supported by numerous studies, that chemical abortion can be prevented by supplemental progesterone before the second pill is taken and their children *in utero* are thus saved from imminent death. James does not allege, nor can she allege, that the *prescribing physicians* are engaged in "consumer fraud." Yet James claims that mere advocacy of *what physicians themselves not only advocate but lawfully prescribe* is somehow "consumer fraud" when merely advocated by the NIFLA Plaintiffs. That untenable claim alone compels affirmance of the NIFLA Injunction barring James' lawfare on this issue.

NIFLA was founded in 1993 to provide training and educational support for pregnancy centers nationwide. Part of that support once

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E) and Local Rule 29.1(b), Thomas More Society states that no party to this appeal authored this brief in whole or in part or contributed money that was intended to fund preparing or submitting the brief. No person other than Thomas More Society contributed money that was intended to fund preparing or submitting the brief.

included telling centers about APR, a medical procedure that every research study ever published on the topic in a medical journal has found safe and effective. But because James disagrees with the science, last spring she sued pregnancy centers across New York for accurately reciting it. Her fig leaf for such viewpoint-discriminatory lawfare: that truthful noncommercial speech about the science behind *a lawfully doctor-prescribed medical protocol* is somehow commercial fraud under GBL §§ 349 and 350.

NIFLA's brief makes compelling arguments about how it had standing in this case and how the facts and law abundantly justified a preliminary injunction—also granted to these amici on James' consent but not appealed. Amici will not rehash those arguments, elaborating on just one narrow point here. A decade ago, this Court made clear in *ONY v. Cornerstone Therapeutics, Inc.* that no speaker who shares an opinion about an open scientific question is liable under commercial fraud statutes if that opinion is based on an accurate description of non-fraudulent data. *See* 720 F.3d 490, 495-98 (2d Cir. 2013). That precedent alone mandates affirmance of the NIFLA Injunction even if all of NIFLA's other arguments were to fail. Amici ask the Court simply to

remind James and other government officials eager to set themselves up as scientific truth commissions that *ONY* precludes this egregious invasion of the wide space for public debate on scientific questions under the First Amendment.

ARGUMENT

I. The Science Is Univocal: APR Is Safe and Effective.

James has long been an unapologetic pro-choice activist, ready to jump online to attack prolife pregnancy centers as "fake abortion clinics" or to bully corporations into making it hard for women to hear about them. Letitia James, *How New York Protects Your Right to Reproductive Health Care*, https://perm.cc/2EZ3-8NPZ (internal marks omitted); *see* Letter from Letitia James to Halimah DeLaine Prado, Google General Counsel (June 28, 2022); Rob Bonta, et al., Open Letter from Attorneys General Regarding CPC Misinformation and Harm (Oct. 23, 2023). When she launched a new campaign of speech suppression last spring, targeting the centers' accurate speech about the science of APR under the fig leaf of state commercial fraud statutes, NIFLA ceased its similar speech to avoid being next in her sights and dragged through the legal

process-as-punishment until common sense and the First Amendment prevailed.

In contrast to James' broadsides on abortion issues, NIFLA's APR statements had always been anodyne and accurate. It recited data from peer-reviewed studies that found APR to be safe and 64-68% effective. In an effort to prevent misunderstanding of the data, NIFLA always spoke in terms of conditions and probabilities: "If you have recently taken the abortion pill," it advised, "it may be possible to stop the effects of the abortion drug and continue your pregnancy." JA577. And NIFLA clearly communicated that there was a point of no return; a baby already slowly starved to death by the first drug could not be helped by progesterone, and so "time is of the essence for effectiveness." JA571. *That is the same advice any physician would provide in prescribing APR.*

James distorts NIFLA's obviously protected speech in three ways on appeal. First, she ludicrously avers that NIFLA tells the public that APR can bring already chemically aborted babies back from the dead. *See* James Br. at 42. Second, she opines that the studies NIFLA points to are scientifically invalid. *See id.* Third, she maintains that merely by citing the findings of some studies, NIFLA misleads New Yorkers into believing

that every obstetrician and gynecologist believes APR works everywhere and all the time. *See id.* NIFLA unsurprisingly has little trouble dismantling the first and third frivolous arguments, so amicus focuses on the second.

What James deems "invalid" studies test a biochemical premise that the pro-choice director of Yale Medical School's reproductive health clinic says just makes obvious "biological sense." Ruth Graham, *A New Front in the War over Reproductive Rights*, N.Y. Times Mag. (July 18, 2017). Mifepristone, the first drug in the standard two-drug chemical abortion regimen, blocks progesterone receptors to slowly starve the baby to death over a few days. *See* Daniel Grossman, et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion*, 92 Contraception 206, 210 (2015). Natural progesterone, acting as a mifepristone antagonist, counteracts that deadly effect. *See* FDA, Mifeprex Drug Approval Package, *Pharmacology Review* 16-17 (Sept. 28, 2000).

Following the scientific method, as opposed to James' scientifically baseless opinions, in 2006 an obstetrician tested whether *supplementing* progesterone might counteract mifepristone even more and thereby

increase the percentage of babies who survive an attempt at chemical abortion. In scientific terms, the inquiry was whether the relationship was causal and monotonic: i.e., whether more progesterone was better.

A young woman named Ashley, desperate to save her baby after being coerced to take mifepristone by her boyfriend, consented to test this scientific *and* commonsense hypothesis. *See* Grattan Brown & Matthew Harrison, *Undoing Mifepristone Abortion for the First Time* (Apr. 12, 2023); Crystal Kupper, *Reversal of Fortunes*, Daily Citizen (Sept. 18,2015). A few months after receiving the supplemental progesterone, she gave birth to a healthy baby girl whom she named Kaylie. *See* Testimony of Matthew Harrison, M.D. to Idaho Senate State Affairs Cmte. (Feb. 12, 2018). APR was thus born the same day.

Case studies like this one are where research into novel obstetric interventions usually begins, as randomly assigning a baby to possibly die in a clinical trial is unethical. If case study results are promising, they beget case series tracking several patients over time to strengthen or weaken an inference that the observed effect was causal rather than a stroke of luck. *The FDA approved mifepristone itself on the basis of just such a case series and no prior clinical trial*, with the full-throated

endorsement of the abortion-supportive American College of Obstetricians and Gynecologists (ACOG). *See* B.H. Lim, et al, *Normal Development After Exposure to Mifepristone in Early Pregnancy*, 336 *The Lancet* 257, 257-58 (1990).

No serious scholar objects to the scientific validity of case series. In two leading peer-reviewed obstetrics journals, 360 research articles since 2000 have relied on case series alone, including a recent study on mifepristone itself. *See* **Exhibit B**; Julia R. Steinberg, et al., *Medical and Procedural Abortions Before 13 Week Gestation and Risk of Psychiatric Disorders*, 231 Am. J. Obstet. & Gynec. 250.e1 (Aug. 2024).

In fact, case studies are considered the second-best form of scientific evidence after clinical trials. Case studies are sufficiently robust for ACOG to issue clinical practice guidelines based on them alone when they happen to support ACOG's pro-choice views. *E.g.*, ACOG, Clinical Practice Guideline No. 8 (Jan. 2024). Indeed, in a recent amicus brief, ACOG and twenty-five other professional scientific associations made no distinction about the strength and validity of clinical guidelines based on clinical trials versus guidelines based on case series. *See* Brief for Council of Med. Specialty Socs. As Amicus Curiae Supporting Appellee at *6-9,

Torrey v. Infectious Diseases Society of Am., 86 F.4th 701 (5th Cir. 2023) (No. 22-40728), 2023 WL 3569968.

Strong evidence from case series shows *without exception* that APR does not cause severe complications and increases the likelihood of saving a pregnancy if begun within a few days of a woman ingesting mifepristone. *See* George Delgado, et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 Issues L. & Med. 21 (2018); Deborah Garratt & Joseph V. Turner, *Progesterone for Preventing Pregnancy Termination After Initiation of Medical Abortion with Mifepristone*, 22 Eur. J. Contracept. Reprod. Health Care 472 (2017); George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46(12) Ann. Pharmacother. 1273 (2012).

Reviewing all extant APR studies in 2023, one independent scholar concluded that this research shows—as strongly as possible without an unethical clinical trial—that APR "is a safe and effective treatment." Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to*

Avert Medication Abortion, 90 Linear. Q. 395 (2023).[2] *Such evidence is precisely why physicians administer the protocol NIFLA advocated and is now free to advocate again, given the NIFLA Injunction*. To advocate consideration as an option for reproductive choice the very protocol *physicians lawfully prescribe* based on *scientific evidence* cannot possibly constitute "consumer fraud." It is that simple.

Based on the science that James disfavors, APR has been endorsed by the American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG) with its more than 7,000 members, the Catholic Medical Association, and Canadian Physicians for Life, among others. *See, e.g.*, AAPLOG, *2019 AAPLOG Position Statement on Abortion Pill Reversal*. Believing the science, at least twelve States have required doctors administering mifepristone to inform women that its effects sometimes can be reversed. *See* Clarke D. Forsythe & Donna Harrison, *State Regulation of Chemical Abortion After Dobbs*, 16 Liberty U. L. Rev. 377, 406-08 (2022). Tellingly, however, while some (but not most) of these disclosure laws have been enjoined, the rationale for enjoining such

[2] For a complete tabulation of APR studies published in peer-review medical journals through March 21, 2025, see **Exhibit A**.

compelled disclosure is essentially the same rationale applicable here: that the government cannot stake out a required official position on a matter of scientific debate and compel members of the public to hew their opinion to the government's view or face punishment. *See, e.g.*, *Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134, 1151 (D.N.D. 2019); *Planned Parenthood of Mont. v. State*, No. DV-21-999 (Mont. Dist. Ct. Feb. 29, 2024), 2024 WL 3886822.

II. Opinions Accurately Reciting Nonfraudulent Scientific Data Are Not Consumer Fraud Under This Court's Precedent.

For the Attorney General to have stated a cognizable claim against NIFLA under GBL § 349, she needed to show that NIFLA engaged in conduct that was "misleading in a material way." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25 (1995). That is an objective and tough standard, requiring that NIFLA's APR statements mislead "a reasonable consumer acting reasonably" under the circumstances surrounding her viewing of those statements. *Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F. Supp. 3d 467, 478 (S.D.N.Y. 2014) (citing *Oswego*, 85 N.Y.2d at 26).

James did not remotely satisfy that standard for the simple reason that *APR statements merely advocate what physicians are legally entitled to do* in consultation with women who change their minds about chemical abortion and decide, while there is still time, to attempt to save their unborn children. That decision, quite simply, is none of James' business.

As under the federal Lanham Act, purportedly deceptive speech under GBL § 349 falls into three buckets: statements (1) of fact; (2) mixing fact and opinion; and (3) opinion. If a statement falls into the first bucket, it is actionable if it is literally or impliedly false. *See Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978). If it falls into the second bucket, it is actionable only if it is both false and implies that the speaker is privy to some secret supporting data that do not actually exist. If a statement falls into the third bucket, it is never actionable if it discloses the facts on which it is based and accurately reports those facts. *See Am. Brands, Inc. v. R. J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976); *see* Rebecca Tushnet, *Running the Gamut from A to B*, 159 U. Pa. L. Rev. 1305, 1320 (2011).

James' opening brief appears to argue in scattered places that NIFLA's APR statements fall into the first bucket and are literally false. That was a bold but losing move if she indeed meant to make it. Under GBL § 349, she would need to show that the science of APR is closed by a longstanding scientific consensus—e.g., Earth is an oblate spheroid or hydrogen is naturally diatomic—or else that the factual claims NIFLA makes are not supported by even the studies it relies on. *See Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 56, 62-64 (2d Cir. 1992). But she does not even try to do either.

James also seems at times to try to argue that NIFLA's APR statements fall into the first bucket but are only impliedly false. If she meant to make that argument, it fails because she needed to proffer an objective measure, such as a survey, to show that a statistically significant percentage of NIFLA's targeted audience are *actually misled*. *See Johnson & Johnson v. SmithKline Beecham Corp.*, 960 F.2d 294 (2d Cir. 1992); *Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272 (2d Cir. 1981). Using the example James offers in her brief, she would need to show that many New Yorkers among the about 1,100 visitors to NIFLA's website each month have been induced to believe that APR can raise from

the dead babies already killed by the effects of mifepristone. *See* James Br. at 42; SEMrush, nifla.org Organic Traffic (Mar. 23, 2025). A year into this litigation, James has yet to identify even *one* person misled by a NIFLA statement about APR. And anyone who knows how savvy New Yorkers are would rather bet his life savings on the success of a Yankees jersey kiosk outside Fenway. *Cf.* Harvey Frommer & Frederic J. Frommer, *Red Sox v. Yankees: The Great Rivalry* 101-21 (2014) ("perhaps the oldest and strongest rivalry in American sports history").

Even if James had surveyed actual reader response to NIFLA's APR statements, as opposed to relying on an utterly non-probative surmise that someone must have been misled, it likely would not help her. New York and federal courts rarely find liability for impliedly false statements of fact under GBL § 349 or the Lanham Act unless the speaker uses the kind of superlative language absent here. *See, e.g.*, *Gillette Co. v. Wilkinson Sword, Inc.*, 1992 WL 30938 (S.D.N.Y. Feb.3, 1992) (misleading to say razor blades provided "the smoothest, most comfortable shave possible"); *Int'l Code Council, Inc. v. Up Codes, Inc.*, 43 F.4th 46, 63 (2d Cir. 2022).

That leaves James the option of attacking NIFLA's APR statements as pure opinion, but that tack too is a nonstarter. Within a few years of GBL § 349 being enacted, district courts in this circuit confronting its new provisions began to hold that pure opinions about scientific findings are not actionable under that law. *See, e.g.*, *Am. Brands, Inc. v. R. J. Reynolds Tobacco Co.*, 413 F. Supp. at 1357.

Here we come to the fatal defect in James' abuse of the judicial process to restrict speech she disagrees with. In *ONY Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d. Cir 2013), this Court agreed that scientific opinions are not actionable under the GBL. *ONY* involved a dispute between two manufacturers of pediatric lung surfactants. The defendant had sponsored a study comparing the surfactants' effectiveness, concluded from the data that its own product was more effective than plaintiff's, published those findings in a peer-reviewed scientific journal, and then issued a press release and promotional materials touting its superior product. *See id.* at 493-95.

The plaintiff alleged those findings contained "five distinct incorrect statements of fact about the relative effectiveness." *Id.* at 494. But the district court dismissed plaintiff's consumer fraud claim based

on a two-link reasoning chain. First, data are facts, while unfalsifiable *inferences* from that data are opinions. Second, because opinions by definition are not falsifiable, they cannot be wrong or deceptive such that they would create cognizable claims under GBL § 349.

This Court affirmed the dismissal of plaintiff's claims, explaining that in a "sufficiently novel areas of research" such as pediatric lung surfactants, conclusions "presented in publications directed to the relevant scientific community" sometimes "may be highly controversial and subject to rigorous debate by qualified experts." *Id.* at 497. But the Court recognized that in such cases it was usually beyond the competence of a court—and always beyond its authority—to decide which contending scientist was right. *See id.* at 497-98.

Importantly, this Court extended that reasoning not just to the defendant's publication of the data in a journal whose readership presumably skewed toward persons with a decent understanding that science is iterative, but also to the press release and promotional materials aimed at the general public. *See id.* at 498. In the Court's view, the First Amendment trusts that the boor and the Brahmin alike can sift science as long as it is presented honestly. And because the peer-review

process gatekeeps that accuracy on the front end at least as well and presumptively better than nonexpert judges could, as long as those results are not distorted by a speaker after the fact, they cannot be literally false. *See id.* at 496-97.

In other words, this Court struck the same balance in *ONY* that it saw elsewhere in First Amendment law: Speech must be unregulated unless paramount government interests, such as public health and safety, clearly require some restriction. Peer-review would protect the most parochial from error while a laissez-faire approach to scientific findings that emerged from that gauntlet would avoid judicial interference with scientific progress. Under that balance, opinions accurately reflecting nonfraudulent scientific data may be published without liability for anyone, but also freely challenged and rejected by anyone. And that balance matches the one New York courts have created for GBL § 349 litigation. *See Gross v. New York Times Co.*, 82 N.Y.2d 146, 154 (1993). The sole general exception, not applicable here, is when a commercial speaker offers an opinion and implies it is based on hidden facts that do not exist, which is outright deception. *See Stega v. N.Y. Downtown Hosp.*, 31 N.Y.3d 661, 674 (2018).

Other circuits have found *ONY*'s reasoning persuasive vis-à-vis similar laws. *See, e.g.*, *Pacira Biosciences, Inc. v. Am. Soc'y of Anesthesiologists, Inc.*, 63 F.4th 240, 247-48 (3d Cir 2023). Little wonder. As five of the Supreme Court Justices made clear in *United States v. Alvarez*, decided the year before *ONY*, science as much as other fields of knowledge often is open to a wide range of colorable views. *See* 567 U.S. 709, 731-32 (2012) (Breyer, J., concurring, joined by Kagan, J.); *id.* at 749 (Alito, J., dissenting, joined by Scalia and Thomas, JJ.). Whether the debate concerns the structure of thousands of points in a Seurat or the structure of thousands of points of light in the night sky, it is always "perilous to permit the state to be the arbiter of truth." *Id.* at 752 (Alito, J., dissenting). It lacks both the expertise and authority to do so.[3] *Accord Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 579 (2011) (stating even in

[3] Some would add that government even lacks the moral entitlement to do so. *See* John Locke, *Two Treatises of Government and A Letter Concerning Toleration* 241 (Yale Univ. Press 2003) (1689). History strongly suggests they might be right given how wrong American governments have been as oracles of scientific truth. The Scopes monkey trial, *Dred Scott*, and involuntary sterilization of women after "three generations of imbeciles" hardly inspire confidence. *Buck v. Bell*, 274 U.S. 200, 207 (1927). But one need not accept Locke's premise to recognize government may not normally meddle in the slow synthesis of scientific truths.

"[t]he commercial marketplace . . . the general rule is that the speaker and the audience, not the government, assess the value of the information provided").

III. NIFLA's APR Statements Are Not Prosecutable under GBL § 349 Because They Are Accurate and Based on Non-Fraudulent Data.

Under *ONY*, NIFLA's statements about APR safety and effectiveness do not create a cognizable GBL § 349 claim because they are pure opinions that disclose and accurately recite non-fraudulent scientific data. Because James has waived the argument that those data are fraudulent by not raising it, amici restrict themselves to the straightforward discussion of how NIFLA's communications about APR's safety and effectiveness accurately recite peer-reviewed research data.

A. APR Safety

Start with NIFLA's claims about APR safety. James has never identified any NIFLA statement about APR safety she thinks is false, misleading, or deceptive. But she appears to try to argue that *anything* NIFLA might say about APR being safe *must* be wrong for two reasons. First, she says that the case series NIFLA principally relies on "have been widely discredited." James Br. at 42. Second, she says that "the only

scientifically valid study undertaken of APR had to be halted after several subjects suffered severe hemorrhaging." *Id.* Neither assertion is true.

James' assertion that the APR studies NIFLA relies on are "widely discredited" relies on four studies she prefers. But these four studies with overlapping authors and no completed original research could never "widely discredit" an opposing view—especially given that one of the four studies was authored by a researcher *censured by the FDA precisely for research malpractice*. *See* FDA, Warning Letter to Mitchell D. Creinin, MD (June 12, 2002). But even accepting James' unwarranted assumption for the sake of argument, her reliance on the four studies she prefers extinguishes her own position due to both a fatal logical error and a blatant mischaracterization of what her preferred studies actually found.

Start with James' fatal blunder of logic. She evinces not the slightest awareness of the internal contradiction involved in her attempt to discredit pro-APR studies on the grounds that they are not clinical trials but "only" case series studies by using studies *that are likewise not clinical trials* but "only" case series studies. If the hundreds of authors who publish in top obstetrics and gynecology journals, as well as ACOG

in its clinical guidelines protocols, are wrong to rely on case series, and "Doctor" James is correct that case series are not scientifically valid evidence, her argument reduces to an infinite loop of self-contradiction: her preferred case series studies and the pro-APR case series studies discredit each other while *not* being able to discredit each other. Even Schrodinger's cat is found in one state or another (dead or alive) once an observer opens the fabled box. But James' argument never escapes its terminally illogical state of superposition.

Just as devastating, and more troubling for anyone concerned about candor to this tribunal, *none of James' preferred studies even suggests APR is unsafe*. The first and second studies do not even make any claim about APR safety. *See* Daniel Grossman, et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion*, 92 Contraception 206 (2015); Khadijah Z. Bhatti, *Medical Abortion Reversal*, 218 Am. J. Obstet. & Gyna. 315 (2018). Much worse, the third and fourth studies James cites found *the opposite* of what she claims they did. The third study reviews the largest APR study to date and concludes: "*No adverse events were reported* among pregnant women." Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating Without Evidence*,

379(16) New Engl. J. Med. 1491, 1492 (2018) (emphasis added). And the fourth study—sponsored by *the manufacturer of mifepristone*—was stopped when women who did not receive supplemental progesterone under the APR protocol began to suffer *more severe complications than women who did receive it*. *See* Mitchell D. Creinin, et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion*, 135 Obstet. & Gynec. 158, 159 (2020).

James resorts to studies that undermine her own argument because no study supports it. To the contrary, research over decades, published in leading medical journals, has found supplemental progesterone support during pregnancy—which is all APR involves—to be safe. *E.g.*, Dominique L. Cope & Diana Monsivais, *Progesterone Receptor Signaling in the Uterus Is Essential for Pregnancy Success*, 11 Cells 1474, 1480 (2022); A.I. Csapo & C.A. Pinto-Dantas, *The Effect of Progesterone on the Human Uterus*, 54 Proceedings of the Nat'l Acad. of Skis. 1069, 1069 (1965). The FDA agrees. *See* FDA, Label for Prometrium (Progesterone, USP) Capsules (June 2009).

Moreover, obstetricians use supplemental progesterone to help thousands of American women a year save their babies during problem

pregnancies without serious side effects. *See* Omar Mansour, et al., *Prescription Medication Use During Pregnancy in the United States from 2011 to 2020*, 231 Am. J. of Obstet. & Gynec. 250.e1, 250.e4 tbl.1 (Aug. 2024). APR can rightly be viewed as the means of addressing another type of problem pregnancy in the hope of bringing the child to term.

Viewed through the prism of decades of research and *ONY*, no reasonable person could conclude that NIFLA's opinion that APR is "safe" is inaccurate. That opinion is based on findings in peer-reviewed research available to the public that, if anything, shows that APR *reduces physical health complications* in its recipients by employing a hormone used millions of times since World War II without known serious side effects. And in common usage, just as much as a legal term of art, the word "safe" means "not causing danger." *Black's Law Dictionary*, *Safe* (12th ed. 2024). James utterly fails to show any danger from the supplemental progesterone *doctors routinely prescribe* to help pregnancies.

In sum, given the scientific evidence James disfavors but cannot contradict, NIFLA's statements are almost tautologies: i.e., that what has been shown to be safe is safe. At the very least, NIFLA's APR statements are non-falsifiable opinions which, even if *arguably*

inaccurate—and they are not—are for that very reason *not deceptive* as *ONY* and the New York state courts interpret the GBL.

B. APR Effectiveness

James fares no better in her argument that NIFLA deceives the public about APR's effectiveness. As with APR safety, James has never identified any NIFLA statement about APR effectiveness she thinks is false, misleading, or deceptive and instead seeks refuge in two familiar redoubts.

First, as noted, she attacks the validity of case series by citing her preferred studies, which rely on case series. And she declares case series not to be valid science, even though ACOG recently has sworn to a sister circuit that they *are* valid science as well as *strong* scientific evidence. *See* Brief of Council of Med. Specialty Socs., *Torrey v. Infectious Diseases Society of Am.*, No. 22-40728, at *6-9 (5th Cir. 2023).

Second, James erects a strawman, claiming without evidence that NIFLA claims APR is effective in raising dead children to life. *See* James Br. at 42 As is her wont, James just makes up facts as she goes. NIFLA's website has been saved to the Internet Archive more than 2,600 times since it went live in 2000, but none of those versions appears to have at

any time said anything a reasonable person could interpret as a claim that NIFLA has discovered how to resuscitate babies already killed by mifepristone. And, as discussed above, James has offered no evidence that even one person has actually been under that illusion. *See Johnson & Johnson v. SmithKline Beecham Corp.*, 960 F.2d 294 (2d Cir. 1992); *Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272 (2d Cir. 1981).

What NIFLA actually says to the public is that APR—meaning simply and only supplemental progesterone—sometimes can reverse the effects of mifepristone, the first of the two abortion pills, *before* it does its deadly work, not after. Again, *every completed scientific study* on APR substantiates that claim. *See, e.g.*, Christina Camilleri & Stephen Sammut, *Progesterone-Mediated Reversal of Mifepristone-Induced Pregnancy Termination in a Rat Model: An Exploratory Investigation*, 12 Sci. Rep. 10942, at 4-6 (2023); George Delgado, et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 Issues L. & Med. 21, 25, 27-28 & tbls.1-2 (2018); Deborah Garratt & Joseph V. Turner, *Progesterone for Preventing Pregnancy Termination after Initiation of Medical Abortion with Mifepristone*, 22 Eur. J. Contracept. Reprod. Health Care 472 (2017); George Delgado &

Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46(12) Ann. Pharmacother. 1723, 1723 (2012).

It does not save James' argument that NIFLA at times has reported that APR can yield a specific childbirth rate of 64-68%, as the above-mentioned studies find that exact range of outcomes. *See* George Delgado, et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 Issues L. & Med. at 26. Deborah Garratt & Joseph V. Turner, *Progesterone for Preventing Pregnancy Termination after Initiation of Medical Abortion with Mifepristone*, 22 Eur. J. Contracept. Reprod. Health Care at 474-75; George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46(12) Ann. Pharmacother. at 1723. Through the date this amicus brief was filed, no published, peer-reviewed study of APR has ever found a success rate outside of that range for a complete study universe.

James appears to try at least halfheartedly to argue otherwise in her brief, citing the same four studies she favors. To give credit to the Attorney General where it is due, those studies refreshingly at least talk about APR effectiveness. But, as already noted, they do not remotely say what she says they do. The first study's own data show that for *every*

study the author could find, the pregnancy completion rate was lower for women who just ingested mifepristone than it was for women who received supplemental progesterone—i.e., the APR protocol. This means under set theory that APR on *average* also was correlated with higher save rates. *See* Daniel Grossman, et al., *Continuing Pregnancy*, 92 Contraception at 209 tbl.1 (2015). James' second cited study merely cites the first, and the fourth cannot measure effectiveness since it was not run to completion.

Much more concerningly, as noted, James' third preferred study says the opposite of what she represents to this Court. Here we provide more detail to show the misrepresentation:

First, the third study's author theorizes that earlier studies showing positive outcomes for APR may have been skewed upward because women who presented for APR were more advanced in their pregnancies to begin with and so less susceptible to fetal demise. *See* Daniel Grossman & Kari White, *Abortion "Reversal"*, 379(16) New Engl. J. Med. at 1492. So, the author segmented the participants in the largest APR study by their gestational age to better match the average gestational age in one mifepristone case series (showing, again, that a

case series is considered valid scientifically). He then excluded all APR patients after a gestational age of seven weeks. *See id.* at 1492 tbl.1.

Second, despite this method the results were not what the author expected. Even after excluding later-stage APR successes, the remaining data suggested that women were nearly *twice as likely to carry their pregnancy to term* after APR than without it. *See id.* The author's statistical reanalysis of the earlier study's data supporting APR showed that the odds that this result could be explained by chance were less than 1 in 14. In short, James' presentation of the third study is positively misleading. [4]

[4] Giving James the benefit of the doubt regarding presentation of her third preferred study, she may have misunderstood that a p-level slightly greater than 0.05 means *no* association between the variables was detected. *See* Daniel Grossman & Kari White, *Abortion "Reversal"*, 379(16) New Engl. J. Med. at 1491 tbl.1. That error is so common among non-statisticians that the American Statistical Association clarified a few years ago that p-values "do not measure the probability that the studied hypothesis is true." Ronald L. Wasserstein, *The ASA's Statement on P-Values: Context, Process, and Purpose*, 70 Am. Statistician 129, 129-30 (2016). And that there is nothing magic about a p-level of 0.049 vs. 0.051; the threshold of p=0.05 was chosen by the statistician who introduced its use into statistics simply because (as the percentage of observations within two standard deviations of the mean for a normal distribution) it would be easier for users to remember. *See* Ronald A. Fisher, *Statistical Methods for Research Workers* 43 (1925).

Viewed through the prism of decades of research, it is impossible for any reasonable person to find NIFLA's statements about APR effectiveness to be misleading. NIFLA's opinion that APR is "effective" is based on findings in peer-reviewed research available to the public, and it accurately reports nonfraudulent and uncontradicted data from that research—data which has survived retesting and segmentation by James' preferred researcher, even though his other work betrays a deep aversion to his own initial findings.[5]

The word "effective" in common usage means "achieving a result." *Black's Law Dictionary*, *Effective* (12th ed. 2024). All APR research to date shows that APR achieves its intended result. And because NIFLA accurately recites that research data when opining that APR is effective,

[5] Few outside science realize how few scientific research findings can be replicated. One meta-study conducted the year this Court decided *ONY* found that of 363 studies informing standards of care widely accepted in the medical community, *40 percent* of the time retesting yielded the *opposite* result while another 22 percent of repeated studies were inconclusive. *See* Vinay Prisad, et al., *A Decade of Reversal*, 88 Mayo Clinic Proc. 790, 790 (2013). Just one year earlier, an attempt to reproduce the findings of 53 landmark cancer studies failed to do so for 47 of them despite extensive collaboration with the authors of the original studies. *See* Monya Baker, *Biotech Giant Publishes Failures to Confirm High-Profile Science*, Nature (Feb. 4, 2016). In other words, very few scientific findings hold up across multiple studies like the findings that APR is safe and effective.

it cannot be held liable under GBL § 349 for its opinion about an open scientific question.

IV. No Reason Exists for the Court to Revisit or Abandon *ONY*.

Although the federal rules and appellate procedure and local rules prohibit this panel from overturning *ONY* outright, James might urge the Court to abandon it *sub silentio* or ignore its reasoning as overruled in the "court of history." *Trump v. Hawaii*, 585 U.S. 667 (2018). For at least three reasons, it has not been, based on the criteria the Supreme Court recently established in a line of three cases to identify such zombie precedents. *See id.*; *Ramos v. Louisiana*, 590 U.S. 83 (2020); *Janus v. Am. Fed. of State, County, and Mun. Employees*, 585 U.S. 878 (2018).

First, *ONY* is well-reasoned, according not only with the text of GBL § 349 when read in light of its context, structure, and statutory history but also with an eye toward the legislative intent behind enacting it. *See* N.Y. Att'y Gen., Mem. for the Governor re Senate Int. 1581, Pr. 1604 (Jan. 8, 1963). Second, it articulates a rule the district courts have found easy to apply in GBL § 349 cases, not only to healthcare but to claims about product safety and effectiveness in general. *See Weight Watchers International, Inc. v. Noom, Inc.*, 403 F. Supp. 3d 361, 370, 377

(S.D.N.Y. 2019); *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 540-41 (S.D.N.Y. 2018); *XYZ Two Way Radio Service, Inc. v. Uber Technologies, Inc.*, 214 F. Supp. 3d 179, 182-84 (E.D.N.Y. 2016). Third, *ONY* is wholly consistent with the Supreme Court's First Amendment decisions since 2013. *See Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

CONCLUSION

A theory of government undergirding American democracy since its beginning is that no freedom can long survive without freedom of speech. *See Cox v. State of La.*, 379 U.S. 536, 552 (1965). That includes speech about science, an issue of public concern that was central to the development of free speech theory to include the everyman rather than (as it was under colonial law) just the so-called experts. *See* Thomas I. Emerson, *Colonial Intentions and Current Realities of the First Amendment*, 125 U. Pa. L. Rev. 737, 741 (1977). But, out of naked viewpoint animus, James has waged lawfare against small pregnancy centers for a year just because they advocate scientific truths she wishes were false.

A victory for James would be dangerous for science, which historically has advanced only by debate leavened with time. *See* Charles

Darwin, *On the Origin of Species* 499, *in* 2 Harv. Classics (Charles W. Eliot ed. 1937) (1859). Scientific battle over ideas is no less heated today; debates from the smelting of galaxies to the melting of glaciers rages hot. And that crucible is more necessary in science than perhaps any other field of knowledge. *See generally* Thomas S. Kuhn, *The Structure of Scientific Revolutions* 143-72 (Univ. of Chicago Press 4th ed. 2012); *see* also *Nat'l Inst. of Family and Life Advocs. v. Becerra*, 585 U.S. 755, 756 (2018) (stressing "the danger of content-based regulations 'in the fields of medicine and public health, where information can save lives") (quoting *Sorrell*, 564 U.S. at 566).

A victory for James would be even more dangerous for democracy, reviving a theory that government is the arbiter of truth, and that the wisdom of the master is greater than the wisdom of the masses. From the beginning of this country, we have known that is not so. *See* Alexis de Tocqueville, *Democracy in America* 165-68 (Harvey C. Mansfield & Delba Winthrop eds. trans. Univ. of Chicago Press 2002) (1835). And in *ONY*, in line with our nation's robust First Amendment protection for speech on matters of public concern, this Court has made it clear that the state is not the master in the realm of scientific opinion.

Therefore, this Court should reiterate its commitment to free and open scientific debate by affirming the district court's preliminary injunction protecting that debate from James' interference.

Respectfully submitted,

Dated: March 25, 2025

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CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Local Rule 29.1(c) and Fed. R. App. P. 32(a)(7))(B) because, excluding the portions exempted by Fed. R. App. P. 32(f), this brief contains 6,414 words.

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook font.

/s/Christopher A. Ferrara
Christopher A. Ferrara

EXHIBIT A: PEER-REVIEWED SCIENTIFIC STUDIES ON ABORTION PILL REVERSAL

	FEDERAL GOVERNMENT AND PEER-REVIEWED SCIENTIFIC SUPPORT FOR THE TRUTH OF IDENTIFIED DEFENDANT STATEMENTS											
	I. Effectiveness or Efficacy				II. Safety			III. Marginal effectiveness or efficacy	IV. Scientific acceptance			
	APR can reverse the effects of mifepristone	Specific success rate	Own clients	Even after 72 hours	Progesterone	APR	Mifepristone		By a professional org.	By ACOG	By FDA	Lack of any controversy
DIRECT SUPPORT	Christina Camilleri & Stephen Sammut, *Progesterone-Mediated Reversal of Mifepristone-Induced Pregnancy Termination in a Rat Model: An Exploratory Investigation* , 12 Sci. Rep. 10942, at 4-6 (2023)	George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone* , 33 Issues L. & Med. at 26	Verified Complaint in Monroe County Action ¶ 95 (CompassCare) (89%)		Dominique L. Cope & Diana Monsivaid, *Progesterone Receptor Signaling in the Uterus Is Essential for Pregnancy Success* , 11 Cells 1474, 1480 (2022)	Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review* , 90 Linacr. Q. 395, 402 (2023).)	Beth Kruse et al., *Management of Side Effects and Complications in Medical Abortion* , 183 Am. J. Obstet. Gynecol. S65, S72 (2000);	George Delgado et al., *A Case Series* , 33 Issues L. & Med. at 27 tbl.1;	Am. Assoc. of Pro-Life Obstetricians & Gynecologists, 2019 AAPLOG Position Statement on Abortion Pill Reversal, https://perma.cc/6RRC-GE2K			
	George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone* , 33 Issues L. Med. 21, 25, 27-28 & tbls.1-2 (2018)	Deborah Garratt & Joseph V. Turner, *Progesterone for Preventing Pregnancy Termination after Initiation of Medical Abortion with Mifepristone* , 22 Eur. J. Contracept. Reprod. Health Care at 474-75			Stefano Palomba et al., *Progesterone Administration for Luteal Phase Deficiency in Human Reproduction: An Old or New Issue* , 8 J. of Ovarian Research 77, 77 (2015)	Delgado, *Progesterone Use* , 46 Ann. Pharmacother. at 1723	Nathalie Kapp et al., *Medical Abortion in the Late First Trimester: A Systematic Review* , 99 Contraception 77 (2019)	Deborah Garratt & Joseph V. Turner, *Progesterone* , 22 Eur. J. Contracept. Reprod. Health Care 472				
	Deborah Garratt & Joseph V. Turner, *Progesterone for Preventing Pregnancy Termination after Initiation of Medical Abortion with Mifepristone* , 22 Eur. J. Contracept. Reprod. Health Care 472 (2017)	George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone* , 46 Ann. Pharmacother. at 1723			Thomas W. Hilgers et al., *The Use of Isomolecular Progesterone in the Support of Pregnancy and Fetal Safety* , 30 Issues in Law & Medicine 159, 159-60 (2015)		Jillian T. Henderson et al., *Safety of Mifepristone Abortions in Clinical Use* , 72 Contraception 175 (2005)	George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone* , 46 Ann. Pharmacother. at 1723 (2012)				
	George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone* , 46 Ann. Pharmacother. 1723, 1723 (2012)				S. Friedler et al., *Luteal Support with Micronized Progesterone Following In-Vitro Fertilization* , 14 Human Reprod. 1944, 1947 (1999)		U.S. Food & Drug Admin., Center for Drug Evaluation and Research, *Application Number NDA 20-843 [Mifepristone]* , Pharmacology Review(s) (1997)					
					A.I. Csapo & C.A. Pinto-Dantas, *The Effect of Progesterone on the Human Uterus* , 54 Proceedings of the National Academy of Sciences 1069, 1069 (1965)							
					Line Rode et al., *Systematic Review of Progesterone for the Prevention of Preterm Birth in Singleton Pregnancies* , 88 Acta Obstetricia et Gynecologica Scandinavica 1180, 1180-89 (2009)							
INDIRECT SUPPORT	ACOG, Clinical Practice Guideline No. 8, First and Second Stage Labor Management (Jan. 2024)					Mifeprex Drug Approval Package, *Pharmacology Review(s)* , U.S. Food & Drug Admin. pp. 16-17 (Sept. 28, 2000)						
	Katrina Mark et al., *Abortion in Women with Severe Preeclampsia and Eclampsia prior to 24 Weeks Gestation* , 103 Contraception 420 (2021)					Barbara J. Pleuvry, *Receptors, Agonists and Antagonists* , 5 Neurosurgical Anaesthesia and Intensive Care, Pharmacology 350, 350 (2004)						
	Society of Family Planning, *Clinical Guidelines, Management of Postabortion Hemorrhage* , 87 Contraception 331 (2013)					John W. Pelley, Elsevier's Integrated Review Biochemistry 33-34 (2d ed. 2011)						
	Linda Prine et al., *Medical Abortion in Family Practice: A Case Series* , 16 J. Am. Bd. Fam. Pract. 290, 291 (July-Aug. 2003)					S. Yamabe, et al., *The Effect of RU486 and Progesterone on Luteal Function during Pregnancy* , 65(5) Nihon Naibunpi Gakkai Zasshi 497 (1989)						
	Kennon Heard et al., *Rupture of Ectopic Pregnancy after Medical Therapy with Methotrexate: A Case Series* . 16 J. Emerg. Med. 857, 859 (1998)					*See* Gian Carlo De Renzo et al., *Progesterone: History, Facts, and Artifacts* , 69 Best Pract. & Res. Clinical Obstetrics & Gynecology 78 (2020)						
NO SUPPORT	Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial* , 135 Obstet. Gynecol. 158 (2020)	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---	--- none ---

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Exhibit B. Peer-reviewed Research Published in the Two Leading Obstetrics and Gynecology Journals Based only on Case Series, 2000-2025

Find articles with these terms

"case series" NOT "clinical trial" NOT "trial"

Journal or book title: American Journal of Obstetrics and Gynecology × Year: 2000-2025 ×

Advanced search

185 results

relevance | date

Research article ● Full text access

1 Safety of ovarian cryopreservation and transplantation in patients with acute leukemia: a case series

American Journal of Obstetrics and Gynecology, January 2024

Murat Sönmezer, Yavuz Emre Şükür, … Kutluk H. Oktay

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Research article ● Full text access

2 New-onset myocardial injury in pregnant patients with coronavirus disease 2019: a case series of 15 patients

American Journal of Obstetrics and Gynecology, April 2021

Brisandy Ruiz Mercedes, Ayna Serwat, … Lina Karout

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Research article ● *Open access*

3 Prevalence, risk factors, and outcome of postprocedural amniotic band disruption sequence after fetoscopic laser surgery in twin-twin transfusion syndrome: a large single-center case series

American Journal of Obstetrics and Gynecology, October 2020

Patricia J. C. Knijnenburg, Femke Slaghekke, … Enrico Lopriore

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Patricia J. C. Knijnenburg, Femke Slaghekke, ... Enrico Lopriore

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"case series" NOT "clinical trial" NOT "trial"

Journal or book title: European Journal of Obstetrics & Gynecology and Reproductive Biology Year: 2000-2025

Advanced search

182 results

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Research article Open access

1 Safety and efficacy of transvaginal natural orifice endoscopic surgery (vNOTES) for gynecologic procedures in the elderly: A case series of 119 consecutive patients

European Journal of Obstetrics & Gynecology and Reproductive Biology, 17 April 2025

James Nef, Yannick Hurni, ... Daniela Huber

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Research article Full text access

2 A multi-cycle approach via DuoStim is beneficial to treat couples indicated to PGT-M plus PGT-A. A propensity score matching-based case series

European Journal of Obstetrics & Gynecology and Reproductive Biology, December 2024

Alberto Vaiarelli, Danilo Cimadomo, ... Filippo Maria Ubaldi

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3 Case series on the management and outcomes of Bartholin gland carcinoma

European Journal of Obstetrics & Gynecology and Reproductive Biology, August 2024

Salamatu Abdul-Aziz, Aarthi S. Jayraj, ... Anupama Rajan Babu

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Research article Full text access

4 Multidisciplinary care to optimise pregnancy outcomes among Jehovah's Witness: Case series over fifteen years in a tertiary teaching hospital

European Journal of Obstetrics & Gynecology and Reproductive Biology, December 2024

Vivian Wai Yan Ng, Mimi Tin Yan Sete, Ka Wang Cheung

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