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Attorneys for Plaintiffs TARA TINDLE AND JAYDEN TINDLE

SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

Tara Tindle and Jayden Tindle,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation and **Does 1–100**.

Defendants.

Case No.: 24STCV34506

Complaint for:

(1) General Negligence
(2) Negligent Misrepresentation
(3) Fraudulent Misrepresentation
(4) Concealment

JURY TRIAL DEMANDED

INTRODUCTION

1. This is a lawsuit against Novartis Pharmaceutical Corporation ("Novartis") for illegally promoting terbutaline, an asthma drug, to treat preterm labor in pregnant women with the help of a prominent professor from a California state university. Despite knowing its ineffectiveness for this use and significant risks of causing abnormal brain development in exposed offspring, Novartis not only violated federal law by promoting terbutaline for preterm labor, but it also violated federal regulations that required Novartis to warn that terbutaline posed risks to fetal health when administered to pregnant women. This lawsuit is brought by a small sample of the millions of children harmed by Novartis's decision to jeopardize public safety for profit.

PARTIES

2. Defendant Novartis, formerly known as "Ciba-Geigy" before 1997, is a New Jersey corporation with headquarters in East Hanover, New Jersey. From 1976 to December 2001, Novartis manufactured, distributed, and sold brand-name terbutaline in the United States as "Brethine."

3. Does 1 through 50 are fictitious defendants, encompassing officers, directors, franchisees, shareholders, founders, owners, operators, agents, servants, employees, representatives, and/or independent contractors of Defendant Novartis who were responsible for the conduct that gives rise to this Complaint, but whose identities are presently unknown to the Plaintiffs. Subsequent references to "Novartis" include Does 1 through 25. As the identities of any of these Does are discovered, Plaintiffs will amend the Complaint to include them.

4. Does 51 through 100 are fictitious defendants representing additional parties responsible for the conduct that gives rise to this Complaint. They are not directly affiliated with the named defendants, but their identities are presently unknown to the Plaintiffs. As the identities of any of these Does are discovered, Plaintiffs will amend the Complaint to include them.

5. Plaintiffs are real persons who suffered serious personal injuries as a result of prenatal terbutaline exposure, as described below.

JURISDICTION & VENUE

6. This Court has subject matter jurisdiction over this case under article VI, section 10, of the California Constitution. Each Plaintiff seeks damages well in excess of this Court's "unlimited"

jurisdictional threshold of $35,000.

7. This Court has specific personal jurisdiction over Novartis based on the following:

7.1. Novartis purposefully availed itself of the California pharmaceutical market by advertising, distributing, and selling drug products—including terbutaline—in California. In addition, at all times relevant to this lawsuit, one of Novartis's three national distribution centers was located in Cerritos, California, from which Novartis distributed terbutaline throughout the United States and California. Novartis also hired a California state employee—Dr. Russell K. Laros, Professor of Medicine at UCSF—to promote terbutaline for preterm labor throughout the United States, and later collaborated with him and UCSF to generate a published study touting terbutaline's purported effectiveness for this use. Novartis also engaged Dr. M.G. Ross of the University of California, Los Angeles, for a similar promotional study and supported terbutaline research at the University of California, Irvine, by supplying terbutaline at zero cost. In addition, 10 of the 11 distributors through which Novartis knowingly sold terbutaline for preterm labor in the United States were California corporations, including Pharmaceutical Corporations of America; Tokos Medical Corporation; Tokos Clinical Services; Women's Homecare; Whitmire Distribution Corporation; Carelink, Inc.; Pharmacy Corporation of America; Paidos Health Care Inc.; Specialized Clinical Service; and Tokos Specialized Clinical Service. In short, California was the epicenter of Novartis's effort to promote and sell terbutaline for preterm labor in the United States between 1985 and 2001.

7.2. This action arises out of, or relates to, Novartis's promotion and sale of terbutaline for preterm labor, which caused Plaintiffs' personal injuries from prenatal exposure to the drug.

7.3. The assertion of personal jurisdiction over Novartis in California would not be unreasonable: Litigating in California would not impose undue burden on Novartis, a sophisticated, multinational pharmaceutical company that frequently litigates lawsuits in this jurisdiction, including at least one lawsuit arising out of terbutaline's use in preterm labor in which Novartis did not contest personal jurisdiction in California. Moreover, such litigation would promote California's interest in protecting California consumers from dangerous drugs

and ensuring public university resources are not exploited in unlawful and fraudulent scheme to sell dangerous drugs to an unwitting public. California litigation would also promote Plaintiffs' interest in obtaining convenient, effective, and efficient relief by, among other things, centralizing related claims and common issues in a single forum against all culpable defendants, thus obviating duplicative proceedings and inconsistent rulings.

8. Venue is proper in this Court because Plaintiffs currently and at all time relevant to the events alleged in this complaint reside in Los Angeles County.

FACTUAL ALLEGATIONS

1. Novartis encouraged doctors to use terbutaline for preterm labor.

9. In 1976, Novartis received FDA approval to market the drug "terbutaline" in the United States as an asthma treatment under the brand-name "Brethine," which, among other things, relaxes smooth muscles in the airway.

10. In the late 1970s, obstetricians began experimenting with terbutaline to treat preterm labor, theorizing it relaxed the uterus's smooth muscles.

11. In 1978, researchers from the Johns Hopkins School of Public Health published a study on terbutaline's emerging use in preterm labor in the *British Journal of Obstetrics and Gynecology*. They observed that "the relevant information about the effect of drugs on the mother and infant was too scanty to make conclusions about side effects possible," that "[d]ata from other sources show that labor inhibitors are potentially dangerous," and that beta-agonists like terbutaline "may unfavorably alter the fetal, placental, or maternal circulation." They thus concluded "that the role of drugs aimed at preventing or delaying premature birth is not yet established, and further good clinical trials are urgently needed."

12. In 1983, a Novartis executive sent an internal memo to company officers and directors, warning that terbutaline was frequently used for preterm labor, but that Novartis never conducted the studies needed to obtain an indication for preterm labor, and therefore that there could be serious consequences for children's health. To avoid tort lawsuits, the memo suggested Novartis either do robust clinical trials to ensure terbutaline is safe and effective for preterm labor or revise the terbutaline warning label emphatically discourage terbutaline's use in preterm labor.

13. Novartis did neither; instead, it hired doctors to promote terbutaline for preterm labor:

13.1. In 1984, Novartis hired Dr. Russell K. Laros—acting in his capacity as a prominent professor at UCSF's "Department of Obstetrics, Gynecology, and Reproductive Sciences"—to travel to and distribute brochures at obstetrics conferences throughout the United States, touting terbutaline's "effectiveness" at "arresting preterm labor." Later in 1984, Novartis hired Dr. Laros to conduct a study at UCSF regarding "the use of terbutaline … in the treatment of preterm labor." In 1985, Novartis paid Dr. Laros $46,000 for that study, which was ultimately published in the August 1991 edition of the *American Journal of Obstetrics and Gynecology*.

13.2. In 1985, Novartis paid a ghost-writer (Richard Stiller) to draft a letter to the editor of the *New England Journal of Medicine*, titled "Use of Terbutaline in Pregnancy." Stiller's draft emphasized terbutaline "is the only beta[-]agonist with a [pregnancy] rating of Category B," has "been tested in rodents … without evidence of … teratogenic effects," and "has been used to inhibit preterm labor." The next day, Novartis sent Stiller's draft to a medical doctor (Charles Scoggin) with instructions to "sign and send it" to "The New England Journal of Medicine" at "10 Shattuck Street, Boston, MA 02115." Scoggin complied, and the letter was published in the journal's August 1985 edition of the New England Journal of Medicine. Within a month, Novartis used the Stiller/Scoggin letter to market terbutaline to OB/GYNs. Years later, Novartis was still directing employees to look for opportunities to show it to "a captive OB/GYN audience" at a conference.

14. Novartis also capitalized on FDA regulatory activities to promote terbutaline for preterm labor:

14.1. In May 1992, an FDA advisory committee convened a two-day hearing to discuss terbutaline's increasingly widespread use in preterm labor. Concluding the hearing, the committee unanimously voted that terbutaline may have a role in obstetrics but urged Novartis to formally "apply for approval of this indication" to facilitate studies on its "safety and efficacy."

14.2. During the FDA advisory committee's hearings, Novartis issued a press release titled, "Off Label Use of Brethine (Terbutaline Sulfate) as a Tocolytic." There, Novartis cited a then recent study that "questioned the effectiveness of ritrodine," the only FDA-approved

tocolytic, and terbutaline's competitor in that market. Novartis then referenced the *New England Journal of Medicine* article and other "published reports" of terbutaline's use in preterm labor, as well as an "article in the *Wall Street Journal* about Tokos Medical Corporation which uses Brethine [i.e., terbutaline] as a tocolytic." Elsewhere, the press release bluntly asked: "Why do physicians use terbutaline as a tocolytic?" The press release also concealed Novartis's role in studying terbutaline for preterm labor: It misleadingly stated that Novartis "has not performed any studies or clinical trials specific to the use of Brethine [i.e., terbutaline] as a tocolytic," despite having funded Dr. Laros's 1985 to study on the subject with $46,000.

15. Novartis's promotion of terbutaline for preterm labor paid off: By the mid-1990s, terbutaline surpassed ritrodine (the lone FDA-approved treatment for preterm labor, and terbutaline's only competitor) as the go-to tocolytic in the United States. By 1998, thousands of doctors were prescribing terbutaline for preterm labor to over 260,000 women in the United States each year. Not coincidentally, preterm labor accounted for 66% of terbutaline's annual sales exceeding $20 million.

16. Novartis knew most terbutaline prescriptions for preterm labor were for "maintenance tocolysis." In *acute tocolysis*, a woman in active labor (perhaps at a small, remote hospital), is given terbutaline to delay delivery long enough (48 to 72 hours) for her transfer to a facility with a neonatal intensive care. But in *maintenance tocolysis*, pregnant women were continuously dosed terbutaline every four hours, around the clock, day after day, typically for weeks, supposedly to prevent the onset of preterm labor.

17. While Novartis earned millions of dollars exposing millions of children to terbutaline for maintenance tocolysis, the FDA acted to curb that practice:

17.1. In 1993, the FDA made unscheduled visits to all three of Novartis's distribution centers to seize documents reflecting terbutaline shipments of terbutaline to 11 entities (10 of which were California companies). Internal emails confirm Novartis knew those entities were using terbutaline for maintenance tocolysis. Indeed, the list included Tokos Medical Corporation, the same provider Novartis specifically highlighted in its May 1992 press release regarding terbutaline's use in preterm labor (a press release that coincided with the FDA Advisory Committee meetings on terbutaline).

17.2. Also in 1993, the FDA invited Novartis to apply for a preterm-labor indication for terbutaline, stressing the need for Novartis to formally study its safety and efficacy as a tocolytic. Internal documents show Novartis executives declined: They emphasized the company had no financial incentive to pursue a formal indication for preterm labor because terbutaline was already the go-to tocolytic without one, and thus a formal indication for that purpose would be costly to obtain and only serve to expose Novartis to lawsuits for adverse effects.

17.3. In 1997, the FDA publicly announced it was investigating "the promotion and increasingly widespread use of … terbutaline … for the treatment/prevention of preterm labor" based on concerns "terbutaline sulfate has not been demonstrated to be effective and is potentially dangerous" to maternal health when used "as a tocolytic agent." In response, a Novartis executive issued an internal email encouraging the company to remain "reactive instead of proactive in addressing any future FDA concerns" with terbutaline's use in preterm labor.

17.4. In 1998, the FDA asked Novartis to provide any documents "given or shown to any … physician that promote, discuss or relate to the use of terbutaline sulfate for the treatment and prevention of preterm labor (tocolytic therapy)." The FDA also sought any "correspondence between any representative of Novartis and any … physician" regarding the use of terbutaline for preterm labor. Novartis did not give the FDA the documents showing it hired Dr. Laros, Stiller, and Dr. Scoggin to broadcast the message that terbutaline was safety and effective for preterm labor.

2. Novartis concealed the risks of using terbutaline for preterm labor.

18. Novartis not only promoted terbutaline for preterm labor, but it also misrepresented the risks terbutaline posed to the fetus on the warning label.

19. Under federal law, a drug manufacturer must ensure a drug's warning label is accurate. To that end, federal regulations require brand-name drug manufacturers to monitor and "promptly review all adverse drug experience information obtained or otherwise received … from any source," including "reports in the scientific literature." (21 C.F.R. § 314.80(b).) A brand-name drug manufacturer must update a drug's warning label "as soon as there is reasonable evidence of an association of a serious hazard with a drug," and notes that "a causal relationship need not have been proved." (21 C.F.R. §

201.80(e); see also 21 C.F.R. § 314.70(c)(6)(iii)(A).) This duty extends to so-called "off-label" uses if the manufacturer knows the drug is commonly prescribed for that purpose. (E.g., 21 C.F.R. § 201.80(e).)

20. A drug manufacturer's highest duty to warn is for pregnancy risks: Federal regulations classify birth defects—particularly latent, neurological birth defects—among the most serious hazards with a drug.

21. To that end, starting in 1979, the FDA required drug manufacturers to include a "Pregnancy Category" (A, B, C, D, or X) on the drug's warning label:

21.1. Pregnancy Category A meant "[s]tudies in pregnant women have not shown that [the drug] increases the risk of fetal abnormalities if administered during the first (second, third, or all) trimester(s) of pregnancy."

21.2. Pregnancy Category B meant "there are no adequate and well-controlled studies in pregnant women," but that "animal reproduction studies have failed to demonstrate a risk to the fetus."

21.3. Pregnancy Category C meant "animal reproduction studies have shown an adverse effect on the fetus."

21.4. Pregnancy Category D meant "investigational or marketing experience" has shown "positive evidence of human fetal risk," but that the risks might outweigh the benefits in, for example, "a life-threatening situation."

21.5. Pregnancy Category X meant "studies in animals or humans have demonstrated fetal abnormalities … and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit."

22. Between 1981 and December 2001, terbutaline's warning label classified it as a "Pregnancy Category B" drug (i.e., animal reproduction studies failed to show a risk to the fetus).

23. That was a lie: Six published, peer-reviewed studies between 1985 and 2001 showed terbutaline crosses the placenta and fetal brain barrier in sufficient quantities to affect brain development in pregnant rats. In particular, they showed that terbutaline (a beta-agonist) stimulates beta-receptors in the fetal brain, disrupting enzymes critical for brain development:

23.1. A 1985 study in *The Journal on Pharmacology & Experimental Therapeutics* showed that giving terbutaline to pregnant rats "may interfere with basic biochemical events which influence neuronal maturation" in "the developing organism."

23.2. A 1989 study published in *Brain Research Bulletin* found significant "evidence" that "prenatal exposure to terbutaline … in the brain of developing rats ... could have a deleterious effect on subsequent development," and thus "that terbutaline may be a neurobehavioral teratogen." This study warned that beta-agonists like terbutaline easily "cross the placenta," posing "significant terbutaline exposure" risks human fetuses.

23.3. A 1990 study published in *Life Sciences* found that "[t]he therapeutic use of" terbutaline in pregnant rats "may be accompanied by alterations of neural development and function in the offspring."

23.4. A 1992 study published in *Research Communications in Chemical Pathology & Pharmacology* found that terbutaline, when "used to arrest premature labor," "crosses the placenta to affect fetal nervous system development."

23.5. A 1998 study published in *Neuroscience Letters* found that terbutaline given pregnant rats "suppress[ed] the proliferation of microglia" in the brains of the rat fetuses.

23.6. An October 2001 study published in *Developmental Brain Research* found that terbutaline "may lead to disruption of neural cell development as a consequence of tocolytic therapy."

24. The six terbutaline studies carried even greater weight in light of studies on pregnant rats involving other beta-agonists, which also showed abnormal brain development in exposed offspring:

24.1. A 1988 study that showed giving "isoproterenol" (a beta-agonist similar to terbutaline) to pregnant rats resulted in an "immediate decline … in the formation of new brain cells" in the fetus.

24.2. A 1992 study showed that giving beta-agonists to pregnant rats resulted in "long-term biochemical, morphological, behavioral and electrophysiological effects" in the fetal brains.

24.3. Another 1992 study showed that nerve cells in immature rat brains are sensitive

to "isoproterenol," suggesting a "potential lasting adverse functional effects" in offspring exposed to that (and other) beta-agonist.

24.4. A 1993 study involving beta-agonists concluded that "all drugs acting [on beta-receptors] may indeed have functional teratogenic potential."

24.5. A 1993 study of the beta-agonist "clenbuterol" concluded that "chronic … clenbuterol treatment" in rat pups "causes changes in the setting of the neurochemical parameters investigated in the frontal cortex."

24.6. A 1994 study showed administrating "isoproterenol" to two-day-old rat pups resulted in "inappropriate hyperstimulation of beta-adrenergic receptors in the developing brain and subsequent, adverse functional deficits."

25. And there was substantial reason to believe these alarming animal data might extrapolate to humans:

25.1. In 1984, a study conducted by Swedish physicians "demonstrate[d] a rapid transfer of terbutaline across the human placenta," and that "during long-term treatment" involving "repeated administration of terbutaline, … the fetus will reach plasma levels similar to its mother."

25.2. In 1986, in a report published in the *British Journal of Obstetrics and Gynecology*, Dutch investigators found statistically poorer academic achievement in six-year-old children born to mothers who had received beta-agonist tocolytic treatment (specifically, ritrodine) than in children born to mothers who received no treatment.

25.3. In a 1989, German researchers published a study showing children exposed in utero to another beta-agonist were found to be more often neurotic and to be more likely to have visual impairments and delayed language development compared to children whose mothers had not received tocolytics.

25.4. Between 1986 and 2001, three additional human studies showed that children born to women treated for preterm labor with ritrodine (a beta-agonist) exhibited impaired school performance, cognitive dysfunction, and an increased risk of psychiatric disorders.

25.5. In 2001, a team of psychiatrists, physicians, and psychologists from the German

Central Institute of Mental Health published the results of a long-term study of child development after maternal tocolysis with beta-adrenergic drugs in *Child Psychiatry and Human Development*. The investigation was funded by the German government as part of "The Manheim Study of At-Risk Children." The study found impairments in motor, socio-emotional, and cognitive development in children born after their mothers had received beta-adrenergic tocolytic treatment. The study concluded: "These drugs are known to produce specific maternal and fetal side effects and thus, one has to look after long-lasting consequences," and they are likely to "exert direct pharmacological functions" because these substances are not only known to cross the placenta but also meet with the immature blood-brain barrier of the fetus." Citing the published rat studies on terbutaline, the German researchers explained that, "specific pharmacodynamic effects on the fetal central nervous system would meet with a very sensitive period of brain development," and that "tocolytics are used mainly during the second half of gestation, when the brain passes through its second growth spurt," and that, "In this period, glia cell proliferation, cell migration, synaptogenesis and myelination take place resulting in an accompanying higher vulnerability of the brain ...."

26. Novartis also knew terbutaline was ineffective for maintenance tocolysis, offering no benefit and only risks:

26.1. In 1982, a team of American military clinical investigators published a study in the *Journal of Military Medicine* comparing the use of terbutaline for maintenance tocolysis with a placebo. The study found "[n]o significant difference in prolongation of pregnancy, birth weight, development of RDS, or infant survival was demonstrable between the two groups."

26.2. In 1984, researchers at the University of California published a study in the *Journal of Reproductive Medicine*, which found no statistical difference in outcomes between terbutaline, magnesium sulfate, and placebo for maintenance tocolysis.

26.3. In 1992, scientists from the University of Texas undertook a comprehensive and critical evaluation of the scientific literature relating to terbutaline published in the *American Journal of Obstetrics and Gynecology*. After evaluating the quality of the studies and trials to date, excluding those that were questionable or flawed, the researchers concluded: "There are no

verified benefits to mother or fetus from long-term therapy with beta-[agonists] to arrest preterm labor. Chronic exposure may adversely affect the fetus. Maternal side effects are inevitable and can be life-threatening." The researchers further emphasized that, at most, beta-agonists like terbutaline may stop contractions for 24 to 48 hours, and that "[t]heir use should therefore be confined to situations where attainment of a 24- to 48-hour delay is the goal." They cautioned that due to "potential serious adverse effects, there are few circumstances in which these drugs are indicated."

26.4. In 1993 and 1995, two additional published, peer-reviewed studies "were unable to demonstrate a significant reduction in preterm birth with Terbutaline," and "did not demonstrate an improvement in pregnancy outcome with the use of Terbutaline."

26.5. In 1995, the American College of Obstetrics and Gynecology published a bulletin noting that published literature showed that terbutaline's value in treating preterm labor was, at most, "limited to an initial brief period of … probably no more than 48-72 hours," and that there is "[n]o benefit from prolonged treatment."

26.6. In 1996, researchers from the University of Tennessee published a study in the *American Journal of Obstetrics and Gynecology* which found that terbutaline use "is not associated with pregnancy prolongation or a reduction in the incidence of recurrent preterm labor." The researchers concluded that maintenance tocolysis with terbutaline "is not associated with pregnancy prolongation or a reduction in the incidence of recurrent preterm labor."

26.7. In 1997, researchers from the University of Iowa published a study in the *American Journal of Perinatology* which concluded that terbutaline maintenance therapy, both oral and subcutaneous, was no more effective than ordinary saline solution.

26.8. Also in 1997, researchers at Indiana University published a study in the *American Journal of Perinatology* which found that "oral maintenance tocolysis has no significant impact on further prolongation of pregnancy after intravenous tocolysis," and that, in fact, "women on oral tocolytic maintenance were significantly more likely than those not on oral therapy to present for reevaluation greater than 24 hours after discharge, and to require reinstitution of parenteral therapy."

26.9. In 1998, a team at the University of Delaware published another study in the *American Journal of Perinatology* which also found that, if tocolysis had any effect at all, "there was a trend toward an increase in preterm delivery rate at less than 37 weeks' gestation in the tocolysis cohort" and that "our data show the preterm delivery rate in those patients with threatened preterm labor is not improved with tocolysis."

26.10. In 1999, the FDA issued a public letter emphasizing that "[t]he published literature clearly suggests that … Terbutaline is … ineffective as a pregnancy maintenance treatment."

26.11. In 2000, the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services ("AHRQ") published a two-volume report entitled "Management of Preterm" labor summarizing a comprehensive assessment of treatments for preterm labor, including maintenance tocolysis. It concluded that "[t]he research to date has made adequately clear that the use of tocolysis in a maintenance capacity following an episode of acute tocolysis has no proven efficacy or effectiveness," and thus "[t]ocolytics are not useful as maintenance interventions."

27. Consistent with its duty to update a drug's warning label "as soon as there is reasonable evidence of an association of a serious hazard with a drug," Novartis was required to update the terbutaline warning label as early as January 1993, but no later than December 2001, as follows:

27.1. Novartis should have raised terbutaline from Pregnancy Category B ("animal reproduction studies have failed to demonstrate a risk to the fetus") to Pregnancy Category C ("animal reproduction studies have shown an adverse effect on the fetus"). (21 CFR § 201.57(c)(9)(i)(A)(2)–(3); *id.*, § 201.80(f)(6)(i)(b)–(c).)

27.2. Novartis should have included a statement warning that published data in pregnant rats that received terbutaline showed abnormal brain development in exposed offspring. (21 CFR § 201.57(c)(9)(i)(A)(2)–(3); *id.*, § 201.80(f)(6)(i)(b)–(c).)

27.3. Novartis should have included a black-box warning against the use of terbutaline for maintenance tocolysis based on, among other things, the animal data showing a risk of abnormal fetal brain development, the data showing terbutaline was ineffective for maintenance

tocolysis.

28. Novartis never raised terbutaline's pregnancy category from B to C, never mentioned the terbutaline rat studies showing abnormal fetal brain development on the terbutaline label, and never included a black-box warning against maintenance tocolysis.

29. Instead, internal emails show Novartis made a strategic decision to "remain reactive instead of proactive" when "warn[ing] the medical community" about "using terbutaline off-label in preterm labor."

30. As Novartis's general counsel later explained in an email, this was code for a strategy in which Novartis added a terse, benign disclaimer to the label that might insulate Novartis from tort liability, but—in a nod to "the fact that 2/3 of sales derive from off label use"—not actually deter its use for preterm labor (and thereby jeopardize Novartis's sales).

31. Thus, in late 1985—just months after Novartis had hired Dr. Laros, Stiller, and Dr. Scoggin to convey the message that terbutaline was safe and effective for treating preterm labor—Novartis added a one-sentence disclaimer ("Terbutaline sulfate is not indicated for tocolysis") to the warning label.

32. And in 1996—when terbutaline had become the go-to tocolytic in the United States—Novartis added "and should not be used" to its disclaimer ("Terbutaline sulfate is not indicated, *and should not be used*, for tocolysis").

33. In 2001, Novartis's terbutaline patent expired, allowing generics to enter the market. Novartis responded by putting its rights to brand-name terbutaline up for sale. Novartis's offering memo touted that 66% of terbutaline's $20 million in annual sales were for preterm labor. Novartis found a willing buyer in aaiPharma, which expressed that it intended to continue—if not expand—terbutaline's use in preterm labor.

34. In December 2001, Novartis sold its rights to market terbutaline in the United States to aaiPharma for $26 million. Under that deal, Novartis earned a royalty on future terbutaline preterm labor sales and continued to manufacturer terbutaline for aaiPharma for an indefinite period. Novartis did not update the terbutaline label before it sold its terbutaline rights to aaiPharma, nor did it advise aaiPharma that updates were urgently needed. Foreseeably, over the next decade, aaiPharma and its successors

continued to use the same "warning" label for terbutaline as Novartis.

35. Also in 2001, Impax submitted a drug application to the FDA seeking to sell generic terbutaline in the United States. As part of its application, federal law required Impax to submit proposed labeling to the FDA which mirrored the brand-name manufacturer's label. But federal law also required Impax to reasonably assess the adequacy of that labelling and recommend any necessary updates. If it looked, Impax would have known terbutaline was mislabeled insofar as it was Pregnancy Category B (instead of C), and omitted any reference to the animal studies showing abnormal brain development in exposed offspring. But Impax did not include or request updated labeling with its drug application; instead, Impax merely promised to mirror the brand-name label, and followed through on that promise. As a result, all generic terbutaline available from 2001 to 2011 bore the same deceptive label Novartis left behind.

3. Plaintiffs were harmed by the use of terbutaline for preterm labor.

36. Between December 2001 and 2007, another dozen additional published, peer-review studies on rats confirmed that terbutaline disrupted brain development in exposed offspring.

37. In 2008, a concerned citizen—James P. Reichmann—submitted a "citizen petition" to the FDA, urging it to increase the pregnancy category on terbutaline from B to at least C (if not higher). As support, Reichmann cited the many studies showing that dosing pregnant rats with terbutaline resulted in abnormal brain development in their offspring, including five of the six studies between 1985 and 2001. (Reichmann omitted Dr. Slotkin's 1985 study, ostensibly because it is the only study that did not include "terbutaline" in the title.)

38. In 2011, the FDA responded to Reichmann's petition. There, the FDA indicated that, effective February 2011, it would require manufacturers to update the warning label by [1] increasing terbutaline from Pregnancy Category B to Pregnancy Category C; [2] adding a warning that published data in pregnant rats that received terbutaline showed abnormal brain development in exposed offspring; and [3] including a black-box warning against the use of terbutaline for maintenance tocolysis. As support, the FDA cited the data showing terbutaline is ineffective for maintenance tocolysis, the reports of maternal deaths and serious adverse events from terbutaline for maintenance tocolysis, and the many studies showing that dosing pregnant rats with terbutaline resulted in abnormal brain development in

the exposed offspring.

39. Although the FDA's 2011 actions undoubtedly prevented millions more children from being hurt by terbutaline, it came too late for many of the millions of children who were needlessly exposed to terbutaline for maintenance tocolysis between 1993 and 2011. Compelling evidence suggests prenatal terbutaline exposure may cause autism in humans:

39.1. In 2005, Dr. Andrew W. Zimmerman of the Kennedy Krieger Institute at Johns Hopkins Medical institution and UCLA researchers published a study—funded by the Centers for Disease Control and Prevention—of fraternal, autistic twins whose mothers had received maintenance terbutaline tocolytic therapy. They found a significant association between continuous terbutaline exposure and autism disorders in fraternal twins. The research team consisted of experts in pediatric neurology, pathology, epidemiology, psychiatry, and pediatrics. The study was funded by the Centers for Disease Control and Prevention, and was formally approved by the Institutional Review Board of the Johns Hopkins Medical Institutions.

39.2. In 2006, a team of researchers from the Kennedy Krieger Institute and Duke Medical Center, led by Drs. Zimmerman and Slotkin, published an abstract of a report of a collaborative study that confirmed that Dr. Slotkin's animal studies provide an appropriate animal model for neuro-inflammation in autism. The report was presented to the 2006 International Meeting for Autism Research in Montreal, Canada.

39.3. A 2011 epidemiology study involving 250,000 pregnant women ("Croen Study") showed that children exposed to terbutaline during gestation had a 400% higher risk of developing autism.

39.4. A 2016 epidemiology study ("Gidaya Study") confirmed the results of the 2011 Croen Study and suggested that children with protracted terbutaline exposure (i.e., maintenance tocolysis) were at even greater risk of developing autism.

40. Plaintiffs are a small sample of Novartis's many victims:

40.1. Plaintiff **Jayden Tindle** was born to Plaintiff Tara Tindle on December 25, 2003. Approximately 20 weeks into her pregnancy, Tara was prescribed maintenance tocolysis with terbutaline for approximately 16–20 weeks. Jayden now suffers from Autism. Tara's

doctor—apparently unaware—never told her there were no adequate studies in humans, and never told her that rat studies showed prenatal terbutaline exposure was associated with abnormal brain development in the offspring. Tara's doctor also did not tell her that studies showed terbutaline did not prevent preterm labor beyond an initial 48- to 72-hour period. Had those facts been conveyed to her, Tara would not have agreed to take terbutaline for maintenance tocolysis. Moreover, if terbutaline carried a black-box warning against maintenance tocolysis, Tara's doctor never would have prescribed it for that purpose in the first place. Until approximately January 2023, when Tara reviewed information online suggesting a potential link between Terbutaline and autism, Tara and Jayden did not suspect a possible association between Jayden's prenatal terbutaline exposure and autism.

FIRST CAUSE OF ACTION
General Negligence
(By all Plaintiffs against all Defendants)

41. Plaintiffs incorporate herein every allegation set forth in the preceding paragraphs as though fully set forth herein.

42. Novartis had a duty to review scientific literature involving its drug products from any source and update the terbutaline warning label to ensure that it provided accurate information about potential hazards of its drug products.

43. Novartis breached its duty to update the terbutaline warning label to ensure that it provided accurate information about potential hazards of the drug:

43.1. Given the multiple studies showing that dosing pregnant rats with terbutaline resulted in abnormal brain development in their offspring, and additional studies showing similar effects with other drugs in the same class, Novartis should have [1] raised the pregnancy classification on terbutaline from Pregnancy Category B to C, and [2] included a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring. Novartis failed to do so.

43.2. Given, among other things, [1] the animal studies showing dosing pregnant rats with terbutaline resulted in abnormal brain development in their offspring and additional studies showing similar effects with other drugs in the same class, [2] that terbutaline was ineffective

for maintenance tocolysis, and [3] that terbutaline was extremely popular for maintenance tocolysis (due at least in part to Novartis's promotional efforts), Novartis should have added a black-box warning to the terbutaline label prohibiting its use for maintenance tocolysis. Novartis failed to do so.

44. Novartis's failure to update the terbutaline warning label to ensure accurate information about the drug's potential hazards reflected a despicable, willful, conscious disregard for the rights and safety of others:

44.1. Novartis knew terbutaline posed a serious risk of harm to the public: Specifically, Novartis knew [1] terbutaline was wildly popular for maintenance tocolysis (and had helped promote it for that purpose), [2] terbutaline was ineffective for that purpose, [3] that there were no there were no adequate or well-controlled studies in humans to assess terbutaline's potential for teratogenic effects and that animal studies showed potential for abnormal brain development from prenatal exposure.

44.2. Novartis could have prevented that harm by [1] raising the pregnancy classification on terbutaline to Pregnancy Category C, [2] including a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, and/or [3] including a black-box warning against maintenance tocolysis.

44.3. Novartis chose not to take steps to prevent widespread harm to the public because it would have cost Novartis millions of dollars a year in terbutaline sales. That a drug company would consciously choose to deceive the public about the risks of its drugs in the pursuit of profit is despicable conduct that ordinary people would look down upon and regard with disgust and contempt.

45. Novartis's failure to timely update the terbutaline warning label to ensure that it provided accurate and up-to-date information about the drug's potential hazards was a substantial factor in Plaintiffs' terbutaline exposure:

45.1. Had Novartis [1] raised the pregnancy classification on terbutaline from Pregnancy Category B to C, and [2] included a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, the physicians

treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

45.2. Had Novartis added a black-box warning to the terbutaline label prohibiting its use for maintenance tocolysis, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

46. Plaintiffs' terbutaline exposure was a substantial factor in causing them to develop autism, which has caused (and will continue to cause) profound harm and disruption to their lives for which they have sustained (and will continue to sustain) economic and noneconomic damages in amounts to be proven at trial.

SECOND CAUSE OF ACTION
Negligent Misrepresentation
(By all Plaintiffs against all Defendants)

47. Plaintiffs incorporate every allegation in the preceding paragraphs as though fully set forth herein.

48. From 1993 through 2001, Novartis represented on the terbutaline warning label, to medical professionals and/or the public, that no animal studies on terbutaline showed teratogenic effects, and that terbutaline was a Pregnancy Category B drug.

49. That representation was untrue: By 1993, numerous published, peer-reviewed animal studies showed that dosing pregnant rats with terbutaline was associated with abnormal brain development in their offspring. By 2001, there were additional studies confirming those findings. Those studies underscored similar effects observed in animal studies of other drugs in the same class, demonstrating that terbutaline should have been a Pregnancy Category C drug.

50. Novartis had no reasonable grounds for representing no animal studies showed teratogenic effects from terbutaline.

51. Novartis intended for medical professionals and/or the public to rely on the content in the terbutaline warning label in choosing whether to proscribe and/or consumer terbutaline, respectively.

52. Plaintiffs' physicians and Plaintiff's mother reasonably relied on the content in the

terbutaline warning label in choosing whether to proscribe and/or consumer terbutaline, respectively.

53. Novartis's misrepresentations regarding the safety of using terbutaline during pregnancy were not only fraudulent, but reflected a willful, conscious disregard for the rights and safety of others:

53.1. Novartis knew terbutaline posed a serious risk of harm to the public: Specifically, Novartis knew [1] terbutaline was wildly popular for maintenance tocolysis (and had helped promote it for that purpose), [2] terbutaline was ineffective for that purpose, [3] that there were no there were no adequate or well-controlled studies in humans to assess terbutaline's potential for teratogenic effects and that animal studies showed potential for abnormal brain development from prenatal exposure.

53.2. Novartis could have prevented that harm by [1] raising the pregnancy classification on terbutaline to Pregnancy Category C, [2] including a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, and/or [3] including a black-box warning against maintenance tocolysis.

53.3. Novartis chose not to take steps to prevent widespread harm to the public because it would have cost Novartis millions of dollars a year in terbutaline sales. That a drug company would consciously choose to deceive the public about the risks of its drugs in the pursuit of profit is despicable conduct that ordinary people would look down upon and regard with contempt.

54. Novartis's misrepresentations regarding the safety of using terbutaline during pregnancy were a substantial factor in Plaintiffs' terbutaline exposure:

54.1. Had Novartis [1] raised the pregnancy classification on terbutaline from Pregnancy Category B to C, and [2] included a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

54.2. Had Novartis added a black-box warning to the terbutaline label prohibiting its use for maintenance tocolysis, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for

maintenance tocolysis.

55. Plaintiffs' terbutaline exposure was a substantial factor in causing them to develop autism, which has caused (and will continue to cause) profound harm and disrupted their lives for which they have sustained (and will continue to sustain) economic and noneconomic damages in amounts to be proven at trial.

THIRD CAUSE OF ACTION
Intentional Misrepresentation
(By all Plaintiffs against Defendants)

56. Plaintiffs incorporate herein every allegation set forth in the preceding paragraphs as though fully set forth herein.

57. From 1993 through 2001, Novartis represented to medical professionals and the public on the terbutaline warning label that there were no animal studies on terbutaline showing teratogenic effects, and that terbutaline was a Pregnancy Category B drug.

58. That representation was untrue: By 1993, there were numerous published, peer-reviewed animal studies showing that dosing pregnant rats with terbutaline caused abnormal brain development in the exposed offspring. Those studies took on even greater significance in light of other animal studies on drugs in the same class which showed similar effects. In light of those studies, terbutaline should have been a Pregnancy Category C drug.

59. Novartis knew there were numerous published, peer-reviewed animal studies showing that dosing pregnant rats with terbutaline caused abnormal brain development in the exposed offspring.

60. Novartis intended for medical professionals and/or the general public to rely on the content in the terbutaline warning label in choosing whether to proscribe and/or consumer terbutaline, respectively.

61. Plaintiffs' physicians and Plaintiff's mother reasonably relied on the content in the terbutaline warning label in choosing whether to proscribe and/or consumer terbutaline, respectively.

62. Novartis's misrepresentations regarding the safety of using terbutaline during pregnancy was not only fraudulent, but reflected a despicable, willful, conscious disregard for the rights and safety of others:

62.1. Novartis terbutaline posed a risk of serious harm to the public: Specifically, Novartis knew [1] terbutaline was wildly popular for maintenance tocolysis (and had helped promote it for that purpose), [2] terbutaline was ineffective for that purpose, [3] that there were no there were no adequate or well-controlled studies in humans to assess terbutaline's potential for teratogenic effects and that animal studies showed potential for abnormal brain development from prenatal exposure.

62.2. Novartis could have prevented that harm by [1] raising the pregnancy classification on terbutaline to Pregnancy Category C, [2] including a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, and/or [3] including a black-box warning against maintenance tocolysis.

62.3. Novartis chose not to take steps to prevent widespread harm to the public because it would have cost Novartis millions of dollars a year in terbutaline sales. That a drug company would consciously deceive the public about the safety of its drugs in the pursuit of profit is despicable conduct that ordinary people would look down upon and regard with disgust and contempt.

63. Novartis's misrepresentations regarding the safety of using terbutaline during pregnancy were a substantial factor in Plaintiffs' terbutaline exposure:

63.1. Had Novartis [1] raised the pregnancy classification on terbutaline from Pregnancy Category B to C, and [2] included a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

63.2. Had Novartis added a black-box warning to the terbutaline label prohibiting its use for maintenance tocolysis, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

64. Plaintiffs' terbutaline exposure was a substantial factor in causing them to develop autism, which has caused (and will continue to cause) significant harm and disruption to their lives for

which they have sustained (and will continue to sustain) economic and noneconomic damages in amounts to be proven at trial.

FOURTH CAUSE OF ACTION
Concealment
(By all Plaintiffs against Defendants)

65. Plaintiffs incorporate herein each and every allegation set forth in the preceding paragraphs as though fully set forth herein.

66. Novartis had a duty to monitor and review scientific literature involving its drug products from any source, foreign and domestic, and timely update the terbutaline warning label to ensure that it provided accurate and up-to-date information about potential hazards of its drug products. Instead, Novartis intentionally chose to omit from the terbutaline label a statement that published, peer-reviewed animal studies showed that dosing pregnant rats with terbutaline caused abnormal brain development in the exposed offspring, and that terbutaline was a Pregnancy Category C drug.

67. Plaintiffs' physicians and Plaintiff's mother did not know that published, peer-reviewed animal studies showed that dosing pregnant rats with terbutaline caused abnormal brain development in the exposed offspring, and that terbutaline was a Pregnancy Category C drug.

68. Novartis intended to deceive physicians and the general public regarding the safety of using terbutaline for preterm labor Novartis because Novartis knew that disclosing the truth about the safety of terbutaline for preterm labor would have cost Novartis millions of dollars a year in terbutaline sales.

69. Novartis's concealment of the risks of using terbutaline during pregnancy was not only fraudulent, but reflected a despicable, willful, conscious disregard for the rights and safety of others:

69.1. Novartis knew that terbutaline posed risk of serious, unnecessary harm to the public: Specifically, Novartis knew [1] terbutaline was wildly popular for maintenance tocolysis (and had helped promote it for that purpose), [2] terbutaline was ineffective for that purpose, [3] that there were no there were no adequate or well-controlled studies in humans to assess terbutaline's potential for teratogenic effects and that animal studies showed potential for abnormal brain development from prenatal exposure.

69.2. Novartis could have prevented that harm by [1] raising the pregnancy

classification on terbutaline to Pregnancy Category C, [2] including a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, and/or [3] including a black-box warning against maintenance tocolysis.

69.3. Novartis chose not to take steps to prevent widespread harm to the public because it would have cost Novartis millions of dollars a year in terbutaline sales. That a drug company would consciously deceive the public about the safety of its drugs in the pursuit of profit is despicable conduct that ordinary people would look down upon and regard with disgust and contempt.

70. Novartis's concealment was a substantial factor in Plaintiffs' terbutaline exposure:

70.1. Had Novartis [1] raised the pregnancy classification on terbutaline from Pregnancy Category B to C, and [2] included a warning on the label that studies in pregnant rats showed that terbutaline resulted in abnormal brain development in their offspring, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

70.2. Had Novartis added a black-box warning to the terbutaline label prohibiting its use for maintenance tocolysis, the physicians treating Plaintiff's mother would not have prescribed—or, at a minimum, Plaintiff's mother would not have agreed to take—terbutaline for maintenance tocolysis.

71. Plaintiffs' terbutaline exposure was a substantial factor in causing them to develop autism, which has caused (and will continue to cause) significant harm and disruption to their lives for which they have sustained (and will continue to sustain) economic and noneconomic damages in amounts to be proven at trial.

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray that judgment be entered against Defendants, and each of them, jointly and severally, as follows:

1. For compensatory damages, including economic and noneconomic damages, according to proof;

2. For punitive damages against Novartis on any applicable causes of action;

3. For the costs of litigation and investigation associated with this suit;

4. For pre-judgment interest at the maximum legal rate on all sums awarded;

5. For injunctive relief; and

6. For such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand their right to a trial by jury on all causes of action for which the right to a jury exists under the U.S. or California Constitutions.

Dated: December 30, 2024

SINGLETON SCHREIBER, LLP

Chritopher R. Rodriguez, Esq.
Attorneys for Plaintiffs